VOLUME ONE

Intellectual Property Management in Health and Agricultural Innovation

a handbook of best practices

EDITED BY

ANATOLE KRATTIGER

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STANLEY P. KOWALSKI

MIHR
A STEP NEARER EQUITY

PIPRA
public intellectual property resource for agriculture

Ministério da Saúde
FIOCRUZ
Fundação Oswaldo Cruz

bioDevelopments
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THE ROCKEFELLER FOUNDATION

Judith Rodin
President

March 21, 2007

Dear Reader,

Over the last decade, the world has been paying increasing attention to the agricultural, health, and economic disparities between industrialized and developing countries. The Rockefeller Foundation is proud to have helped develop and launch some of the numerous initiatives to address these issues—initiatives such as the African Agricultural Technology Foundation, the Alliance for a Green Revolution in Africa, the International AIDS Vaccine Initiative, the Global Alliance for TB Drug Development, and others.

We believe, however, that launching the success of these and other similar initiatives requires that we both engage directly with research universities in the industrialized world and encourage the growing innovation capacity of developing countries. The Public Intellectual Property Resource for Agriculture (PIPRA) and the Centre for the Management of Intellectual Property in Health Research and Development (MIHR) were created for precisely these reasons. Their mission is to enhance the power of publicly funded research institutions to harness new technologies and to ensure that the benefits of globalization are shared more equitably. This *Handbook* and the companion *Executive Guide* and online version are a natural outcome of their efforts to contribute new solutions to this two-fold challenge. A follow-on interactive electronic version will reach an even wider audience and, we hope, provide even greater benefits.

The Rockefeller Foundation is delighted to have supported the creation of this unique resource. It holds lessons that are valuable (in many senses of the word) for policy-makers, leaders of research institutions, researchers, and technology managers alike—in both industrialized and developing countries. Indeed, this *Handbook* and *Executive Guide*, a testament to the committed, excellent work of MIHR and PIPRA, might be the most thorough primer on intellectual property management for the public interest ever assembled. As such, it will be an indispensable tool for both planners and practitioners for years to come.

With best wishes,

Judith Rodin

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Message from the Board of Patrons

Dear Reader,

Intellectual property can be a powerful tool. When effectively and ethically managed, it can both accelerate the development of lifesaving, poverty-alleviating innovations and secure access to them. Both development and access are urgently needed in health and agriculture to improve the lives of people in need—particularly those living in the developing world.

This *Handbook* and its companion *Executive Guide* constitute an authoritative, comprehensive, and practical reference on intellectual property management and best practices. These works will be invaluable for anyone seeking to use intellectual property strategically to enhance economic growth and equitably distribute innovative technologies. This *Handbook* and *Executive Guide* uniquely contributes to efforts in global health and food security. We are pleased to endorse its use. ■

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A number of organizations, after seeing sample chapters of the *Handbook*, came forward to purchase copies for wide distribution in developing countries. We are grateful for their generosity and extend our thanks in advance to others who will join their ranks. For an updated list of Distribution Supporters, please visit www.ipHandbook.org.

In-kind support provided by AUTM and PIIPA.

Individuals are also encouraged to purchase *Handbooks* on behalf of developing countries; we will distribute such orders at cost.

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Foreword by Norman E. Borlaug

This *Handbook* is timely for several reasons. Whether we like it or not, when it comes to technology transfer, global integration has created a complex system of intellectual property management. This system includes public sector research institutions in developing countries that need guidance on how to negotiate the new and changing terrain. The *Handbook* aims to provide these institutions with such guidance in the form of a reference resource. But the *Handbook* is more than that. It not only explains the intellectual property system, but shows how both public sector research institutions and developed countries can use intellectual property to achieve their humanitarian and socio-economic objectives.

The past 50 years make up the most productive period in history, in terms of agriculture. Innovations in agricultural science and technology made possible the Green Revolution, which is reputed to have spared one billion people the pain of hunger and starvation. New health innovations have helped control the scourges of polio, leprosy, and smallpox. Although we have seen the greatest reductions in hunger in history, it has not been enough. And despite the enormous potential of modern medicine, its reach is still too short for the hundreds of millions most in need of its preventative and curative powers.

Several billion people around the globe require access to new agricultural technologies that could feed families while protecting the environment, as well as new health innovations to combat HIV/AIDS, malaria, tuberculosis, dengue, and a host of other diseases that typically afflict the poor in developing countries. New science and technology—including biotechnology—have the potential to satisfy these needs.

Today, the world food supply is nearly six billion gross metric tons and three billion net metric tons of edible dry matter. It includes cereals, roots and tubers, legumes, fruits and vegetables, livestock and fish. Within the next 50 years, the world's population is likely to increase 60%–80%, requiring global food production to nearly double. We will have to achieve this increase on a shrinking agricultural land base, with most of the increased production to occur in the countries that will consume it. Compounding the problem is the fact that more than half of the world's 800 million hungry people are small-scale farmers who cultivate environmentally sensitive marginal lands in developing countries. Bringing the power of science and technology to bear on the protection of these fragile environments is one of the greatest challenges of the 21st century.

Borlaug NE. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

Despite these serious and daunting challenges, there is reason for hope. With the new biotechnology tools, we are poised for another period of rapid agricultural innovation. New science has the power to increase yields, address agroclimatic extremes, and mitigate a range of environmental and biological problems. Private industry has invested billions of dollars in research to make astonishing new discoveries and products, such as genetically modified crops. Unfortunately, with the notable exception of insect resistant Bt cotton in China and India, relatively few of the new crops developed by private industry are reaching smallholder farmers in the developing world. This situation must be corrected as soon as possible.

The world of scientific innovation works differently today than it did 50, or even 20, years ago. Developing countries can no longer rely primarily on innovations from the public sector, because the private sector has taken the lead in inventing new technologies. Even those innovations developed by public sector research institutions are inextricably part of a global IP regime since they normally build on inventions made by both public and private entities.

As part of a global system, scientific institutions in developing countries need to understand how the IP system works to be able to capitalize on new opportunities. Moreover, global public sector research no longer marches to its own beat; to move forward, it must now work in tandem with the private sector. The promise offered by the new system is enormous; developing countries need to know how to negotiate access and how to build partnerships based on mutual value exchange.

This *Handbook* is a valuable guide to navigating the complex—but bountiful—world of an increasingly global innovation system. The reader will find relevant case studies, concrete observations, and practical suggestions. The *Handbook* should be most useful to government policy-makers, senior managers of public research institutions, technology transfer officers, and scientists in developing and developed countries. It is a resource that can help governments and other institutions move forward to meet the agricultural and health challenges of tomorrow. ■

December 2006
El Batán, Mexico

NORMAN E. BORLAUG, *CIMMYT, Apdo. Postal 6-641, 06600 Mexico, D.F., Mexico.* N.Borlaug@cgiar.org

Foreword by R. A. Mashelkar

Intellectual property (IP) is no longer seen as a self-contained domain in which specialists alone work and dwell. It is viewed as an integral part of innovation-driven socio-economic development across the globe and is increasingly becoming an effective policy instrument with respect to a range of technological, socio-economic, and political concerns. This *Handbook* of best practices in intellectual property management, with its novel and useful *Executive Guide* is, therefore, an extraordinary contribution that has arrived at precisely the right time.

The issues of generation, valuation, protection, and valorization of intellectual property are growing in complexity. There is increasing demand for new forms of IP protection. Economies are changing, with a new knowledge-based economy replacing "bricks-and-mortar" based economies. Scientific knowledge is growing exponentially. A new "geography of science" exists with innovative developing countries, such as India, China, and Brazil, having emerged as major contributors to science and technology. Policy-makers, researchers, and entrepreneurs have begun to appreciate the vast resource of traditional knowledge in the developing world and to recognize the complex issues connected with intellectual property therein. Not long ago, IP experts had only to deal with inanimate objects. Today, IP involving plants and animals, including humans, raises new complex issues and perplexing questions. Therefore, a book dealing with guidance on these issues with authority and clarity was sorely needed. The timely issuance of the *Handbook* and *Executive Guide* fulfills that need. The book is authoritative, comprising contributions by many of the leading practitioners and thought leaders in the field of IP management. The book has clarity. Its best practices and strategies have been explained in a way that is very easy to assimilate.

Books on intellectual property that were published in the past, while in many ways valuable, dealt only with enterprises and institutions in developed countries. This *Handbook* represents the first major effort to deal with issues of concern within the developing world. Furthermore, the role of public sector research institutions in fulfilling the socio-economic goals and objectives of developing nations, by contributing immensely to the public good as well as to the private good, had never before been written about extensively. This *Handbook* fills this void admirably.

Mashelkar RA. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

In the past, issues of emerging global innovation networks related only to North–North partnerships. But today North–South partnerships as well as South–South partnerships are emerging. As "technonationalism" finds a new equilibrium with "technoglobalism," IP management issues are becoming ever more complex. New forms of knowledge in the private domain as well as the public domain are being created. It is no longer Linux versus Windows—it is Linux with Windows! In general, how do we create a new nexus between the public and the private? The *Handbook* has taken up this new challenge head-on.

Drafting, interpreting, and analyzing the techno-legal and business information contained in IP documents requires specialized skills. Monitoring, through online databases, the wealth of information in patents and other forms of intellectual property in order to ward off threats to national IP portfolios is becoming critical. Analyzing such information, for market intelligence, to identify strategic alliances, and to exploit potential niche areas for the innovative use of intellectual property will, itself, give rise to new knowledge-based businesses. This *Handbook* is invaluable from this perspective, as well.

Today, start-up companies and spinouts reach beyond Stanford, M.I.T., Cambridge, and Oxford. Leadership in China reports that Chinese universities have set up several hundred high-tech start-ups. India is introducing a Bayh-Dole-type law for Indian universities and research institutions. In short, the phenomenon of wealth creation through the knowledge generated at universities is spreading across the world. The *Handbook* offers valuable guidance to university inventors and administrators with regard to licensing, negotiating agreements, technology transfer, dispute resolution, and so on.

One of the most fascinating sections presents institutional case studies, providing insights from Stanford, M.I.T., Cambridge, and other leading public sector research institutions. The case studies will be most revealing for institutions in emerging economies setting up their own technology transfer systems and wishing to emulate those universities.

When a patenting culture starts in an institution, issues of how to read and write patent applications, how to document inventions, as well as how to prepare laboratory notebooks and invention disclosures become crucial. In India, there was nothing to guide us when our own "patent literacy movement" began. We learned the hard way. How much easier and productive our work would have been had the *Handbook* and *Executive Guide* been available to us then!

The issues of IP management in low- and middle-income countries are vastly complex. In particular, lifesaving innovations in health and livelihood-generating innovations in agriculture directly affect those countries' socio-economic development. Special attention has been given in the *Handbook* to address these issues.

I do hope this *Handbook* will not only help in providing guiding principles and best practices in IP management, but will become a lighthouse that will show the way toward a more equitable and inclusive world. After all, making intellectual property work for the poor, whether it is owned by the public or by private entities, can be the only way to create an innovation-led inclusive growth movement.

March 2007
Pune, India

R. A. MASHELKAR, *Bhatnagar Fellow, National Chemical Laboratory, Pune 411 008, India. ram@ncl.res.in.*

Foreword by Francis Gurry

Intellectual property (IP) has become a much richer field of endeavor as it has moved from isolationism in the world of policy to a position of engagement. From a one-dimensional technical specialization, intellectual property has become a multidimensional complex of policies. The transition has not, however, been without cost, in this case in the form of greater complexity. The range of policy fora in which intellectual property is discussed has expanded, seemingly without limit, to encompass most international organizations, as each of the policy domains for which these organizations are responsible confronts the implications of IP rights in the new environment of the knowledge economy. These policy intersections recur at each of the regional, bilateral, and national levels. And the cast of actors involved in the drama contains a much wider and more diverse range of characters, performing a more demanding repertoire than would have been imaginable two decades ago. Nowhere is this development more striking than in the life sciences, especially related to innovation for public health and agriculture, where the promises of new technology that may serve the most fundamental of human needs vie with complex concerns over the impact of technologies, ethical issues, and claims over fundamental justice and human rights.

Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices will serve as an invaluable resource in this challenging new environment. The *Handbook* is based on a number of orientations that contribute in highly positive ways to an understanding of the utility, value, and limitations of IP rights as a system of law, a mechanism for policy development, and a policy instrument.

The *Handbook's* first positive orientation is the practical approach embraced by it and by the companion *Executive Guide*. The increased attention that intellectual property has, quite understandably, attracted has brought with it a certain tendency to conflate IP issues with some of the *grandes idées* that permeate the reflections of contemporary society, such as globalization, the ethical limits of scientific endeavor, and distributional equity. This tendency has had an adverse effect on IP management because it has redirected the focus of intellectual property away from practical issues; intellectual property is not necessarily neutral with respect to any of these grand movements of thought. But we would do well to remember that policies involving intellectual property are operational policies, the effects of which depend heavily on how the intellectual property is deployed and used. Solid practical guidance and experience are precious resources and they are to be found in abundance in the *Handbook*.

Gurry F. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

Practical approaches and solutions offer a welcome contrast to the notion that everything has a legislative solution. Legislation, whether national or international, is of limited value and is always without meaning unless given life through practical action or implementation. We have experienced an explosion of IP legislation at the international level in the past 15 years, with ten new multilateral treaties being concluded between 1989 and 2000. Experience of the practical management of IP rights provides a rich knowledge base for evaluating and harnessing the benefits of this legislative landscape and for assessing the full range of options open to public- and private-sector actors to deliver, in practice, the ostensible benefits of this intense phase of legislative activity.

A second very positive orientation of the *Handbook* is through the espousal of a methodology of best practices. In the complex world of international negotiations, solutions are often based on the identification of the lowest common denominator of the varied positions and underlying interests of the countries involved. Such an approach is often necessary for finding agreement in a world with, as yet, a still underdeveloped sense of the common sphere. Few examples are to be found of agreements based on the identification of best practices, as a positive expression of the common interest, and agreement on the aspiration of striving toward such best practices. While the world awaits more widespread acceptance of the methodology of best practices with regard to the international legislative process, the *Handbook* makes a major contribution, by providing a description of the use of that methodology, with respect to practical choices for the management of intellectual property within the current legislative environment.

An understanding of best practices is essential for the *Handbook's strategic* orientation—a *strategic* approach to the management of intellectual property. The complexity of the environment of intellectual property demands the use of effective strategies for navigating the sophisticated institutional architecture and for utilizing the potential that intellectual property offers for the generation, deployment, and diffusion of new knowledge in the commercial, scientific, and public sectors. The patent system has developed the most comprehensive, systematic, and accessible record of humanity's technology. Fifteen years ago, this treasure of knowledge was known only to a small group of experts who had access to the paper collections in which the record was stored. Digital technology has combined with the accessibility of the Internet to make this record available, free of charge, to the whole world. When mined intelligently, this wealth of raw data can provide the technological and policy information that enables the public and private sectors to have a more strategic approach to the identification of research opportunities, freedom to operate, and business strategies.

The Centre for the Management of Intellectual Property in Health Research and Development (MIHR) and the Public Intellectual Property Resource for Agriculture (PIPRA) are to be commended for the development and publication of the *Handbook*, which will advance the understanding and practice of intellectual property in a constructive, pragmatic, and highly effective manner.

March 2007
Geneva, Switzerland

FRANCIS GURRY, *Deputy Director-General, World Intellectual Property Organization (WIPO), 34, chemin des Colombettes, 1211 Geneva 20, Switzerland. francis.gurry@wipo.int*

Foreword by Howard A. Zucker

The past 25 years have witnessed major challenges and successes in the field of public health. Carefully planned and implemented measures for prevention and control have shown their worth in battling formidable infectious scourges: smallpox was eradicated in 1979, and the public health menace measles has been contained. New drugs have been developed for HIV infection, dramatically improving the prognosis of those who receive antiretroviral therapy. Even with new menaces, such as avian influenza, and setbacks to such programs as polio eradication, the control of communicable diseases is technically feasible.

What is technically possible, however, has not always been accessible by developing countries. Indeed, access to appropriate treatments for diseases and conditions that disproportionately affect developing countries is still a big stumbling block. Part of the problem stems from inadequate health-services coverage: one-third of the world's population lacks regular access to essential modern medicine (up to one-half, in certain parts of Africa and Asia). Direct financial constraints contribute to the problem. Drug discovery and development is a complex, lengthy, and costly process. As recently reviewed in the World Health Organization Report of the Commission on Intellectual Property Rights, Innovation and Public Health (see pages 17 and 76 of that report*), even moderate estimates of the cost of R&D for some drugs put the total between US$115 million and US$240 million.

Socio-cultural inequalities also have a profound affect on distribution. The majority of potential patients live in the poorer parts of the world, whereas the majority of drug and vaccine producers—and purchasers—are found in affluent countries. Although developing countries have more than 80 percent of the world's population, they account for only about 10% of drug sales. Major pharmaceutical producers—however great their desire to benefit all—are answerable to market forces and to the wishes of shareholders.

For health products, both demand and supply are out of balance. Many public-health-policy experts have pointed to the concept of IP (intellectual property) rights—the protection of intellectual and financial investments in new drugs and vaccines—as contributing to this imbalance and inequity. As part of the ongoing international debate about the wider aspects of the relationship between IP rights, innovation, and public health, the World Health Assembly under the auspices of the World Health Organization decided to establish an independent Commission to analyze the issue. The Commission's report, released in

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Zucker HA. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

2006, states that governments around the world have recognized moral and legal issues with respect to ensuring general access to existing drugs (see pages 8 and 9 of that report). This access is essential for sustaining government efforts in developing countries and elsewhere to control disease.

As a follow-up to the Commission's report, a working group comprising government officials and other key stakeholders in public health, innovation, and intellectual property is developing a global strategy and plan of action. The goal is to secure an enhanced and sustainable basis for need-driven health research and development aimed at curing or treating diseases that disproportionately affect developing countries. The strategy being discussed includes "*making intellectual property work for health*" as one of three major challenges. Among eight elements of the proposed plan of action for implementing the strategy is the management of intellectual property, including such aspects as legislation, incentives, documentation, training, and regulation.

In deliberations of the intergovernmental working group, Member States have identified IP management as a key element of progress in the fight against diseases, an element that poses complex and sensitive problems in the realms of ethics, economics, and health policies. This *Handbook of Best Practices* is both timely and highly relevant. It is hoped that the *Handbook* will help build capacity in decision making at the national level by assisting academics, researchers, and policy-makers—especially in the developing world—to clarify many of the issues that currently influence the relationship between generalized access to drugs and the protection of IP rights.

March 2007
Geneva, Switzerland

* http://www.who.int/intellectualproperty/report/en/index.html

HOWARD A. ZUCKER, *Assistant Director-General, Health Technology and Pharmaceuticals, Representative of the Director-General on Intellectual Property, Innovation and Public Health, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland.* zuckerh@who.int

Foreword by Sir Gordon Conway

From 1998 to 2004, I served as president of the Rockefeller Foundation. During that time, it's fair to say there was no universally accepted understanding of the exact relationship between intellectual property (IP) and affordable essential goods for the poor. The foundation chose to approach this issue in a variety of ways, including support for the creation of the Centre for the Management of Intellectual Property in Health Research and Development (MIHR) and the Public Intellectual Property Resource for Agriculture (PIPRA). Until now, these organizations have worked independently. But although they differ in many respects, they share a common goal: to develop and disseminate best practices for the management of IP for the public good. Now, for the first time, the organizations have joined forces to weave together the common threads of their respective fields in order to create this unique and comprehensive book titled *IP Management in Health and Agricultural Innovation: A Handbook of Best Practices.*

I would like to reflect a bit on the founding principles of these complementary organizations. Both PIPRA and MIHR were developed to promote the ethical stewardship of new technologies in their respective fields, based on the idea that publicly owned IP can be a *currency* to improve access to health and agricultural products and know-how. Yet the idea for each organization arose independently within The Rockefeller Foundation, following separate consultations with the agricultural and health communities. During the time that the foundation's rice biotechnology program was operational, food security officers were keenly aware that many proprietary technologies developed in public institutions were then locked up in large corporations, a problem that was becoming evident to experts at U.S. universities as well. The "health equity" theme encountered similar problems as the foundation was working to establish global public–private partnerships for the development of affordable drugs and vaccines.

How had this situation developed? In many cases, research institutions in developed countries simply hadn't considered the impact of their technology-licensing practices on developing countries. Public institutions in both developed and developing countries lacked sound policies that were specifically designed to maximize the benefits of global public goods resulting from their own public–private partnerships in R&D. To address these problems, local technology managers would need to become better informed and empowered to think globally, while public research institutions would need sound insti-

Conway G. 2007. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

tutional policies to ensure that public investment would lead to affordable essential goods for the poor.

So far, MIHR's efforts have focused on capacity building, working to build a cadre of technology management professionals in developing countries and to raise the stature of these professionals. MIHR has also worked to develop and promote a "tool kit" of best practices for technology managers in both developed and developing countries to encourage licensing practices that would benefit global health.

PIPRA, in contrast to MIHR, is a consortium made up of more than 40 major American research universities and not-for-profit research institutions in the United States and abroad. The consortium was established to enhance global access to agricultural technologies that are developed by its member institutions. PIPRA promotes research collaboration and collective management of IP among its members for public benefit.

The PIPRA consortium is creating a broad patent/license database that will make it possible to determine readily both the range of technologies available from its member institutions and the manners in which these technologies will be made available to allow for specific applications. Where freedom to operate is clear, PIPRA is developing strategies that will promote the use of technologies by scientists to address the agricultural needs of poor farmers in developing countries. PIPRA is also creating public sector tools for use of improved subsistence crops for developing countries and of specialty crops to be grown in the United States.

The PIPRA business plan envisioned future work in the building of agricultural technology–management capacity in developing countries—an effort that has been central to the mission of MIHR. At the same time, MIHR's business plan envisioned the creation of a patent-and-licensing database for health technologies, and MIHR is currently exploring the creation of a PIPRA-like consortium of university technology-management offices based in developed countries. In biotechnology, the similarities between agriculture and health range from the reagents used in the laboratory to their national regulatory and industrial policies. The potential for collaboration between PIPRA and MIHR on a wide range of issues is obvious. This publication is an exciting first step in that direction.

I believe the global community must do more to promote the ethical stewardship of new technologies arising from public funding in developed countries to benefit agriculture and health in the developing world. At the same time, we must begin to recognize that developing countries themselves are increasingly capable of contributing solutions to their own food shortages and public health challenges. This *Handbook* advances these goals. It is an important step toward both building upon and transcending the work of MIHR and PIPRA, by creating new transnational networks that involve multiple partners—donors and doers alike—who believe that the power of innovation can address the needs of the poor. ■

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Message from the Editorial Board: From Best Principles to Best Practice

As members of the Editorial Board, we represent not only a diversity of professional backgrounds, institutions, and geographic regions, but also a diversity of viewpoints about intellectual property (IP). We agree on many things and we share a common goal: to broaden and accelerate access—especially in developing countries—to life-saving and poverty-alleviating innovations in health and agriculture. A fundamental vision of a more equitable world—represented in the points that follow—binds us together in this endeavor.

- **Intellectual property is a tool to foster innovation.** Intellectual property is here. And here to stay. Whether viewed as a legal concept, a social construct, a business asset, or an instrument to achieve humanitarian objectives, the value of intellectual property cannot be disputed. The notion that inventions can become *property* and can therefore be owned and sold, has encouraged scientists and researchers to invent, and entrepreneurs and companies to invest in innovation, by allowing them to profit from the resulting technologies. But by permitting entrepreneurs to exclude competitors and set higher prices, IP protection may also prevent some individuals, or populations, from being able to access products. There are many ways, however, that intellectual property can be utilized and distributed. Through the publishing of this *Handbook*, the companion *Executive Guide,* and the online version, we intend to help **put intellectual property to work for the public sector and the public interest**. We agree that intellectual property should be neither feared, nor blindly embraced; rather, it should be *managed* to maximize the benefits of innovation for *all* of society, *especially* the poor.

- **IP rights are a compromise and an imperfect solution.** They represent the search for balance between making all knowledge freely available within the *public domain* and granting *ownership* of valuable discoveries to the inventors. Historically, we have seen that this balance encourages investment—and reinvestment—in innovation, although this innovation too infrequently is directed toward the needs of the poor. Reaching an appropriate balance requires

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continuous, sound IP management, and our desire to encourage this was a major impetus for compiling this *Handbook* and for writing the *Executive Guide*. Fortunately, as numerous case studies have shown, the public sector can craft effective solutions that can achieve, or at least approach, a suitable balance. This can be accomplished by using the existing IP system, especially as it addresses situations in which companies agree to donate or otherwise share their intellectual property.

- **Genius can flourish anywhere, and the emerging global systems of innovation in health and agriculture open up new prospects for innovation everywhere.** This notion has profound implications for the management of innovation, technology transfer, market competition, and economic development in every country, regardless of its economic status. Provided with opportunities and resources, scientists and scholars from any locale can create promising inventions with the potential to become valuable technology. And whether inventions are home grown or come from outside, authoritative IP management will play a crucial role in enabling and preserving access to the resulting innovations.

- **Policies to promote the *creation* and *management* of intellectual property by public sector institutions should give first priority to advancing the mission of those institutions.** In most countries, the mission of universities is education, research, and public service. Universities are not revenue generators. Technology transfer should support the larger mission, and not merely the budgets, of those institutions.

- The historical trend has been for intellectual property to benefit mostly the affluent. This is due, in part, to the fact that **insufficient attention has been paid by the public sector to managing intellectual property.** This lack of focused attention must be corrected. Public sector IP management is a rather young discipline, and there have been enormous changes in the public sector's involvement in health research since the 1970s and in agri-biotechnology since the 1990s. The public sector is only now beginning to appreciate how it can use its own intellectual property—and leverage that of others—to help meet its social mission, including its responsibilities to the poor. We believe that there is growing interest, within both the public and private sectors, in using intellectual property for public benefit but, also, a lack of knowledge and capacity. This *Handbook* is designed to help address these needs.

We hope this *Handbook* and *Executive Guide* will encourage all parties to take greater advantage of the unprecedented opportunity to benefit from the strategic management of intellectual property aimed at promoting the public welfare—especially those people who have, until now, been unable to partake in technology's benefits—and that this will contribute to building a healthier and more equitable world. ■

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Pictured above, from left to right: Carlos Fernandez, Alan Bennett, Anatole Krattiger, Lita Nelsen, Jennifer Thomson, Kanikaram Satyanarayana, and Richard Mahoney

Left: Gregory Graff and Stanley Kowalski

Prelude

The many voices in this *Handbook* make up an expert chorus in the field of intellectual property (IP) management. Motivated by their passion for a better world, these virtuosos volunteered to share their experiences as part of a broader effort to bring innovation to the poor and improve the lives of millions of people. These selfless, ground-breaking experts bring to mind another revolutionary, Ludwig van Beethoven, who declared, "I have never thought of writing for reputation and honor. What I have in my heart must come out; that is the reason why I compose." The compositions here are obviously less sublime than Beethoven's, but their potential to inspire is nonetheless comparable: they are always written from the heart.

The creativity in these chapters reflects the fact that IP management is an emerging discipline, one best described not as science but as art. This is why the title pages of every chapter announce that this *Handbook* is "Sharing the Art of IP Management." These chapters offer lucid, cogent analyses of the role of intellectual property in many practical contexts and give free play to the imagination, inspiring readers to try new strategies, risk improvisation, and embrace new motifs. Such creativity is a necessary response to the increasing complexity and importance of the nexus of intellectual property and the public good.

Given that intellectual property is a critical institutional management and global policy issue, it can no longer be ignored by public sector-research institutions or left to the legal establishment. Policy-makers, leaders of scientific institutions, licensing experts, and scientists everywhere all need to act in concert to make the most of their work. But protecting intellectual property is just the beginning. The real challenge is to use one's intellectual property and to leverage that of others. This approach is at least as important for the public sector as it is for the private sector, given its humanitarian and socio-economic mandate.

This *concerto grosso* gathers the experiences of IP professionals from North, South, East, and West, and offers innovative knowledge and strategies that can be applied to many institutional settings. Because increasing numbers of developing countries are seeking to optimize the economic, social, and cultural value of their IP assets and resources, I believe this *Handbook* will find a ready audience. The suite of chapters, composed by nearly 200 authors, offers pragmatic suggestions and reference resources that will pave the way to greater access to health solutions and agricultural innovations. The authors write about

Krattiger A. 2007. Prelude. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

the topics from various perspectives, an approach that inevitably led to some overlap. This overlap allows the reader to see a topic from several perspectives. The authors have distinctive voices, and, as with Beethoven's famous counterpoint, the distinctive parts are precisely what make the whole so compelling.

Driven by rapid advances in science and technology and by the dawn of a worldwide, networked society, the increasing economic and humanitarian centrality of intellectual property will lead to more sophisticated and complex institutional infrastructures. The process is happening even as you read this Prelude. This is no time, therefore, to remain in complacent isolation. It is time to join your voices—and aggregate your values and your actions—to form a network of effective partnerships. A solo performance will lack the power of a full orchestra, and solo efforts at innovation will be stymied without collaboration.

The strength of this *Handbook* is the depth and breadth of its information. But just as notes only become music when the bow meets the viola string and the timpani sounds, so these chapters will matter only when the reader translates them into action. My highest hope is that this *Handbook* will incite a passionate, rousing performance, one that will touch the lives of others and reverberate far beyond these pages.

Anatole Krattiger
Editor-in-Chief

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Acknowledgments

Like the progress of any invention from bench to bedside (to use a health-related metaphor), or from sowing to harvesting (to borrow from agriculture), the road leading to the creation of this *Handbook*, and its companion *Executive Guide* and online version, has required a great deal of effort and more than a little good fortune. As editor-in-chief, I have discovered that compiling a book composed of 158 chapters and prefatory comments, written by nearly 200 authors, presents many unique challenges but offers many more unique rewards.

The authors, first and foremost, deserve special thanks for their willingness to share their experiences and insights, their cooperation in meeting sometimes rather tight deadlines, and for their readiness to volunteer their valuable time (thanks are also due to their employers for allowing the authors to take the time to write). The hard work of these authors is the good fortune of any reader of this *Handbook*.

Special thanks go to the Rockefeller Foundation, particularly Ariel Pablos-Méndez and Charles Gardner, in health; Gary Toenniessen and Deborah Delmer, in agriculture; and Jacob Werksman (now at the World Resources Institute). Under their leadership, the Centre for the Management of Intellectual Property in Health Research and Development (MIHR) and the Public Intellectual Property Resource for Agriculture (PIPRA) were established several years ago. Their inspired vision and determination, along with the foresight of Judith Rodin, president of the Rockefeller Foundation, has enabled us to bring you this *Handbook*. On behalf of all the users of the *Handbook*, the Editorial Board, and MIHR and PIPRA, I would like to offer my sincere appreciation to the Rockefeller Foundation for its commitment to and primary funding of this venture. Funding from the Ewing Marion Kauffman Foundation is also gratefully acknowledged. Lesa Mitchell's interest in the *Executive Guide* was particularly welcome. Their combined sponsorship of these two foundations made the preparation of this *Handbook* possible. We would like to emphasize, however, that all of the policy, content, and editorial decisions were the sole purview of the Editorial Board. Naturally, as editor-in-chief, I take full responsibility for any errors or omissions.

We are grateful for the generosity of our Distribution Supporters. After the *Handbook* content had been prepared, a number of organizations were provided copies of sample chapters which prompted some to come forward to purchase copies for wide distribution in low- and middle-income countries. It is particularly noteworthy that the Distribution Supporters include several institutions from developing economies, in addition to academic and public-sector research institutions, philanthropic foundations, and companies. The impact of this *Handbook* will be greatly enhanced by the support of the Distribution Supporters–including those that we hope will come forward in the future.

The Editorial Board would like to express its gratitude to all the members of the Board of Patrons for their generous endorsement of the *Handbook*. Their wise counsel is much valued.

The Editorial Board also wishes to thank the Association of University Technology Managers (AUTM) for allowing us to choose, update, and edit selected papers from the *AUTM Technology Transfer Practice Manual*, which appear as chapters in this *Handbook*, as well as for giving us permission to reproduce case studies from the association's *Better World Project* and *Reports from the Field* (which appear in the *Executive Guide*). These contributions add much breadth and depth to the *Handbook*'s content. Mark Crowell, John Fraser, Stu Gordon, Vicki Loise, and Lisa Richter were all especially helpful. The Editorial Board would also like to thank the Public Interest Intellectual Property Advisors, Inc. (PIIPA), especially Michael Gollin and Steven Price, for assistance in enlisting the help of the law firms within its network; members of those law firms contributed many important chapters. The individuals proved their commitment to PIIPA's ideals by responding so promptly to our request and willingly contributing their ideas and experiences to the *Handbook*. The University Companies Association of the United Kingdom (UNICO) deserves appreciation for sharing a valuable *UNICO Practical Guide*. My sincere gratitude also goes to the Guide's main author, Mark Anderson, of Anderson & Company, for his cooperation during the editing phase. I extend my gratitude to *Intellectual Asset Magazine* (*IAM*, published by Globe White Page, Ltd.) and particularly its editor, Joff Wild, for allowing the *Handbook*'s editors to edit and update an important chapter that previously appeared as an article in *IAM*. Thanks go also to *Les Nouvelles*, published by the Licensing Executives Society, for allowing us to revise two of its articles for inclusion in the *Handbook*.

Particular thanks go to the Whitehead Institute for Biomedical Research, which, through the good offices of Amina Hamzaoui, granted us a license to its valuable, proprietary patent- and agreements-management system, WIIPS™ (the Whitehead Institute Intellectual Property System), and granted us the right to sublicense the system to technology transfer offices through the online version of the *Handbook*.

The members of the Editorial Board are most grateful to the colleagues at MIHR in Oxford, U.K. First, the Editorial Board would like to thank Robert Eiss, CEO, for his resourcefulness in facilitating progress on the *Handbook*. Thanks are due also to Junko Chapman for coordinating, most diligently and always with characteristic Japanese courteousness, all of the authors' biographies, deeds, and photographs (the latter appear in the online version of the *Handbook*). Rachelle Harris deserves special appreciation for her industrious help—and always enthusiastic support—on many different crucial fronts. Thanks to the administrative staff at MIHR who always went the extra mile to get things done. Sincere thanks go to the entire Board of Trustees of MIHR, particularly the chair, Pramilla Senanayake, for their foresight in establishing a Board subcommittee for the *Handbook*. That committee, composed of Lita Nelsen, Richard T. Mahoney, and Jerry Keusch, was astonishingly effective. I thank them for their pragmatism and encouragement.

This endeavor has truly been a collaborative effort between MIHR and PIPRA—an essential partnership that made this *Handbook* possible. Members of PIPRA's staff, led by Alan Bennett and Greg Graff (both members of the Editorial Board), Sara Boettiger, and Cecilia Chi-Ham, were always a pleasure to work with. Their efforts, always indispensable, were executed with PIPRA's characteristic professionalism and efficiency.

Without its skillful and effective editorial and production team, this *Handbook* could not have taken shape nor reached its high level of readability and quality. My personal and most sincere thanks go to David Alvarez, for his unstinting help and commitment. He

worked with me throughout this project and his good humor made crunch times more bearable. Thanks also to his most able and enthusiastic manuscript editors, Jacqueline Stuhmiller and Katy Dixon. I am most grateful also to Paula Douglass for her diligent, sharp, and sensitive editing of the manuscripts and her exacting standards. I wish to especially acknowledge the efforts of the contributing editors, Stan Kowalski and Greg Graff, for their perseverance. Their ability to organize and process complex and diverse material proved indispensable.

The elegant design work by Linette Lao will be evident to anyone holding this *Handbook*. She is truly a pleasure to work with, and I am grateful to her staff—Mary Penn, Julie Morelli, and Kristin Schrader—who sometimes worked around the clock on the layout and design of this book. On behalf of all of the *Handbook*'s readers, I thank eagle-eyed Barry Hall who performed the final copyediting of each and every chapter.

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It is a particular pleasure to acknowledge the creativity and superb work of the staff of Dynamic Diagrams, Inc.—Lisa Agustin and her team of Timothy Roy, Fred Toth, Matt DeMeis, and Henry Woodbury—for their excellent work in developing the online version of this *Handbook*. Their enthusiasm and focus have taken the online version further than we could ever have imagined. Jacob Werksman's foresight proved particularly valuable.

A special word of appreciation goes to Charles Arntzen at the Biodesign Institute at Arizona State University for having recognized the importance of this *Handbook* and for his thoughtful support. Michael Crow, president of Arizona State University, with his vision and enthusiasm, encouraged me both directly and indirectly. I am indebted to John Dodds of Dodds & Associates for having taught me a great deal about the ins and outs of intellectual property management. His advice on legal matters during the chapter review process was extremely helpful.

I have been most fortunate, as editor-in-chief, to have had the assistance and support of an outstanding Editorial Board. The hard work, deep commitment, expert guidance, and collective experience of these dedicated and talented Board members have inspired and motivated me, personally and professionally, and have kept this project on course. I am grateful for having had the opportunity to lead this worthwhile and far-reaching endeavor with these fine individuals.

Finally, on behalf of the Editorial Board, I would specifically like to thank Richard T. Mahoney, co-editor-in-chief of this *Handbook* and sole editor of an earlier and more concise version. Richard's book—and life work—inspired me throughout the work on this *Handbook*. His enthusiastic support and creativity and generous investment of time and energy over the last two years were always delivered *allegro maestoso.* His good humor and pragmatism—which helped keep everything in perspective—have contributed in immeasurable ways to creating this *Handbook* and making it available to you. ■

Anatole Krattiger
Editor-in-Chief

About MIHR
Centre for the Management of Intellectual Property in Health Research and Development

To contribute to a world in which the thoughtful stewardship and creative management of intellectual property leads to better health for the poorest.

Over successive generations, innovations resulting from research have dramatically improved life expectancy and quality of life. However, the benefits of these innovations are not reaching the populations with the greatest need. Stark disparities persist with regard to health status both among and within populations. Today there is an urgent need to identify practical mechanisms that translate R&D investments more effectively into affordable interventions for diseases of the poor. Central to resolving the issue is the need to develop and promote forms of IP management and technology transfer practices that enable and empower local public–private technology partnerships, that direct them toward public health priorities, and that follow licensing practices that ensure access for the poor.

MIHR was established in 2002 with funds from The Rockefeller Foundation, to advance the goal of improving availability of health products needed by the poorest in developing countries. MIHR is a not-for-profit global organization headquartered in Oxford, U.K. Its foundational tenet is that improved management of innovation and intellectual property (IP) by the public sector is a key means to achieve that goal.

The organization works to improve the processes of innovation management in the biomedical arena by building skills, know-how, and awareness in developing countries and by contributing to the understanding of sustainable innovation and IP policies that affect global health research.

MIHR also works to ensure that holders and managers of technology worldwide are aware of the need for and potential applicability of their inventions for improving health in developing countries. The Centre accomplishes this by facilitating local development of appropriate, affordable, and innovative biomedical technologies for poor populations. MIHR contributes to economic development by enhancing essential linkages between sectors, institutions, and disciplines involved in biomedical innovation and by enhancing the capabilities relevant to technology transfer that contribute to economic and social welfare.

MIHR's core objectives are:

- to create a broad and sustained program of capacity building in IP and technology management to promote global health equity through North–South and South–South institutional partnerships and networks
- to help ensure that access considerations for global health are pursued in parallel with product development, so that successfully developed products become available and affordable to populations in need
- to develop technology and IP management approaches that create incentives for research cooperation in global health by supporting analysis and new models

MIHR achieves its goals by working through and with other institutions. It functions with a small core operational staff, a Committee of Interested Parties, and a Board of Trustees. ■

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About PIPRA
Public Intellectual Property Resource for Agriculture

A public sector collaboration for agricultural IP management:
Enabling access to intellectual property for the development of improved crops

Patenting of agricultural biotechnologies has expanded dramatically over the last 25 years, and today a lack of access to patented technologies represents a significant barrier to new crop development. Companies are addressing the development of major crops and large market opportunities, yet most crops in developing countries and specialty crops in developed countries are being neglected. Developing countries are not receiving research investment or opportunties to benefit from the many promising technologies developed and patented by both public and private sector researchers.

The public sector and publicly supported research continues to play a major role, as it has historically, in agricultural innovation. This is particularly true in developing countries where the public sector and publicly supported research institutions are virtually the only innovative forces. In spite of this and the now well-established importance of intellectual property (IP) in agricultural innovation, public sector institutions have not developed the skill base and infrastructure needed to actively manage intellectual property. Consequently, these institutions find that their research programs may be blocked at the point of application or that they are unable to effectively transfer their own technology for private sector development.

The primary objective of the Public Intellectual Property Resource for Agriculture (PIPRA) is to promote access to agricultural technologies developed in public and/or private nonprofit research institutions for both humanitarian and neglected commercial purposes. PIPRA was created as a result of lengthy consultations involving two philanthropic foundations, the Rockefeller and McKnight foundations, and approximately 12 public and/or private nonprofit agricultural research institutions. The consultations identified many of the IP issues and barriers that were affecting the ability of public institutions to address their historic mission of deploying new agricultural technologies.

In response, PIPRA has established a strategy and a series of programs that promote broad access to agricultural technologies. The strategy is based on bringing together a strong membership base of the major public or nonprofit agricultural technology developers of the world. PIPRA is seeking, through its membership base, to build a framework of open and collaborative communication and principles for IP management and to begin to coordinate the highly fragmented portfolio of agricultural intellectual property owned by its member institutions.

PIPRA does not subscribe to a single philosophy or approach to addressing IP issues. Instead, PIPRA believes in employing a wide range of available IP management tactics. These include defensive publishing, trademarks, bailment, open source, patenting, and careful licensing. In each case PIPRA chooses the best tools available to achieve the goals of a specific project. This approach is practical in that it recognizes that technologies may need to be *sourced* from a wide range of public and private technology developers who have their own objectives and their own IP strategies. PIPRA has developed sufficient internal capability to work flexibly in navigating

a path to enable agricultural projects that meet the complementary objectives of a community of public/nonprofit technology developers.

PIPRA's services, its broad membership base, its extensive knowledge of public sector agriculture, its legal network, and its capacity for legal research, work to reduce the IP hurdles that exist along the path from research, through development, to distribution. This work enables the strategic use of IP rights to further the goals of public sector research and reduces the diversion of individual institutional resources into the legal issues of technology access and IP rights.

PIPRA's primary strategies to improve access to technologies are to:

- provide an IP clearinghouse for access to public-sector patented technologies
- provide a resource for the analysis of patented technologies for implementation of specific projects
- develop gene transfer and gene-based-trait technologies that have maximum legal freedom to operate
- manage pools of public sector technologies to promote availability and reduce transaction costs associated with the transfer of rights to patented technologies
- support the development of IP management best practices and capacity enhancement in developing countries. ■

About the Online Version of this *Handbook*

visit www.ipHandbook.org

Disclaimer

The publishers, editors, and authors have given their best efforts in preparing this publication, and, while we believe the *Handbook* (including the *Executive Guide* and the online version) will all be useful resources relating to intellectual property and the management thereof, the *Handbook* is not intended to serve as the sole source of information on the topic. Readers are advised to seek independent legal counsel and/or other professional advice for all intellectual property and contractual matters with regard to appropriate practices for specific situations and countries. No warranties or representations of any kind are made as to the accuracy, usefulness, or completeness of any suggestions or information provided in the *Handbook*. Neither MIHR, PIPRA, nor any of the contributors to the *Handbook*, nor the editors, funding agencies, or sponsors will be liable for any loss or damage arising out of the use of any information or suggestions in the *Handbook*. This comprehensive limitation of liability applies to all damages of any kind, including (without limitation) compensatory, direct, or consequential damages; loss of data, income, or profit; loss of or damage to property; and claims of third parties. All Web pages have last been accessed between 15 February and 18 March 2007.

SECTION 1

Innovation and IP Management: A Contextual Overview

The Role of IP Management in Health and Agricultural Innovation

RICHARD T. MAHONEY, *Director, Vaccine Access, Pediatric Dengue Vaccine Initiative, International Vaccine Institute, Republic of Korea*

ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute; and Adjunct Professor, Cornell University, U.S.A.*

ABSTRACT

Recent national and international changes in intellectual property (IP) legislative frameworks are likely to have profound effects on the ways in which health and agricultural innovations reach the poor and on how public and private research and development institutions pursue their work. Whereas IP rights are sometimes viewed as creating barriers to access to innovations in health and agriculture, we argue that it is not intellectual property, *per se*, that raises barriers, but rather how intellectual property is used and managed, particularly by public sector institutions. Above all, we argue that intellectual property is only one of six components of innovation. It is rarely the most important component.

The chapter reviews recent dramatic developments in institutional aspects of intellectual property, as well as global policy shifts and international studies that, among other outcomes, affected the environment for the creation of MIHR and PIPRA. In the field of health, changes have been particularly pronounced with the founding of a new form of institution for innovation: product-development partnerships (PDPs). As a result, we make the case for a fundamental shift in the way in which IP management in health and agricultural innovation is viewed and conducted. In addition, we argue that IP management should be seen as an important element in developing countries' strategies to become more innovative in addressing diseases of poverty, the alleviation of poverty, and malnutrition. The public sector can employ new ways to achieve its goals within the evolving IP framework. These new ways can help it better mobilize the resources to take a product through the process of innovation. These new ways should include, a) creative licensing practices that ensure global access and affordability, b) improved institutional IP management capabilities, c) the formulation of comprehensive national IP policies, and d) the strengthening of IP court systems and patent offices.

These are what best practices in IP management are all about, and what this *Handbook* seeks to help bring about and promote.

1. INTRODUCTION

Changes in both national and international legislative frameworks have profoundly affected how innovation reaches the poor and how public and private research and development institutions pursue their work. In this regard, the experience of the United States with the Bayh-Dole Act of 1980, which harmonized the numerous IP ownership policies of U.S. government agencies, is quite instructive.[1] The act significantly changed how academic institutions manage intellectual property. Universities had to adapt to an increasingly knowledge-based economy, a trend that is continuing and even intensifying. And because of the increasing interaction between developed and developing economies and the increased number and complexity of relationships between the public and private sectors, the need for understanding these partnerships and how they can best operate is becoming compelling. Some of the major changes in this environment of the last decade in health, agriculture, and intellectual property itself are shown in Box 1.

Mahoney RT and A Krattiger. The Role of IP Management in Health and Agricultural Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

In addition, the last several years have been marked both by big changes in institutional IP infrastructures and by dramatic developments in the world of non-governmental organizations (NGOs), public sector research institutions, and public–private partnerships (see Box 2 for a discussion on agricultural biotechnology-related aspects). These developments promise to reshape the global IP environment, especially for developing countries. Some of the more significant of these events include:[2]

- 2003: The founding of the African Agricultural Technology Foundation (AATF)
- 2003: The founding of the Centre for the Management of Intellectual Property in Health Research and Development (MIHR)
- 2003: The creation, within AUTM, of the Technology Managers for Global Health (TMGH) group
- 2004: The founding of the Public Intellectual Property Resource for Agriculture (PIPRA)

In the field of health, the changes have been no less dramatic. A number of product-development partnerships (PDPs), concerned with most of the high priority diseases in developing countries, emerged during the 1990s and 2000s. PDPs must deal daily with IP management issues, and the lessons they are learning about the role of intellectual property are of great interest. MIHR has convened two meetings to analyze IP management in PDPs, both of which took place at the Aeras Global TB Vaccine Foundation, the first in December 2004 and the second in July 2006.[3] In fact, MIHR's founding and development in

Box 1: Major Recent Events in the Global IP system

Concerning IP in General

- 2002: Report of the Commission on Intellectual Property Rights of the United Kingdom[4]
- 2005: Entry of many low- and middle-income countries into TRIPS on January 1

Primarily Health-Related

- 2001: Meeting of the 4th Ministerial Conference of the World Trade Organization (WTO), which adopted the Doha Declaration concerning the TRIPS Agreement and Public Health[5]
- 2005: Approval of the amendment to the TRIPS Agreement providing for the supply of drugs manufactured under compulsory licenses for developing countries without manufacturing capability
- 2006: Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health[6]

Primarily Agriculture-Related

- 2001: Creation of the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore[7]
- 2001: Creation of the International Treaty on Plant Genetic Resources for Food and Agriculture, under the Food and Agriculture Organization of the United Nations (FAO)
- 2002: Establishment of the Global Crop Diversity Trust, by FAO and the World Bank
- 2002: Adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization, under the Convention on Biological Diversity

Box 2: Putting Public-Sector Agricultural Intellectual Property to Work

During the 1990s, the field of agricultural biotechnology was consolidated. A few large companies owned important elements of the enabling technology platforms. That ownership, coupled with strong R&D capability, existing marketing and distribution networks, and substantial cash flows from agro-chemicals and seeds, gave the companies incentives to invest heavily in the development of agricultural biotechnology products. With these increased R&D investments, the companies became the dominant providers of new crop genetics and genetically modified crops.[8] During the same period, biosafety regulatory requirements led to greatly increased R&D costs that slowed public sector developments of agri-biotechnology crops, especially public sector crop breeding programs.[9] Research on minor crops and on traits of low economic value in developing country agriculture also decreased, even though these crops and traits have high social, humanitarian, and environmental value.[10]

A significant turning point in the relationship between the public sector and intellectual property in agriculture occurred when a freedom-to-operate (FTO) review, commissioned by the Rockefeller Foundation, led by one of us (AK), of pro-Vitamin A-containing Golden Rice showed that around 70 patents and patent applications were applicable to the improved rice.[11] Fortunately, all of these constraints were resolved in a few months by a straightforward IP management strategy (grant back of rights to a single entity that could use the rights for the benefit of developing countries). The rapid resolution of these obstacles demonstrated, first of all, how effective IP management, coupled with strong collaborations between the public and private sectors, can help achieve humanitarian goals. The IP constraints did not delay the development of the product, and their resolution did not cost much, especially when compared to the overall R&D costs. The FTO review, moreover, served as a wake-up call to the public sector to pay more attention to IP management as a powerful tool.

Concern about potential constraints on public sector research and innovation in agriculture spurred the public sector's interest in intellectual property. One important response was work that led to the formation of the Public Intellectual Property Resource for Agriculture (PIPRA).[12] Supported by the Rockefeller and McKnight foundations, among others, PIPRA is a public sector initiative that recognizes that continuing and enhancing relationships with the private sector are critical components of successfully utilizing intellectual property to meet public sector goals.

As part of its initial work, PIPRA began a study of the structure of IP ownership in agricultural biotechnology. In the words of the study's authors, Richard C. Atkinson and colleagues:

This study found that roughly one-fourth of the patented inventions were made by public-sector researchers, which is substantially larger than the IP portfolio held by any single agricultural biotechnology company. It is, however, highly fragmented across institutions and across technology categories. And much of this IP has been licensed, often under terms that are confidential but which have likely resulted in greatly restricted access to the underlying technologies. This study suggested that, apart from a few important exceptions, public-sector scientists have invented many of the types of technologies that are necessary to conduct basic biological research and develop new transgenic plant varieties. For instance, they have developed technologies to transfer genes into plant cells; have characterized specific DNA elements that drive unique patterns of gene expression; and have identified many genes that confer important plant traits. Such discoveries underscore the fact that public-sector research institutions have been significant sources of technological innovation ... .[13]

We believe that these innovations can be put to work more directly to help the poor with more focused public sector IP management.

many ways reflect, and perhaps have helped to influence, the changing environment of IP management. We summarize here the story of MIHR's founding to help understand the major changes that have occurred and are underway.

We believe that the events of the last decade have led the international development community in health and agriculture to fundamentally reconceptualize the role of intellectual property in health and agricultural innovation, especially in relation to the needs of the poor. In the 1980s and 1990s, many individuals argued that intellectual property and patents were bad for people's health and innovative biotechnology products bad for their food. According to this argument, intellectual property was controlled by large pharmaceutical and agricultural companies that used the power of IP rights to capture markets, limit consumer choice in both health and agriculture, and, above all, raise prices. This not only priced the poor out of the market, but also discouraged further innovation of products needed by the poor.[14]

The claims of these arguments hold, however, only when the public sector responds passively to the global IP system. Like everyone else, the public sector needs to adapt to the changes in this system so that it can seize new opportunities and take advantage of previously unavailable options. Indeed, by neglecting to utilize the IP system effectively, the public sector not only neglects its own interests but the interests of those it serves. Without effective IP management, the public sector risks squandering the new powers that the revised IP system provides. Intellectual property is a tool, and the impact of a tool depends on *who* uses it, *how* it is used, and for *what* purpose.

This perspective has led to new efforts, including the founding of MIHR (see below) and of PIPRA (see Box 3), to make IP management a powerful tool for the benefit of the public sector.

2. THE ROAD LEADING TO MIHR

Toward the end of the 1990s, staff of the Health Equity program at the Rockefeller Foundation became concerned about the possible impact of patents and other intellectual property on the development and availability of new health technologies that addressed diseases affecting people in developing countries. In the 1990s, the staff had observed a significant amount of agricultural intellectual property captured by multinational companies, a situation that made it difficult to conduct certain kinds of agricultural research for the benefit of poor countries. The Rockefeller Foundation staff sought to ensure that a similar situation did not occur vis-à-vis health technology development. The Foundation therefore commissioned a group of individuals, led by one of us (RTM), to assess in detail the needs and opportunities in intellectual property and health. The results of this assessment eventually led to the founding of MIHR.

The study was launched in April 2001. At the time there was a lot of confusion about the role and impact of patents and other intellectual property. It was feared that crucial intellectual property would be controlled by private entities, and that this control would make it impossible to conduct product research and development. With respect to existing products, there was concern that patents provided virtual monopolies for companies—monopolies that the companies would use to extract high rents on the marketplace, making it difficult, if not impossible, for the poor to access the technologies that could benefit them.

The Rockefeller Foundation study immediately faced a practical difficulty: little research had been done on needs and opportunities in intellectual property and health. Only a small body of published literature addressed issues of interest to the foundation. Moreover, few scholars were studying these issues. The study team therefore decided to carry out its work by interviewing a wide array of individuals in the public and private sectors and in developed and developing countries. Nearly 200 individuals were interviewed, sometimes in groups but most often one-on-one. The following highlights some of the study's significant findings.

The study began by contextualizing the problem. In market economies, the private sector is driven by the desire to maximize returns on investment. Modern economic theory holds that

maximizing such returns spurs economic growth. Because selling highly profitable health products to the well-to-do leads to the highest maximization of return on investment, the private sector accords priority to products for these individuals. Conversely, the private sector does not and cannot be expected to accord priority to the needs of the very poor.

The public sector, on the other hand, is driven, in democracies, by its search to maximize human well-being. Modern social theory holds that all humans, regardless of citizenship, economic status, or other demographic variables, should be given the chance to maximize their well-being. Because the poor suffer the lowest quality of health, and because they often cannot afford to buy needed pharmaceuticals, the public sector has the responsibility of according priority to these individuals.

Within this political and economic framework, which is certain to be with us for the foreseeable future, intellectual property has grown increasingly important. Capitalist companies energetically seek and avidly protect intellectual property to obtain adequate returns on investment. Indeed, it is widely accepted that intellectual property is essential for the private sector. But what about the public sector? Does or can intellectual property help achieve important public sector goals?

3. THE SOCIAL AND ECONOMIC IMPERATIVES OF PRODUCT DEVELOPMENT AND ACCESS

On the most pragmatic level, intellectual property is important to the public sector because it is important to the private sector. If public sector

Box 3: The Public Intellectual Property Resource for Agriculture (PIPRA)

PIPRA is an international initiative undertaken by universities, foundations, and nonprofit research institutions to make agricultural technologies more easily available for the development and distribution of subsistence crops in the developing world and specialty crops in the developed world.

With the introduction of biotechnology in agriculture, researchers have a unique opportunity to contribute to the development of improved staple and specialty crop varieties. However, developing new crop varieties with biotechnology depends on access to multiple technologies, which are often patented or otherwise protected by IP rights. Ownership of these rights is fragmented across many institutions in the public and private sector, a situation that makes it difficult to identify who holds what rights to what technologies, and in which countries. Such information is necessary, however, to establish whether or not a new crop variety is at risk of infringing those rights. The current situation thus creates barriers to commercializing new staple and specialty crop varieties. PIPRA members believe that if public-sector institutions collaborated in gathering information about and in the use of agricultural IP rights, it would be easier for them to speed up the creation and commercialization of improved staple and specialty crops and thereby fulfill part of their public missions. Specifically, PIPRA focuses on the following principal activities:

- Reviewing public sector licensing practices
- Implementing a collective public IP asset database
- Developing shared technology packages
- Providing information, engaging other organizations, and stimulating discussions
- Engaging private sector organizations

Source: Adapted from PIPRA.[15]

organizations, such as PDPs, want to collaborate with the private sector to develop new, valuable health technologies, they must address IP issues. Many, if not all, of the PDPs have recognized this. In fact, their experiences have led many of them to reassess the role that intellectual property plays in making health and agricultural products available to the poor. Before PDPs, critics contended that intellectual property allowed private pharmaceutical companies to dominate markets, perpetuating high prices and excluding the poor. The experience of PDPs, however, shows not only that intellectual property can be utilized to serve the needs of the poor, but also that its misuse or waste slows the development of new technologies for developing countries.

But how can the public sector best use the IP system? Should it seek to minimize the problems that emerge from patents and other forms of intellectual property? Or should it take a more active role and seek to take advantage of some of the powers provided by intellectual property? To answer these questions, one must be able to see what capabilities and what benefits might accrue from the exercise of these powers.

The study ultimately concluded that there is a very important reason for public sector support of intellectual property: it is an essential tool for achieving safe and effective health technologies. Why? The answer is found in a combination of government actions and economic imperatives. During the latter half of the 20th century, developed countries created whole new systems of drug regulation. Of these, the Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA) in the United States is one of the more influential. One of the motivations for its founding was the death of several children from polio vaccinations; the vaccine turned out to contain live poliovirus.[16] Rules and regulations, therefore, were established to produce and distribute vaccines and drugs that are safe and effective. Over the years, these rules and regulations have become steadily more rigorous, making it increasingly expensive to develop new, safe, and effective pharmaceuticals. As the costs of developing drugs rose, the pharmaceutical industry had to raise greater amounts of capital in order to pay for them. The investors who put up such huge sums naturally sought high returns on their risky investments, and such high returns could not be achieved without IP protection. In fact, the existence of intellectual property allowed the private sector to mobilize the funds necessary to develop safe and effective pharmaceuticals. The public sector could not (or at least did not) provide these funds, nor was it capable of developing the new products that were needed.

The study therefore concluded that the IP regime plays an essential role in achieving an important public sector goal: the development of safe and effective pharmaceuticals. Accordingly, its next question was whether or not intellectual property had some additional practical benefits for the public sector. The study consequently identified a number of licensing practices that public sector organizations have used for the public's benefit. If the public sector owned valuable intellectual property, it could license that intellectual property to private sector companies with conditions that benefited the public sector. For example, the licensing terms could require favorable pricing to the public sector. Moreover, by licensing to more than one company, the public sector could foster competition that could lead to lower prices for consumers. And finally, the public sector could require that the product be made available to both the lucrative private sector market and to the public sector.

In addition, the emergence of Innovative Developing Countries (IDCs),[17] such as Brazil, China, and India, is changing the face of global health and agricultural innovation. These countries and others like them will certainly contribute significantly to biomedical R&D in the near future. A major unresolved question, however, is whether their innovations will benefit the poor within their own borders and in other less well-off countries. It is important to identify innovation strategies and IP management policies and practices that will help ensure that the investments of IDCs in R&D benefit the poor.

The study also concluded that the public sector, especially in developing countries, had very little capability—in terms of staff, policies, and

practices—to extract the benefits that could be obtained were they to implement enlightened licensing practices. The study therefore proposed programs to document best licensing practices and capacity-building initiatives. These are two of MIHR's major programs, and this *Handbook* addresses both of these goals: it seeks to document best practices and to be a teaching and capacity-building resource.

As noted above, one of the concerns the study addressed was the extent to which the existence of patents and other intellectual property might inhibit or prevent the development of products needed by the poor in developing countries. The study, like that of Golden Rice (see Box 2 above), concluded that intellectual property rarely, if ever, blocks product development. This conclusion was supported by interviews with individuals in both the public and private sectors. They noted that there were several ways that companies or product developers could address "blocking patents." First, one could seek a license from the patent owner. If this attempt was unsuccessful, other courses of action could be taken. For example, if an expert opinion determined that the blocking patents might not withstand legal challenge, then one could proceed without a license. In addition, Europe has a general research exemption that allows one to undertake research using a patented technology without having to obtain a license for that technology. In the United States, however, "safe harbor" provisions[18] greatly facilitated the development of a vigorous generic drug industry through a research exemption of the patent laws allowing them to make and use (but not to sell) a drug during its period of patent protection. This exclusion was critical to developing data necessary for regulatory approval once the patents had expired. A third option is to "invent around" intellectual property: in other words, to create a similar technology that does not infringe on any existing patents. For vaccines, this is a common practice because it is often difficult to secure one or more dominating patents (that is, patents that would make it nearly impossible to invent around). Yet another strategy is to develop and market the products in countries where patents have not yet been filed.[19] This was the strategy used by several Korean manufacturers that jointly developed a hepatitis B vaccine.[20]

The study's analysis concluded that intellectual property is almost never the most important factor affecting the development and availability of pharmaceuticals and vaccines. Instead, the most important factor seems to be the existence or absence of a market for those pharmaceuticals. Hepatitis B again presents a cogent case study. From a price of greater than $18 a dose, hepatitis B vaccine cost fell to less than $0.30 a dose once the public sector "made a market," i.e. started buying tens of millions of doses per year.[21] This finding about the relative lack of importance of IP led Rockefeller Foundation staff to study all of the major issues affecting the development and availability of pharmaceuticals. Briefly, the analysis revealed that the other factors were: support for research and development, the existence of domestic markets (including national health systems), the existence of international trade in the products (including procurement by international public-sector procurement agencies), the operation of capable regulatory systems, and the ability to manufacture products to high standards. Intellectual property was only one of six factors—and rarely the most important. These six factors are referred to as the "components of innovation."

We believe that placing intellectual property in a broader product-development context is necessary to improve the development and availability of health technologies for the poor. Conversely, any strategy that focuses only on IP issues is bound to fail and may be counterproductive. Thus, efforts to promote compulsory licensing to get low prices for pharmaceuticals in developing countries must overcome not only IP difficulties but also the obstacles presented by other components of innovation: the existence of capable manufacturing facilities that meet international standards, the availability of funds to procure the products for both domestic and international distribution, and the cost of obtaining regulatory approval for products manufactured under compulsory licenses. These are all significant, costly hurdles; any one of them could prevent a compulsory license from being useful

or cost effective, i.e. the cost of production under a compulsory license may be greater than the cost that could have been obtained through direct procurement of bulk quantities either individually by nations or through mechanisms such as the GAVI Alliance. (The Global Fund to Fight AIDS, TB and Malaria is [as of mid-2007] reconsidering it procurement policies. Rather than allowing each country to do its own procurement, the Fund is considering doing bulk procurement to ensure getting the best prices.)

4. INNOVATION AND IP MANAGEMENT IN A POST-TRIPS WORLD

Shortly after the MIHR study began, the Doha Declaration was approved. It called for according higher priority to public health than to trade concerns, and it emphasized that countries were free to use the "flexibilities" of TRIPS to protect public health. A few years after MIHR was established, the Doha Declaration was approved as an amendment to the TRIPS agreement. In the interval between the Doha meeting and the approval of the amendment, there were vigorous debates about the potential impact of TRIPS on access to medicines in developing countries. Some felt that TRIPS would be disastrous for developing countries. There were fears that it would suppress R&D, cause generics to disappear, and rapidly raise drug prices. Others felt that TRIPS would create a surge of support in developing countries for R&D, encourage joint ventures between pharmaceutical companies in developed and developing countries, and have little if any impact on the availability and prices of generics.

In January 2005, India and many other developing countries came under the rules of TRIPS. In December 2005, MIHR and the Indian Council of Medical Research convened an international symposium to examine the impact of TRIPS. The full report of the symposium has since been published.[22] In short, the meeting's conclusions tend to support the positive predictions mentioned above. Of perhaps greater importance, however, the meeting emphasized the need for developing countries to increase their capacities to manage intellectual property in ways that meet their own needs. The meeting also concluded that innovation is such a complex process—of which intellectual property is only one component—that it would be very difficult to document the impact of TRIPS on innovation; conversely, any impacts will be the result of a combination of factors, and will never be due to intellectual property alone.

Toward the end of the MIHR study that began in 2001, but before the establishment of MIHR, the UK Commission on Intellectual Property Rights (CIPR) issued its report,[23] which was read with great interest by the MIHR study team. A core conclusion of the CIPR report was that a one-size-fits-all approach to intellectual property was undesirable. Each country should have some freedom to adopt and implement laws and regulations that fit its own needs. Most recently, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) report has emerged. It takes an even broader view of intellectual property and innovation than the CIPR report. Both reports come to the following conclusions:

- Innovation takes place in a complex environment in which intellectual property is only one factor, and rarely is the most important.
- Developing countries need to determine what kinds of rules and regulations best address their particular needs.
- IP management capabilities in developing countries need to be rapidly improved in order to ensure that intellectual property is used to improve health.

An analysis of IP management and innovation by Morel and colleagues[24] found that donors have already marshaled significant resources and created organizational structures that accelerate the development of new health products and that procure and distribute drugs and vaccines for the poor. Their analysis concluded with a proposal for complementary strategies to improve health equity: national governments should support product-development efforts, and the public and private sectors need a coherent strategy to address each of the six interrelated components of innovation, also called determinants.[25]

5. CONCLUSIONS

The Rockefeller Foundation launched in-depth evaluations of the role of intellectual property in innovation of health and agricultural technologies that benefit the poor, especially those in developing countries. Its efforts and those of the many individuals and organizations that have worked in this space to date have helped to reconceptualize the relationship between the global intellectual property system and developing countries. This reconceptualization has the following elements:

- The dominant political/social framework of capitalism, markets, and democracy accords high priority to the protection of intellectual property. This framework is going to be with us for the foreseeable future, and so the public sector needs to find ways to achieve its goals within this framework.
- Intellectual property is important to the private sector because it helps investors achieve high returns on their investments.
- Intellectual property is also of importance to the public sector because:
  - It mobilizes the resources that are needed to take a product through the process of research and development (especially those steps that are designed to ensure the product's safety and efficacy).
  - It can help the poor. Creative licensing practices, for example, can help ensure global access and affordability.
- IP management capabilities need to be improved, particularly in developing countries, so that intellectual property can be managed for the benefit of the poor.
- Intellectual property is only one of six components of innovation and is rarely the most important. Efforts to meet the needs of the poor must also:
  - Support R&D
  - Develop national health programs and agricultural extension systems that are sustaining domestic markets, including distribution systems in both the public and private sectors
  - Be conducive to facilitating trade in health and agricultural technologies and products (both input and output)
  - Encourage high-quality manufacturing of drugs and vaccines and investments in high-quality seed production and that of other agricultural inputs
  - Adopt policies and develop safe and effective regulatory systems (for drug and vaccine registration; biosafety and food safety for applications of biotechnology in food, feed, and fiber; and seed quality certifications)
- Each country needs to take advantage of the freedoms granted by TRIPS and formulate and implement policies and practices that best meet its own needs. Short-cut solutions to technology needs in medicine and health, such as compulsory licenses, are unlikely to be as effective or sustainable as are collaborative efforts between the public and private sectors. Countries would benefit substantially from developing their internal IP management capabilities, strengthening their IP court systems and patent offices, and according priority to meeting the needs of the poor.

When it comes to increasing developing countries' access to fundamental innovations in health and agriculture, success requires knowledge, capacity, and active engagement. These are what best practices in IP management are all about and what this *Handbook* seeks to help create and promote. ■

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1 The Patent and Trademark Amendment Act of 1980 (35 U.S.C. §§ 200–211). See, also in this *Handbook,* chapters 3.2 By RA Nugent and GT Keusch and 3.4 by SK Finston.

2 While these developments trace their origins to many

sources, it is important to note that the Rockefeller Foundation played a lead role in each.

3 See, also in this *Handbook,* chapter 2.3 by R Eiss, KE Hanna and RT Mahoney.

4 Commission on Intellectual Property Rights. 2002. Integrating Intellectual Property Rights and Development Policy. Final Report of the Commission on Intellectual Property Rights. DFID: London. www.iprcommission.org.

5 WT/MIN(01)/DEC/W/2, 14 November 2001. www.wto.org (full text in Annex I).

6 www.who.int/intellectualproperty/report/en/index.html.

7 www.wipo.int/tk/en/.

8 Graff GD, GC Rausser and AA Small. 2003. Agricultural Biotechnology's Complementary Intellectual Assets. *Review of Economics & Statistics* 85(2):349–363.

9 Wright BD. 1998. Public Germplasm Development at a Crossroads: Biotechnology and Intellectual Property. *California Agriculture* 52(6):8–13; Kowalski S. 2007. Rational Risk/Benefit Analysis of Genetically Modified Crops. *Journal of Intellectual Property Rights* 12:92–103.

10 Krattiger AF. 2000. Food Biotechnology: Promising Havoc or Hope for the Poor? *Proteus* (Special Millennium Issue on Food) 17: 3–8; von Braun J, M Qaim and AF Krattiger (eds.) 2000. *Agricultural Biotechnology in Developing Countries: Towards Optimizing the Benefits for the Poor*. Kluwer Academic Publishers. The Hague. p. 433; Wambugu FM. 1999. Why Africa Needs Agricultural Biotech. *Nature* 400(6739):15–16.

11 Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm. Vitamin A deficiency (VAD) is one such problem. In many areas of the world where rice is a basic staple food, thousands of impoverished people lose their eyesight because of VAD. In fact, severe VAD (xerophthalmia, also called night blindness) leads to permanent blindness: 500,000 people, 250,000 of them children, go blind every year. VAD also leads to a depressed immune system that increases the incidence and severity of infectious diseases and infant mortality rates. See also www.goldenrice.org/Content2-How/how9_IP.html.

12 Graff G, A Bennett, B Wright and D Zilberman. 2001. Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table. *IP Strategy Today* No. 3-2001. pp 15–38. www.bioDevelopments.org/ip.

13 Atkinson RC, RN Beachy, G Conway, FA Cordova, MA Fox, KA Holbrook, DF Klessig, RL McCormick, PM McPherson, HR Rawlings III, R Rapson, LN Vanderhoef, JD Wiley, and CE Young. 2003. Public Sector Collaboration for Agricultural IP Management. *Science* 301(5630):174–175.

14 't Hoen E. 2002. TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution." *Chicago Journal of International Law* 3(1): 27–48.

15 www.pipra.org/.

16 The Center was first established within the National Institutes of Health but was later moved to the FDA.

17 Morel CM, T Acharya, D Broun, A Dangi, C Elias, NK Ganguly, CA Gardner, RK Gupta, J Haycock, AD Heher, PT Hotez, HE Kettler, GT Keusch, AF Krattiger, FT Kreutz, S Lall, K Lee, R Mahoney, A Martinez-Palomo, RA Mashelkar, SA Matlin, M Mzimba, J Oehler, FG Ridley, P Senanayake, P Singera and M Yun. Health Innovation Networks to Help Developing Countries Address Neglected Diseases. *Science* 309: 401–4.

18 Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984).

19 For a comprehensive discussion on FTO strategies, particularly for the public sector, see, also in this *Handbook*, chapter 14.1 by A Krattiger.

20 See, also in this *Handbook*, chapter 1.2 by RT Mahoney.

21 Advances in molecular pharming, the so-called third generation biotechnology plant products, are bringing agricultural biotechnology and health innovations closely together. For a recent review, see Arntzen C, B Dodet, R Hammond, A Karasev, M Russell and S Plotkin. 2004. Plant-derived Vaccines and Antibodies: Potential and Limitations. *Vaccine* 23:1753–1885. See, also in this *Handbook*, chapter 17.23 by A Krattiger and RT Mahoney.

22 See, also in this *Handbook*, chapter 3.7 by R Eiss, RT Mahoney and K Satyanarayana.

23 See *supra* note 2.

24 Morel C, D Broun, A Dangi, C Elias, C Gardner, RK Gupta, J Haycock, T Heher, P Hotez, H Kettler, G Keusch, A Krattiger, F Kreutz, K Lee, R Mahoney, RA Mashelkar, Hong-ki Min, S Matlin, M Mzimba, J Oehler, R Ridley, P Senanayake, H Thorsteinsdóttir, PA Singer and Mikyung Yun. 2005. Health Innovation in Developing Countries to Address Diseases of the Poor. *Innovation Strategy Today* 1(1):1–15. www.biodevelopments.org/innovation/index.htm.

25 Mahoney R. 2004. Policy Analysis: An Essential Research Tool for the Introduction of Vaccines in Developing Countries. *Journal of Health, Population and Nutrition* 22: 331–37.

Building Product Innovation Capability in Health

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ABSTRACT

This chapter presents a theoretical framework to explain the role of intellectual property (IP) in innovation and applies the framework to the growth of the pharmaceutical industry. Developing countries progress through stages of capability to reach the status of Innovative Developing Country (IDC). To reach the status of an IDC, countries need to give concerted attention to six components of product innovation: R&D in the public and private sectors, regulatory mechanisms for drugs and vaccines to achieve safety and efficacy, the ability to manufacture to high standards new health technology products, national distribution systems in both the public and private sectors, international distribution systems (including supply of drugs and vaccines through international organizations such as UNICEF, the operation of global funds, and trade among countries), and systems for managing IP.

An analysis of pharmaceutical innovation in Korea's vaccine industry concludes that its success in developing its impressive capabilities was achieved by paying close attention to all six components of innovation. Yet unknown is the extent to which the Agreement on Trade-Related Aspects of Intellectual Property will stimulate or thwart progress in the other innovation components when IP is quickly moved to an advanced stage.

1. INTRODUCTION

Several developing countries, including Brazil, China, India, and South Africa, are rapidly increasing funding for biotechnology. These countries and others are improving their drug regulatory agencies and are adopting modern laws and regulations for IP management, as well. Some of the pharmaceutical companies in those countries have entered the international market with both generics and self-developed products. Rapid economic development is leading to expanded domestic markets. This expansion is increasing demand for products that address domestic diseases. Countries that are developing in the ways mentioned here are referred to as Innovative Developing Countries (IDCs).[1] Because diseases of the poor disproportionately affect these and other developing countries, IDCs may become a major source of health product innovation for diseases of the poor.

The changes in IP management taking place in IDCs need to be assessed so that the international development community can understand how IDCs can best participate in and, in some instances, actually lead efforts to develop new health technologies for the poor in developing countries. Such an assessment should consider changes in biotechnology manufacture, local demand for these products, potential for export, the nature and extent of public and private sector support for biotechnology research, and the changing environment of IP, drug, and vaccine regulations. This chapter describes a framework for analyzing these factors.

Mahoney RT. 2007. Building Product Innovation Capability in Health. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2. A FRAMEWORK FOR ANALYZING THE PHARMACEUTICAL INDUSTRY

2.1 *The six components*

The framework allows us to analyze the development of the pharmaceutical industry in developing countries through six components:

1. R&D in the public and private sectors
2. Ability to manufacture to high standards new health technology products
3. National distribution systems in both the public and private sectors
4. International distribution systems, including supply through international organizations such as UNICEF, the operation of global funds, and trade between countries
5. Systems to manage IP
6. Systems for drug and vaccine regulation to achieve safety and efficacy

The components of the framework are linked dynamically. Progress in one requires progress in most—if not all—of the other components. It is difficult to improve R&D capability without first increasing manufacturing capability or having a national or international export market (requiring a distribution system) to generate resources for investment in production facilities. It is likewise difficult to enter markets in developed countries without good IP or regulatory systems. And while developing countries can access new technologies by entering into joint ventures with sophisticated firms in developed countries, these foreign firms will decide to form joint ventures based on the value of the domestic market in the developing country, the capability of local R&D centers, and IP protection levels. The interconnectedness of the six components is clearly very strong. And IP is an important aspect in all of them.

2.2 *From knowledge access to the role of IP*

IP policy-making in developing countries seems to be driven by conflicting goals. One goal is to encourage the influx of foreign technology. This can be achieved by providing enough protection for IP rights to enable foreign IP owners to pursue profits through licensing, marketing, and investment in the recipient country. This protection is needed especially when domestic R&D is focused on imitating or modifying foreign technology. On the other hand, developing countries have been able to access foreign technology cheaply and build manufacturing capability more quickly when unfettered by IP rights. This has worked to keep IP protection levels low, especially since few domestic innovators are harmed by such a regime. Instead of viewing the goals of foreign IP owners and domestic innovators as simply opposed, however, a closer analysis leads to a dynamic perspective. In the early stage of development, conflicts with foreign IP holders are minimal, typically, because domestic capability is poor and few foreign firms are interested in bringing technologies to the country. As the country's technological capability improves, poor protection of foreign IP rights is likely to conflict with the further growth of domestic capability. In the last stage, when local firms are able to generate their own IP, local demand for greater IP protection increases, reducing conflicts with foreign IP holders.[2]

2.3 *The special role of drug and vaccine regulation*

One key difference between the pharmaceutical industry and most other industries is the role of the stringency of the regulatory system for drugs and vaccines. As a country develops, the IP system and the regulatory system often progress in tandem.[3] In the early stage, there is little need for a well-developed national regulatory system. Most drugs and vaccines are imported from other countries, and it is assumed that the regulatory agencies of the producing countries have ensured their safety and efficacy. Any local production is contracted by foreign companies, which ensure quality control in order to meet regulatory standards in their home country or other countries where the products will be sold.

However, as the local production of copied products intended for the domestic market becomes important, the need for local regulation emerges. The government now has an interest in ensuring quality products. Initially, its main activities are to check composition and review the production facilities. Later, domestic companies demand a much more developed regulatory

capability. They want greater regulation and a capable regulatory agency for two reasons: to establish an approval process for newly developed products and to support the development and sustenance of export markets.

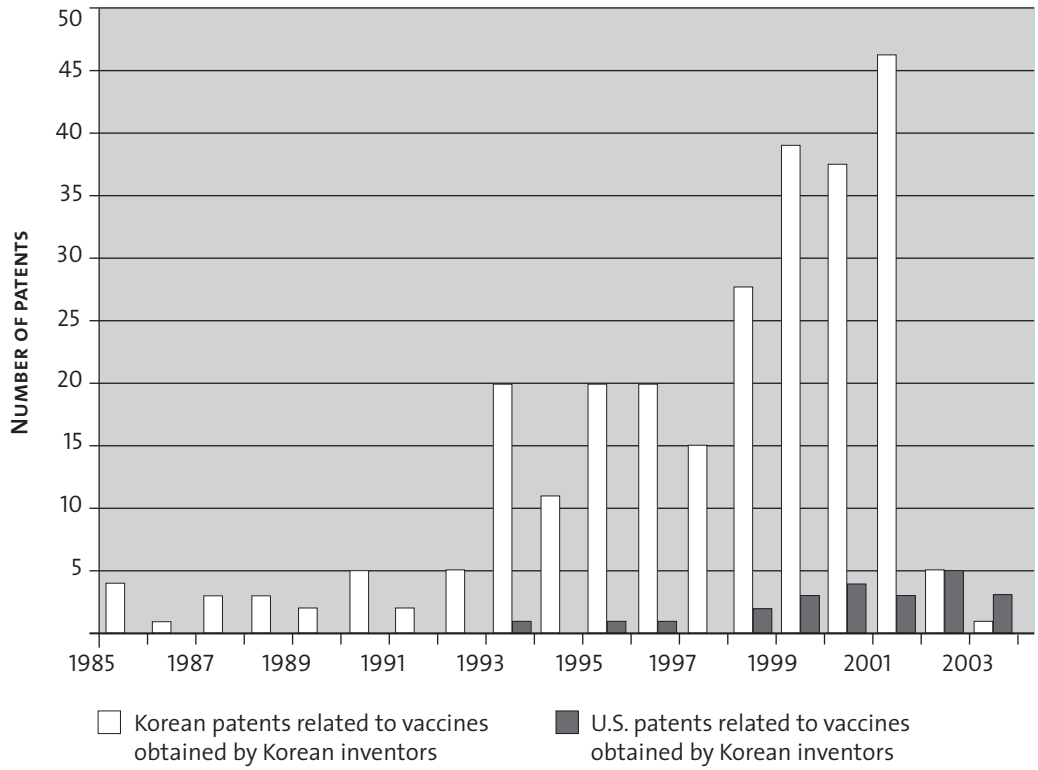
3. IP AND THE GROWTH OF BIOTECHNOLOGY IN KOREA

3.1 *A dynamic version of the framework*

The growth of biotechnology in developing countries is illustrated in Figure 1, which shows the patenting trends in Korea and the United States by Korean vaccine inventors. Korea is a good example for purposes of this chapter because of its rapid development in biotechnology. Korean vaccine biotechnology evolved rapidly, especially beginning in the mid-1990s.

The growth of the biotechnology industry in Korea can be interpreted in terms of the six framework components illustrated in Table 1. Showing the varying levels of capability with respect to each of the components of innovation at each stage, the table illustrates how developing countries can progress through four stages of capability in pharmaceuticals. The table distinguishes between national and international distribution and breaks out support for R&D into public and private sectors. The table illustrates that there are different systems of IP management at different stages of development. The table assists our thinking about one of the challenges brought about by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), namely that all developing countries that are signatories of the Agreement will have to move immediately to Stage 3. Several countries, such as

Figure 1: Vaccine-Related Patents Obtained by Koreans



Source: Based on data from the U.S. Patent and Trademark Office (PTO)[4]

Table 1: The Four Stages in the Development of Biotechnology

	Development of Manufacturing	Development of Distribution Systems		Development of R&D Capability		IP Systems	Drug and Vaccine Regulation
		National	International	Private Sector	Public Sector		
Stage 1. Establishing the foundation	Importation of finished goods or assembly of parts into finished products	Small domestic market	Very little, except as toll manufacturer	Very little	Very little	Initial development allowing patents for local inventors; no interest from foreign inventors	Very limited
Stage 2. Capacity Building	Production on license or by copy	Growing local market of increasing interest to foreign companies; import substitution	Growing companies learning how to establish export markets	R&D to understand technology either to produce on license or to copy	Development of university and independent research centers; capacity building	Interest growing among foreign inventors; local inventors starting to file more patents	Limited services but without enforcement capabilities
Stage 3. Maturation IDCs	Manufacture of domestically developed, high technology products	Rapidly growing domestic market of interest to foreign companies	Increasing exports that account for a growing share of GNP	Small-scale, advanced R&D effort capable of creating new products for domestic and export market	Vast acceleration of funding for R&D; development of major research centers; linking with private sector	Advanced IP system but with certain limitations such as lack of enforcement	Advanced capabilities but not at highest level because of lack of enforcement capabilities
Stage 4. The Most-Developed Countries, with a drug or Vaccine Industry	Highest capabilities to produce high technology drugs and vaccines	Highly profitable market in both the public and private sectors, generating profits to support, in part, advanced research	Global companies	Generous support for health research from basic to applied; large research investment by private companies, including large pharmaceutical manufacturers and biotechnology companies		Sophisticated system of IP management operating according to the requirements of the TRIPS Agreement	Sophisticated agency overseeing regulatory approvals of drugs and vaccines; government oversees clinical trials and production facilities and enforces regulations

Brazil, China, and India, have achieved this goal. Others are in the process. The major unresolved issue is whether the immediate move to Stage 3 IP systems will provide a pull effect on the other components of innovation or whether it will lead to imbalances that will adversely affect access to pharmaceutical products.

3.2 *Development of IP systems in Korea*

Korea provides a useful case study of a country that developed economically and, for the most part, independently enhanced IP protection without the requirements of TRIPS. Now in Stage 3, Korea was able to develop a vaccine industry very rapidly because it addressed each of the framework components stage-by-stage. It passed through the first two stages of the framework in roughly ten-year steps during the 1980s and 1990s. Having joined the World Intellectual Property Organization (WIPO) in 1979, Korea acceded to the Paris Convention in 1980 and the Patent Cooperation Treaty (PCT) in 1984. The country revised its laws in 1987 to allow product patents. By the end of the 1980s, Korean laws and policies largely conformed to the requirements that TRIPS would eventually impose.

As with the development of biotechnology R&D capability, Korea completed Stage 1 of its IP system in about 1990. It acceded to the TRIPS Agreement in 1995 and further revised its IP laws in 1997–98 to reach full compliance with TRIPS. The World Trade Organization (WTO) conducted a trade policy review of Korea in 2000 and concluded that "*protection of [intellectual property] rights has been strengthened by the signing of the new treaties, increased international cooperation, and stricter enforcement.*"[5]

Unlike the United States, universities and research institutes in Korea were not major sources of technology for the country's industry during the 1980s and most of the 1990s. Most companies wishing to obtain new technology had to look outside the country. In the United States, on the other hand, the Bayh-Dole legislation had gone into effect in 1980, and universities invested heavily in efforts to manage new IP that they developed. This included not only the out-licensing of patents for inventions made by research scientists, but also the creation of spin-outs, in which a professor set up a company for the specific purpose of developing an invention into a commercial product. Beginning in the late 1990s, Korea followed suit, revolutionizing its laws and regulations concerning IP management by public institutions. Public universities were allowed to retain ownership of new IP and were encouraged to set up technology transfer offices. The Technology Transfer Facilitation Law was passed, mandating the establishment of technology transfer offices and setting guidelines for sharing licensing income with a specific allotment for the inventors.

Based in part on the patent data in Table 1, Korea seems to have completed Stage 2 of its IP system in about 2000, again in tandem with its progress in biotechnology R&D capability. Thus, the country was able to develop its IP system in tandem with the growth of capability in the five other components of innovation. It will be interesting to see what happens in other developing countries that, under the TRIPS Agreement, must move immediately to Stage 3 in IP systems. A broader survey of the development of IP systems in Korea is available in Lee, et al.[6] While we lack sufficient data to make any unequivocal conclusions, it is worth noting that Korea was able to move forward by addressing all six innovation components.

4. CONCLUSION

The framework shows that IP is an important component of innovation in pharmaceutical development, but it is only one of six. As the analysis of biotechnology shows, the regulatory system is also a very important component. Above all, however, the above analysis demonstrates that developing countries will pass through the four stages of development as they increase their capabilities in biotechnology innovation. Such progress is possible only by attending to each of the six components of innovation. A key question that the framework highlights is what impact the immediate movement of IP systems to Stage 3 will have on countries that are still in Stage 1 or 2 of pharmaceutical innovative capability. Will it hin-

der or help their progress? We lack the data needed to assess the impact of this TRIPS requirement for moving from Stage 1 to Stage 3. But the case study of Korea shows that it was able to undertake a wide range of initiatives that helped it to advance in biotechnology. The country addressed all six components of innovation. In particular, it made its IP systems compatible with those of more developed countries and thus compatible with TRIPS. At least with respect to vaccines, Korea has experienced considerable success in biotechnology. We conclude that TRIPS should not inhibit efforts to enhance biotechnological capabilities. It may actually promote such efforts. Conversely, arguments that TRIPS is inimical to the interests of developing countries seem premature at best. At worst, they are counterproductive because they may lead countries to seek higher levels of biotechnology capability ineffectively: They will not be able to participate in international trade (other than as importers) because their products will not be accepted in markets that observe IP rights. ■

ACKNOWLEDGMENTS

This chapter draws extensively on the following paper: Mahoney R, K Lee and M Yun. 2005. Intellectual Property, Drug Regulation, and Building Product Innovation Capability in Biotechnology: The Case of Hepatitis B Vaccine in Korea. *Innovation Strategy Today* 1(2): 33–44. www.biodevelopments.org/innovation/index.htm

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1 The term *innovative developing countries* has been introduced by Dr. Charles Gardner, Associate Director, Health Equity, The Rockefeller Foundation.

2 Lee K, CS Lim and DH Park. 2003. The Role of the Industrial Property Rights in the Technological Development of Korea. World Intellectual Property Organization: Geneva.

3 Mahoney R, A Pablos-Mendez and S Ramachandran. 2003. The Introduction of New Vaccines into Developing Countries III: The Role of Intellectual Property. *Vaccine* 22 (5–6):786–792.

4 www.uspto.gov.

5 WTO. 2000. Trade Policy Review: Korea 2000. World Trade Organization: Geneva. www.wto.int/english/tratop_e/tpr_e/tp138_e.htm.

6 See *supra* note 2.

IP Management and Deal Making for Global Health Outcomes: The New "Return on Imagination" (ROI)

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ABSTRACT

The benefits of technology transfer are everywhere apparent, and perhaps the best news—as this *Handbook's* compilation of case studies demonstrates—is that these benefits are already reaching developing countries. Building on the success of the U.S. Bayh-Dole Act, countries everywhere are seeking to better utilize the research capacities of their universities and public research institutions. The growth of such technology transfer initiatives is inspiring, as are the innovative varieties of partnerships that have developed to ensure that the world's poor benefit from the global intellectual property system.

1. INTRODUCTION

Technology transfer works. Evidence of its success is everywhere and even unavoidable. We benefit from it when we get into a car and buckle up, when we sweeten our coffee with saccharin, and when we search the Internet using Google™. And we all enjoy better health because of the success of technology transfer: Allegra®; Taxol®, Trusopt®, pap smears, hepatitus B vaccine, the carcinoembryonic antigen immunoassay for colon cancer, insulin, the Rheo-Knee (the high-tech replacement knee), a nontoxic drug therapy for Chagas disease, and the nicotine patch are just a few of the health care innovations based on early inventions in university laboratories.

In addition to educating the next generation and creating new knowledge, universities are contributing to saving lives, enhancing the quality of life, and increasing productivity in the economy. This innovation explosion began in the United States with the passage of the Bayh-Dole Act, which allowed universities and public research institutions to patent inventions based on publicly funded research and then license the inventions to the private sector. The goal was to move inventions from the laboratory onto store shelves by attracting the private investments needed for commercialization. In the words of one of its authors in the U.S. Senate, *"The Bayh-Dole Act more than fulfilled our hopes and dreams. Many, many lives are the better for the success our universities, small businesses and nonprofit organizations have had as a result of this law. It simply works."* Indeed, it is no accident that the rest of the world is copying the Bayh-Dole model. The European Union, Japan, China, India, and many other countries hope to tap their own cutting-edge university research to develop new products. And, as the following case studies demonstrate, the rising tide of innovation has the capacity to improve the quality of life for people in both developed and developing countries.

2. TECHNOLOGY TRANSFER BY THE NUMBERS

One way to look at how technology transfer is changing the world is to consider the statistics (culled from the *AUTM Licensing* Survey™ which

Fraser J. 2007. IP Management and Deal Making for Global Health Outcomes: The New "Return on Imagination" (ROI). In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

regularly surveys U.S. and Canadian members). In fiscal year 2004, U.S. institutions:[1]

- spent US$40 billion in research and development
- issued 4,783 licenses
- managed 27,322 active licenses
- facilitated 462 new spinout companies, bringing the total since 1980 to 4,543

Each of the 27,322 licenses reflects a one-to-one relationship between a U.S. academic center and a company focused on a product development project. While reflecting the fact that such innovations are increasingly an engine of the "knowledge economy," what is really impressive about these numbers is the myriad ways academic technology transfer impacts people—through new products that save lives, enhance quality of life, and increase economic productivity.

Those of us who are involved in technology transfer have some idea of how far-reaching and valuable this work is, but even we cannot fully realize the scope of the impact of technology transfer. As technology transfer expands inside developing countries, creative mechanisms are emerging to further its impact and bring it to bear on global health outcomes. The Association of University Technology Managers (AUTM) has increased its efforts to spotlight some of the products that have originated at universities around the world. The Better World Project (BWR) is an ongoing series of publications and an online database.[2] With two publications showcasing 125 products, BWR includes an electronic database of stories that document the outcomes of academic technology transfer in human terms (new editions are due out in March each year).

3. THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

Another conspicuous sign of the growth of technology transfer is the continued growth of AUTM. Currently, the organization brings together more than 3,500 technology transfer professionals, in more than 30 countries, to define, develop, and promote leadership excellence in academic technology transfer.

More specifically, among AUTM members:

- 65% are based in academic technology transfer offices (TTOs)
- 35% work outside of academia, in corporate and service sectors
- 80% reside and work in the United States
- 9% live in Canada
- 11% live in other parts of the world

It is evident that, though relatively small in number, this varied global network of professionals is effecting change throughout the world.

4. THE TECHNOLOGY TRANSFER SPINOUT

Rather than asking existing companies to develop university-based products, universities and their faculties are increasingly turning to a new mechanism—the spinout company. This is a new company typically created to produce and market intellectual property developed at a university by one of its employees. In fiscal year 2004, AUTM reported 462 new U.S. companies had been formed in this way. More than 4,443 spinout companies have been reported since 1980. These companies seek public and private funding (from venture capital companies) to grow and put products in the marketplace.

4.1 *Social responsibility: public–private partnerships for product development*

Product development partnerships (PDPs) are a relatively recent phenomenon. They are similar to spinout companies in that they are tightly focused organizations created to develop products for neglected diseases in developing countries with the aim of reducing the disease burden and improving health. Several PDPs have licensed university innovations to include the technologies in their product development efforts. PDPs were set up as virtual product-development companies for such infectious diseases as tuberculosis, HIV, and malaria. The companies are supported by philanthropic funds, employ corporate expertise, are structured to reduce costs, and are driven by the urgent need to make an impact. As the following cases

studies involving PDPs reveal, they are marked by creativity, a trait that will be invaluable as these organizations move through clinical trials, address manufacturing products, and face the critical issue of distribution and patient compliance.

4.2 *Creativity for diseases in the developing world: Venture Philanthropy*

Venture Philanthropy was developed over the same period as were PDPs. The mission of Venture Philanthropy is to align good science with good business for developing new and improved drugs. In several cases, individual serial entrepreneurs whose families have been stricken by disease have created disease-specific foundations, raised foundation philanthropic and individual donations, and applied the entrepreneurial business model approach to disease research. For example, the Milken Institute[3] has been instrumental in educating people and in highlighting best practices. Its recently published report[4] offers innovative financial solutions offered to help solve the serious decline in funding for early-stage biomedical research.

5. CAUSE FOR ENTHUSIASM: THE BIG NEWS ABOUT THE BIG PICTURE

While some voices continue to raise objections about the fairness of the global IP system, others are seizing new opportunities provided by the system to improve the lives of the poor in the developing world. The evidence is clear: creative work is raising our expectations and allowing us to pursue hopes that seemed like unattainable utopian dreams before technology transfer released the power of human imagination. The University has always been the site of such visionary imaginations, and it is fitting that a new age of potentially greater global equity has been envisioned in its classrooms and laboratories. Indeed, the age of technology transfer is changing the perception and importance of these university-connected activities. Measures of the success of academic technology transfer have broadened beyond economics to include numbers of lives saved, reductions in the disease burden, improvements in the quality of life, and increases in productivity.

Our understanding of what we do as technology transfer officers is changing. Traditionally, the mission of the TTO was to bring university-generated intellectual property into public use as rapidly as possible. The TTO did this through corporate partnerships that protected academic freedoms and, in many cases, generated a financial return to the university, inventors, and their departments.

TTOs still serve these functions. But over the years, academic technology transfer has evolved to serve a broader purpose: to enhance the reputation of academic institutions and to help them achieve their missions of education, research and community outreach by facilitating research relationships with the private sector for the benefit of all.

Anyone who reads subsequent pages of this *Handbook*, case studies that document the success of technology transfer, will feel the same enthusiasm and hope for the future that technology transfer officers feel. Today, problems can be tackled that yesterday appeared intractable. And let me say to my fellow technology transfer officers: we should hold our heads high when we talk about our work and our mission. When someone asks you "What do you do?" be ready to tell them, "As a technology transfer professional, I help make the world a better place." If they ask what financial return on investment (ROI) you hope to make, tell them, "Oh, ROI—you mean 'Return on Imagination.' Let me show you what is possible."

Then give them a copy of this *Handbook*, and point to the successes in these case studies! ■

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1 AUTM 2005. AUTM Licensing Survey.™ FY 2004. Association of University Technology Managers: Northbrook, Illinois. www.autm.net.

2 Visit the Web site at www.betterworldproject.net.

3 www.milkeninstitute.org.

4 Financial Innovations for Accelerating Medical Solutions [Financial Innovations Lab Report, Vol. 2] Milken Institute, October 2006. www.milkeninstitute.org/publications/publications.taf?function=detail&ID=580&cat=finlab.

Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions

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ABSTRACT

If universities adopt sound licensing practices, the universities will not only help stimulate investment in research on diseases that primarily afflict the poor in developing countries, but also ensure that the products of the research are affordable and widely available in those countries. Ensuring global access is one of the central goals of intellectual property management. But universities confront two main obstacles in their efforts to achieve the goal. First, university administrators, technology transfer officers, and business people are too often unaware of both the need to ensure access to new health technologies in developing countries and the manner in which patenting and licensing practices can be an integral component of global access strategies. Second, there is only a short history of experience in incorporating such concerns in negotiating licenses, so no best practices have yet evolved. This chapter offers a few possible approaches to ensuring broad access to university inventions while preserving incentives to development, including patenting inventions in a select list of developing countries. The chapter concludes by urging all of the players in this field to build upon their own experience and to take creative risks in the pursuit of new solutions.

1. INTRODUCTION

From a humanitarian point of view, a patent system presents a paradox. How can a system designed to restrict access to technologies, including medical technologies, also be used to maximize availability of needed medicines and vaccines at affordable prices? One way of looking at that paradox is to consider an extreme case: if all the medicines and vaccines needed for diseases in developing countries existed today, the patent system might be unnecessary. The absence of patents, some experts suggest, would presumably allow for maximum competition, driving prices down and thereby maximizing affordability and availability.

But for many of the diseases of developing countries, few drugs or preventatives exist; in some cases none exists. Patent protection can provide the necessary incentive to encourage industry to use its skills and resources to discover, develop, test, ensure quality control of, manufacture, and distribute new drugs and vaccines. Few companies—if any—would embark on the long trail of new-drug discovery and development, if they could not be protected by patents from competitors.

Thus, patents are neither inherently bad nor inherently good with regard to this purpose, but—like all tools—must be used wisely.

Research institutions, such as universities, medical schools, and other nonprofit institutions engaged in biological and medical research (collectively referred to as "universities" in this chapter), have a special role to play regarding the use of patents for developing and distributing drugs and vaccines for developing countries. These

Nelsen L and A Krattiger. 2007. Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

institutions are often the source of the core technology and, occasionally, lead compounds that could be developed into drugs and vaccines.

Despite the avowed public purpose of their technology transfer activities, universities have recently come under criticism for using patents in a way that could inhibit (and in very few cases, has inhibited), the distribution of medicines at accessible costs to developing countries. Critics argue that by granting exclusive licenses to developed-country pharmaceutical companies, the universities are allowing the pharmaceutical companies, sometimes, to prevent local companies from producing and selling drugs, potentially at affordable prices—thus effectively denying life-saving drugs to poor people in these countries.

Although nonprofit research institutions are not often involved in these issues, (in part because the fraction of medically related patents owned by these institutions is small), their visibility, coupled with the universities' public responsibility, is causing university technology transfer offices to modify their licensing practices for patents relevant to healthcare in developing countries.

Some thinkers have suggested that the best thing universities can do to ensure access is to cease patenting medically related inventions and place everything in the public domain. But doing so would be both unrealistic and counterproductive. Patents have been shown to be a powerful tool for directing investment into the development of technologies that would otherwise lie fallow. University inventions are usually at such an early stage (*embryonic* is a term commonly used to describe them) that investment in development involves substantial risk. Neither the technical practicality nor the market acceptability of the invention is proven. And many more inventions fail to reach than do reach the market—particularly in the medical field. Patents are an essential way for companies to manage the risk, and the use of patents is even more important for medicines and vaccines, where the costs of development and particularly of clinical trials require much larger investments and much greater risk.

Universities and research institutions hope for some financial return from their patents, but contrary to widely held beliefs, this return is seldom large. On average, U.S. universities receive licensing royalties equivalent to only 2%–4% of their research budgets. Most universities believe that the primary purpose of their technology transfer activities is either (1) to induce investment in developing technologies to bring products to public use, (2) to aid local economic development through spinout companies based on licenses to their technology, or (3) both.

Given their commitment to encouraging the development of new technologies via patenting, universities need sophisticated policies and procedures in licensing to ensure that the poor will have access to medicines based on the universities' technologies. Potentially, the access policies developed by universities may—if the policies are practical, properly implemented, and publicized—become "norms" that will be more widely adopted by the private sector.

Awareness about these issues is new; techniques for addressing the problem are only just emerging, and there is no consensus yet on best practices. The remainder of this chapter addresses some potential solutions.

2. RAISING AWARENESS

The first task in encouraging effective licensing policies and practices is to raise awareness of the issues (discussed in section 1 above) in the research institution community. Technology transfer officers need to become aware of developing country health-care needs and the universities' responsibilities with respect to those needs. Given the general commitment of universities to transfer technology to promote public welfare, this awareness alone will go a long way toward preventing the inadvertent granting of licenses that lack consideration for the health needs of developing countries. Senior administrators and researchers also need to become more aware of the issues involved so that these professionals will acknowledge the broader value of licensing terms that may be somewhat less profitable from an economic standpoint, but that may address

urgent medical problems in poor parts of the world. Finally, consistent university policies on these issues will raise awareness inside the companies universities work with, making such companies more readily accepting of licensing terms that address these issues.

Awareness is already growing. In the United States, the Association of University Technology Managers (AUTM) began to publicize this issue to its members in 2003. This organization is having a substantial impact on the understanding of technology transfer professionals with respect to these concerns: more than 90% of technology transfer professionals from nonprofit research institutions in the United States and Canada belong to AUTM, along with several hundred professionals from other countries. An AUTM Special Interest Group, formed in 2003, has evolved into the Technology Managers for Global Health (TMGH),[1] which is partially supported by MIHR (the Centre for the Management of IP in Health Research and Development). TMGH's purpose is to raise awareness about global health issues and, with AUTM, to compile a collection of best-practice policies and licensing terms that can be distributed to AUTM members and others. The interest shown on the part of the greater AUTM membership is especially encouraging. At its 2006 annual meeting, the opening plenary session of AUTM was on "Innovative Policies and Practices in Technology Transfer: A Global Health Perspective." The meeting agenda included a program of education with several workshops on global-health technology transfer issues.

Through its guidelines on the patenting and licensing of research tools, the National Institutes of Health (NIH) have helped alert universities to the need for thoughtful policies in exclusive licensing.[2] The NIH wants to make certain that researchers in the health arena have access to research materials without undue hindrance by patents, and so NIH has issued guidelines for patenting and licensing research tools. The two objectives—fostering access to medicines and making research materials widely available—often merge in the minds of technology transfer professionals, making them more aware of the need to exercise care when licensing university technology.

3. SUGGESTED APPROACHES

3.1 *Considering where to file patents*

When a research institution patents and licenses out a technology, usually the institution can—if it insists—continue to own the patent after licensing. (This is the practice in most U.S. universities.) The institution can then control, by contract with the licensee, which countries the patent will be filed in. Determining a strategy of where to file, however, is not easy.

3.1.1 *Prohibition-of-filing strategy*

Where a drug or vaccine in question has a large developed-country market, one possible strategy is to prohibit the patent from being filed in developing countries. Most of the licensee's profits would presumably come from markets in developed countries—with or without developing country patents. The loss of potential revenue from developing countries (which in any case could not afford to purchase large quantities of the medicines at developed country prices) would be negligible, and the licensee mostly likely would not be substantially disadvantaged by this approach. The absence of patents in the developing world, however, could allow "generic" competitors to produce the drugs in those countries at low prices.

This strategy will be effective *only* if:

- The developed country market for the medicine is large. If the developed country market is only a specialty "travelers' market" and the primary demand for the medicine is in developing countries (malaria vaccines are a good example), this strategy may not be acceptable to the licensee company.
- The drug or vaccine is relatively easy to manufacture and does not rely on special know-how possessed only by the licensee company (including valuable regulator dossiers). This is more likely with simple chemical drugs than with biological drugs (including vaccines), whose techniques for

production and purification may be beyond the capabilities of most developing country manufactures. Also, if the drug is easy to manufacture, then safeguards must be in place to avoid parallel imports.[3]

- The research institution owns the core patent for the drug or vaccine, while other "secondary" patents, owned by the licensee, are not critical to developing and manufacturing the medicine. If secondary patents are critical and the licensee chooses to file them in developing countries, then attempts by the university to provide its own technology free of charge may be moot. The only benefit would be to shelter the university from criticism. Theoretically, it is also possible for the university to demand in its licensing agreement that the licensee not file such secondary patents in developing countries, but it is doubtful that the university would have the negotiating power to make that demand—particularly if the university's invention, at the time it is licensed, is still far from a product.

3.1.2 *When patent filing in developing countries may be beneficial for access*

When the demand for a drug or vaccine is primarily (or exclusively) in developing countries and there are no alternative products, the primary problem is to develop a sufficiently profitable market to provide an incentive for the private sector to invest in R&D. The only other alternative is for governments or nongovernmental organizations (NGOs) to fund all of the research, development, clinical testing costs, and manufacture. But having a public sector entity develop a commercially viable product is usually impossible.

Patents may provide an incentive to the private sector to invest by aggregating the developing world market into a single, larger market. To be successful, this strategy relies on:

- sufficient available resources for buying the product once it is developed (Governments and NGOs may have to step in to supply money to the public sector of low-income developing countries so that the product can be purchased—particularly if there is no private travelers' market that can support higher prices.)
- adequate systems for quality control and regulatory approval to ensure consistent, high-quality products in the absence of developed country regulatory controls
- a belief that the legal systems in the nonmanufacturing countries will be strong and consistent enough to allow the supplier to enforce its patent rights and to maintain its monopoly for a reasonable period of time
- a willingness of governments and NGOs to accept prices that are high enough for suppliers to recoup research and development costs

3.1.3 *Licensing strategies*

Research institutions have the most control over optimizing the use of their inventions at the time of licensing. It is before the invention is licensed that the university can best ensure that the invention will be used to advance—or at least not hinder—solutions to developing country health needs.

The first decision is whether to grant (1) a fully exclusive license, (2) an exclusive license limited by product type, (3) an exclusive license limited by geographical territory, or (4) a nonexclusive license.[4] Considering two extreme cases is illuminating:

- Where the invention is a tool for discovery that is useful to many without significant development, then nonexclusive licensing is probably most appropriate for developed country use. Patents in developing countries will essentially be unnecessary. (Many universities will also require that the patents not be asserted against nonprofit research institutions in any country, thus allowing free access by such institutions.)
- Where the patent covers the core invention of a potential new drug or a vaccine that require many years and tens, if not hundreds, of million dollars of investment, an exclusive license may be the best strategy. In such a case, patenting in selected developing

countries may be an important element in a strategy to ensure global access.

Exclusive licensing places a large responsibility on the university to negotiate license clauses that ensure both development of the product and rapid distribution to developing countries at affordable prices. Not every member of the university technology transfer community is yet conscious of this requirement. Best practices have not yet been established for such negotiations, and so strategies need to be based on evolving experience. A few situations, we know in retrospect, were clearly mistakes—experiences we can now learn from. Some better, but still experimental strategies include:

- **development of milestones**. As a condition for a company maintaining a license, the university requires that the company devote at least a certain reasonable minimum of resources (money or staff time) to developing the technology. The university may also require certain success milestones (for example, first clinical trials by a certain date, product on the market by a certain later date, and so forth).[5] However, success milestones are particularly difficult to negotiate for very early-stage technology.
- **requirement of delivery of product for developing countries**. The university may require the company to begin testing and distributing the product for developing countries simultaneously, or nearly simultaneously, with its introduction to developed countries. This is particularly important for vaccines, for which the trickle-down theory[6] has sometimes deprived developing countries of suitable product for decades.
- **control over pricing in developing countries**. This is usually set at a small percentage over cost (so-called cost-plus pricing). This may be particularly relevant where there is a large—and presumably profitable—market as in the developed world.
- **sublicensing**. If the company cannot deliver the product or deliver it at acceptable prices, then the university may require the company to sublicense the patent to others. When manufacturing the product is simple, this strategy may work, but when the product requires substantial company know-how and background technology, the "victory" in forcing a sublicense of the patent alone may be a hollow one. This is particularly true for complex biological drugs and many vaccines. The university should therefore negotiate clauses that make sublicensing as attractive as possible, so that the company will cooperate fully in the venture. A paper by Friedman and colleagues[7] describes such a strategy by the Pharmacia Company. The company enthusiastically sublicenses the patent along with its know-how and exerts some control over the quality of the product. The benefits to the company are primarily to its reputation, with a justifiable pride in the good that is done, but allowing sublicensing also protects the company from the criticism of not meeting the needs of the poor in developing countries.

4. CONCLUSION

University technology transfer professionals are becoming more aware of their obligations to ensure that the poor have access to medicines based on university technologies. To a large extent, universities are embracing this obligation in the hope that well-crafted patent and licensing policies can be powerful tools to provide such access. But there are no clear-cut mechanisms, nor many precedents to guide professionals in this endeavor. This chapter presented just a few of the strategies that research institutions can pursue in their quest to provide developing countries with access to new medicines. Each of these strategies has been tried, but they are all relatively new and will need further refinements. This can only be achieved, however, in actual negotiations between research institutions and companies. New approaches will also certainly develop in the future. None of these efforts will be effective unless both research institutions and companies first become more aware of their obligations to the poor in developing countries. Awareness is only the first step, however, for none of these strategies will thrive unless

they meet the needs of both the research institutions and the companies that are developing new technologies to improve human health. Building upon the knowledge and successes we already possess, we must not only strive for novel, creative solutions but also take reasonable risks in the pursuit of these much-needed solutions. ■

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1 See www.tmgh.org.

2 NIH. 2005. Best Practices for the Licensing of Genomic Inventions: Final Notice. *Federal Register* 70(68): 18413–415. www.ott.nih.gov/pdfs/70FR18413.pdf.

3 See, also in this *Handbook*, chapter 15.4 by D Matthews and V Munoz-Tellez.

4 See, also in this *Handbook*, chapter 11.8 by SL Shotwell.

5 See, also in this *Handbook*, chapter 2.7 by J Oehler.

6 Trickle-down theory relates to a product that may at first be so expensive that only wealthy people can afford it. The theory states that over time, however, the price will fall until it is available to the general public. In other words, the benefits trickle down.

7 Friedman MA, H den Besten and A Attaran. 2003. Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries. *Lancet* 361: 341–44. www.fightingmalaria.org/pdfs/Lancet%20Article.pdf.

Genomics, Ethics, and Intellectual Property

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ABSTRACT

Ethical concerns and controversies about patenting are playing an increasingly prominent role in the development and applications of the biosciences. Despite the growing importance of ethical issues, there is currently no consensus or clarity on the ethical principles that should guide patenting of human, animal, and plant genes and cells. The three major areas of contention are: (1) whether some or all patents on genes and cells are unethical per se, based on concerns such as commodification, dignity, and similar concepts; (2) how tissue samples are collected, particularly in reference to the principles of prior informed consent and benefit sharing; and (3) how patents are used to restrict access to medical and agricultural use of biotechnology innovations. Given the lack of any agreed guiding principles for navigating these issues, policy-makers, decision-makers, scientists, and users of biotechnology have no choice but to address these contested ethical concerns using a case-by-case approach.

1. INTRODUCTION

Over the past three decades, much ink has been spilt about the ethics of patenting in the life sciences. Unfortunately, these dialogues and debates have produced very little clarity and consensus on the ethical principles and practices that should apply to patenting of biological materials. Policy-makers, decision-makers, companies, scientists, and product end users therefore must navigate through a complex web of unsettled legal principles, moral arguments, social norms, and political influences that collectively represent the ethical landscape for patents in this field. Failure to adequately consider and conform to these influences can result in an eruption of controversy, disruption, and opposition. At the same time, excessive caution and hewing to the most extreme views and positions has the potential to impede the scientific, economic, and developmental benefits of life-science research and innovation.

This chapter does not attempt to fully explicate or resolve the many ethical issues relating to life-science patents. Rather, its more modest goal is to briefly describe the various ethical controversies and landmines related to the patenting of genes and other biological materials, and to discuss how such issues are being resolved or managed in practice. The major controversies can be grouped into the following three categories: (1) whether some or all biotechnology patents are unethical per se; (2) the manner in which the patented invention was obtained or discovered; and (3) how the patent is used.

2. ETHICS OF PATENTS

A threshold question is whether biological patents are per se unethical. Some individuals, groups, cultures, and nations adhere to a position that any patenting of human, animal, or plant genes and tissues is unethical. Various ethical arguments have been advanced against any patenting of genetic or related biomedical innovations. One

Marchant GE. 2007. Genomics, Ethics, and Intellectual Property. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

of the most common arguments is that patenting commodifies life-forms. A related critique is that living materials are naturally occurring, and thus isolation and description of "nature's handiwork" should not qualify as patentable subject matter.[1] Other ethical concerns include fears that patenting will facilitate and accelerate applications and commercialization of biotechnology that are themselves viewed to be unethical by some, that patenting will lead to greater animal suffering, and that patenting undermines the dignity of humans and other species by making their genes and cells subject to ownership by others.[2]

A prominent expression of this deontological opposition to biotechnology patents was a statement, issued by almost 200 religious leaders in 1995 opposing any patents of human or genetically engineered animal tissues, that asserted that "*[w]e believe that humans and animals are creations of God, not humans, and as such should not be patented as human interventions.*"[3] Another much-publicized denunciation of gene patenting was the 2000 statement of the French Justice Minister, Elisabeth Guigou, that human gene patents are contrary to the ethical norms of France. The Council for Responsible Genetics issued a Genetic Bill of Rights, which contends that "*all people have the right to a world in which living organisms cannot be patented, including human beings, animals, plants, and all of their parts.*"[4]

While some organizations and individuals denounce patenting of living materials on some or all of the grounds identified above, others defend the patentability of genes and other living materials on ethical grounds.[5, 6, 7] For example, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) International Bioethics Committee concluded that the "*law on intellectual property serves useful purposes, has a foundation in ethical principles and universal human rights, and often contributes to the benefit of humanity.*"[8] Moreover, religious leaders are not unified in their opposition to patents for genes and other living tissues, with many prominent religious organizations and individuals expressly or implicitly supporting such patents.[9]

Others argue that while there may indeed be important ethical and policy concerns with some biotechnological inventions, the patent office is not the appropriate forum to address those concerns, if only because patent examiners have no specialized training in ethics and policy. Yet another argument is that eliminating patent protections from biotechnology inventions would make those innovations less rather than more ethical, in part by making new technologies less transparent as companies rely more on trade secrets in place of patents and their requirement for public disclosure.[10]

A blanket prohibition on any patents of genes or other biological materials is inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires countries to provide IP protection for most biotechnology products. Thus, any existing and prospective nation-state member of the World Trade Organization (WTO) is unlikely to try to adopt or enforce a generic prohibition on biological patents. While advocates against any patenting may advance the political and ethical arguments summarized above against all patenting, such arguments will have little or no legal force and relevance.

More relevant will often be arguments that specific patents or types of patents are unethical. For example, the TRIPS agreement allows WTO countries to exclude bioengineered animals from patentability. Thus, each nation must individually decide whether it will extend its patent laws to animals, and these debates generally focus on ethical arguments about animal rights and commodification of life.

More generally, the TRIPS agreement specifically provides that nations may elect to include a provision in their patent laws that deny patents for specific innovations and inventions that are not ethical. For example, the European Union has an *ordre public,* or public morality clause that denies patent protections to inventions that are contrary to public morality. Other nations, including the United States, have declined to include such a morality clause, and the U.S. Patent and Trademark Office claims that it does not have the authority to deny otherwise valid patents based

on the morality or ethical characteristics of the underlying invention.

The U.S. courts have also disavowed any role in reviewing the ethical or policy aspects of patents. In approving the first patent of a living organism in the United States, the U.S. Supreme Court stated:

[W]e are without competence to entertain these arguments… The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[11]

In jurisdictions that recognize a morality exception to patents, controversial patents are subject to challenge under such clauses, both during initial application, and in subsequent post-issuance challenges. For example, challenges to European patents for the BRCA1/2 breast cancer genes and the oncogene mouse have been challenged under the ordre public clause several years after the original patents issued, which resulted in the patents being narrowed but not rescinded.[12] The European Union's ordre public clause also prohibits patents related to human cloning, modifying human germ lines, using human embryos for commercial purposes, and genetically engineering animals in ways that cause suffering without a substantial medical benefit to humans. In other cases, challenges under the ordre public clause to biotechnology patents have failed.[13] One criticism of the ordre public provision is that the European Patent Office has failed to articulate a clear definition and criteria for the provision's application, resulting in case-by-case analyses that do not always use consistent approaches.[14]

No issue has generated more outrage and concern than attempts to patent products and processes based on traditional knowledge. The 1992 Convention on Biological Diversity encourages nations to respect and protect traditional knowledge. Any attempts to patent products based on traditional knowledge is likely to generate considerable controversy, as demonstrated by the disputes that erupted over patents issued for basmati rice, neem, and tumeric, all of which were subsequently abandoned or revoked in response to a chorus of objections.[15] The bottom line is that any attempt to patent products that are derived from traditional knowledge are likely to generate considerable opposition and controversy, which may only be avoided if the biological material is collected consistent with the principles of prior informed consent and benefit-sharing discussed in the next section.

3. OBTAINING BIOLOGICAL SAMPLES

Another area of ethical controversy over some biotechnology patents relates to the manner in which the biological samples used for the patentable discovery were collected. In most human genetic research, the prevailing scientific norm is that donors of tissue for research retain no property or other rights in their cells or genes.[16] This means tissue donors receive no financial compensation for their samples (other than reimbursement of their out-of-pocket expenses), are given no share of any profits or revenues that may result from any commercial products developed using the donated tissues, and have no patent rights to any patentable discoveries that may result from research using their tissues. The legal and property rights of local populations and national governments with regard to animal and plant specimens collected within their territory and used for a patented discovery are uncertain and often disputed. At the international level, some of the most inflamed controversies have involved claims of *biopiracy* in which scientists from an industrialized nation seek patents based on human, animal, or plant materials collected from other, less-developed nations. Two specific issues that have been at the forefront of these ethical debates about the collection of biological samples are prior consent and benefit sharing.

3.1 *Prior consent*

Prior consent refers to the procurement of advance approval from the relevant entities before

taking biological samples. One issue relating to prior consent is who must provide such consent. The consent may need to be given by the specific individuals from whom the tissue is taken (in the case of human samples), from the local community, tribe, or local government in the region from which the samples would be taken, and from the national governmental authorities. Controversies have arisen when only some but not all of these three levels (individual, local, and national) of decision-makers have provided prior consent. For example, the U.S. National Institutes of Health (NIH) sought a patent in 1991 for a cell line derived from a member of the Hagahai, an isolated tribe in Papua New Guinea, that had a high frequency of a gene related to leukemia. The focus of the ensuing international controversy over this patent application, which was subsequently abandoned in response to the pressure, was whether the NIH was required to obtain informed consent separately from the individual donor, the Hagahai tribe, and the Papua New Guinea government.[17, 18]

Another example of an international controversy over the alleged lack of appropriate prior informed consent relates to the Guaymi Indians, the largest indigenous tribe in Panama.[19, 20] Thousands of Guaymi tribal members are infected with an HIV-like virus known as the Human T-Lymphotropic Virus Type 2 (HTVL-II). The U.S. Centers for Disease Control and Prevention (CDC) undertook a research project to investigate infection in the early 1990s, and subsequently the U.S. Department of Commerce applied for a patent claiming a cell line isolated from blood taken from a 26-year old Guaymi woman being treated for leukemia in Panama. The United States claimed that the woman gave oral consent in the hospital (although the woman was reportedly illiterate, unschooled, and quite sick, which raises questions about the effectiveness of the informed consent). However, the focus of the ensuing controversy was that the tribe was never informed of, nor asked to consent to, the removal of the blood sample to the United States, the establishment of cell lines using those samples, or the patent application. The president of the Guaymi General Congress strongly criticized the patent application as "*immoral, contrary to the Guaymi view of nature, and our place in it.*" The United States subsequently dropped the patent application in response to the controversy. The lesson from these examples is that any patent application based on tissues from identifiable populations, such as indigenous tribes, may be subject to significant controversy if prior informed consent is not obtained from the person or persons providing the tissue samples as well as the tribal authorities and, perhaps also, the national government.

The content and form of the information provided in the prior consent has also been controversial. In particular, must the consent process include disclosure that the collected material may be used to secure a patent? According to one critic of current consent procedures, "*over the past thirty years, blood, tissue, and other bodily fluid samples have been collected from individuals and used in genetic research without the person's consent or knowledge. If a lucrative gene was found, it was patented. Once a gene is identified and patented, its availability is often severely restricted, even to the people who provided tissue samples and funding for the genetic research.*"[21]

The European Union's Group of Advisers on the Ethical Implications of Biotechnology has endorsed the need for prior consent before using a donor's tissue to develop a patentable invention:

The ethical principle of informed and free consent of the person from whom retrievals are performed must be respected. This principle includes that the information of this person is complete and specific, in particular on the potential patent application on the invention which could be made from the use of this element. An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent, will not fulfil the ethical requirements.[22]

In its directive on patenting of biotechnology inventions, the European Union carried forward this recommendation in Recital 26, which provides *"Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have*

had an opportunity of expressing free and informed consent thereto, in accordance with national law"[23] However, because this statement is in the recitals of the directive, it is not legally binding but only hortatory. There are also practical problems with a requirement for prior consent in this context—the original researchers, or subsequent researchers who may have access to the tissue, may not have the intent or knowledge at the time of tissue collection that they will be pursuing a patent application based on that tissue. In addition, except for rare cases (including in *Moore v. The Regents of the University of California* discussed below), most patentable inventions resulting from human tissue are based on findings using large numbers of samples, complicating and attenuating the requirement for prior consent on future patents from each individual tissue donor.

The most famous—some would say infamous—court case on this issue is *Moore v. The Regents of the University of California* decided by the California Supreme Court in 1991.[24] Moore had his spleen removed by doctors at the UCLA Medical Center as part of his treatment for cancer, but unbeknownst to him, his doctors used the removed tissue to create a potentially lucrative patented cell line. The doctors did not disclose their intentions to Moore that they would patent his cells without sharing any of the proceeds, nor did they request his permission to do so. Even more egregiously, they affirmatively misled Moore into returning to the hospital on several subsequent occasions to collect additional tissue. The California Supreme Court rejected Moore's argument that he continued to own his cells after they were removed from his body, but the court refused to dismiss Moore's claim that his doctors failed to provide adequate informed consent by not disclosing their potential financial interest in Moore's cells.

A more recent U.S. case raised similar issues, but this time in the research context rather than the clinical setting. Parents of children with the inherited Canavan disease convinced a medical researcher to attempt to isolate the gene responsible for the disease, and provided tissue samples from affected children and their families and helped to raise funds for the research.[25] The researcher successfully identified the gene, but, without informing the parents who had donated tissue samples to the research, the researcher's employer (Miami Children's Hospital) patented the gene, and the genetic test based on the gene, and began charging a modest licensing fee to clinics that had starting using the newly discovered genetic test. The families and various support organizations were outraged by these actions and sued the hospital alleging various legal claims including conversion, failure to provide informed consent, unjust enrichment, and breach of fiduciary duty. The federal district court dismissed most of the families' claims, but concluded that the unjust-enrichment claim was sufficiently viable to go forward, and the case subsequently settled.[26] This case, like the *Moore* case before it, demonstrates that a physician or researcher may have a legal duty to inform tissue donors of their intent to pursue patents using the donor's tissue, but even if such disclosure is not legally mandated, the failure to obtain prior informed consent from tissue donors runs the risk of provoking ethical controversies that can result in bad publicity and expensive, time-consuming litigation.

The ethical duty of informed consent is less established in the context of plant and animal samples compared to human tissue collection, but there has been considerable momentum toward recognizing such a duty in recent years. The 1992 Convention on Biological Diversity requires informed consent from the appropriate national authorities as a condition of access to plant or animal genetic resources. Several nations have adopted their own laws requiring prior informed consent to the collection of plant and animal resources.[27] Several recent international studies and proposals have been published on this subject in recent years, but the legal and ethical status of informed consent requirements for nonhuman biological materials continues to be hotly debated and uncertain.

3.2 *Benefit Sharing*

A second major issue is whether entities that collect tissue samples that are used to patent a product are ethically obliged to share the economic benefits of their discoveries with the individuals

or population from whom the samples were taken. The Human Genome Organization (HUGO) adopted a Statement on Benefit Sharing with regard to human genetic research in 2000, which states: "*in the interest of justice, the last decade has witnessed an emerging international consensus that groups participating in research should, at a minimum, receive some benefit.*"[28] The statement suggests that profit-making research institutions "*should dedicate 1-3% of their after-tax net profits to healthcare infrastructure and/or humanitarian efforts to benefit communities donating genetic samples.*" For nonprofit institutions, "*immediate health benefits as determined by community needs could be provided.*" Similarly, Article 19 of the International Declaration on Human Genetic Data provides that: "*Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with society as a whole and the international community.*"[29]

An important precedent for benefit sharing in human genetic research is the ill-fated Human Genome Diversity Project (HGDP), which sought to collect genetic samples from as many human populations as possible on the planet. Although the project was never implemented, largely because of ethical critiques and controversies about the project,[30] it did adopt precedent-setting ethical guidelines that recognized an ethical duty for benefit sharing.[31] The guidelines specify that "*a fair share of the financial rewards shall return to the sampled populations*" when the research results in commercial products. The suggested mechanisms for returning such payments to the donors include (1) paying "*a set percentage royalty … for the benefit of the sampled populations*" or (2) negotiating "*a reasonable financial payment with a trustee for the sampled populations, with the proceeds for the population's benefit.*"

With regard to food and agricultural products, the 1992 Convention on Biological Diversity clearly recognized that sovereign states have the authority to regulate the collection and use of genetic resources within their territory by providing in Article 15 that "*the authority to determine access to genetic resources rests with the national government and is subject to national legislation.*"[32] The Convention also recognizes in Article 1 the principle of "*fair and equitable sharing of the benefits*" of biodiversity. The Treaty on Plant Genetic Resources for Food and Agriculture, negotiated under the Food and Agriculture Organization (FAO) of the United Nations and concluded in 2001, goes further and establishes the principles of "facilitated access" and "sharing of benefits" for the commercial or scientific uses of the nation's resources by out-of-country entities.[33] Of course, these treaty obligations are only mandatory for nations that have ratified the treaty, and many prominent nations including the United States and some European nations have yet to ratify the 2001 treaty. In addition, many individual nations have adopted their own laws restricting access to biological materials within their borders that usually require some form of benefit sharing and prior consent. By one recent count, more than 40 nations have enacted such laws since 1993.[34]

Despite the endorsement of benefit sharing in the various statements and international agreements described above, benefit sharing remains a controversial and uncertain principle. One practical problem is that many scientific researchers are not provided funds in their research grants for providing economic compensation to individuals or populations providing the tissue samples. Another problem is that there is uncertainty in many cases in identifying who should decide how the benefits are allocated within populations. When the samples are taken from a discrete community or tribe with a recognized governance structure, the allocation of the benefits is usually not problematic in that the existing local government can take responsibility for using and distributing the benefits, but when the population is more dispersed or more difficult to clearly define, the distribution of benefits becomes more difficult. Finally, there is an ethical objection that paying significant financial benefits to individual tissue donors may unduly induce some individuals to participate in research.

In sum, while some legal rules and precedents address the issues of prior consent and benefit sharing in certain limited contexts, these issues are primarily ethical issues at the present time, in the absence of applicable laws. At their core,

the largely unresolved ethical debates on these issues represent a concern with the fairness and distributional aspects of biotechnology research and commercialization, and are important factors that should be considered in the context of any research project or program involving the collection of biological samples from plants, animals, or human populations.

4. USE OF PATENTS

The final major area of controversy associated with patents of biological materials is the use (or misuse) of such patents after they have issued. Perhaps the most common concern is that the availability of the patented invention is unduly restricted or costly due to high licensing fees, exclusive licensing, or similar access-limiting strategies by the patent owner.[35] Such practices may inhibit access to the benefits associated with the patented technology by entities with limited funding, including public research institutes, patients, farmers, some healthcare providers, university researchers, and similar entities. This restricted availability could adversely affect, in particular, subsistence agriculture, medical research, and health care.

For example, critics allege that Myriad Genetic's patents on the BRCA1 and BRCA2 breast-cancer genes, and the nearly US$3000 licensing fee per use it charges, adversely affects scientific research and health care.[36] This high licensing fee and monopoly prevent some nonprofit and other clinical-care units from offering a genetic test for these mutations, particularly for patients without health insurance or the means to pay for such tests, and may also burden or restrict scientific research related to hereditary breast cancer, although the company provides a substantial discount in the license fee to university and nonprofit researchers.[37]

A 2003 survey of 132 directors of diagnostic laboratories found that 25 percent had stopped performing a medical test because of a patent or license and 53% stopped research efforts because of a patent or license.[38] The practice of exclusive licensing also limits access to important scientific tools, materials, and procedures. A survey in the late 1990s found that out of 27 disease gene patents studied, 14 had been licensed, and all the licenses were exclusive.[39] The American College of Medical Genetics has adopted a position statement advocating broad licensing of patents on genes with clinical implications and that "*[l]icensing agreements should not limit access through excessive royalties and other unreasonable terms.*"[40]

Other commentators are concerned that the "upstream" patenting of research tools and genes will create a "tragedy of the anticommons" that will result in excessive and overlapping proprietary hurdles that will impede scientific research.[41] A recent survey of 1,240 university geneticists found that patenting and commercialization of research may be impeding the scientific ideals of openness and sharing, with 73% of respondents claiming that withholding of data by colleagues is slowing progress in their field.[42]

Yet another argument is that some biotechnology patent holders are exploiting their patent rights to provide greater market power and profits, to the detriment of patients, farmers, and other potential end users of the patented technologies. For example, some farmers and public interest groups have alleged that Monsanto's patents on genetically modified crops such as the herbicide tolerant Roundup Ready® technology are being used to promote sales of Monsanto's Roundup herbicide through license agreements that requires farmers who buy Roundup Ready® seeds to also use Monsanto's Roundup® rather than competing brands of the herbicide glyphosate. In several cases, lawsuits have been filed against Monsanto for "patent misuse," but to date these legal claims have been unsuccessful,[43] leaving the issue to be debated in the ethical realm.

As with all other ethical issues relating to biotechnology patenting, the alleged harmful effects of patenting on scientific research and healthcare are not uncontroverted. Many biotechnology and pharmaceutical companies consider their patents to be the lifeblood of their business, without which they could not raise and invest the substantial amounts of money needed to develop innovative products that can enhance human health. Some independent analyses have concluded, contrary to some of the arguments summarized above, that

the benefits of patenting outweigh the costs in the context of both scientific research and health care,[44] or that the problems feared from biological patents have largely not manifested.[45]

Some commentators have suggested that companies and other patent holders can take steps to minimize these consequentialist arguments against patenting, including not enforcing patents against university researchers and charging reduced licensing fees for clinical testing by nonprofit clinics and hospitals.[46] Other policy approaches that have been suggested for addressing these concerns include requirements for compulsory licensing, prohibition of exclusive licensing, liability exemptions for clinical uses of patented materials and tests, an expanded experimental-use exemption, the development of patent pools, and open-source approaches to biomedical research.

A related and relatively new issue is the use of patent rights to promote certain ethical or political objectives. For example, Myriad Genetics, which has the exclusive patent rights to the BRCA1/2 breast-cancer genes in the United States and some other jurisdictions, refuses to allow the patent to be licensed for prenatal testing for these genetic markers.[47] This is an example of the patent right being used to achieve a policy outcome—that is, preventing prenatal testing (and presumably follow-up abortion in some cases) for cancer-susceptibility traits.

One group of researchers has suggested that patent licensing could be used as a "moral tollbooth" to ensure the ethical use of biotechnology technologies.[48] Under this proposal, patent holders could be held liable for the unethical use of genetic inventions. The authors suggest "*that a patent holder could be expected to ensure that a licensee of that invention be required to meet emerging legal and ethical norms associated with the use of the technology, such as the requirement to provide fully informed consent or genetic counseling where appropriate.*"[49]

5. CONCLUSION

Ethical issues and controversies about biotechnology patents are a significant, and growing, factor in the development and implementation of biomedical and agricultural technologies. In a few limited contexts, ethical concerns have been translated into legal rules that specify a clear course of conduct, but those situations are the exception. In most cases, ethical concerns about gene patents have not been incorporated into laws, and the ethical issues remain largely unresolved and hotly debated. The lack of clear ethical principles and guidelines creates a problem for actors in this field. As the U.S. Office of Technology Assessment recognized many years ago:

Uncertainty about how courts will resolve disputes between specimen sources and specimen users could be detrimental to both academic researchers and the infant biotechnology industry… [R]egardless of the merit of claims by the different interested parties, resolving the current uncertainty may be more important to the future of biotechnology than resolving it in any particular way.[50]

In the absence of greater ethical consensus and clarity, decision-makers must navigate the ethical minefields of biotechnology patents on a case-by-case basis, seeking to avoid the ethical hot spots that will likely trigger controversy, disruption, and opposition, while avoiding being paralyzed into inaction by the matrix of conflicting ethical viewpoints and positions that exist. ■

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SECTION 2

Specific Strategies and Mechanisms for Facilitating Access to Innovation

Reservation of Rights for Humanitarian Uses

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ABSTRACT

An explicit reservation of rights in a commercial technology license can ensure that the licensor's institutional objectives to support humanitarian applications of its technology are not inadvertently blocked or sidetracked by overly broad terms in the commercial license. Many universities routinely use a reservation of rights to guarantee continued use of licensed technologies within the ongoing research or educational programs of the university. Clauses included in license agreements to reserve rights for humanitarian use of technology are still rare, but awareness is increasing of the utility and importance of such clauses, particularly as philanthropic-research sponsors begin to require grantees to ensure that results and discoveries will be made available for humanitarian purposes. The structure of a clause to reserve rights for humanitarian use ideally both expresses the philosophical intent of the licensee and clearly defines the boundaries of humanitarian use, particularly in relation to commercial use.

1. INTRODUCTION

The reservation of certain rights in commercial license agreements is a means for the technology provider (the licensor) to declare its explicit intent to reserve or retain certain rights over the technology—to not grant those rights under the license—in order to help ensure that the terms of the license will not block other specific goals that the licensor may have. Such goals are typically noncommercial and therefore do not directly impair the licensee's ability to commercialize the technology, but they may be important to ensure that the licensor can continue to meet other institutional objectives such as education, research, and public service. In the case of university research, this typically includes the goal of ensuring that future noncommercial research is not blocked and, increasingly, that humanitarian uses and applications of the technology are not blocked.[1] This chapter will briefly address a single issue—that of creating an explicit reservation of rights in a commercial technology license to ensure that institutional objectives to support humanitarian applications of its technology are not inadvertently sidetracked by an overly broad commercial license. Furthermore, the regular use of this type of *reservation-of-rights* clause provides a means to regularly articulate an institution's commitment to manage technologies for the broadest public benefit.

2. RESERVATION-OF-RIGHTS CLAUSE

License agreements broadly define the terms under which a technology provider (licensor) will transfer intellectual property and/or tangible property to a technology user or developer (licensee), usually for commercial development. In many cases, the license agreement is nonexclusive or it carefully defines the use of the technology for a specific field or a specific geography. In such cases, the licensee does not grant—but

Bennett AB. 2007. Reservation of Rights for Humanitarian Uses. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

instead retains—rights to the technology in all areas other than those defined within the scope of the license, and therefore a specific reservation of rights may not be necessary. However, for some technologies and in some technology sectors—including biotechnology—broad exclusive licenses are often required to induce follow-on investment in research and development. In these cases it can be important for the licensee to explicitly reserve rights to ensure that its noncommercial institutional objectives are not blocked by the exclusive terms of the commercial license.

For example, universities frequently incorporate a clause that reserves rights to carry on research using licensed patents and/or technology. This has become increasingly important since the *Madey v. Duke University*[2] ruling effectively narrowed, beyond any practical use, the research exemption codified in U.S. patent law for university research.[3] This lack of a research exemption in the United States has created the unusual situation where a university invention, if licensed exclusively, may be unavailable for ongoing research even in the very laboratory where the invention itself was made. To address this situation, many universities in their exclusive license agreements now reserve rights for the use of inventions within their own institution or, even more broadly, within all academic or nonprofit research institutions.

The University of California and Stanford University routinely incorporate clauses into their exclusive license agreements (Box 1). This type of reservation-of-rights clause is perhaps the most common type used in university license agreements, although even this straightforward and reasonable term still is not used by many universities in their exclusive license agreements.

Clauses in university license agreements that reserve rights for humanitarian use of the technology are an exception, rather than a rule, but awareness of the utility and potential importance of such clauses is increasing. Today there are examples of research sponsors and programs—such as philanthropic foundations—that require grantees to ensure that research results and discoveries will be made available for humanitarian purposes. Based on this type of sponsor requirement, grantees who execute a commercial license to any technology developed under the research agreement would thus be required to include a clause that acknowledged this existing obligation and reserved rights for humanitarian purposes.

3. THE STRUCTURE OF A RESERVATION OF RIGHTS

A reservation of rights for humanitarian uses can be a very simple statement expressing the philosophical intent of the licensee. For example, at the Donald Danforth Plant Science Center all research and license agreements include a statement that the "*Company and Danforth Center shall diligently and in good faith negotiate the terms of a worldwide license, making provision for preserving*

Box 1: Sample Reservation of Rights in Exclusive Licensing Agreements

The University of California

Nothing in this Agreement will be deemed to limit the right of The Regents (the University)... to make and use the Invention ... and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.

Stanford University

Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution.

the availability of the intellectual property (IP) for meeting the needs of developing countries."[4] While this has the advantages of being simple and ensuring that the licensee is on notice with regard to the intention of the licensor, the statement may not provide sufficient definition of "*meeting the needs of developing countries*" for the licensor to assess the extent to which this statement may affect its commercial markets. As a consequence, more elaborate clauses have been crafted in efforts to clearly define the boundaries of humanitarian uses, particularly in relation to commercial uses.

3.1 *Definitions*

The definitions are the most critical component of a reservation of humanitarian use rights. The key definitions are:

Humanitarian purposes. There are several approaches used to define humanitarian purposes: by income level, by uses (subsistence or commercial), and by geography. Each approach has its own set of limitations. Using a definition that equates *humanitarian uses* with *subsistence uses* has been adopted for some agricultural applications but will probably not be applicable in the health sector, since few technology applications can be achieved without significant investment by a commercial partner (this is becoming increasingly true in agricultural innovations as well). Where subsistence uses are part of the definition, it may be important to define income levels of the subsistence "users." This criterion has been applied in the case of the humanitarian license for Golden Rice[5] but could raise difficult practical issues for compliance or monitoring. Alternatively, *humanitarian uses* can be defined geographically by specifying all uses of the technology within developing countries.

Developing countries. If *humanitarian uses* is defined geographically then an explicit definition of *developing countries* is needed. For example, *developing countries* can be defined as those listed by the World Bank or other international agencies. While this definition can effectively segment the commercial and humanitarian uses of a technology, the current lists of developing countries may not capture the entire set of desired geographies. Such a definition should have flexibility to allow the expansion of the geographical list. In addition, if such a geographical definition of humanitarian uses is used, then the issue of use and sales outside of this defined territory should be explicitly addressed.

Commercial purposes. Because the reservation of rights for humanitarian uses is designed to be used in the context of a commercial license and, specifically, to segment the markets for a technology between commercial and humanitarian uses, it may be important to define the scope of commercial uses as well.

3.2 *Reservation of rights*

The reservation of rights is the operative paragraph of the clause, and its structure will rely upon and follow the above definitions. The reservation of rights needs to clearly articulate what rights are being reserved and should leave no doubt that the reserved rights may be granted to other appropriate companies or organizations that can fulfill the humanitarian objectives. This may be a topic of discussion in license negotiations, largely because it is likely to be an unfamiliar term to a commercial licensee.

4. STANDARD CLAUSES

There are relatively few examples of standardized reservation-of-rights clauses, because they are likely to be crafted individually to meet specific situations. However, as an object lesson, here are two examples, one developed for agricultural technology licenses and one developed for health technology licenses.

The Public Intellectual Property Resource of Agriculture (PIPRA) has crafted a standard reservation of humanitarian-use-rights clause that encourages its members to include in commercial licenses for agricultural technologies, particularly in exclusive licenses. The clause (Box 2) may serve as a model or starting point for similar license clauses that seek similar objectives.

The Office of Technology Licensing at the University of California, Davis crafted a reservation-of-rights clause intended for a commercial license of a health technology (Box 3). Likewise,

Box 2: PIPRA's Reservation of Rights for Humanitarian Uses

Definitions.
"Humanitarian Purposes" means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.
"Commercial Purposes" means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service.
"Developing Country" means any one of those countries identified as low-income or lower-middle-income economies by the World Bank Group at the time of the effective date of this agreement and all other countries mutually agreed to by Licensor and Licensee (the current list of countries is typically given in an appendix to the agreement).[6]

Reservation of rights.
Notwithstanding other provision of rights granted under this agreement, University hereby reserves an irrevocable, nonexclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

Box 3: Reservation of Rights for Humanitarian Use: University of California, Davis

1.40 "Humanitarian Purposes" means (a) the use of Licensed Products covered under Compound Patent Rights ("Compound Products") for research and development purposes by any organization or other third party, anywhere in the world that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country, and (b) the use of the Compound Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country.

1.41 "Commercial Purposes" means to make, have made, use, have used, import, or export a product, good, method, or service for the purpose of selling or offering to sell such product, good, method, or service.

1.42 "Economically Disadvantaged Country" ("EDC") means all countries listed on the United Nations Conference on Trade and Development list of "Least Developed Countries" in effect as of the Effective Date of this Agreement which are set forth on Appendix I hereto.

2.14 In any license to the Licensee, Licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the Licensee will be required to give away the Compound Products for free or at cost.

(Continued on Next Page)

it may serve as a model or starting point for similar license clauses that seek such an objective.

5. CONCLUSIONS

It has recently been suggested that national public policy guidance is needed to support measures that require that publicly funded research results be managed in a way that preserves the opportunity to mobilize new technologies to meet humanitarian needs of the world's poorest people in addition to meeting the commercial needs of the developed world.[7] In the absence of such national policies, voluntary measures can still be taken to ensure that research results, new discoveries, and patented inventions are not unnecessarily blocked from serving humanitarian purposes and meeting the needs of the world's poor. For public research institutions, a reservation of humanitarian rights in commercial technology licenses is one mechanism to help it meet its mission to serve the public benefit through both commercial and humanitarian channels. ■

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1 The broader topic of humanitarian access to health and agricultural innovations and a discussion of strategies to ensure broader access are also addressed in this *Handbook* in various chapters, most notably chapter 2.2 by AL Brewster, SA Hansen and AR Chapman. For specific aspects of the topic, see in this *Handbook*, chapter 12.1 by RT Mahoney.

2 (307 F.3d 1351 [Fed. Cir. 2002]) .

3 Ludwig SP and JC Chumney. 2003. No Room for Experiment: The Federal Circuit's Narrow Construction of the Experimental Use Defense. *Nature Biotechnology* 21:453.

4 Beachy R. 2003. IP Policies and Serving the Public. *Science* 299:473. See also in this *Handbook*, chapter 17.10 by K Schubert.

5 Brewster AL, AR Chapman and SA Hansen. 2005. Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation. *Innovation Strategy Today* 1(3):203-216. www.biodevelopments.org/innovation/index.htm.

6 web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS0,,contentMDK:20420458~menuPK:64133156~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html. Last updated by the World Bank July 2006.

7 Boettiger S and AB Bennett. 2006. Bayh-Dole: If We Knew Then What We Know Now. *Nature Biotechnology*. 24:320–24.

Box 3 (continued)

2.15 Notwithstanding other provision of rights granted under this Agreement, The Regents [the university] hereby reserves the right to license the Compound Patent Rights to any third parties for solely Humanitarian Purposes. Such licenses for Humanitarian Purposes will expressly exclude the right of the third party licensee to export or sell the Compound Products from an EDC into a market outside of the EDC where Licensee has introduced or will introduce a Compound Product and where Patent Rights exist. In any such license, the third party licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the third party licensee will be required to give away the Compound Products for free or at cost. For avoidance of doubt, the third party licensee may be permitted to export Compound Products from the EDC of origin to other EDCs and all other countries mutually agreed to by The Regents and Licensee.

Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation

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ABSTRACT

Because certain patenting and licensing strategies can inhibit the development and dissemination of products for developing countries, intellectual property management strategies need to be developed that can help remove some of these obstacles. It is equally important to apply creative patent management strategies that actively promote access to needed products in developing countries. Care must be taken, however, to ensure that patents on research inputs do not discourage or unreasonably increase the cost for product development that targets needs in small or unprofitable markets. The American Association for the Advancement of Science project on Science and Intellectual Property in the Public Interest convened a working group to explore these issues in 2004. This chapter draws upon the expertise of that group to identify licensing strategies that are effective in promoting humanitarian access to health and agricultural product innovations and expanding their use among poor and disadvantaged groups, particularly in low-income countries. The chapter encourages more public sector IP managers to understand and employ strategies that will achieve these goals and seeks to help private sector licensees to understand the rationale behind and potential benefits of such strategies. Indeed, humanitarian licensing strategies should more and more become the norm by contributing to the development and dissemination of essential medicines and agricultural technologies for developing countries.

1. INTRODUCTION

1.1 *Patents and neglected markets*

Intellectual property (IP) rights play an increasingly important role in the development, manufacture, and distribution of products in agriculture and health. During the past 25 years, there has been an unprecedented increase in the scope, level, role, and geographic and subject-matter coverage of IP protection.[1] Strong patent protection is intended to contribute to increased research investments and a favorable climate for technology transfer. But it may not always produce these effects. In fact, IP licensing practices may inhibit access to IP-protected knowledge, research tools, and products.

The unmet medical and agricultural needs of developing countries are vast. Reflecting the technological and financial disparity between developed and developing countries, low- and middle-income countries account for less than 10% of worldwide research and development expenditures.[2] And despite increasing levels of investment in pharmaceutical R&D during the past 30 years, only 1% of new compounds marketed have been for developing-world diseases.[3] Recent research has identified some increase in innovative activity related to diseases specific to poor countries, though this activity "remains extremely low relative to pharmaceutical research overall,"[4] and has resulted, in large part, from increased public R&D funding for global health.[4, 5] Similarly, private sector agricultural research is more likely to focus on specialty crops of interest to developed countries than on staple crops that are important to resource-poor farmers in developing countries.[6]

Brewster AL, SA Hansen and AR Chapman. 2007. Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

1.2 *Background and related initiatives*

Our discussion of strategies builds on the initiatives, experience, and proposals of other organizations for the management of IP. The United Nations Millennium Project Task Force on Science, Technology, and Innovation recommended expanding mechanisms for inventors to make their ideas available royalty free for uses that meet the needs of poor countries, noting in its final report that "only a handful of mechanisms are designed to promote such activities."[7] However, beginning in the 1980s, and expanding through the 1990s and the early years of the 21st century, an increasing number of organizations have been using IP management practices to promote the health and food security of underserved populations. These include the Program for Appropriate Technologies in Health (PATH) and the Population Council, as well as various other public and public/private partnerships, such as the International AIDS Vaccine Initiative, the Global Alliance for TB Drug Development, the Global Vaccine Initiative, the Diseases of the Most Impoverished Program of the International Vaccine Institute, and the Centre for the Management of Intellectual Property in Health Research and Development (MIHR). International entities (for example, the World Health Organization [WHO]) have undertaken humanitarian licensing, as have national entities such as the U.S. National Institutes of Health (NIH), which now includes humanitarian clauses in its licensing agreements as appropriate. Several governmental organizations in developing countries, such as the Council for Scientific and Industrial Research of India, are beginning to undertake humanitarian licensing. Agricultural organizations with relevant experience include the African Agricultural Technology Foundation[8] (AATF), the International Service for the Acquisition of Agri-biotech Applications (ISAAA), and the institutes of the Consultative Group on International Agricultural Research (CGIAR).

One of the most noted examples of humanitarian IP management involves vitamin-A-enriched Golden Rice. Although developed mainly with public sector funding and research, around 45 patents associated with Golden Rice are owned by approximately 30 companies and public institutions in the United States, and only a few patents are held in developing countries.[9] The inventors of Golden Rice licensed their inventions related to golden gice to Greenovation, a biotech spinout company from the University of Freiburg, which is owned by the inventors themselves. Greenovation then exclusively licensed its Golden-Rice-related patents to AstraZeneca, PLC (now Syngenta). Subsequently, Syngenta entered into a license agreement with the inventors that allowed them, and Syngenta, to license Golden Rice technologies to developing countries. Other companies holding Golden-Rice-related patents also agreed to the same arrangement. That arrangement allows both Syngenta and the inventors to grant licenses—with the right to sublicense—to any bona fide research organization for the development of Golden Rice. The rice can be used royalty free and allows farmers to earn as much as US$10,000 per year from its sale. Higher sales would require farmers to acquire a commercial license from Syngenta.[10] The example of Golden Rice illustrates that it is possible to make IP available for research and commercialization in developing countries.

Yale University offers another example of humanitarian IP management. It holds a key patent on stavudine (d4T), a widely used HIV/AIDS antiretroviral drug. Yale renegotiated its exclusive license with Bristol-Myers Squibb Co. to incorporate renegotiated humanitarian terms, allowing the drug to be subsequently licensed for generic production in South Africa. The university also negotiated a price cut, immediately reducing the price of d4T in Africa to 1/30th of the price in the United States. When the generic product came on the market, it further reduced the price by as much as 40%.

Other examples of humanitarian IP management include Cornell University's transfer of ring-spot-virus-resistant papaya to Thailand, as well as several projects brokered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). The latter include local varieties of potato transferred from Monsanto Co. to Mexico, as well as ring-spot-virus-resistant

and delayed-ripening papayas transferred from Monsanto and Syngenta, respectively, to Southeast Asia.[11] Finally, a recent agreement between Gilead Sciences and the South African drugmaker Aspen Pharmacare is another example of humanitarian IP management for health products. Gilead will allow Aspen to produce generic versions of the HIV/AIDS antiretrovirals Truvada® and Viread®, and university inventors who own foundational patents for both drugs have agreed to waive royalties in the developing countries served by Aspen.[12]

1.3 *Intended audience*

This paper is written primarily for licensors, particularly university-based technology transfer managers and public sector intellectual property managers and, secondarily, for the staff of intellectual property departments in corporations with which these entities may enter into agreements or who may themselves decide to adopt some of the following strategies. Foundations or agencies that fund research and that may wish to encourage or require their grantees to engage in humanitarian IP management are another important audience.

1.3.1 *Public sector*

Universities and public sector institutions play key roles in the development of medicines and agricultural products. Their roles are generally early in the process, and because university-based research is most often upstream, final products based on their research often involve significant development by others. The manner in which public sector researchers make their "upstream" technologies and research tools available can influence whether populations in developing countries have access to the end products of this research.[13]

In recent years a number of nonprofit public/private partnerships (PPPs) have formed with the mission of developing health and agricultural products for markets that are neglected by traditional for-profit R&D companies. These PPPs are typically funded by foundations or public sources and may receive in-kind support, or in some cases direct funding, from private companies.

Like typical drug companies, health-focused PPPs often develop a portfolio of candidate products, hoping that a few will be safe and effective enough to treat their focal condition. Examples of PPPs that develop pharmaceuticals are listed in Box 1.

If a university has already licensed IP to a company, renegotiating to provide access for a PPP can be costly and difficult—even if the PPP seeks to develop the invention into a noncompeting product. However, the university can take steps at the beginning of the technology transfer process to facilitate the use of its invention for developing products that serve the poor. If a technology does not interest commercial licensees, university IP managers can seek PPPs or other nontraditional license partners to develop it for neglected markets. To be able to take advantage of these opportunities, it is very important for universities to establish policies and guidelines to manage university-generated IP for humanitarian use and applications.

Why should universities and public sector institutions take advantage of these opportunities to promote humanitarian use? Most universities and public sector research institutions seek to contribute to the wellbeing of humankind through their patenting and licensing activities. For example, each of the top four university recipients of U.S patents in 2004[16] states public benefit as an explicit goal in its patent policy:

- University of California (424 patents). "*It is the intent of the President of the University of California, in administering intellectual property rights for the public benefit, to encourage and assist members of the faculty, staff, and others associated with the University in the use of the patent system with respect to their discoveries and inventions in a manner that is equitable to all parties involved.*"[17]
- California Institute of Technology (135 patents). "*It is the policy of the Institute that such patents be used for the public benefit. If there are innovations or discoveries that result in the filing of patent applications and the acquisition of patents, the Institute intends to serve the public interest by prudent and ap-*

Box 1: PPPs That Develop Pharmaceuticals

Aeras (Aeras Global TB Vaccine Foundation)
www.aeras.org

Children's Vaccine Programme at PATH
www.childrensvaccine.org

CONRAD
www.conrad.org

DNDi (Drugs for Neglected Diseases Initiative)
www.dndi.org

FIND (Foundation for Innovative New Diagnostics)
www.finddiagnostics.org

Gates Foundation/University of North Carolina Partnership for the Development of New Drugs
www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=85&typobj=0

Global Microbicide Project
www.gmp.org

Global Vaccines Inc.
www.globalvaccines.org

Human Hookworm Vaccine Initiative at Sabin Vaccine Institute
www.sabin.org/hookworm_slides.htm

IAVI: International AIDS Vaccine Initiative
www.iavi.org

Infectious Disease Research Institute
www.idri.org

iOWH (Institute for OneWorld Health)
www.oneworldhealth.org

IPM (International Partnership for Microbicides)
www.ipm-microbicides.org

MMV (Medicines for Malaria Venture)
www.mmv.org

MVI (Malaria Vaccine Initiative)
www.malariavaccine.org

PATH (Program for Appropriate Technology in Health)
www.path.org

PDVI (Pediatric Dengue Vaccine Initiative)
www.pdvi.org

PneumoADIP (Pneumococcal Vaccines Accelerated Development and Introduction Plan)
www.pneumoADIP.org

TB Alliance (Global Alliance for TB Drug Development)
www.tballiance.org

Source: Compiled from Gardner and Garner[14] and Merz.[15]

propriate efforts to transfer the technology to those who will facilitate public use."[18]

- Massachusetts Institute of Technology (132 patents): "*It has long been acknowledged that the primary functions of a university are education, research, and public service. It is in the context of public service that M.I.T. supports efforts directed toward bringing the fruits of M.I.T. research to public use and benefit.*"[19]
- University of Texas (101 patents): "*It is the objective of this policy to encourage the development of inventions and other intellectual creations for the best interest of the public, the creator, and the research sponsor, if any, and to permit the timely protection and disclosure of such intellectual property by development, commercialization after securing available protection for the creation, by publication, or both.*"[20]

Public funding agencies also seek to promote public benefit. The mission of NIH, for example, is to support biomedical research to extend healthy life by reducing illness worldwide. NIH therefore seeks to understand and overcome the obstacles hindering the public availability of inventions made by NIH scientists. To this end, NIH engages in a variety of forms of humanitarian licensing and humanitarian-use agreements.[21] Many other public sector actors and universities are also interested in "doing the right thing" in terms of promoting access, but they often do not know how to proceed.[22]

We anticipate that at least some types of humanitarian IP strategies will have little or no impact on licensing revenues for the technology creators. Whether that will be the case may depend on whether humanitarian licensing becomes commonly practiced and accepted. It may be important for a university or research institute's administration to commit to humanitarian

Box 2: Developing a Low-Cost Malaria Treatment

Strategy employed: ***Agreeing on IP management conditions in advance***

A research group sponsored by the Medicines for Malaria Venture (MMV) has developed a promising, low-cost malaria treatment known as OZ277 /RBx11160. MMV supported collaboration between scientists at the University of Nebraska, Swiss Tropical Research Institute, Monash University, and the F. Hoffman-La Roche, Ltd. to develop OZ. The drug incorporates some chemical features of the plant-derived antimalarial artemesin, but can be produced through synthetic chemical processes, making it significantly cheaper. Patents covering OZ have been assigned to MMV, and MMV has engaged the Indian drug manufacturer Ranbaxy to further develop it. Upon regulatory approval, Ranbaxy Laboratories, Ltd. will distribute OZ at low cost in malaria endemic countries. MMV facilitated arrangements for patent, royalty, and pricing structures to benefit those in need by establishing an IP management plan with its collaborators in advance. Below are excerpts from the Statement of MMV Collaborative Principles:

> *MMV's central objective is to ensure the sustainable and continuous generation of appropriate new malaria medicines that are accessible to all of those in need in developing countries at the lowest prices practicable.*
>
> *MMV requires intellectual property rights on a royalty-free basis to the relevant intellectual property, in the field of malaria, and developed through the collaboration.*
>
> *MMV will seek the right to the relevant background intellectual property necessary to achieve the objectives identified herein.*
>
> *MMV would not normally have a desire to retain any interest in relevant intellectual property rights for use outside the field of malaria or to constrain such use by its collaborators.*

Source: MMV and JC CraftMedicines for Malaria Ventures. Statement of MMV Collaboration Principles. Personal communication, J. Carl Craft, Chief Scientific Officer, MMV.[23]

IP management as an extension of the institution's public mission (Box 2). This might enable technology licensing officers to risk sacrificing small amounts of licensing revenue when there is an opportunity to enhance product development initiatives for the poor. In addition, institutional administrations can foster approaches among technology licensing officers that would enhance such product development initiatives when financial promise is low.

1.3.2 *Private Sector*

Why address intellectual property managers in the commercial sector? Most technologies developed by universities and public sector institutions are at early stages of development and require private companies to invest more in research and development to create practical applications. Universities generally license these early-stage technologies to the private sector. The success of humanitarian licensing therefore depends on the willingness of private sector actors to accept certain conditions and requirements that would increase access later in the product development and marketing stages.

We think there are two reasons that commercial licensees may support humanitarian licensing. First, commercial entities usually expect major financial returns in developed world markets, but developing country markets are often considered unprofitable. Hence, many types of humanitarian licensing may not harm the financial interest of the commercial licensee. Moreover, a corporation may advance its reputation for social responsibility and win greater esteem from the public by accepting humanitarian licensing.

Multinational companies have already shown a willingness to segment their markets and offer concessionary terms to facilitate access to their products in poor countries. A number of examples have been highlighted already, including AstraZeneca, Bristol-Myers, Gilead, Monsanto, and Syngenta. Activities by Chiron Corp., GlaxoSmithKline, Pioneer International, Inc. (affiliate of E. I. du Pont de Nemours and Company), and Roche are mentioned later.

2. HUMANITARIAN LICENSING STRATEGIES

In this section we discuss some successful strategies and some new proposals for managing IP to facilitate humanitarian use and applications. These include case studies in which IP owners have used nontraditional IP management techniques to promote the development of products for neglected markets. In this section, we describe general approaches to licensing and some specific license features that a patent owner can use when transferring technology to a commercial entity.

2.1 *Identifying the intended beneficiaries*

Rights reserved or obligations set out to facilitate access in developing countries will need to specify the intended beneficiaries. In the end, all humanitarian licensing efforts should strive to benefit underserved people in developing countries by providing greater access to needed technologies. However, defining this population or identifying the institutions that could serve this population with the licensed technology may require different approaches, depending on the particular technology and requirements of the primary licensee. Below are some options for defining the beneficiaries of humanitarian license terms.

A developing country can be defined in a number of ways, for example, by reference to the United Nations list of least developed countries, by locale, or by reference to lists provided by the Organisation for Economic Co-operation and Development (OECD) countries, the World Bank, or the Food and Agriculture Organization (FAO). Beneficiary countries may also be mutually agreed to by the contracting parties, who may also need to decide whether the agreement will cover middle-income as well as low-income countries.

In addition to or in place of defining a list of countries covered by the reservations and/or exemptions in a humanitarian license, negotiators may wish to further define the population in those countries that would be covered. The intended population might be "the poor," "those in need," subsistence farmers, populations in geographically underserved regions, or a particular market segment.

A market segmentation, or dual market, approach is often used to target intended beneficiaries and is involved in many of the strategies discussed in this paper. With this approach, an exclusive license might give a private sector entity the sole right to use a technology in profitable markets, while allowing others to use the technology at no cost or reduced royalties to serve market segments that do not interest the private sector.

In the licensing arrangements for Golden Rice, a humanitarian-use clause was used to segment access to an agricultural technology, committing the owners of key proprietary components to donating their technology to the poor. Negotiations over how exactly to define and make operational such "donations" are ongoing. These negotiations focus on defining the humanitarian-use market and ultimately on the precise wording of the humanitarian-use clause. This humanitarian-use clause will determine who qualifies as a beneficiary of royalty-free access to Golden Rice and exactly how they would benefit.[24]

Although market segmentation strategies have been employed successfully,[25] certain challenges remain, namely the containment of the IP within the targeted markets. In addition to the humanitarian transfer of products to the intended populations, many developing countries may also have emerging private markets for the same goods. Markets that would not be attractive to large companies may nevertheless present niche opportunities for smaller companies. Market segmentation might be most successful where noncommercial markets can be sharply delineated by region, which makes it easier to exclude spillovers to nontargeted markets.[26] In addition, market segmentation often requires intense negotiation, the development of trust between partners, and the capacity to enforce agreements.

2.2 *Nonexclusive licensing*

In nonexclusive licensing, in addition to the primary license agreement, the licensor retains the freedom to license the technology to other parties. Some institutions (for example, NIH) seek to use nonexclusive licensing or to license to multiple companies whenever possible. If a university can accomplish technology transfer to a company using nonexclusive licensing, it is free to subsequently license the technology for humanitarian applications. Sometimes a commercial licensee insists upon an exclusive license, in which case public sector licensors may limit the exclusive license to developed-country markets (as discussed later) or for specific product applications.

2.3 *Transferring technology to public-private partnerships (PPPs)*

When it is clear that a technology could benefit neglected markets (for example, a low-cost HIV diagnostic or an agricultural trait important for subsistence agriculture), university technology managers may be able to transfer the technology to a nonprofit corporation for product development either on an exclusive or nonexclusive basis. The business models of PPPs vary. Some conduct in-house product development; others manage collaborative development by public and private sector labs (Box 3). The transfer of technology could take forms ranging from direct licensing or donation of a patented invention to contributions of know-how or scientific expertise.

Another possible model is an arrangement in which a commercial licensee focused on markets in affluent countries makes the technology available to a PPP on concessionary terms for marketing or development for poor countries. In order to minimize transaction costs for the PPP, it is highly preferable for the university to engage with the nonprofit developer before completing negotiations with the commercial licensee.

University technology managers can also facilitate nonprofit product-development efforts by offering PPPs ownership of patents that the university no longer wishes to maintain. Even when a technology does not appear to have a clear application for developing regions, it may prove useful for some aspect of the PPP's work to develop products for these regions.

2.4 *Transferring technology to companies in developing countries*

Technology managers may seek commercial partners in low- or middle-income countries to develop technologies that address conditions specific to

those regions. These companies are likely to have greater interest in developing products that meet the needs of these countries than commercial entities in wealthier countries. They may also be able to develop, produce, and distribute products at much lower cost than typical partners in the United States or other industrialized countries.

2.5 *Out-licensing*

Out-licensing is primarily executed by drug companies that are already producing name-brand versions of a patented drug, but universities could negotiate with corporate licensees to ensure that out-licensing to generic companies takes place. Under the out-licensing approach, drug patent holders award nonexclusive licenses to generics manufacturers, allowing them to produce cheap copies of drugs for sale exclusively in designated poor countries. The generic makers are prohibited from selling products in the patent holder's developed country markets, and they may be required to modify their packaging so as to discourage reimportation by making the generic versions easier for customs officials to identify. Generic producers pay a royalty to the patent holder, and are encouraged to compete on price. An advantage of this semicooperative approach is that generic makers in developing countries can get more information from the patent holder than just the patented technology itself, such as manufacturing expertise and regulatory data. In the rare case that a university holds IP that needs little additional development, it could essentially make the out-licensing arrangement itself by licensing the patent to a name-brand pharmaceutical company (as opposed to a company specializing in the production and marketing of generics) for wealthy markets and to generic manufacturers for production in developing countries. It may be more difficult, though not impossible, to encourage the sharing of manufacturing expertise and regulatory information.

2.6 *Conditions in funding agreements*

Foundations, government agencies, and other organizations can require that funded work be licensed under humanitarian terms by inserting conditions into funding agreements. Establishing humanitarian IP management conditions in advance can simplify later negotiations, help researchers and IP managers plan ahead, and increase the prospects of success (Box 4). The Rockefeller Foundation has crafted language to include in research agreements for this purpose, offering a model for ways that funders can increase humanitarian access to the research supported by their grants. The Rockefeller Foundation requires grantees, whether or not they claim or obtain

Box 3: CDA Malaria Treatment

Strategy employed:
PPP-sponsored product development and preferential pricing requirement

The WHO Tropical Disease Research program, the Medicines for Malaria Venture (MMV), and GlaxoSmithKline have formed a partnership to build upon the two-drug antimalarial LapDap™ by adding artesunate to the combination. The new therapy will be called CDA, for its ingredients chloroproguanil, dapsone, and artesunate. The original LapDap was conceived by scientists from the Wellcome Trust Laboratory in Nairobi and the University of Liverpool, then brought to market by a public/private partnership involving MMV, British universities, the Wellcome Trust, GlaxoSmithKline, and the U.K. Department for International Development. It was approved by the U.K. Medicines and Healthcare Products Regulatory Agency in 2003. Under the agreement for developing the new triple-drug combination, it will be made available at preferential prices to the public sector in malaria endemic countries.

Source: TDR News.[27]

patents or other proprietary rights in their discoveries, "*to license or otherwise make available the Discoveries to third parties in the commercial and public sectors (to the extent permitted under the MTAs) for the purpose of furthering the creation, reproduction, modification, and/or sale of the improved end product.*"

2.7 *Humanitarian conditionality in licensing agreements*

Licensing conditions may require the licensee to do specific good things to benefit disadvantaged populations. These conditions are sometimes referred to as white knight clauses. These may include marketing a product in developing nations at a reduced royalty or price, donating materials for clinical trials, or cooperating with a humanitarian licensee in a specified way (for example, by providing clinical or field trial results). A licensor could also insert language requiring the licensee to make products developed from improvements to the technology available in low- and middle-income countries at a reduced cost.

NIH often uses these clauses in its agreements to ensure that the licensee undertakes specific actions to benefit the public sector (for example, mandating the supply-back of licensed products or services, health education programs, indigent access programs, reduced royalties for developing countries, biodiversity compliance for natural products, and other means of ensuring developing country access for licensed products). NIH also requires licensees to create a worldwide development and marketing plan to facilitate developing country access to licensed products, the implementation of which it monitors through agreed-upon benchmarks.[29]

2.8 *Performance milestones*

A *milestone* is a performance requirement on the part of the licensee. Milestones are often used in public/private partnerships and sponsored research agreements to measure a project's progress and success. An example of a humanitarian licensing milestone might be a requirement that on or before the date of the first phase of a clinical trial for a new drug, the licensee will have identified a generic manufacturer in a middle-income country to produce the licensed technology at a reasonable price for developing countries. Subsequently, if this milestone is not met, other provisions and reservations in the agreement would be activated, for example, loss of exclusivity, sublicensing, exercise of march-in rights, and even termination of the agreement.

2.9 *Ensuring accessibility through pricing*

To help ensure access to products, the licensor may require that any product developed and brought to the market be distributed at a reasonable price. Despite the inherent difficulties in defining what is reasonable, price is a readily measurable condition that is easier to monitor than more broadly defined requirements concerning access.[30] This model could be expanded, whereby licenses to companies include an appro-

Box 4: Developing a Portable HIV Diagnostic

Strategy employed: *Condition in funding agreement*

When technology transfer officers at Massachusetts General Hospital and the University of Texas were licensing a prototype HIV diagnostic device to a start-up company, the requirements of the foundation funders allowed the foundations to grant additional licenses to entities capable of meeting charitable objectives in LDCs. Since it is a portable device, the technology could provide an inexpensive, practical means of diagnosing HIV in resource-poor settings.

Source: Foskett, Menapace and Basu.[28]

priate balance of incentives to the licensee and market access for the poor. Licensees might be required to meet certain milestones, such as government procurement targets in defined countries, and at prices that are deemed appropriate for that market. Here, an appropriate price may be defined as the cost of production plus a small profit, usually in the 5%–10% range prior to being allowed to commercialize the product in more lucrative markets.[31] To ensure that an appropriate price is reached and maintained, the licensor may include contractual language that mandates the submission of manufacturing cost reports and product cost calculation details on a regular basis.[32]

2.10 ***Reserving rights in license agreements***

It is important to think through how the humanitarian-purpose licensee will actually use the technology and to reserve an appropriate set of rights and exemptions. For example, the negotiators will certainly want to consider the scope of research rights and, depending on the particular technology and application, the scope of international trade rights. The humanitarian licensee might need the right to carry out research or manufacture within the commercial licensee's territory, so long as the research is done only for developing nation needs or the manufacture for export to developing nations. The commercial licensee may then wish to be protected against re-export into its primary commercial market. As noted earlier, the humanitarian licensee may also need rights for commercial use in low- and middle-income regions. Although the reservation may be defined as humanitarian use, licensors may wish to consider additional, more specific reservations as described below.

2.11 ***Research exemption***

One of the several goals of humanitarian IP management is to encourage research to develop products appropriate to the needs of the developing world. To this end, licensors could opt to insert into licensing agreements a research exemption clause that exempts specified categories and types of research from patent infringement in using its proprietary technologies, (for example, to develop products that broadly benefit the public or the population of poor countries). The University of California technology transfer office has begun to insert such research exemption clauses into licensing agreements.[33] Other universities already reserve research rights for academic institutions in their standard exclusive licensing agreements (for example, Stanford, whose standard license language is reproduced in Box 5). Such a clause could facilitate humanitarian use of the technology if it also reserved rights for nonprofit research institutions developing products for use in developing countries.

2.12 ***Sublicenses for developing countries***

Unless provided for in the agreement, a licensee generally does not have sublicensing rights.

Box 5: Stanford Reservation of Academic Research Rights in Standard License Agreement

Strategy employed: ***Reservation of research rights***

3.4 Retained Rights. Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and use Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Stanford and any such other institution have the right to publish any information included in the Technology or a Licensed Patent.

Source: Stanford Office of Technology Licensing.[34]

Should the parties agree to allow sublicensing, the main agreement should specify the rights and obligations of the licensee with respect to the sublicensee(s). In allowing for sublicenses, consideration should be given to the possibility of the original licensee entering into sublicenses inconsistent with the humanitarian goals of the agreement. This should be restricted. It is general practice for the licensor to hold the licensee responsible for assuring that the sublicensee fulfills all the requirements of the principal license. The best way to ensure that the sublicensee has obligations comparable to the licensee's is for the licensor to draft the sublicense terms. The licensor can thus be certain that all the humanitarian requirements within the primary agreement are included.

2.13 *March-in rights*

A licensor may wish to reserve march-in rights if the humanitarian purposes or milestones embodied in the agreement are not met (for example, revoking a license or sublicensing to third parties in order to ensure access).

2.14 *Treatment of future rights in license agreements*

2.14.1 *Reach-through clauses*

Reach-through clauses attempt to reach beyond the licensed technology and to ensure that the licensee treats new technologies, developed through use of the licensed technology or under a cooperative agreement, honoring the same kinds of development obligations covered by the original license. This type of clause is often used by public–private partnerships to encourage the development of specific technologies that benefit developing nations while allowing the private sector partner to benefit in the developed world.

Licensors can also help make inventions more available to populations in need by insisting on certain terms when licensing inventions to commercial partners. Opportunities to transfer technologies to be developed by public–private partnerships or by other organizations can also be pursued.

2.14.2 *Grant-back clauses*

If it is likely that the commercial licensee will develop improvements to the technology, it would be wise to require that the licensee grant back nonexclusive rights to those improvements. This would ensure that they would be available later for a humanitarian purpose licensee. The same might go for access to test results or regulatory data. If either party is concerned about liability issues, there might be, for example, requirements for any humanitarian licensee to be adequately insured or to be operating in compliance with relevant regulations.

2.14.3 *Amending existing agreements*

While the goal of this document is to promote humanitarian licensing from the outset, when agreements already exist they can be amended or revised to meet humanitarian needs. There are several examples of successful renegotiations. For example, the humanitarian license mentioned earlier between Yale University and Bristol-Myers Squibb was actually the result of a renegotiation of their license for the AIDS drug d4T, which permitted generic d4T to be made and used in South Africa. There are also examples from the agricultural sector in which parties successfully addressed barriers posed by a worldwide exclusive license between a university and a company. In one case, a company insisted that no license was required to use the licensed technology in a certain country. It stated this in a letter that permitted the university to transfer a gene construct directly to the country. In general, renegotiating license terms is not desirable because it increases transaction costs, delays projects, and may not always succeed. However, while there are clear benefits to addressing these issues up front wherever possible, the fact that an agreement has already been concluded should not discourage participants from revisiting the agreement when an unforeseen need arises.

3. PROPOSALS FOR NEW APPROACHES FOR HUMANITARIAN LICENSING OF IP

Two new proposals conclude our discussion of specific strategies for humanitarian licensing: (1)

considering a shorter length for an exclusive license and (2) equitable access licensing.

3.1 *Shorter lengths of license exclusivity*

Instead of granting exclusive licenses that match the term of the patent, the licensor can grant licenses for shorter periods, allowing access by multiple licensors over the life of the patent. There may be practical complications to this approach, since universities often receive patent-cost reimbursements from licensees, which in turn require exclusivity until expiration of the patent term. Granting short-term exclusive licenses would likely require the university to bear all the costs related to maintaining and enforcing the patent, which it could only afford to do if the patent itself was bringing in significant licensing revenues. In that case, the university may be reluctant to end its licensing relationship with the high-revenue licensor.[35]

3.2 *Equitable access licensing*

Universities can also make use of an equitable access license to create enabling conditions for competition in low- and middle-income countries. An equitable access license (1) ensures freedom to operate for any party that manufactures and distributes the licensed technology and any derivative products in low- and middle-income countries and (2) minimizes administrative overhead and political contingency by initiating a self-enforcing open licensing regime. In such a license, a university and licensee agree that any licensed technology, as well as licensee improvements (including improvement patents and registration data), to be sold in low- or middle-income countries will be openly licensed to any company that meets Good Manufacturing Practice standards.[36] This arrangement allows multiple producers (including producers in high-income countries) to compete to produce low-price products for sale only in low- and middle-income countries simply after notifying the parties to the license.

The Equitable Access License developed by Universities Allied for Essential Medicines (UAEM) includes a humanitarian research clause to encourage research on neglected diseases. It provides that any party may pursue research anywhere in the world using the university technology and licensee improvements without paying a royalty, if the research targets a neglected disease.[37]

4. NEXT STEPS FOR AAAS HUMANITARIAN IP MANAGEMENT INITIATIVE

This document emphasizes the importance of managing public sector IP to facilitate humanitarian use and applications. It seeks to raise awareness about some of the techniques that have been pursued so far, and we are optimistic that additional approaches will emerge as more institutions undertake IP management with humanitarian use and applications in mind. We certainly do not mean to preclude other options.

Even if technology managers adopt humanitarian IP management strategies in the construction, negotiation, and formalization of legal agreements, they will also need to connect with development partners who can utilize the protected technologies to serve unmet needs in developing countries. In some cases, these partners may not yet exist. But when they do, it will be important to establish simple, efficient ways for them to identify technologies that public sector institutions are willing to share.

We believe that the number and variety of technologies being managed with humanitarian goals in mind will continue to increase, and so the Science and Intellectual Property in the Public Interest (SIPPI) project plans to explore ways to increase the transparency of license terms covering these technologies, thus making this information more widely available to potential beneficiaries.

In continuing its work on humanitarian licensing, the SIPPI project will identify ways to encourage the use of humanitarian licensing practices and increase the transparency of license terms covering technologies in health and agricultural innovation, thus making that information more widely available to potential beneficiaries. It is pursuing the following interrelated activities as a means to advance the use of humanitarian licensing strategies.

Promoting the use of humanitarian licensing practices. In collaboration with the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), SIPPI plans to identify and develop approaches for encouraging technology managers to adopt humanitarian licensing models. That will be accomplished through a wide range of outreach activities that will include holding workshops to coincide with meetings of the Association of University Technology Managers and the Association of American Universities, and hosting a series of meetings on this topic at the AAAS headquarters in Washington, D.C., as well as at SIPPI's annual meeting.

Developing a Web-based clearinghouse. We will develop and implement a Web-based clearinghouse of technologies that are available for humanitarian licensing for product development. The clearinghouse will be designed as an openly accessible database listing technologies available for humanitarian use. It will identify the owner of the technology and provide information as to the specific licensing terms for each listed technology, including type of license, field of use, and the intended beneficiaries for the use of the technology. In addition to facilitating access to technologies, the clearinghouse will allow technology transfer managers to submit detailed information about new technologies and, similar to the *creative commons* model, will supply online tools to build specific humanitarian licenses for those technologies. This model will allow the clearinghouse to continue serving its intended purpose over the long term. ■

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1 CIPR. 2002. Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy. Final Report of the Commission on Intellectual Property Rights, p. 2. DFID: London. www.iprcommission.org.

2 Ibid.

3 Shetty P. More Creative Thinking Needed on Drug R&D. (editorial) 3 May 2005 *SciDev.net*. www.scidev.net/content/editorials/eng/more-creative-thinking-needed-on-drug-rd.cfm.

4 Lanjouw J and M MacLeod. 2005. Statistical Trends in Pharmaceutical Research for Poor Countries. Commissioned by the WHO Commission on Intellectual Property, Innovation, and Public Health. www.who.int/intellectualproperty/studies/stats/en/index.html. The authors found an increase in indicators of innovative

activity (patenting and bibliometric citation) related to some diseases specific to developing countries between 1980 and 2002, but only the subset still in need of better, low-cost treatments. The authors found a downtrend in innovative activity among the subset for which treatments already exist. The authors suggest that although the increase in innovation coincides in part with the introduction of stronger patent protection in developing countries, increased public R&D funding for global health and political developments is likely to have made significant contributions over the same interval. Still, drug innovation targeting developing countries remains a tiny fraction of drug innovation overall.

5 Moran M. 2005. A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need. *PLOS Medicine* 2 (9). The author reports an increase in neglected-disease drug development projects since the year 2000, including activity by multinational companies, small companies, and public-private partnerships (PPPs). She observes that "*commercial incentives were largely irrelevant to the decision by multinational companies to reenter the neglected disease field, while small companies involved in neglected disease R&D were indeed responding to commercial drivers. In most cases, the involvement or planned involvement of PPPs was crucial to company involvement, commercial or otherwise*."

6 See the discussion of these issues on the Web site of PIPRA. www.pipra.org/purpose.htm.

7 UN Millennium Project. 2005. Innovation: Applying Knowledge in Development. Task Force on Science, Technology, and Innovation, p. 170.

8 See, also in this *Handbook*, chapter 17.18 by R Y Boadi and M Bokanga.

9 Contrary to the often-quoted 70-plus patents, Kryder, Kowalski and Krattiger (see below) clearly showed that the 70-plus patents included patent applications and patent families in different countries. Only 45 unique patents were identified at the time. Kryder RD, S Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of Pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* 20. p. 74. www.isaaa.org.

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18 www.ogc.caltech.edu/patent Policy.htm.

19 web.mit.edu/tlo/www/guide.4.htm.

20 The University of Texas System: Rules and Regulations of the Board of Regents, Series: 90101. www.utsystem.edu/ogc/intellectualProperty/polguide.htm.

21 Salicrup L, RF Harris and ML Rohrbaugh. 2005. Partnerships in Technology Transfer: An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to Worldwide Application. *IP Strategy Today*, 12:1–12. www.biodevelopments.org/ip/ipst12.pdf.

22 See *supra* note 13, at p.7.

23 Medicines for Malaria Ventures. "Statement of MMV Collaboration Principles." Personal communication, J. Carl Craft, Chief Scientific Officer, MMV. See also "Ranbaxy and MMV Achieve Potential Breakthrough in Malaria, Drug Enters Human Trials Phase." Ranbaxy Lab. Press Release, 18 August 2004. www.ranbaxy.com/newsroom/pressrelease_det.asp?sno=169.

24 See *supra* note 11, at p. 18.

25 For example, a license by Monsanto to the Kenya Agricultural Research Institute allows for unrestricted use of certain Monsanto technology and know-how for the development of virus-resistant sweet potatoes in Kenya and Africa. Other agreements allow for the use of insect resistance in maize transferred by Syngenta to Africa but cannot be used outside of the region; IRRI negotiated the rights for use of a stem-borer-resistant gene for rice from Plantech for all developing countries as defined by the UN. (Byerlee D and K Fischer 2001.Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries, *IP Strategy Today*, 1:14. www.biodevelopments.org/ip.

26 See Byerlee and Fischer at *supra* note 25.

27 TDR News No. 72. 2004. Artesunate combinations are coming: partnership develops LapDap plus artesunate. www.who.int/tdr/publications/tdrnews/news72/lapdap.htm.

28 Foskett H, R Menapace and S Shah Basu. 2003. Developing Inventions for Neglected Diseases. Poster Presentation, AUTM annual meeting.

29 Rorbaugh M. 2005. Technology Transfer to Benefit Public Health in LDCs. Global Health & Technology Transfer Meeting (presentation made 15 March), NIH Office of Technology Transfer.

30 See *supra* note 13, at 9.

31 The Concept Foundation (CF) has been a pioneer in licensing that helps to ensure access through appropriate pricing mechanisms. It has partnered with 10 different PPPs with pharmaceutical companies worldwide. It has licensed technology to nine manufacturer in five developing countries. CP has had products manufactured in eight countries and made available in more than 30 developing countries. Its first product, Cyclofem®, an injectable hormonal contraceptive, was made available to public sector health services in 1993. Since then, over 140 million doses of Cyclofem have been manufactured and distributed by CF licensees worldwide. Around 16 million HIV rapid tests have been distributed by CF licensees to public sector health services worldwide as well. www.conceptfoundation.org.

32 See, also in this *Handbook*, chapter 2.7 by J Oehler.

33 See, also in this *Handbook*, chapter 2.1 by AB Bennett.

34 otl.stanford.edu/industry/resources/exclusive.pdf.

35 U Balakrishnan. 2004. University of Iowa. Personal communication.

36 The World Health Organization has established a detailed set of Good Manufacturing Practice (GMP) standards, and many individual countries maintain their own GMP requirements for regulatory approval.

37 Kapczynski A, S Chaifetz, Z Katz and Y Beukler. 2005. Addressing Global Health Inequities: An Open Licensing Approach for University Innovations. *Berkeley Technology Law Journal* 20:2. btlj.boalt.org/data/articles/20-2_spring-2005_2-benkler.pdf.

Ensuring Global Access through Effective IP Management: Strategies of Product-Development Partnerships

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ABSTRACT

In the last decade, product development partnerships (PDPs) have become significant components of efforts to develop and disseminate therapies for diseases in the developing world. PDPs seek to fill a gap left by the private sector—a gap that leaves 90% of the world's disease burden with only 10% of the world's research money—through innovative, comprehensive partnership strategies that tap into the strengths of both the private and public sectors. This chapter, based on the proceedings of a conference titled Ensuring Global Access through Effective Management of Intellectual Property in 2006, provides an overview of the history and approaches of numerous PDPs. The chapter is anchored by reports from eight different PDPs and aims toward explaining what potential problems to guard against, what does not work, and—above all what does work—when the public sector plugs into the dynamism of the private sector to try to meet the health and agricultural needs of developing countries. Recognizing that there is no single business model, PDPs employ a common toolbox to manage intellectual property for global health outcomes. It includes defining a discrete territorial market; establishing distinct structures for public sector and private sector markets; determining field of use in a strategic manner; establishing royalty rates to optimize incentives; and providing for access to the developed technology in the event that the research/industry partner abandons the project. Other key areas of discussion, where parallels between PDPs exist, include global-access strategies, pricing issues, the importance of market segmentation, production capacity, strategic early-stage licensing, the IP landscape, and systemic challenges. Collectively, PDPs have broadened the creative understanding of practical ways to resolve the public-policy dilemma of balancing private incentives to generate needed R&D investment with the goal of access to those in need.

1. INTRODUCTION

Infectious diseases such as HIV/AIDS, tuberculosis (TB), and malaria are among the world's leading killers, affecting the poorest people in the most impoverished countries. Yet affordable and accessible interventions are frequently unavailable to them. Moreover, neglected diseases such as leishmaniasis and Chagas' disease kill or disable millions of people in the developing world every year. Treatment options for these diseases are either inadequate or nonexistent because of a lack of public funds and private sector incentive to research and develop new drugs and vaccines. This lack of R&D has created what some call the 10/90 gap; less than 10% of global health R&D spending worldwide is focused on diseases or conditions that account for 90% of the world's disease burden.[1]

Focusing science and technology innovation on tackling these diseases is a necessary, but not sufficient, condition for progress. Improving global health will also require concerted efforts by academic and industrial scientists, technology developers, IP (intellectual property) experts, investors, government officials, policy-makers, and public-health officials. Partnerships are needed, not only to develop the products and strategies for delivering interventions to populations most in need, but also to forge IP and technology transfer agreements that will protect private

Eiss R, KE Hanna and RT Mahoney. Ensuring Global Access through Effective IP Management: Strategies of Product-Development Partnerships. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

interests while simultaneously promoting public health. Mahoney and Morel have named this new era, "the Era of Partnerships."[2] They argue for an innovation framework having six components:

1. Development and expansion of national health delivery systems, including an attractive, domestic, private-sector market for health products
2. Development of manufacturing capability for health products
3. Development of a drug and vaccine regulatory system
4. Development of an IP regulatory system
5. Development of R&D capability by the public and private sectors
6. Development of international trade systems for health products, including global procurement funds

The authors note that the components are comprehensive in that they cover all the areas necessary to innovate successfully.[3] All of the components are dynamically linked and attention to all is required, since the failure of one component will almost certainly guarantee failure for the whole effort. Thus, though the IP system is only one component of innovation, it is a necessary component. Product development partnerships (PDPs) must therefore attend to all the components of innovation, including intellectual property, in the quest to ensure global access.[4]

The emergence of PDPs over the past decade has provided a unique mechanism, a hybrid public/private approach, by which to generate new products for the neglected diseases of poverty. PDPs employ a variety of strategies to achieve goals (for example, creating new technologies and ensuring that the developed technology is available and affordable to as many beneficiaries as possible in the developing world). The most basic challenge is to provide access to needed technologies and pay close attention to how the technology is to be distributed or marketed, while simultaneously offering appropriate incentives to private sector partners to encourage the commitment of research, development, and manufacturing resources. To do this, PDPs are both charting new territory and employing management models that borrow frequently from the private sector. Moreover, in some cases PDPs have reinvented R&D approaches for preventing and treating human diseases. Unlike traditional R&D agreements, PDPs must make deals that extend well beyond the scope of traditional commercial agreements, stipulating access conditions to ensure that the product reaches the target population. These terms and conditions frequently focus on the strategic use of intellectual property and often have to address such issues as market segmentation, pricing, and distribution.

The experiences of PDPs have shown that several factors are driving some companies to work collaboratively and to share disease-related intellectual property. These factors include corporate social responsibility and strategic considerations, such as positioning in emerging markets. An additional incentive is the potential that R&D projects with PDPs may have relevance for commercial compounds. For example, MMV carries out joint studies on malaria tetracycline resistance with industrial partners, which benefits their commercial anti-bacterial research.

PDPs are an increasing and innovative group of organizations. The diverse experiences of PDPs can help inform the makeup and negotiation of R&D partnerships and lead to better agreements dealing with the various forms of IP. Several PDPs are reaching a new mature phase, with products in clinical development for poverty-related diseases. These PDPs have designed workable solutions to ensure access and affordability, from planning production that will meet the size of demand, to addressing issues of end-user acceptability. PDPs are pioneering a new form of social contract to promote the development of health products where commercial incentive is lacking.

To promote and facilitate discussion among those who have embarked on or are developing plans for PDPs, the Centre for the Management of Intellectual Property in Health Research and Development (MIHR) and the Aeras Global TB Vaccine Foundation, in partnership with the Bill and Melinda Gates Foundation, convened a meeting titled Ensuring Global Access through Effective Management of Intellectual Property in 2006.[5] It built on a similar joint meeting held

in 2004, also involving around 50 participants including senior management, legal counsel, program officers, and business development professionals from institutions and organizations involved with PDPs.[6]

This chapter summarizes presentations made at the meeting by representative PDPs. Their stories illustrate the diversity of approaches used in making R&D agreements and managing intellectual property in the context of global health. The structure of these agreements defines and is influenced by the relationships among the partners. As Oehler noted:

By the nature of their business model, the commercial interests of private sector companies are, on the whole, oriented toward maximizing profitability. It is not justified to expect that private sector business will automatically ensure best services to the public sector and focus the generation and use of intellectual property toward maximized public-sector benefits.

To prepare for a situation where the original targets of a license agreement are delayed or are not achieved, and to avoid the situation where projected public-sector benefits are delayed or are not realized, it is good practice to establish contractual milestones that regulate target achievement under the license and to set incentives to keep to timelines and performance accordingly. This allows licensor and licensee(s) to focus resources on their efforts to perform as was agreed upon in the first place.[7]

2. PDPS IN ACTION

2.1 *Collaborative research with centralized IP management: DNDi*

Nicoletta Dentico noted that several PDPs focus on creating R&D partnerships to achieve outcomes that would otherwise be impossible. For example, in 2003, seven organizations from around the world joined forces to establish the Drugs for Neglected Diseases initiative (DNDi).[8] Among the seven were five public-sector institutions, one humanitarian organization, and one international research organization.

DNDi was created in response to the fact that of all the new drugs developed over the past 30 years, drugs for tropical diseases and TB account for only 1.3%. The organization itself does not conduct research and scientific work to develop drugs. Instead, it capitalizes on existing, fragmented R&D capacity, especially in the developing world, and complements it with additional expertise as needed. According to Dentico, the DNDi policy advisor, this integrative approach helps cut costs.

The group builds its portfolio by identifying medical needs and R&D opportunities and then seeking letters of interest to conduct R&D projects. Current projects by academic and industrial laboratories are focused on identifying new drug candidates for tropical diseases, such as trypanosomiasis, which afflicts over 66 million people in 36 countries of Sub-Saharan Africa. Other projects involve developing products that simplify and reduce the length of malaria treatments. Participating partners provide funding, pharmaceutical development, in vitro and molecular studies, development of analytical models, animal toxicity testing, and clinical trials, all under DNDi coordination and management. This collaborative mode of operation blends centralized management, which gives a clear project-specific focus, and decentralized operations, which mimic modern drug companies.

DNDi has also built regional networks of scientists actively involved in the research of new drugs for neglected diseases in Asia, Africa, and Latin America. These regional networks, coordinated by DNDi regional liaison officers, are vital to the success of DNDi. They are able to collect data on available regional expertise, capacity, and patients' needs, and they actively advocate for DNDi by encouraging scientists to submit proposals to DNDi.

DNDi negotiates intellectual property and knowledge dissemination agreements to obtain the best possible conditions for patients and to ensure that the fruits of DNDi-sponsored research will be readily available and affordable in developing countries. Exclusive rights, titles, and interest in the results of a given research project are retained by DNDi, including but not limited to any resulting patents on any inventions. DNDi decides on the best way to make the results of a

research project available to the public, including by putting the results in the public domain with no limitations.

In addition, DNDi may choose a number of IP management options: (1) apply for patent protection to protect some or all of the outputs of a research project, (2) keep such outputs confidential, or (3) take any other measures that would promote DNDi's mission (such as publicly disclosing the results). To ensure that DNDi can make full use of the results of a research project, DNDi asks partners to grant a nonexclusive, worldwide, royalty-free, irrevocable license to use any background IP rights that may be needed to develop and commercialize a compound developed during the course of a research project.

According to the experience of DNDi, forging agreements with North American universities is often a lengthy process: the average negotiating time with academic entities in the United States and Canada is eight months, whereas the average negotiating time in Europe is four months. Dentico added that PDPs could provide useful collaborative R&D models to borrow from and to create precedents for improving the current R&D environment. This is especially the case for filling needs not adequately addressed by government investment, which often focuses on the earliest stages of research. Unlike some other PDPs, DNDi focuses much of its efforts at the public sector level. In addition, DNDi wages public information campaigns that urge citizens to advocate governments to fund research on diseases of the poor.

2.2 *Bridging academe and industry through social entrepreneurship: iOWH*

Often characterized as the first nonprofit pharmaceutical company in the United States, the Institute for OneWorld Health (iOWH) is another example of a PDP focused on finding new drug candidates for the developing world. Katherine Woo, director of scientific affairs at iOWH, pointed out that the focus of the company is to remove the profit element from the business plan and to build a global organization with core competencies in R&D and regulatory approval for new drugs. A defining feature of iOWH is its social entrepreneurial component, which aims to deliver medicines to the world's neediest populations.

According to Katherine Woo, the strategy is to assemble an experienced team of pharmaceutical scientists to identify the most promising drug and vaccine candidates—often, the most promising drug candidates are those that have been discarded for lack of a viable market. Once such candidates are identified, iOWH focuses on developing them into safe, effective, and affordable medicines. The group then partners with companies, nonprofit hospitals, and organizations in the developing world to complete the requisite animal studies, conduct clinical trials, secure quality manufacturing in disease endemic countries, obtain regulatory approval, and distribute newly approved therapies.

The group's strategy, according to Woo, is based on the assumption that pharmaceutical R&D to create the new medicines for the developing world need not involve huge costs. By partnering and collaborating with industry and researchers, securing donated intellectual property, and relying on and using the scientific and manufacturing capacity of the developing world, needed vaccines and drugs can be delivered affordably and effectively. The PDP's goal is to provide the bridge between novel bench science and its conversion into applications for the developing world. For example, industrial scientists are brought together to assist university scientists on late-stage processes, such as high-throughput screening and lead optimization of potential new drugs.

Carrying basic scientific research forward through product development requires the participation of many groups; however, one partner ultimately must take responsibility and be held accountable if new drug development is to be successful. In many cases iOWH serves as that global development partner. It takes responsibility for markets in the least developed countries (dual market opportunities) and obtains resources from private foundations and governments to fund the development costs of taking a new drug through to market in the developing world. In addition, iOWH provides international regulatory expertise to increase the number of countries in which important new drugs are marketed.

The company interprets global access as affordable prices, a sustainable supply, and engaged distributors. It directly controls pricing as much as possible and attempts to maintain maximum flexibility to engage downstream partners (for example, by offering royalty-free licenses). Negotiations on geographic coverage for marketing, public sector price and exclusivity considerations can be complex and protracted.

As a nonprofit corporation, OneWorld Health provides a tax deduction for the projected future value of donated intellectual property. However, iOWH seeks exclusive licensing to protect investment by philanthropy. Woo emphasized that iOWH tries to avoid being surprised in its IP management strategy and that they are always on the lookout for intellectual property that has the potential to discourage important research in developing countries. When the IP requirements of a partner become too burdensome or onerous, the group sometimes walks away from the deal and searches for another partner.

2.3 *Managing intellectual property in a research consortium: IAVI*

Some PDPs serve as enabling bodies to create incentive systems, modes of operation, and negotiators for IP management. The International AIDS Vaccine Initiative (IAVI) focuses on spurring R&D for the development of safe, effective, and accessible preventive AIDS vaccines for use throughout the world. Labeeb Abboud observed that, in addition, IAVI is involved in advocacy work, seeking to secure and sustain global, national, and local community involvement and commitment for the development of an AIDS vaccine. Efforts focus on the developing world, where the epidemic is most severe.

IAVI is supporting research into several key, unresolved questions of vaccine development. Among other projects and lines of investigation, their effort involves a consortium of academic and industrial research laboratories focusing on HIV-neutralizing antibodies, mechanisms of protection, and vector design. The consortium currently has 16 members located in the United States and Europe. IAVI negotiates the joint work plan and provides a governance structure. The members of the research consortium have agreed to common provisions relating to IP management and ownership, including access provisions. IAVI is provided with license rights to program intellectual property, and certain background intellectual property, and is responsible for diligently pursuing further development. Future licensing revenues are to be shared among all members, with the expectation that no royalties will be received from developing country sales. Key to the effective functioning of the consortium are the close working relationships among its members.

IAVI also has had several vaccine development programs; it is currently conducting human clinical trials of three vaccine candidates in the United States, Europe, Africa, and India. Although consistency in IP management is sought, flexibility in the approach to IP ownership, management, and licensing is also important. Ownership may be determined by inventorship, by ownership of background intellectual property, or by funding. License rights to program intellectual property may be exclusive or nonexclusive, and they may be worldwide or restricted to certain geographic sectors. With respect to partnerships in which IAVI's partners control the intellectual property or license rights, and thus are responsible for manufacturing and distributing a future vaccine, IAVI's contracts require that the partners make access commitments for the developing world (relating to price, quantity, and availability) and provide IAVI with remedies, such as march-in rights, to ensure that products developed through the consortium are made available to people in need.

There are a number of challenges that arise in the contracting process, as well as in the management of the ongoing relationships with partners. Some of the greatest challenges are in the IP area, with regard to due diligence, management (when to file and where), meeting the requirements of donors (including audits), and establishing termination rights.

2.4 *Tailoring IP provisions for each agreement: Aeras Foundation*

The Aeras Global TB Vaccine Foundation, founded in 1997, is an international nonprofit PDP working toward developing a vaccine against TB,

both at Aeras facilities and in collaboration with academic/industrial partners. Rita Khanna, the foundation's legal counsel, explained that Aeras actively pursues and helps fund joint-development activities with leading TB vaccine developers around the world. It also develops candidate vaccines in its own laboratory. Aeras's partners with other groups in order to develop vaccine candidates and field sites for clinical development and to ensure vaccine supply. Aeras' partners include companies in nine countries, academic laboratories in eight countries, and five foundation or government partners. It is the goal of Aeras to develop, test, characterize, license, manufacture, and distribute at least one new TB vaccine within 10 years.

Aeras takes promising research and early-development candidates through preclinical regulatory requirements; clinical phase one, two, and three studies; process development; manufacturing; and release. The overarching scientific strategy is to improve the current, widely used bacille Calmette-Guérin (BCG) vaccine—which has limited efficacy—and boost the current BCG vaccine with either a recombinant TB protein plus adjuvant or a recombinant viral vector making TB antigens. Prime-boost regimens of this sort have proven to be the most powerful inducers of immune responses and protection against TB in animal models.

The focus of Aeras's IP management strategy, according to Khanna, is to ensure global access to any resulting vaccine. Aeras has executed numerous research collaborations, licensing, and other agreements with commercial and academic partners. In one joint development collaboration, the partner owns the background intellectual property, while the ownership of new intellectual property is determined by inventorship. Aeras has a royalty-free, sublicensable exclusive license to distribute and sell in developing countries and public markets in emerging economy countries (EECs), and the partner has a royalty-free, sublicensable exclusive license to commercialize in developed countries and private markets in EECs. The partner has the first right to negotiate—and right of first refusal—to an exclusive manufacturing contract to supply Aeras with vaccine for sale in developing countries and public markets in EECs. If the partner is not able to meet the demand of vaccine for distribution by Aeras, then the partner must transfer the rights to Aeras or to a mutually acceptable third party. Should the partner breach the contract, Aeras would negotiate a license to continue commercialization for developing countries and EECs.

A second type of agreement has many of the same provisions, except Aeras and the partner have a royalty-free, coexclusive license to distribute and sell in developing countries with a right to grant one sublicense. In this scenario, the collaborator has the exclusive right to commercialize in developed countries and EECs. In addition, Aeras has a royalty-free license for EECs if the partner has not pursued regulatory approval within three years of regulatory approval in an industrialized country. The partner has manufacturing rights for the first five years only. Should the partner breach this contract, Aeras has a nonexclusive license to continue development in the licensed territories or the right to select an alternative manufacturer.

In similar agreements, Aeras has negotiated terms in which the collaborator may use a "reasonable commercial effort" to manufacture and supply the product. In addition, the collaborator may provide the vaccine at two-tier differential pricing in public and private markets. In this scenario, no IP rights are granted to Aeras.

Other agreements focus on license rights: Aeras has a nonexclusive license in EECs in one case and an exclusive, worldwide license in another case. In these types of agreements, Aeras owns improvements and pays license fees, patent prosecution costs (past and future), minimum annual royalties, milestone payments, and royalty on net sales. These agreements typically include royalty-stacking terms.

In a clinical trial agreement, Aeras retains rights in intellectual property relating to clinical trials, although there is joint ownership of intellectual property resulting from epidemiological studies. In a sponsored-research agreement, Aeras provides funding for the research and has an exclusive, first right to negotiate an exclusive or nonexclusive, royalty-bearing license to make, use, and sell any patentable inventions conceived

and reduced to practice during the term of and in the performance of the research supported by Aeras. In another sponsored-research agreement, Aeras owns all rights, title, and interest in and to any intellectual property, material, data, and records derived from performance of research supported by Aeras.

Many of these agreements contain other key provisions related to confidentiality, publishing rights, patent enforcement and infringement, indemnification, liability and insurance, law and jurisdiction, dispute resolution and arbitration, and termination.

2.5 *Ensuring access to new drugs: from aspiration to operation at MMV*

Richard Wilder noted that while many PDPs focus on early-stage efforts to discover and deliver new drugs for neglected diseases, few have reached the point of delivery. Indeed, planning for the access and delivery of new drugs in disease-endemic countries cannot be accomplished by one PDP working alone.

The efforts of Medicines for Malaria Venture (MMV) are focused on both delivery and R&D. Formed in 1999, MMV is a nonprofit organization created to discover, develop, and deliver new antimalarial drugs through effective public–private partnerships. MMV brings together global public health organizations, the pharmaceutical industry, government ministries, research institutions, and foundations to combine their expertise and resources to ensure the needed research, development, and release of antimalarial drugs.

Currently, MMV is managing more than 20 projects that are in various stages of drug R&D, and several in Phase Three clinical trials, with reports that good progress is being made. The group's goal is to register at least one new antimalarial drug before 2010 and to maintain a sustainable pipeline of antimalarials that can meet the needs of the more than 2.4 billion people at risk.

These goals are bolstered by MMV's groundbreaking collaboration with nearly 40 public and private institutions around the world. In particular, MMV entered into discussions with pharmaceutical companies conducting anticancer therapy research that led to the development of compounds that are highly active against the malaria parasite.

Because much of MMV's focus is on later-stage issues, it already is discussing with collaborators provisions for pricing agreements, negotiating third-party rights, and ensuring that sufficient quantities of the drug are available once developed. Provisions for handoff are discussed and negotiated well in advance. All parties must understand the goals, the need for speed, and a clear view of the regulatory pathway in each country where drugs are being tested. MMV negotiates time limits for late-stage clinical trials and filings. Products are registered and launched immediately following regulatory approval. In addition, deals with collaborators include requirements for quality assurance.

MMV manages the ownership and licensing of intellectual property so that the partners' interests are reflected in the terms of agreements. Depending on the situation, MMV might own the intellectual property outright, retain licenses to the intellectual property, or place conditions in its agreements that, if not met, will transfer IP rights back to MMV. Sometimes MMV's ownership of IP rights is unnecessary because the group is working with a company to both discover and develop a promising compound as an antimalarial. In those cases, the company might retain ownership of the IP rights for use in meeting their obligations to MMV to develop and bring an antimalarial to market.

MMV's agreements specify the conditions that have to be met, including price specifications and access requirements (for example, access milestones). The experience of MMV suggests that setting access milestones should not be done too late in the process, when time pressures are heightened. Pricing agreements, moreover, are particularly challenging because of the division of markets in many countries where MMV is working. And difficulties can arise if the price issues are driven too far in advance. An advance commitment to a set price ceiling can, for example, deter investment. If a partner company cannot or will not meet the conditions of the agreement, MMV requires that IP rights be returned so it can seek another partner. However, the focus of deals

is not on IP rights per se, but rather on the ability of MMV to ensure that new antimalarial drugs under development are brought to market and made affordable and accessible to those who need them in the developing world. From MMV's perspective, IP rights are merely a tool to help bring partners together toward a common goal.

2.6 *Securing candidate products through creative licensing: IPM*

The International Partnership for Microbicides (IPM) is a nonprofit PDP established in 2002 to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries. Paul Model explained that IPM's basic strategy involves the licensing of active compounds from commercial pharmaceutical companies for development as microbicides. IPM already has announced compound licenses with Johnson & Johnson/Tibotec, Merck, and Bristol Myers-Squibb. IPM has found that larger pharmaceutical companies are more likely to grant licenses on a no profit/no loss basis.

IPM promotes the rapid development and delivery of safe and effective microbicide products by pioneering best-practices approaches to:

- screen compounds and design optimal formulations
- develop clinical trial sites and conduct clinical trials
- identify appropriate regulatory pathways for microbicide products
- establish manufacturing and distribution capacity to ensure rapid access to a microbicide as soon as it becomes available

IPM also funds, co-funds, or leverages resources to support the drug development projects of other entities. In some cases, however, the most efficient approach is for IPM to take the lead in developing, testing, and conducting clinical trials of promising microbicide compounds. In this role, IPM is the technology developer and receives a nonexclusive license from the owner of the compound that is royalty free and permits distribution on an affordable basis in resource-poor countries. Rules and procedures are, however, imposed on access to the compound for research purposes. Importantly, the compounds in development remain proprietary. Thus, a grant-back license to the owner of a compound typically is required for modifications to the compound. Grant-back licenses of products or formulations are subject to negotiation.

According to Model, one of the more important aspects of negotiations involves defining what constitutes a resource-poor country. In his experience, each partner has its own list of countries; there is often disagreement over whether certain countries, such as China, India, and Brazil, qualify as resource-poor. However, so far IPM and its partners have succeeded in reaching agreement on this issue. In some cases, IPM has obtained worldwide rights, recognizing that compounds are still proprietary and ensuring that products will be made available on an "affordable basis."

Other important issues involve territory and access. Some granting organizations are particularly concerned about access to results of funded research. IPM has encountered complex "public sector pricing regimes" in grant agreements that are similar to those proposed to several other organizations. These may present inconsistencies with the structure of the licenses that IPM has been able to negotiate with commercial pharmaceutical companies. IPM strives in all cases to reach agreement on affordable-basis criteria in all agreements. These criteria include no compensation for intellectual property or development costs, manufacture at lowest reasonable cost consistent with quality, and recognition that IPM's rights under its licenses are limited. Although some collaborators are initially resistant to these or other terms, peer pressure and the desire to do the right thing are frequently the motivating factors in closing a deal.

2.7 *Deal making with a marketed product: TB Alliance*

Two billion people—one-third of the global population—are infected with *Mycobacterium tuberculosis*. More than eight million people develop active diseases every year and two million people die from the disease. Existing drugs are 40 years old and impose a daily regimen that is long and

cumbersome, which slows the control of the disease and promotes the rise of drug-resistance. In addition, TB/HIV co-infections are fueling each other, and multidrug-resistant TB (MDR-TB) and extremely drug resistant TB (XDR-TB) cases are on the rise.

Gerald Siuta explained that the Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, product-development partnership that aims to accelerate the discovery and/or development of affordable, new TB drugs. It is hoped that such drugs will shorten treatment and be easier to take, be more effective against drug-resistant strains, be appropriate for patients with HIV-TB co-infection, and be capable of improving the treatment of latent infection.

In its first five years, the TB Alliance has built the most robust TB drug pipeline in history, helping to fill a gap left by the private sector. Any new drug regimen must be more than just highly effective and easy to use; it must also be universally affordable, adopted, and accessible. According to Siuta, this "AAA" goal guides all decisions on project selection and development, as well as concurrent work to influence the policy and regulatory environments to foster appropriate pricing in developing countries, ensure that new drugs are incorporated into existing treatment programs, and facilitate procurement and distribution to those patients who most need the drugs.

One of two TB Alliance's projects now in the clinical phase is the testing of moxifloxacin for the treatment of TB. Moxifloxacin is a fluroquinolone antibiotic already approved in 104 countries to treat respiratory and skin infections. It is novel in that it kills mycobacterium TB through DNA inhibition. Moxifloxacin has been shown to reduce treatment time by two months when substituted for isoniazid. Moreover, it is safe when used in combination with antiretrovirals.

In October 2005, the TB Alliance and Bayer Healthcare announced a partnership to coordinate a global clinical trial program to study the potential of moxifloxacin to shorten the standard six-month treatment of TB. Clinical trials will assess the efficacy and safety of moxifloxacin as a front-line agent for the treatment of TB. If successful, the partnership will register moxifloxacin for a TB indication. Both parties are committed to making the product affordable and accessible to patients in the developing world. Nearly 2,500 TB patients are being enrolled in trials in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States, and Zambia.

Bayer has committed to donating moxifloxacin to each clinical trial site, covering the costs of regulatory filing, and providing moxifloxacin at an affordable price for patients with TB in the developing world. The TB Alliance has committed to coordinate and help cover the costs of the clinical trials, ensure coordination of information and results for registration goals, and leverage substantial support from the U.S. Centers for Disease Control and Prevention, the Orphan Products Development Center of the U.S. Food and Drug Administration, and the European and Developing Countries Clinical Trials Partnership.

A crucial aspect of the deal was ensuring that Bayer's market for moxifloxacin was protected. At the same time, if a TB indication is approved, there is a potential for dual markets in which there would be separate pricing and distribution plans.

2.8 *A focus on diagnostics: FIND*

Herbert Clemens discussed The Foundation for Innovative New Diagnostics (FIND), launched in 2003 at the World Health Assembly in Geneva. FIND is a nonprofit organization based in Switzerland and dedicated to the development of rapid, accurate, and affordable diagnostic tests for poverty-related diseases in the developing world.

FIND aims to provide a bridge that can effectively link academic research and the diagnostic industry to the specific needs of developing countries. The agency provides this bridge by leveraging the strengths of its diverse partners to develop technological platforms for diagnosing poverty-related diseases in the public, as well as the private, health sector. Working in close collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) of the United Nations Children's Fund, the United Nations Development Program (UNDP), the

World Bank and the World Health Organization (WHO), the diagnostics industry, and other organizations, the Foundation develops and validates affordable, novel diagnostic tests for diseases in high-burden countries. It is leveraging new technologies that have revolutionized the simplicity, speed, and accuracy of diagnostic tools for identifying diseases in the developed world.

FIND conducts its business essentially as a spinout venture and has project portfolios in the areas of malaria, TB, and sleeping sickness. Although it is involved in project management at all levels—financial, administration, strategic planning, business development, communications, information technology, and legal services—FIND focuses on the middle spectrum of product development. FIND leverages its investments to secure affordable pricing in developing countries, thus helping to ensure equitable access to diagnostic products for those most in need of them.

Clemens noted that although FIND has IP expectations for each project, there is a high degree of good faith among collaborators. IP ownership generally rests with the partner. At the end of a project, FIND negotiates with the collaborator on how to dispose of the intellectual property.

One of the most challenging issues is dealing with market segmentation. Of the 193 countries in the world, only 25% are developed, and many have dual markets, so FIND must arrive at pricing agreements that satisfy both the market requirements of a sponsor (unit product cost plus mark up) and FIND's own access requirements

2.9 *Biotechnology investment in global health: BVGH*

Christopher Earl observed that biotechnology companies lead the world in developing new health care products, often for "orphan diseases," conditions for which the development of drugs in not commercially viable or that are rare. However, few companies have focused on developing treatments for neglected diseases. While many biotechnology industry leaders are dedicated to contributing to advances in global health, their companies often perceive market, financial, and information barriers that limit their involvement.

BIO Ventures for Global Health (BVGH) combines expertise in industry, in investing, and in policy to bridge biotechnology and global health. It operates on the assumption that because technology platforms are already built and "*money is already sunk*," there is good reason to take advantage of the existing infrastructure for creating medicine for diseases of the developing world.

BVGH was spun out of the Biotechnology Industry Organization (BIO) and is supported by the Bill and Melinda Gates Foundation and The Rockefeller Foundation, as well as by leading biotechnology companies. Earl noted that with more than 4,000 companies and 270 approved products on the market, the biotechnology industry has created an extraordinarily diverse set of high-technology platforms for drug discovery, and thus is well situated to take on the challenges of global health.

BVGH's approach is market based: it seeks to create or facilitate economic incentives and market mechanisms. Its approaches include: (1) identifying targets for the development of new drugs, vaccines, and diagnostics; (2) identifying market opportunities for neglected diseases through a series of disease-specific business cases; (3) working with companies to build global health strategies that optimally employ their core capabilities; and (4) expanding access to information and resources, providing opportunities to exchange information, facilitating new partnerships, and securing financing for the most persuasive projects.

According to Earl, the biotechnology industry is made up of three tiers. Top-tier companies are the largest and "*act like pharmaceutical companies*." These companies are in the process of building social responsibility models within their organizations. Second-tier companies are institutionally backed. They are "*preprofitable*," their investors are "*tough,*" and company strategies are still focused very much on opportunity costs and avoiding potential loss of focus. The third tier consist of very small companies, essentially "*mom and pop*" operations. The second tier companies are often the best targets for BVGH efforts

because they have the infrastructure in place, have financial backing, and yet are not committed to a binding, long-term R&D plan. Moreover, if a PDP already has pathways for production or manufacturing, it reduces the opportunity costs for such companies in that they can transfer their technology directly to the effort without high costs.

In brokering deals between PDPs and biotechnology companies, the innovation should be in the product, not in the deal. Anytime one can use existing agreements as models for moving forward, time and costs will be minimized, both of which are at a premium for PDPs and midsize biotechnology companies.

2.10 *An agricultural model for cooperative IP management: PIPRA*

The Public Intellectual Property Resource for Agriculture (PIPRA) is not a PDP, but rather an initiative by universities, foundations, and nonprofit research institutions to make agricultural technologies more easily available for the development and distribution of subsistence crops for humanitarian purposes in the developing world and for specialty crops in the developed world.

Alan Bennett explained that although the IP stakes are low in agriculture, the social and human health stakes are quite high. Traditionally, discoveries in public research institutions and agricultural universities were seen as "*public goods*" that flowed directly down the chain of public institutions to farmers and businesses. This system formed the basis for crop improvements and a robust seed industry in developed countries while significantly increasing food production in several developing countries.

In the past few decades, however, changes in U.S. patent law and university technology transfer programs have resulted in an increasing use of the patent system to protect agricultural innovations. In many cases, dominant patents held by the public sector were licensed for private use. Companies then adopted and often improved discoveries from public sector institutions and turned them into crop varieties for commercial markets. However, because of the many public institutions conducting agricultural research, the overall portfolio of public sector technologies is highly fragmented across multiple institutions and technology categories. Information about existing technologies and where rights are held is difficult to find. In addition, more intellectual property has been licensed to the private sector, sometimes under terms that are confidential and often that provide exclusive rights to the licensee. Since applied research and crop genetic improvement is a derivative process based on preexisting plant material, each incremental improvement that involves biotechnology can bring with it a number of intellectual property and germplasm constraints, which accumulate in the plant material. As a result, it has become more difficult for public sector researchers to access technologies to fulfill their missions, especially with regard to developing sustainable agriculture for the developing world.

The development of vitamin A-enhanced rice, or "Golden Rice," illustrates the consequences of the complex IP ownership of agricultural biotechnology. Golden Rice provides dietary vitamin A when consumed. Thus, it offers direct health benefits to millions of poor children in developing countries, where vitamin-A deficiency causes 500,000 cases of blindness each year, and is a contributing factor in over two million premature deaths each year. However, when the time came to prepare this product, many of the techniques used by the researchers were patented in some countries, and some of the materials had been used informally, or under legal agreements that restricted further dissemination. There were 70 proprietary technologies involved, including 40 issued patents in the United States and more than a dozen material transfer agreements (MTAs). Although these issues have now been largely resolved through the cooperation of the private and public sector, much effort was expended to overcome these barriers.

As a result of this and other cases, PIPRA was formed to help public sector agricultural-research institutions achieve their public missions by ensuring access to the intellectual property they need to develop and distribute improved crops. Two PIPRA programs of relevance are focused on IP best practices and management. One program

is exploring and clarifying the implications of public sector IP licensing practices and is seeking a series of best practices that will encourage the commercial development of publicly funded research innovations. At the same time, PIPRA will also retain rights that public research institutions need to fulfill their mission of research for the broader public benefit.

Another PIPRA program involves building an IP database. Currently, the database contains over 6,600 patents and patent applications from 39 different countries. Using the database, these patents are searchable with respect to various parameters, including licensing status. The data represents the agricultural portfolios of 27 participating universities and nonprofit research institutions. The goal of the database is to inform public sector researchers about their freedom to operate (that is, clear all IP barriers to bringing a new product to market). The software also finds ways to invalidate patents and minimize the chances of patent blocking. Use of the database and PIPRA's analytical services are free for academic research and humanitarian purposes.

3. KEY LESSONS

Many different models exist for identifying candidate drugs, vaccines, and technologies, from owning inventions to finding new uses or markets for already-marketed products or abandoned product lines. After patents have been issued, the IP issues and liability concerns become simpler to manage, since there will be an increasing amount of safety data available. Partners owning the intellectual property are able to provide the background technology and expertise, setting conditions for licensing and access.

There is no single business model that PDPs ought to pursue. PDPs vary from virtual organizations that contract all aspects of product development, to universities and firms, to PDPs that have developed considerable international capacities and expertise in product management and regulatory affairs. Regardless of the type, all PDPs negotiate diverse ranges of agreements, including, sponsored-research contracts, know-how and patent licenses, and distributorship agreements.

Although their business models vary, PDPs employ a common set of strategies to manage intellectual property for global health outcomes, usefully summarized by Antony Taubman of the World Intellectual Property Organization. These include:

- defining a discrete territorial market (separating industrialized markets from developing countries, or focusing on target markets), allowing investments and earnings from Organisation for Economic Co-operation and Development markets to subsidize product availability in developing countries
- establishing distinct structures for public sector marketing, social marketing, and private markets (for example, more open licensing for the public sector balanced by exclusivity over lucrative markets)
- determining field of use in a manner that enables the covered technology or product to extend to indications for conditions of prevalence in industrialized countries, where feasible, as an investment incentive
- establishing royalty rates in a manner that benefits the party requiring the greatest incentive
- providing for access to the developed technology in the event that the research/industry partner abandons the project or does not service a particular sector, including background and foreground intellectual property, product development know-how, and regulatory approval data

If the industrial partner bears some of the risk, because of early-stage involvement either through investment or conduct of R&D, then IP issues, such as agreements about royalties, licenses, and access, must be resolved early on. These issues can be quite complex. The different levels and forms of contribution by the partner will influence the extent of and flexibility of the terms. If multiple partners are involved, each with background intellectual property and expectations for foreground intellectual property, then royalty-stacking provisions may be required.

3.1 *Preparing for access*

As PDPs plan for access, they face a series of practical and conceptual challenges to ensure supply, an affordable price, and effective delivery once the product is successfully developed. An analysis prepared for WHO's Commission on Intellectual Property Rights, Innovation and Public Health by Jon Merz, indicates that many PDP R&D contracts defer downstream issues related to manufacturing and distribution to future resolution. Operational challenges face PDPs with regard to pricing to the public sector, market segmentation, market sizing, ensuring the lowest sustainable cost of production, and quality control, as well post-launch issues, such as pharmacovigilance and product liability.

Specifying requirements and strategies for access early on is critical so that unsurmountable hurdles or costly delays are not encountered once the product is developed. Indeed, experience demonstrates that even where certain products have been developed for distribution in developing countries, uptake has been sluggish or stalled due to a variety of downstream constraints. This has been the case, for example, with the combination antimalarial Coartem; praziquantel, for the treatment of schistosomiasis; and the slow uptake of hepatitis B vaccines. Some PDPs, especially those that face inadequate delivery systems in target countries (regarding deployment of microbicides or HIV vaccines, for example), have identified preparation for access as a core aspect of their mission and have begun to document their needs. Moreover, the GAVI Accelerated Development and Introduction Plans are forging approaches for the phased introduction of selected vaccines.[9] In some cases, PDPs also may be able to work with *access* public–private partnerships in fields where they exist (e.g., Roll Back Malaria Partnership), especially with regard to pricing and financing mechanisms and delivery networks in target countries.

An important tool in intellectual property management is the detailed development of contractual milestones in licensing intellectual property from public to private sector, including provisions for performance review and modifications, when required. Key milestones include pricing to the public sector, territory and exclusivity; regulatory work and time to market; royalties and terms; and termination of the licensing agreement.

3.2 *Pricing issues*

A key consideration in access negotiations is target pricing. PDPs typically require the product to be made available at affordable or reasonable pricing, which may lead to complex negotiations about how to calculate price, or consideration of available price discriminate models. Price setting requires both parties to know in advance the technical details of production, marketing, and distributions costs. A clear framework to compute manufacturing cost is required. Since many PDPs enter negotiations based on early-stage discoveries, stipulating price in a contractual arrangement could be a risky or impractical proposition. In most instances, the cost of the final product is the cost of production plus a reasonably negotiated mark-up. Assessments on what constitutes an affordable price are complex, since they take into account the epidemiology of the disease, purchasing power of those affected, and government financing schemes, among other factors. In comparison to drugs, where one can project costs once a compound is identified, pricing is more difficult with vaccines because one does not know in advance what the acceptable price will be or what a government might support. There was general agreement that pricing done too far in advance can deter industry partners and discourage extended R&D commitments. Approaches to calculating price are a priority topic for focused exchange among PDPs and relevant experts.

3.3 *Market segmentation*

Market segmentation has emerged as a common issue in negotiation. Although there are common sources for differentiating countries (for example, World Bank income data), challenges emerge with the division of rights in so-called mixed-payer markets, such as Brazil and India. As more agreements are pursued, it would be useful to generate descriptive case studies on price tiering and its effectiveness at segmenting domestic

markets. A correlative need is to prevent arbitrage or leakage between public and private markets.

3.4 *Production and capacity issues*

Production also must be addressed. PDPs pose a new business model with new challenges, (for example, convincing a party to build a factory with uptake, rights, and options for manufacturing and operations that are uncertain). Identifying existing facilities is a strength for some PDPs. Those working in vaccines, however, have a greater challenge in that for regulatory reasons, they must find a purpose-built factory for every vaccine. While excess capacity can typically be absorbed for drug manufacturing plants, the same is therefore not the case for vaccines. Thus, the price of a vaccine is linked to the cost of production and investment in the manufacturing plant.

Another critical issue is projecting and assuring capacity commitments as products approach the large-scale processing stage. Some therefore suggest that in some cases there should be publicly dedicated capacity for manufacturing and that PDPs should enter into deals with that expectation in mind.

3.5 *Early-stage licensing*

In negotiations with universities, several PDPs note challenges with in-licensing the needed technologies from academic institutions. Universities may overvalue inventions or lack flexibility. However, through the efforts of organizations such as MIHR and PIPRA, many universities are becoming increasingly able to use IP tools to promote access in developing countries, such as through the use of humanitarian licensing provisions.

There are several constructive actions that could assist the PDPs, including the establishment of inventories of IP rights held and a survey of the licensing status in key global health fields. A prototype database is being developed at the U.S. National Institutes of Health (NIH), based on the U.S. Federal Interagency Edison database of invention reports. At the institutional level, there is growing interest among technology transfer offices to operate against performance expectations aligned with both economic and social goals. AUTM is considering new initiatives in performance metrics, which potentially could facilitate academic licensing to PDPs, if measurements incorporate global health or global access considerations.

In some instances, negotiations with small biotechnology firms are comparably difficult. Such firms are sometimes concerned that sharing platform technologies for use in the development of noncommercial products may weaken commercial positions. The types of outreach initiatives undertaken with universities may equally benefit small biotechnology companies (for example, through dissemination of case studies). A key challenge is to demonstrate creditable demand to encourage risk taking by corporate partners. In several areas (HIV, pneumococcal, and rotavirus vaccines), useful modeling work is being pursued to assess demand and its implications for financing mechanisms.

3.6 *Negotiating the IP landscape*

PDPs practice due diligence and, where needed, engage in IP mapping exercises to ensure freedom to operate. IP assembly issues are becoming more challenging, due to the increasing need for proprietary tools. This is especially the case for broad umbrella or vaccine component patents, where a variety of technologies may be required to express or purify an antigen, bolster immunity, or devise a delivery system. Related problems include royalty stacking and lack of ownership of intellectual property to cross license.

Responses to patent thickets include license mapping and exploring creative licensing schemes. There is an emerging range of IP management tools that can be applied, depending on the particular needs of the scientific challenge. However, more systematic efforts are needed to identify where and when current or emerging IP management strategies might best be considered and to facilitate their application. The challenge may be to identify the specific technology platforms around where public and private sector product development interests strongly coincide. It is also important to identify the key institutions to bring together to discuss such a consortium-based approach. Negotiating the patent landscape

and access to research tools is a general challenge for the scientific community. However, creative models in the health sciences may find the most fertile ground in the context of global health products, since they represent noncommercial, or "low margin," R&D.

3.7 *Systemic challenges*

The workshop emphasized the broader systemic needs of the PDPs, including distribution challenges within countries with poor infrastructures. Reducing the time gap between development and implementation also will require the continued development of an international clinical trials system that engages local investigators, communities, ethical review committees, and regulatory bodies in low- and middle-income countries. It will require adequate systems for quality control and regulatory approval to assure consistent, high-quality products in the absence of first-world regulatory control, and legal systems within manufacturing countries that enable the supplier to effectively support its patent rights. To reach their goal, PDPs will need greater engagement of the scientific community and funding agencies in operational and health-services research, including mode and cost of delivery, patient acceptability and compliance, dosage and toxicity, and methods to adapt interventions to local conditions and integrate them into existing services.

4. CONCLUSIONS

Workshop presenters broadly endorsed the usefulness of bringing together diverse groups of practitioners to address the challenges of IP management for global health outcomes. The value of such a platform increases as the numbers of practitioners and institutions associated with PDPs expand. There is value in continuing broad discussion, as well as in more focused discussion with respect to specific issues, such as calculating price. From discussions at the workshop ideas emerged in regard to a number of actions that could both contribute to a wider understanding of issues surrounding intellectual property:

- developing best practice standards and disseminating these widely
- developing and disseminating case studies of various IP approaches related to market segmentation, tiered pricing, and royalties
- pursuing focused workshops on common issues such as pricing, product liability, early-stage licensing, and sponsored-research agreements with academe, or IP assembly and freedom to operate
- organizing inventories of IP rights held and the licensing status of these IP rights in key global health fields
- encouraging academic licensing practices that make products more accessible to impoverished populations and provisions within research sponsorship agreements that are responsive to the special requirements of PDPs
- supporting IP mapping and/or IP-landscape analysis for products of particular priority, or disseminating such landscapes where available
- instituting training programs and personnel exchanges to build research and technology management competencies and partnerships in low- and middle-income countries
- encouraging needed market analysis, such as estimates of need, to engage corporate interest

It is clear that many PDPs have matured over the past few years, progressing along the continuum from R&D to dissemination. Many have secured funding and negotiated successful deals, sometimes with numerous partners. Most, however, are still in the early stage of product development, and few have reached the threshold of product completion and distribution. Thus, there are no real outcomes to measure at this time. Moreover, deals are highly contextual. Still, although best practices will continue to emerge and be refined, a set of best principles or working tenets for ensuring product access and availability has clearly been established. In all cases, the role of intellectual property in PDP agreements is to provide incentives for private investment in public health and to structure and define the nature of the relationship among the partners with regard to how rights will be shared or exercised. There

is nothing particularly novel about the terms of agreements reached by PDPs; rather, it is their totality as a public/private hybrid that sets them apart. Collectively, the PDPs are broadening our creative understanding of practical ways to resolve the public-policy dilemma of balancing private incentives to generate needed R&D investment with the goal of access to those in need. ■

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1 Global Forum for Health Research. 1999. The 10/90 Report on Health Research. Geneva: Global Forum for Health Research

2 Mahoney R and CM. Morel. 2006. A Global Health Innovation System. *Innovation Strategy Today* 2(1): 1–12. www.bioDevelopments.org/innovation.

3 Other activities such as financing and capacity building are *crosscutting means* to address the components. They are not components of innovation in and of themselves.

4 See also Mahoney RT, A Krattiger, J Clemens and R Curtiss III. 2007. The Introduction of New Vaccines into Developing Countries IV: Global Access Strategies. *Vaccine* (in press).

5 25 and 26 July 2006 at the Aeras facility in Rockville, Maryland, U.S.A. The meeting included representatives of PDPs, industry, and academe, who shared their perspectives on IP issues, partnership strategies, and value propositions or incentives in deal making. The involvement of corporate and academic partners helped facilitate discussions about the dynamics that shape and direct successful public-private partnerships. For example, there is a strong interest on the part of the PDPs in building knowledge among university technology managers of the special needs and requirements of the PDPs as nonprofit enterprises. Correspondingly, PDPs can learn from university technology offices how to more effectively negotiate sponsored research or early-stage licensing agreements with universities, given the requirements and needs of academic environments.

6 To view the 2004 MIHR report, see: www.globalforumhealth.org/filesupld/ippph/dealmaking.pdf. The 2006 meeting, like its predecessor, provided a platform for exchanging emerging best practices in structuring and negotiating product development agreements for technologies needed in developing countries. Presentations centered on case studies of several PDPs to illustrate terms, conditions, and strategies that may be employed to help ensure product availability and access. Topics included: segmentation of markets, pricing, negotiating with universities, liability issues, ownership and use of clinical trial and regulatory data, partnerships with emerging suppliers, and technical assistance needs to ensure technology transfer. Discussions were focused on best practices for deal making in various contexts, from understanding complementarities of missions to negotiating contract language.

7 See, also in this *Handbook*, chapter 2.7 by J Oehler. See also Kaplan W. 2005. www.who.int/intellectualproperty/studies/W.Kaplan2.pdf.

8 See, also in this *Handbook*, chapter 17.9 by J Banerji and B Pecoul.

9 www.gavialliance.org.

Patenting and Licensing Research Tools

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ABSTRACT

Research tools encompass a wide range of resources, including genes/gene fragments, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools such as polymerase chain reaction, methods, laboratory equipment and machines, databases and computer software. Access to research tools is integral to advancing progress in biotechnological R&D, in both the biomedical and agricultural sciences. However, a complex web of research tool patents has arisen as a result of the revolution in molecular biology and coincident changes in public policy and patent law. These patents can pose a potential block to accessing research tools. For developing countries, several approaches can be formulated and then implemented in order to overcome potential problems associated with research tools. These include changes in patenting policies, research exemptions in patent law to reduce the risk of infringement in R&D, compulsory licensing to allow access to upstream technologies, and institutional adaptations to facilitate access to needed technologies, such as guidelines intended to promote more appropriate behavior by participants in the system. With carefully formulated, multitiered approaches, research tool patenting and licensing (and its possible impact on innovation in health and agricultural research) may be effectively managed.

1. INTRODUCTION

Research tools are difficult to define precisely. They may be described, broadly, as any tangible or informational input required in the process of discovering a drug, a medical therapy, a diagnostic method, or a new crop variety. In short, anything that a researcher needs to use or access in the course of research—such as an assay, a genomic database, an animal model, crop germplasm and so on—may be classified as a research tool.[1] Research tools are defined by the U.S. National Institutes of Health (NIH) as the full range of resources that scientists use in the laboratory, including *"cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software."*[2] To this definition, one should add genes and gene fragments.

The classic statement on the possible consequences of protection by intellectual property (IP) rights of research tools in biomedical research was made by Heller and Eisenberg:

> *… the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an "anticommons" in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.*[3]

Clift C. 2007. Patenting and Licensing Research Tools. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Similar concerns have been expressed about agricultural research, for example by Boettiger and Bennett.[4]

2. RESEARCH TOOLS: KEY EVENTS

There are three key events of relevance to the global debate on the pros and cons of patenting research tools, all of which date from 1980, or thereabouts.

2.1 *Event one: the revolution in molecular biology*

The revolution in molecular biology has fostered the development of wholly new branches of scientific investigation, such as proteomics (the science of proteins expressed by genes), which has transformed the way research is conducted, as well as widened, enormously, the potential for scientific advances to address fundamental human problems in health and agriculture. Many of the immediate products of such research are intermediate or platform technologies of use to other researchers, but not (with certain exceptions such as diagnostic tests) final products capable of application by medical practitioners or farmers.

2.2 *Event two: the Chakrabarty case*

The landmark 1980 U.S. Supreme Court decision, *Diamond v. Chakrabarty*,[5] established that genetic inventions (in this case a genetically engineered bacterium capable of breaking down crude oil) were patentable subject matter under U.S. law. The application of the patent system in this way facilitated the development of a viable business model for the biotechnology industry. With the development of potentially revenue-earning products, often a long way off for many companies, they could nevertheless raise money, or realize value (for example, via licensing, assignment, or other forms of acquisition) through the patents taken out on research tools or other upstream genetic technologies.[6]

2.3 *Event three: the Bayh-Dole Act*

The 1980 Bayh-Dole Act amended the patent code in the United States, granting universities permission to patent inventions resulting from government-funded (federal) research, subject to government march-in rights. This was based on the premise that implementation of the Bayh-Dole Act would hasten innovation, facilitate the commercialization of research, and thereby move new and innovative products into the marketplace more quickly. As a result universities themselves have become key players in the development and patenting of new biotechnology inventions, most of which are in the nature of research tools rather than final products. Increasingly universities have developed extensive patent portfolios in both agricultural and biomedical technologies. Subsequently, most of the developed world has pursued similar policies to the United States in promoting the commercialization of the products of university research.

3. RESEARCH TOOLS: IMPLICATIONS AND CHALLENGES

The more technologically advanced developing countries, including Brazil, India and China, have in recent years pursued essentially similar policies to the United States in promoting the commercialization of the products of university research. But developing countries, even those with a relatively well-developed scientific and medical infrastructure, face very different circumstances from those in the United States and other developed countries. Although most developed countries have tried to emulate Bayh-Dole policies in different ways, the success of such policies in the United States owes much to institutional arrangements specific to the United States and is based on its unique higher education system and history of interactions between universities and businesses.[7]

An emphasis on patenting and licensing by universities as the chief means by which technology transfer occurs, as compared to publication and open knowledge sharing, may have negative implications for research in the area of public health or agriculture, as well as other areas. Since revenue prospects will be greater for products that would have a market in a developed country, this promise may further distort the allocation of research funding away from the specific public health problems of developing countries. Therefore, care must be taken to ensure that

research priorities, particularly those that could directly benefit poor people, are not distorted by the quest for larger licensing income.

Concerns about access to research tools apply both to the public and private sectors. In the public sector, for example, one university may wish to access the patented technology of another for research. Universities may wish to access private sector technologies, and vice versa. Private sector companies may experience difficulties in accessing each others' technologies.

Some see one university paying another to license a technology as perverse when most research in universities is publicly funded, even if the university is privately funded. But this is a logical consequence of introducing patenting into the university arena. In the United States, in the Supreme Court case *Madey v. Duke*,[8] the Court found that, since the "business" of Duke University was research and teaching, there was no exemption from patent infringement in its research, as the use of the patented invention was in furtherance of that business. The profit or nonprofit status of the user was not a critical factor for the court. Although not part of the court's judgment, the implication was that as universities were now enthusiastic users of patents and licenses, and litigated to enforce their patent rights, it would therefore be inconsistent for universities to seek exemptions for the use of third-party patented inventions for R&D in their own programs.

4. THE REALITY OF RESEARCH TOOLS

4.1 *Biomedical research*

In developed countries the evidence to date, which mainly comes from the United States, suggests that researchers in both the public and private sector have found various ways of coping with the new environment of patented research tools.

In biomedical research, working solutions include licensing, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools, and challenging patents in court. Changes in the institutional environment, such as the tightening of gene patenting rules introduced by the U.S. Patent and Trademark Office, and guidelines produced by NIH to encourage good patenting and licensing practices, appear to have further reduced the threat of breakdown and access restrictions, although the environment remains uncertain. It is clear, however, that these various working solutions involve costs in terms of either time or money or both.[9]

Furthermore, a recent study in the U.S. of researchers in academia, government and nonprofit organizations, and industry suggests that difficulties in gaining access to materials (for example, data or cell lines) through Material Transfer Agreements (MTAs) may have more significant implications for the conduct of research than patenting itself.[10]

A critical finding is that industry researchers experience significantly greater delays and difficulties in accessing proprietary technologies than academic researchers. In large part this is because industry researchers work, self-evidently, in a more commercial environment, are more patent aware than academics, and more liable to respect the patent rights of others and to assert their own rights with respect to their own proprietary technologies (including research tools). By contrast, while commercial activity and pressures have become much more widespread in academic circles, and patenting is common, researchers are less aware of patent issues, more likely not to check whether the technologies they use are protected, and less likely to assert their own rights against other academic researchers.

Another recent report from the Committee on IP Rights in Genomic and Protein Research and Innovation reached the following conclusion:

…the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property. Thus, for the time being, it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers. For a number of reasons, however, the committee concluded that the patent landscape, which already is becoming complicated in areas such as gene expression and protein-protein interactions,

could become considerably more complex and burdensome over time.[11]

Accordingly the committee made recommendations that addressed "*an increasingly problematic environment for research in genomics and proteomics as more knowledge is created, more patent applications are filed, and more restrictions are placed on the availability of and access to information and resources*."

A special case is that of genetic diagnostic tests, which may be used either clinically or in the course of follow-on research. They, therefore, have a dual nature, both as a final product, and as a discovery tool. A survey of over 100 laboratories in the United States concluded that patenting and licensing practices in this field had had a negative impact on clinical use and the development of further genetic tests.[12]

These survey results relate to mainstream research of potential commercial value. Furthermore, it is likely that transaction costs could weigh more heavily on those working with limited resources on projects focusing on specific diseases particularly affecting developing countries. On the other hand, some public–private partnerships (for example, the Global Alliance for TB Drug Development) say that their philanthropic mandates can be useful in encouraging companies to license their IP more easily, and more cheaply, than would be likely in a wholly commercial exchange. It is, therefore, difficult to draw valid, general conclusions from the evidence currently available.

There is also very little empirical evidence of the impact of research tool patents in the biomedical field in developing countries themselves. More experience and empirical research are needed. The impact of such patents may be more significant in developing countries than in developed countries, as research institutions or companies in developing countries generally lack the legal and negotiating capacity to engage in complex negotiations and lack the organizational flexibility and funds to pay license fees, if required by patent holders.

4.2 *Agricultural research*

The institutional context for agricultural research, by which in this context we mainly mean crop research, differs from biomedical research. The size of the sector, and of the potential commercial market, is much smaller than in medicine. There is also a tradition of public sector institutes taking research right through to the point of commercialization (at least in traditional breeding programs), whereas in medicine commercialization is overwhelmingly a private sector activity.

The advent of biotechnology and the spread of gene patenting is one reason why the private sector in agricultural research has come to be dominated by a few large companies. In particular, the existence of a large number of overlapping patents for relatively important technologies has been a powerful incentive for merger and acquisitions, as well as strategic alliances. For example, patents on the Bt gene which can confer insect resistance on a wide range of different crops are strategically important for the whole industry. Controlling or denying access to strategic technologies is both commercially important to their owners and, correspondingly, liable to adversely affect research on crops where the commercial market is small (for example, subsistence crops in developing countries).

With respect to IP, research tools and agricultural research, a recent survey concluded that evidence:

…suggests that the effects on research of lack of access to needed technology have been more serious on average for biotechnologists working on agriculture than for those focused on human health. This might reflect the smaller set of promising technologies in agriculture and the lower level of resources available to help scientists surmount or invent around roadblocks. [13]

It also seems to be the case that patented genetic crop material (such as the Bt gene) is viewed as having more commercial value than many of the research tools used in biomedical research. Thus, whereas patent holders may disregard infringements in upstream biomedical research, or think it not cost effective to sue for infringement, in the case of more downstream agricultural research this may not be so.

5. ADDRESSING THE RESEARCH TOOLS CHALLENGE

Developing countries have a number of possible options, at the level of policy and practice, to address the possibility that proprietary restrictions will unduly limit the use of research tools. Possible approaches used or considered to address this issue include the following:

- changes in patenting policies
- research exemptions in patent law to reduce the risk of infringement in R&D
- compulsory licensing to allow access to upstream technologies
- institutional adaptations to facilitate access to needed technologies, such as guidelines intended to promote more appropriate behavior by participants in the system

5.1 *Patenting policies*

Countries may adopt different approaches to patenting. On the one hand, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Article 27 (1) obliges countries to grant patents across all fields of technology provided that the technology is new, involves an inventive step (or is *nonobvious,*) and is capable of industrial application (or is *useful*). On the other hand, the agreement allows various exclusions from patentability, such as discoveries of natural phenomena (which could include genes) that do not meet the patentability criteria.

Governments may choose whether or not to allow the patenting of genetic material. Plants and animals may be excluded from patentability, except for microorganisms, and nonbiological and microbiological processes. The TRIPS agreement does not specify how countries should define what an "invention" is, or how the criteria of patentability should be interpreted. Nor does it actually refer to genes, or genetic material, at any point.

The desirability of restricting patentability of genetic discoveries in this way will need to be assessed according to the circumstances of each country. For instance, countries that are mainly users of research tools patented abroad might promote the use of such tools by limiting their patentability. Other countries, with more advanced capacities in genomics, might favor a less-stringent interpretation of patentability but would need to be mindful of the possibility of restrictions on their widespread use.

If patents are granted, they can limit the scope of the claims to what has actually been invented. Patenting policy in biotechnology should aim to facilitate R&D of healthcare products and new agricultural crops. Unlike some other countries, France and Germany have introduced rules that limit the scope of patent protection for human gene sequences to the specific use disclosed in the patent application, thus excluding protection for future, as yet undiscovered, uses.[14] These rules were introduced because broad protection may disadvantage those wishing to build on the invention, while narrower claims may facilitate their downstream use.

5.2 *Research exemptions*

The TRIPS agreement allows the use of limited exemptions under Article 30, which has a possible application to the research tool issue as well as others:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

In most of Europe, exemptions exist for acts performed privately, for purposes that are noncommercial, and for experimentation on the subject matter of the invention, even for commercial purposes.

In the United States, by contrast, there are no equivalent statutory exemptions, even for noncommercial or research uses. In the past, however, the courts have generally recognized some scope for *"making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage… ."* In 2002, as noted above, the case of *Madey v. Duke* essentially ended this informal research exemption.[15]

There is an active debate in several countries about the appropriate scope of any research exemption. In 2004, the U.S. National Academies of Science (NAS) published a report on the U.S. patent system recommending that

the introduction of a formal research exemption for noncommercial purposes.[16] This recommendation was repeated in the subsequent report on genomic and proteomic research.[17]

Thus, there is a broad spectrum of ways in which the research exemptions allowed under the TRIPS agreement are implemented in different countries, and how these are interpreted by courts. The essential point, in this context, is how to ensure that follow-on research that may be important to innovation in the fields of health and agriculture is not inhibited. The appropriate scope of the research exemption must be considered in this light.

5.3 *Compulsory licensing*

In most countries, the law allows governments to issue compulsory licenses on a number of grounds, including in circumstances where the development of a research field of importance to public health or agriculture could be inhibited by the actions of particular patentees. For example, in the United Kingdom there are extensive powers in the Patent Act that, although rarely used, can remedy such situations. Section 48A (1) of the act, for instance, covers:

refusal of the proprietor of the patent to grant a licence or licences on reasonable terms … the exploitation … of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered.

Similar provisions exist in many other countries. In the United States, the Patent Act does not provide for compulsory licensing as such, but there are similar march-in rights, as part of the Bayh-Dole amendments, only where federal funding of an invention is involved (Section 203).

In the European Union, the 1998 Biotechnology Directive, which has been implemented in national law by many member states, contains provisions that allow for compulsory licensing of patents or plant variety rights if prior negotiations with the owner are unsuccessful, provided that the resultant invention constitutes significant technical progress of considerable economic interest compared to the original invention claimed in the patent or plant variety right.

5.4 *Institutional adaptations*

Various initiatives have been considered or implemented to adapt or modify institutional practices around patenting and licensing.

One example of adaptation to the changing technical environment was the announcement in 2001 by the U.S. Patent Office of new guidelines on expressed sequence tags (short pieces of DNA that help to identify when particular genes are being expressed in cells). These guidelines tighten the specifications regarding what constitutes "utility," and provide guidance to patent examiners about how to apply the utility criterion to biotechnological inventions. In such cases, patentability can be established only if the patent application discloses a *specific*, *substantial* and *credible* utility.[18] It was intended that this new standard would prevent patents being granted on inventions for which only a speculative application is disclosed. The introduction of these tighter criteria may be one reason, among others, why patent applications in this area have declined recently.

Countries may also consider guidelines or other means to encourage or mandate patenting and licensing policies that promote innovation. In the United States, NIH, as the principal funder of academic biomedical research, took the lead in publishing in 1999 principles and guidelines on sharing biomedical research resources. These sought to promote the widest possible dissemination of research tools developed with NIH funds, in the interests of accelerating scientific discovery and facilitating product development. At the same time NIH considered that *"reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development."*[19]

In 2005, NIH introduced voluntary guidelines ("best practices") on the patenting and licensing of genetic inventions funded by NIH grants. On patenting, the guidelines said it should be considered whether:

…significant further research and development by the private sector is required to bring the

invention to practical and commercial application. Intellectual property protection should be sought when it is clear that private sector investment will be necessary to develop and make the invention widely available. By contrast, when significant further research and development investment is not required, such as with many research material and research tool technologies, best practices dictate that patent protection rarely should be sought.

On licensing, the guidelines provided a more extensive set of principles that support nonexclusive licensing as a general rule. Where exclusive licensing might be necessary to promote further development, the guidelines suggest that care should be taken to license only in the specific area where the licensee is working, to avoid blocking off other areas of research that may use the same technology. In addition, they said consideration should be given to including specific provisions to protect further research and public health. For instance, a license could reserve the right for the invention to be used in nonprofit research organizations for either research or educational uses.[20] Boettiger and Bennett argue that since the NIH guidelines appear to be working well, they should be applied across the board where federal funding is involved, keeping in mind, specifically, the situation in agricultural biotechnology.[21]

Guidelines on the licensing of genetic inventions have also been produced by the Organisation for Economic Co-operation and Development (OECD).[22] Apart from the text of the guidelines, an appendix contains a useful list of Web links to model agreements on various aspects of licensing and material transfers.

The international network of agricultural research centers, that is, the Consultative Group on International Agricultural Research (CGIAR), has a policy on IP, with the underlying principle to *"take every possible measure to facilitate access to research products for the public benefit, in particular in developing countries,"* while recognizing also that there will be exceptional circumstances when taking out patents may be necessary for the various centers to pursue their specific objectives.[23]

Some U.S. universities are indeed experimenting with new licensing arrangements. For instance, Stanford University proposes wording, along the following lines, as a standard means of establishing freedom for universities, public sector research organizations or, indeed, organizations such as public–private partnerships to be able to use particular technologies that it licenses exclusively to a third party:

Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and use Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Stanford and any such other institution has the right to publish any information included in the Technology or a Licensed Patent.[24]

The organization Universities Allied for Essential Medicines has been set up in the United States to explore how universities can help ensure that biomedical end products, such as drugs, are made more accessible in poor countries, and to increase the amount of research conducted on neglected diseases, or those diseases predominantly affecting people who are too poor to constitute a market attractive to private sector R&D investment. The organization recognizes that university scientists are major contributors in the drug-development pipeline and that universities have an avowed commitment to advancing the public good.[25] The organization has developed a model equitable access license to further these aims.[26]

A body of technology managers called the Technology Managers for Global Health has been formed, as a subgroup within the influential Association of University Technology Managers in the United States, to press for similar sorts of arrangements to those promulgated by the Universities Allied for Essential Medicines and others. In conjunction with the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), a co-sponsor of this *Handbook*, the Technology Managers for Global Health has published a booklet providing case studies of academic licensing to product

development partnerships for treatments for diseases affecting developing countries particularly.[27]

Another initiative seeks to draw on the success of the Open Source Initiative (OSI) which has developed a more or less proven research model, based on a general public license that makes modifications of a software program freely available to others to use or develop further. The important aspect of this approach is that it mobilizes innovative effort from a range of developers at little cost.

CAMBIA, a nonprofit organization based in Australia, both undertakes research in molecular biology in agriculture directed at the needs of developing countries and also seeks to overcome the problems of fragmented technologies by developing patent and technology databases and innovative licensing techniques that draw on the experience of OSI. CAMBIA has prepared a model license[28] that has the objective of creating a common pool within which improvements can be freely shared. On the other hand, the terms of this license may conflict with the existing licensing terms of other technologies, which should form part of the common pool.

The Public Intellectual Property Resource for Agriculture (PIPRA), the other co-sponsor of this *Handbook*, is an organization comprising universities, foundations, and nonprofit research institutions, which aims to make agricultural technologies more easily available for the development and distribution of subsistence crops for humanitarian purposes in the developing world. PIPRA seeks, through a variety of activities, including the compilation of patent and licensing databases, to mitigate problems arising from the fragmentation of proprietary technologies and materials among different institutions. It has also proposed a draft license to facilitate research relevant to developing countries.[29]

Another institutional approach is the potential use of patent pools. In 2000, a report by the U.S. Patent Office on patent pools and biotechnology patents concluded that the *"use of patent pools in the biotechnology field could serve the interests of both the public and private industry, a win-win situation*."[30] Among the benefits cited for this approach to licensing were: efficiency in obtaining rights to patented technology through one-stop licensing mechanisms; the distribution of risks associated with research and development; and the elimination of *blocking* patents or *stacking* licenses, and the consequent encouragement of cooperative efforts. Patent pools, therefore, could be most useful for technologies particularly relevant to developing countries, because the lack of strong market incentives may enable agreements that would otherwise be more difficult to engineer. Low-margin research directed toward problems of poor people might be promoted. Patent pools have also been proposed for the development of vaccines, which is appropriate given the large number of products owned by different entities and, consequently, the complexity of identifying, tracking, and obtaining licenses for patented technologies.

Patent pools have been established in the consumer electronics industry, specifically in relation to the broad adoption of industry standards. The biotechnology industry, however, is very different from the electronics industry. An OECD report noted:

…the pharmaceutical biotechnology industry may be fundamentally different from the electronics sector. It is not an industry in which defining standards is important, and assuring interoperability of technologies is not very important, especially not in the development of therapeutics. A company's worth is tightly tied to its intellectual property and fosters a "bunker mentality." There are likely to be disagreements among partners over the value of the different patents in a pool, and dominant players may not have a strong incentive to join the pool. If a limited field of application and essential patents can be defined, the patent pool model is worthy of consideration in biotechnology…[31]

The suitability of the patent pool for biotechnology patents certainly requires further study, as does the role of government in promoting them.

For these reasons, and others, patent pools in biotechnology have not developed as a response to fragmented patent ownership. In agricultural biotechnology in particular, cross-licensing and, ultimately, mergers and acquisitions are the common response.

6. CONCLUSIONS

While no specific guidance or conclusions can cover the specific circumstances of policy-makers, researchers, universities, research institutions, foundations or other organizations in given developed or developing countries, the several guidelines, enumerated below, might help to conceptualize a starting point within a broader framework:

- Developing countries need to consider implementing patent legislation, consistent with TRIPS, that meets their objectives, in particular with respect to genetic discoveries.
- Countries need to consider in their own legislation what form of research exemption might be appropriate, in their own circumstances, to foster research and innovation in health and agriculture.
- Countries should consider providing in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the health and agriculture problems of developing countries.
- Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products for human health and agriculture.
- Public funding bodies should introduce policies for sensible patenting and licensing practices, for technologies arising from their funding, to promote downstream innovation.
- Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries, and to products derived therefrom, are facilitated through appropriate licensing policies and practices. ■

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Valuation and Licensing in Global Health

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ABSTRACT

Since 1999, two trends have transformed the landscape of treating endemic diseases in the developing world: (1) the establishment of highly effective drug development public private partnerships, which have secured substantial amounts of philanthropic funding to develop new drugs for developing countries and (2) the emergence of tiered pricing for drugs that are under patent protection and that treat diseases in both the developed and the developing world. As a result, the options have increased for both academic institutions and companies for developing new therapies for low- and middle-income countries. This also means that traditional bilateral licensing arrangements will be replaced by multimember networks that bring together the necessary skills for R&D, regulatory work, intellectual property (IP) management, production, and distribution and marketing. New licensing approaches will be needed to ensure that IP issues facilitate, rather than hinder, such collaborations and transactions. This chapter presents evidence that suggests that all parties to such transactions should strive for a no profit–no loss financial model in order to maximize humanitarian benefits.

1. TWO PHARMACEUTICAL INDUSTRIES: TWO PRICING PHILOSOPHIES

In developed countries, the pharmaceutical industry consists of two quite separate and largely nonoverlapping sectors:[1]

- In the *research-driven sector*, new drugs are developed and tested through clinical trials. Typically, a new drug application (NDA) is filed with the FDA; when the NDA is approved, the drugs are sold at legal, patent-protected, monopoly prices based on the benefits the drugs provide to patients.
- In the *generic sector*, drugs that are nearing the end of their patent protection term are prepared for market and, when patents expire, sold competitively at commodity prices based on the cost of production.

According to the Generic Pharmaceutical Association, using IMS health data, generics accounted for 56% of all prescriptions dispensed in the United States in 2005, but less than 13.1% of every dollar spent on prescription drugs. Generics cost, on average, 30% to 80% less than their branded counterparts.[2] Prices for generic drugs are typically 10% to 20% of their prepatent expiration price and are cost based (that is, the price is based on a mark up over the cost of production).[3] Analysis of the financial results of publicly traded generic-drug companies shows that these companies typically operate with a gross margin—the amount by which sales exceed the cost of goods sold—of around 50%.[4] This margin covers the companies' general and administrative costs, marketing and selling costs, and profits.

2. DRUG PRICES IN DEVELOPED COUNTRIES

The United States has had a love–hate relationship with the research-driven sector of the

Stevens AJ 2007. Valuation and Licensing in Global Health. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

pharmaceutical industry almost from its inception. Consumers love the new life-saving medications that the industry has been able to discover, but they hate the prices resulting from the patent-protected monopoly.

The issue first emerged in the late 1940s, with the launch of the tetracycline family of antibiotics.[5] This was the first family of antibiotics to be discovered by the U.S. pharmaceutical industry itself. The first antibiotics—penicillin, streptomycin, and neomycin—had been discovered in academic laboratories (penicillin at St. Mary's Hospital in London, U.K. and Oxford University with the critical process scale-up under wartime conditions led by the U.S. Department of Agriculture[6] and streptomycin, and neomycin at Rutgers University[7]). All were licensed non-exclusively and the resulting competition caused prices to fall rapidly.

By contrast, thanks to the patent protection they enjoyed, prices for tetracyclines remained high. However, eventually competition came from overseas. At that time, Italy was the "rogue state" of pharmaceutical patents, and through bids by an Italian company for a U.S. military procurement of tetracyclines, the government became aware of the high profit margins on the patented drugs. This discovery led to hearings focused on the pharmaceutical industry led by U.S. Senator Estes Kefauver, Chairman of the Senate Antitrust and Monopoly Subcommittee, from 1959 to 1963. Kefauver correctly identified that the pharmaceutical industry was making enormous profits on the new generation of antibiotics. Disclosures of price markups of thousands of percents led to sensational headlines across the country and to widespread public outrage. He identified a number of other problems in the industry, notably the lack of any requirement for systematic testing for the safety and efficacy of new drugs and the industry's freedom to advertise new drugs with the flimsiest of scientific support for their claims.

Kefauver drafted a law to increase regulation of the industry. The report included requirements for demonstration of safety and efficacy and for compulsory licensing of patents three years after product launch. His colleague, U.S. Representative Oren Harris, introduced companion legislation in the U.S. House of Representatives, and the combined bill became known as the Kefauver-Harris Amendments to the Antitrust Act. Hearings went on for seven months, in the face of strong opposition from the Pharmaceutical Manufacturers Association and the American Medical Association, and the legislation may well have died were it not for the thalidomide catastrophe, which demonstrated the critical need for a much more rigorous review of new drugs. The Kefauver-Harris Amendment passed, though without the compulsory licensing provision. And while it started the process of FDA reform, no action was taken at that time to control pricing.

The only substantive action the United States has taken to control drug prices has been the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act. This legislation greatly facilitated the development of a vigorous generic drug industry. Companies received an exemption—the Section 271(e) research exemption of the patent laws—allowing them to make and use (but not to sell) a drug during its period of patent protection, for purposes of developing data to prove that a new version of the drug was equivalent to the patented version. The company could then file an Abbreviated New Drug Application (ANDA) with the FDA and be ready to put its generic version of the drug on sale as soon as patents expired. Absent this research exemption, a drug company would enjoy a de facto year or two of additional exclusivity, since generic producers would not be able to make and use the drug for testing until the patent had actually expired.

Despite these legislative changes, drug prices remain a major issue in the United States. The problem was exacerbated when the products of the biotechnology industry were introduced in the mid-1980s. These had substantially higher production costs than those of traditional (small-molecule or simple chemical) drugs, resulting in prices of thousands of dollars per year per patient, an order of magnitude higher

than traditional drugs, already perceived to be high priced. More recently, *orphan drugs* such as Genzyme's Ceredase® for Gaucher's disease and some cancer treatments are even more costly, costing as much as US$300,000 per patient per year.

A combination of third-party payers for the insured and compassionate-access programs for the uninsured has allowed the generally high-priced drug market to persist in the United States. In Canada, Europe, and Japan, however, a combination of single purchaser systems and legislative activities have led to lower prices than those in the United States, although prices for drugs in these countries are still well above the costs of production. The opportunity for American citizens to purchase the same patented drugs in Canada or online at low cost has aggravated the concern of patients over high drug prices in the United States. This has made an impression on the Congress and local government officials.

3. THE DEVELOPING WORLD AND TWO-TIER PRICING

In the developing world, situations have varied widely. Countries such as India, Argentina, and Brazil encouraged the development of the generic-drug industry by recognizing only pharmaceutical process patents. Thus, drugs whose composition of matter was patent-protected in the United States and Europe could legally be produced in these countries by a company that could develop a novel production process. However, countries without their own generic-drug industries could afford only to import drugs whose patents had expired and were subject to generic competition.

The second issue for developing countries is that the diseases that afflict them tend to be very different from those that afflict the developed world, although more recently it has become apparent that the "*diseases of the poor are not the only diseases of the poor*."[8] While Western drug companies have set out to discover and develop drugs to treat the diseases of the developed world, through which they are able to earn an attractive return, these companies have, for the most part, ignored tropical diseases. One study showed that of the 1,339 new drugs introduced between 1975 and 1999, only 13 addressed tropical diseases, and only three addressed tuberculosis, which still takes an enormous human toll in the developing world. A later study identified that even these 13 drugs were poorly suited to the needs of the developing world.[9]

Fortunately, serendipity has sometimes worked to help the developing world. For instance in the early 1980s, the animal health division of Merck (now Merial, Inc.) developed an antiparasitic called ivermectin (Ivomec Plus Cattle Injection®), to treat gastrointestinal roundworms, lungworms, sucking lice, mange mites, cattle grubs, and adult liver flukes in cattle. Ivermectin also had a large market for use in treating lungworm infection in dogs and cats. In addition, the drug was found to effectively treat two human parasitic diseases in sub-Saharan Africa:

- Onchocerciasis, commonly known as river blindness, is a nematode infection transmitted through the bite of black flies. The disease causes intense itching, disfiguring dermatitis, eye lesions, and, over time, blindness.
- Lymphatic filariasis, commonly referred to as elephantiasis, coexists with river blindness in a number of African countries and also occurs in a small number of Latin American countries.

Merck developed ivermectin under the tradename Mectizan® for registration to treat humans for these conditions, but it was the UNICEF-UNDP-World Bank-WHO[10] Special Programme for Research and Training in Tropical Diseases that subsequently conducted the extensive trials needed to establish the safety of mass administered Mectizan® for eradication or control purposes. Merck then created a donation program that has donated enough Mectizan® to treat over 40 million patients a year since 1987.

GlaxoSmithKline (GSK) donates a treatment for parasitic worms, albendazole, which is co-administered with Mectizan®.[11] These

programs have had a major impact on rates of infection for these diseases.

4. AIDS

4.1. *AIDS in the developed world*

The uneasy status quo in the pharmaceutical industry fell apart with the AIDS crisis and the political activism that emerged from it. The crisis created a demand for access to effective, new drugs.

The response to the emergence of HIV/AIDS represents a triumph for basic scientific research in the U.S. and Europe, largely funded by government, and its integration with the pharmaceutical and biotechnology industries. While it now appears that the first person to die of AIDS was an inhabitant of the Democratic Republic of the Congo who died in 1959[12] and that the HIV virus was slowly spreading and infecting people during the 1970s, (a U.S. teen who died in 1969 and a Norwegian sailor who died around 1976 have also subsequently been shown to have been infected with HIV[13]) it was not until 1981 that physicians in San Francisco and New York started noticing an unusual incidence of a rare cancer, Karposi's sarcoma, and of a rare form of pneumonia, *pneumocystis carinii pneumonia*, or PCP, in the gay community. It was only then that it became clear that a new disease was emerging.[14]

Although a new Republican administration took office in early 1981 that was unsympathetic to the gay community, investigators at the U.S. National Institutes of Health (NIH) quickly realized the risk posed by HIV. Scientists at NIH recognized the virus' unique ability to infect and destroy the human immune system. As a result, NIH quickly devoted substantial resources to fighting HIV and, together with the Centers for Disease Control and Prevention (CDC), included funds for investigating its epidemiology in Africa. Progress in fighting the disease was rapid:

- In 1983, Luc Montagnier of the Pasteur Institute in Paris identified a putative infectious agent, which he called lymphadenopathy-associated virus or LAV.
- In 1984, Robert Gallo of the National Cancer Institute in Washington, D.C., confirmed that LAV and a virus he had identified and called human T-cell lymphotropic virus III or HTLV-III were identical and that it was the etiologic agent of AIDS.[15]
- In 1985, a diagnostic test was developed, licensed, and put into routine use for screening blood donations.
- In 1987, Retrovir (AZT), the first drug that was effective against HIV, received FDA approval.
- In 1992, a second antiretroviral drug, Hivid (ddC, discovered by NIH scientists and marketed by Roche), was approved and combination therapy was started.
- In 1996, Invirase (saquinavir; marketed by Roche) the first drug of a second class of drugs, the protease inhibitors, was approved and "triple therapy" was launched.

With triple therapy, HIV infection was transformed from a delayed death sentence, to the extent that opportunistic infections or Kaposi's sarcoma could be treated, into a chronic condition whose victims could enjoy a reasonable quality of life for longer and longer periods as the drug regimen improved. HIV was only the second viral disease for which an effective treatment (as opposed to a prophylactic vaccine) had been discovered, the first having been the use of Acyclovir to treat herpes simplex in 1982.

4.2. *The impact of AIDS on the developing world*

The incidence and impact of AIDS in the developing world, particularly sub-Saharan Africa, dwarfs anything seen in the developed world. In some countries today, a third or more of the adult population is infected with HIV. While prevalence in some Asian countries remains low, the sheer size of the population of India or China means that there are an enormous number of infected people in these countries, official denials notwithstanding.

As AIDS began to be well-controlled in developed countries thanks to highly active antiretroviral therapy (the "triple cocktail" or HAART) in the mid- to late-1990s, the developing world started to demand the same access to these life-

saving medications. But there was a critical difference between AIDS and other diseases. There simply were no older, patent-expired drugs available from generic manufacturers to provide to the developing world. The disease was new, and the drugs to treat it even newer, so the drugs were all still under patent protection and would be for years to come. AZT's patent would be the first to expire, in 2005.

Brazil invoked public-health-crisis measures included in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which allowed it to override international patents and make AIDS drugs in its state-owned pharmaceutical factories and make them available to HIV-infected Brazilians under a free-drug program. Between 1997 and 2002, the cost of treating an AIDS patient in Brazil fell from US$6,500 to US$1,500 per year,[16] and the number of deaths from AIDS was reduced to half.

Conditions in Africa were desperate. There was no capacity to do what Brazil had done, and the cost of importing AIDS drugs at developed-world prices, at an annual per patient cost that was many multiples of average per capita GDP, meant very few people were able to receive treatment. In 2001, 25 million people in Africa were infected with HIV, but only 25,000—just 0.1% of the infected population—were receiving HAART.[17]

In December 1997, the Mandela government passed amendments to the South African Medicines Act to break patents and to allow the manufacture or importation of generic versions. In 1999, the World Health Organization (WHO) raised the issue of patents in the pricing of AIDS medications in developing countries.

In response, six major pharmaceutical companies—Merck, Bristol-Myers, GSK, Pfizer,[18] and Boehringer-Ingelheim—approached WHO in 2000 with an offer to lower prices on AIDS drugs in Africa. The initiative was called Accelerating Access. In return, the companies asked that WHO help distribute the drugs. Discussions began and progressed slowly. Individual companies started various philanthropic initiatives, primarily focused on education, research, and community outreach, but critics were not assuaged and continued to demand lower prices for drugs.

A year after the launch of the initiative, only three countries—Senegal, Uganda, and Rwanda—had reached specific agreements with WHO. Antiretroviral therapy cost US$1,000 to US$1,500 per patient per year through this initiative, which is around 10% of U.S. prices. Then Medecins Sans Frontiéres (MSF) entered the debate. Everything changed in February 2001, when the Indian generics manufacturer Cipla offered to supply MSF with triple cocktail pills for US$350 per patient. Cipla offered to supply African governments with the pills for US$600 per patient per year, US$400 below the Accelerating Access price. Cipla's initiative demonstrated that most pharmaceutical companies only applied for patents in South Africa. Only GSK, Boehringer-Ingelheim, and Agouron tended to apply for patents throughout Africa.

In 2001, 39 pharmaceutical companies filed suit against the South African government to enforce their IP rights and prevent Medecins Sans Frontiéres from buying Cipla's products.

4.3 *Yale University and Zerit*

A pivotal catalyst for change was Amy Kapczynski, a first-year student at Yale Law School in early 2001.

A seemingly innocuous decision made at Yale in 1987—one that most academic institutions would make without hesitation even today without thinking twice about it—backfired and became a major issue in the debate about global health and fair access to medicines. Yale's fateful decision was to allow the licensee of one of their drugs to decide in which countries to apply for patent protection.

The story began in the early 1960s at the Detroit Institute of Cancer Research (now the Barbara Ann Karmanos Cancer Institute), where Jerome Horowitz, working on the then-prevalent theory that cancer was caused by viruses, synthesized a number of compounds that would inhibit DNA replication in the expectation that they would be effective against cancer. Some of the compounds Horowitz synthesized included:

- AZT
- ddC
- ddI
- d4T

The theory was incorrect for the overwhelming majority of types of cancer, so the compounds were not effective and were shelved.

When the HIV epidemic emerged, Horowitz' work resurfaced. Several of his compounds were evaluated against HIV and found to be effective. AZT (Burroughs Wellcome), ddC and ddI (both discovered by the NIH) were all discovered by evaluating the efficacy of Horowitz compounds against HIV

Tai-Shun Lin and William Prusoff of Yale University worked with another Horowitz compound, d4T (stavudine), with funding from NIH and Bristol-Myers Squibb (BMS), to evaluate d4T's effectiveness against HIV. BMS received an exclusive option to exclusive license to any patents that emerged from the work. Prusoff and Lin found d4T to be effective, and Yale filed for a method-of-treating patent on December 17, 1986 (U.S. patent No. 4,978,655 was eventually issued on December 18, 1990). Bristol-Myers Squibb exercised its option and signed a license January 12, 1988. As is normal in academic licenses, Yale gave BMS the right to file in foreign countries, with Yale identified as the assignee, and the company filed corresponding applications in major western countries, such as Europe, Japan, and Canada. Critically, the company decided to include South Africa, Mexico, and Egypt in its filings.

BMS commenced clinical development of stavudine and received FDA approval on June 24, 1994. The product was trademarked Zerit®. In 2001, 13 years after the license had been signed, the South African patent made Zerit too expensive for most South African AIDS patients, particularly those living in the poorest areas (typically the townships). Because South Africa is the commercial gateway to Sub-Saharan Africa, Zerit was similarly unavailable everywhere else on the continent.

Zerit was on the list of essential medicines compiled by Toby Kasper, the head of the Access to Essential Medicines Program for MSF. He had met Amy Kapczynski at an AIDS conference in Durban in July 2000 and immediately realized that Amy could help put pressure on Yale for a better license deal from within.[19] Kapczynski's first recruit to this cause was possibly one of the most embarrassing to Yale—William Prusoff, the inventor of Zerit. Then Kaczynski turned to Michael Merson, Dean of Yale's School of Public Health, who formerly headed the AIDS program of WHO.

On February 14, 2001, MSF wrote to Yale and asked if it "*would consider the importation of generic versions of stavudine for use in providing treatment free of charge to people with HIV/AIDS unable to afford treatment an infringement of your intellectual property rights*," and if not, if Yale would "*issue a voluntary license to allow the importation and use of generic stavudine in South Africa*."

On February 28, 2001: Yale replied, denying the request on legal grounds, because it had granted an exclusive license to BMS. Kapczynski then put reporters at the *Yale Daily News* on the trail of the story. The student paper published its first story on the subject on March 2, 2001, which served to mobilize opinion on campus. A group of students in the graduate student union—which had already been campaigning against Yale's relationship with corporate sponsors—circulated a petition calling on the school to ease its patent. The group collected 600 signatures from students, professors, and researchers on campus. The students also assailed Yale for its close ties with BMS—the company had donated US$250,000 to the school in 1999. Kapczynski carried out legal research on campus and tried, unsuccessfully, to get a copy of the license agreement. She provided the information she discovered to MSF.

On March 9, 2001, MSF responded to Yale suggesting that Yale's own policy stated that a key objective of their technology transfer program was intended to be "*the benefit of society in general*" and pointing out that d4T was not reaching those who needed it in South Africa. Finally, MSF also suggested that Yale had the ultimate power over their patent and could breach their contract with BMS if need be.

Two days later, *The New York Times* ran a story "Yale Pressed to Help Cut Drug Costs in Africa." The impact was almost immediate. On March 14, 2001, BMS issued a statement that

"*The Company will ensure that its patents do not prevent inexpensive HIV/AIDS therapy in Africa. The patent for Zerit, rights to which are owned by Yale University and Bristol-Myers Squibb, will be made available at no cost to treat AIDS in South Africa under an agreement the Company has recently concluded with Yale*." In June 2001 Bristol-Myers signed an "*agreement not to sue*" with Aspen Pharmacare, South Africa's leading generic manufacturer.

So, in less than two years, the world pharmaceutical paradigm had been turned upside down. "Two tier" pricing, whereby drugs could in the future be sold at generic prices in developing countries during the period of patent protected exclusivity had been established. There is some evidence that the pharmaceutical industry, or at least its vaccine sector, has started to accept the concept of tiered or segmented pricing according to ability to pay.[20]

5. THE APPROPRIATE LICENSING APPROACH?

The Yale lesson discussed above shows that every license to a drug or vaccine candidate with the remotest potential for treating developing world needs must include fair-access licensing provisions from the outset. This is because after the license is executed, the university cedes to the licensee control of both the development strategy and the patenting strategy.[21]

The objectives of a licensing program for drugs with the potential to treat developing country diseases should be:

- to maximize the possibilities that the drug will be developed
- to structure the arrangements so that tiered pricing will result, with the poorest countries having access to drugs at the lowest prices

An excellent review of potential licensing approaches and structures was published by the open-access online journal *Innovation Strategy Today* in a special issue jointly published with the American Association for the Advancement of Science.[22] However, the article does not propose any model languages or standard approaches.

Others, however, have put forward such suggestions. With its considerable experience in both developing and licensing neglected disease treatments,[23] the NIH has developed a set of white-knight-model licensing provisions (see Box 1).

A set of provisions has also been developed at Boston University (BU) (see Box 2). They are meant for use as a starting point to discuss products that have markets in both the developed and the developing world. The provisions utilize a nonassert approach to manufacture for sale in developing countries.

If the products envisioned by a partnership would only have relevance in the developing world, then the role of IP protection may only be to provide an incentive for a developing country manufacturer to obtain a license to develop the product, and a second source approach may provide sufficient safeguards. BU's model provisions for these approaches are given in Boxes 2 and 3.

These licensing principles remain valid, even though traditional one-to-one licensing models are not adequate for the complex networks that have evolved over the past five to seven years and have transformed the prospects for effective and affordable therapies for the developing world. The emergence of drug development public-private-partnerships (PPPs), which have secured large amounts of philanthropic funding from the Bill and Melinda Gates Foundation, The Rockefeller Foundation, and so forth, have transformed drug development for neglected diseases:[24]

- Large companies have been motivated to contribute their drug-discovery skills and resources because they are secure in the knowledge that others would be responsible for funding late-stage clinical development.
- Small companies have secured funding to develop technologies with dual-market uses, with the PPPs securing license rights for developing countries at zero or low royalty rates, and the small company retaining rights for use in developed countries.

- Academic institutions have had a new channel to advance their neglected disease discoveries.
- Developing country pharmaceutical companies have found their production and distribution skills in demand.

In addition, the PPPs have had the financial clout to insist on affordability conditions as part of the transactions they have negotiated.

6. LICENSE TERMS FOR DEVELOPING COUNTRY MARKETS

As has been discussed in many forums, it is possible to obtain copies of a substantial number of license agreements from public filings with the Securities and Exchange Commission (SEC).[25] However, only development-stage companies that are publicly traded, or that have filed registration statements to become publicly traded, need to make such filings, and only for material agreements—those affecting 10% of company sales or 5% of company assets.

These restrictions mean that the transactions discussed here are unavailable from SEC sources; the examples that follow are all based on voluntary disclosures. Because the underlying agreements are unavailable and because the examples are based on third-party accounts, these third-party accounts are reported here generally verbatim from the cited sources (sections 6.2 through 6.12 of this chapter).

In the course of researching this article, the author was surprised at the lack of transparency in what was expected to be the most transparent sector of licensing. PPPs, companies, and academic institutions that were approached to discuss transactions they had publicly announced having entered into all expressed an unwillingness to reveal details, even when it was made clear that the information would be used to create a guide for others.

Box 1: National Institutes of Health: Excerpts of White Knight Provisions

Within six (6) months of New Drug Application/Biologic License Application approval in the United States or its equivalent in Europe, Licensee shall send a written report to the Public Health Service detailing the potential Public Sector market to fulfill the public health need for the approved drug or vaccine in Developing Countries, including the impact of any approved competing drug or vaccine. The report shall also include Licensee's proposed amendment to the Commercial Development Plan, Appendix E [not included here], and the Benchmarks and Performance, Appendix D [not included here] to address the needs for Licensed Products in Developing Countries. Licensee will diligently consider if it is possible from a commercial and technical point of view, to satisfy said potential Public Sector market, either directly with Licensee's own resources and/or through joint ventures with third parties. Acceptance of this report and amendment is required by PHS in writing; such acceptance will not be unreasonably denied.

"Public Sector" means the government of a Developing Country, or any entity empowered by the government of a Developing Country to act for said government in matters applicable to this Agreement, organizations within the United Nations system including the World Health Global Organization and UNICEF, and other nonprofit agencies which may purchase drugs or vaccines for delivery, manufacture and/or sale in Developing Countries.

"Developing Country" means countries eligible for support from the Global Fund for Children's Vaccines (GAVI) or successor organization, which at the effective date of this Agreement are those countries with a Gross National Product of less than US$1,000 per capita per year, and at the effective date of this Agreement include the countries listed in Appendix G [not included here].

Source: Stephen Ferguson, NIH, personal communication.

Box 2: Boston University's Nonassert Approach

1. Include in the "WHEREAS" clauses:

WHEREAS, University and Licensee acknowledge that it may serve the public good to make certain drugs available at affordable prices to Non-Market Countries in certain circumstances, with appropriate safeguards to Licensee's economic interests in other markets.

2. Include in the "Definitions":

Market Countries shall mean:

(a) All current and future member countries of the Organisation for Economic Cooperation and Development (OECD), presently consisting of Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States; and

(b) All current and future members of the European Union; and

(c) Russian Federation, Republic of China (Chinese Taipei), Korea, Malaysia and Singapore.

Amend the definition of ***Net Sales*** to exclude sales of products made pursuant to the Non-Suit provision of Section [XX; not given here] from the calculation of Net Sales

Non-Market Countries shall mean all countries other than Market Countries.

Public Sector shall include:

(a) The sovereign government of a country;

(b) Agencies of the United Nations, the World Health Organization, and the World Bank;

(c) Organizations which are members of the International Committee of the Red Cross and Red Crescent;

(d) International charitable agencies (also known as Non-Governmental Organizations or NGOs), including but not limited to Oxfam, Medecins Sans Frontiéres, and so forth;

(e) Organizations substantially supported by philanthropic organizations including but not limited to the Bill and Melinda Gates Foundation, the Rockefeller Foundation, and so forth, specifically including global product development and distribution public-private partnerships.

Trade Dress shall mean the physical appearance of Product as sold in any Market Country by Licensee, including but not limited to such characteristics as shape, color, flavor, tradename, trademark, service mark, etc.

3. Include in the "Grant" clauses:

Non-suit: University and Licensee on behalf of themselves and any successors-in-interest to the Intellectual Property covenant that they will not, before or after the date of this Agreement, assert any claim of infringement (including direct infringement, contributory infringement, and inducing infringement) of the Intellectual Property against any person or entity that sells or offers to sell the Licensed Product to Public Sector entities for use in Non-Market countries, or any entity that manufactures or otherwise makes the Licensed Product for sale to Public Sector entities for use in Non-Market countries, or any person or entity that uses the Licensed Product in a Non-Market country, to the extent such claims relate to or arise out of such manufacture, sale or offer to sell.

Notwithstanding any other provision herein, this non-suit provision shall not apply to Products that bear any element of the Trade Dress used by Licensee in any of the Market Countries, or to Products that have not gained regulatory approval from either the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA) or been pre-qualified by the World Health Organization pre-qualification scheme.

6.1 *Compulsory licensing models*

Several approaches to establishing fair license terms (and, as will be discussed in Section 6.2 below licensing structures themselves) for developing country markets have looked to compulsory licensing principles for guidance. Such approaches, authorized under the TRIPS Agreement, talk about "adequate remuneration" to the patent holder but without offering specific guidelines.[26] A comprehensive review of the issues of compensation in compulsory licensing has been undertaken by Scherer.[27]

For much of the 1970s and 1980s, Canada had an extensive compulsory pharmaceutical licensing policy. In general, Canada required the recipient of a compulsory license to pay the patent holder a 4% royalty on the *licensee's* sales price. After the Doha Round of WTO, Canada was the first country to implement the TRIPS compulsory licensing principles to supply countries that could not produce drugs for their own use. Canada has continued to use a 4% royalty rate, adjusted for the gross domestic product (GDP) of the country, so that in the poorest countries, a royalty rate of 0.2% would apply.[28, 29]

6.2 *Equitable access license*

Universities Allied for Essential Medicines, which grew out of Amy Kapczynski 's student colleagues (see section 4.3 above), has endorsed an Equitable Access and Neglected Disease License[30] (EAL) created by a working group at Yale. The EAL proposes a US$50,000 fee plus a 5% royalty for licenses to sell in countries defined by the World Bank as "middle-income countries" and a US$5,000 fee and a 2% royalty on sales in the World Bank's "low-income countries. These fees would be split 50:50 with the primary licensee. However, the license terms require the licensee to share with the university all of the know-how necessary to make, use, and sell the licensed products in developing countries, so that the university can, in turn, transfer that know-how to the developing country licensees. The developing country licensees will, likewise, share any know-how they develop with the university. Universities Allied for Essential Medicines formalized this approach as the Philadelphia Consensus Statement at their annual meeting in Philadelphia in October 2006 and provided a mechanism for individuals and organizations to sign on.

The structure the EAL would establish provides the ideal mechanism for providing low-cost drugs to developing countries, but it is a utopian standard that will likely create a strong disincentive to large companies to take out licenses to develop academic technologies. A 1% or 2.5% royalty on sales in developing countries in which the target per patient cost is in cents rather than dollars is unlikely to provide a sufficient incentive for them to provide all of their production know-how to the licensing university. Spinouts are probably equally likely to resist these terms because of their potential to scare away potential downstream partners. In addition, the EAL would put a considerable administrative burden on the university's technology transfer office managing these various flows of confidential know-how. The EAL would therefore likely violate the first of Hippocrates' maxims as applied to academic licensing: First Do No Harm.

As of this writing (February 2007), a significant number of individuals and not-for-profits operating in the global health arena have signed on to the Philadelphia Consensus Statement. Noticeably, no universities have signed on as

Box 3: Boston University Second Source Approach

1. Include in the "Grant" clauses:

Second Source: University may, at any time after the first anniversary of Licensee's receipt of the first regulatory approval to sell Licensed Products, start to qualify a supplier for up to one third of annual requirements of Licensed Products.

corporate entities, and only one person with current, and one person with prior executive authority for academic licensing were listed as initial signatories.

6.3 *Global Alliance for TB Drug Development—Chiron*

In one of the first drug development deals between a drugmaker and a nonprofit organization, the Global Alliance for TB Drug Development announced that it had licensed PA-824, a compound effective against *M. tuberculosis*, from Chiron Corp.[31] PA-824 was discovered and protected by PathoGenesis Inc., which was subsequently acquired by Chiron. Chiron has provided a worldwide exclusive license to the TB Alliance for PA-824 and all its analogs, in return for a modest, one-time licensing fee (modest, that is, compared to the industry average of US$1 million to US$3 million)[32] and yearly threshold R&D investments by the alliance to ensure rapid progress. All preclinical R&D on PA-824 is subcontracted to commercial clinical research organizations (CROs; paid by the TB Alliance), and project management (paid by the NIH) is conducted by the Research Triangle Institute, a not-for-profit that conducts contract research for the NIH and others. If and when development is successful, Chiron has the option of buying back the OECD rights by reimbursing the TB alliance for all development costs. The TB alliance would retain rights in all developing country markets. The deal includes "an expansive commitment" to affordable pricing. The agreement has a grant-back clause that allows Chiron to reenter the TB drug development process, within a specific time period, in wealthy countries. The deal also includes manufacturing options for the company.

Though it has not proceeded beyond the laboratory, the compound, called PA-824, has been shown to be effective against drug-resistant strains of *M. tuberculosis* in tests carried out in vitro. Researchers believe PA-824 may be powerful enough to considerably shorten the current short-course-treatment time of six months, which would enable more people to complete treatment.

6.4 *Institute for OneWorld Health—Celera Genomics*

The Institute for OneWorld Health (iOWH) is a not-for-profit drug company founded by Victoria Hale, a former employee of Genentech and winner of a McArthur Foundation Genius Award in 2006. The company sources drug candidates for the treatment of diseases in developing countries from universities and drug companies and then seeks philanthropic donations to fund clinical development.

In 2002, iOWH licensed Celera Genomics' CRA-3316 as a potential new treatment for Chagas' disease. CRA-3316, formerly known as APC-3116, is a cysteine protease inhibitor. Development has been started in collaboration with NIH.[33] Celera licensed CRA 3316 to iOWH royalty free because, according to Wayne Montgomery, who heads intellectual property at Celera, "*the drug would have gathered dust otherwise*."[34]

6.5 *Institute for OneWorld Health—University of California Berkeley—Amyris Biotechnologies*[35]

In December 2004, the Bill and Melinda Gates Foundation awarded a five-year product development grant to iOWH to create a three-way partnership between iOWH, a university (University of California, Berkeley), and a for-profit company (Amyris Biotechnologies, Inc.). Using synthetic biology, industrial fermentation, and chemical synthesis, the goal of this project is to significantly reduce the cost of artemisinin, a key precursor in the production of artemisinin combination therapies (ACT) for malaria. Artemisinin is chemically converted to one of several derivatives that are then combined with other drugs to make an ACT.

Artemisinin is currently extracted from wormwood plant, which is supplied by farmers in Vietnam and China (and more recently from Africa). Seasonality and availability of the plant contribute to the drug's high price. The project, funded by the Gates foundation, hopes to eliminate the need for plant extraction by utilizing a platform technology of "synthetic biology" developed by Jay Keasling at UC Berkeley. The

goal is to lower the cost of artemisinin-containing drugs ten-fold by producing a consistent, reliable, high-quality supply of artemisinin in microbes.

The US$42.6 million grant was divided among the three parties: US$8 million to UC Berkeley for continued basic research; US$12 million to Amyris for applied research on the fermentation and chemical processes; and US$22.6 million to iOWH to perform the required regulatory work and lead the implementation of the product development strategy for the developing world. UC Berkeley's role focuses on the engineering of drug-precursor-producing microbe. Amyris's efforts span the engineering of the production microbe to optimizing the semi-synthesis of the drug through fermentation and novel downstream synthetic chemistry. The role of iOWHs includes developing a commercialization strategy based on a thorough understanding of worldwide regulatory requirements and an analysis of the current ACT manufacturing supply-chain and distribution models. This one grant enables activities in all three areas of development. It creates an integrated team of partners, each applying its expertise to streamline translation from bench to bedside. The financial terms of the partnership are as follows:

License Grant(s)

- The arrangement is governed by a three-party collaboration agreement and two license agreements (from UC Berkeley to each of Amyris and iOWH).
- UC Berkeley granted iOWH a royalty-free license for the manufacture of artemisinin-based malaria treatments used in the developing world. UC Berkeley further shall grant royalty-free licenses to iOWH for intellectual property developed under the three-party collaboration agreement for use in manufacturing artemisinin-based malaria treatments used in the developing world, and iOWH is to establish partnerships for ACT manufacture and distribution.
- UC Berkeley granted Amyris licenses to develop the manufacturing process for the developing world malaria market. Amyris also has licenses for the developed world malaria market, nonmalaria indications of artemisinin, and alternative uses of the platform worldwide. UC Berkeley further shall grant similar licenses to Amyris for intellectual property developed under the three-part collaboration agreement.
- Amyris shall grant iOWH a royalty-free license for intellectual property developed under the three-part collaboration agreement for the manufacture of artemisinin-based malaria treatments used in the developing world.

Royalties

- The license from UC Berkeley to iOWH is royalty free.
- The license from UC Berkeley to Amyris is royalty free for the developing world malaria market (development for iOWH), and royalty bearing for the developed world and nonmalaria indications in the developing world.

Patents

- Patent costs for UC Berkeley's preexisting patents are shared between iOWH and Amyris.
- UC Berkeley patents on intellectual property arising from the collaborative research may be filed by UC Berkeley and licensed to iOWH and/or Amyris under the prearranged terms mentioned above. Costs are shared by the licensee on a pro rata basis. UC Berkeley has no obligation to file an application if it does not have a commitment by a licensee to pay patent costs.
- Patents that are the sole property of Amyris and/or iOWH may be filed by Amyris and/or iOWH as the case may be, at their own expense.
- Logistics of filing and payment of costs on jointly owned intellectual property will be negotiated in good faith by the joint owners when such joint intellectual property arises. If the joint owners cannot agree, and if iOWH has an ownership interest in a joint property, then iOWH may file and prosecute on behalf of the owners at its own expense.

6.6 *Aeras Global TB Vaccine Foundation—Vanderbilt University*[36]

On May 4, 2006, Aeras and Vanderbilt University announced an exclusive license agreement for a TB vaccine based on technology developed at Vanderbilt. The technology enhances the ability of the Bacille Calmette-Guérin (BCG) vaccine to trigger immune-system responses. Under the agreement, Aeras will use the technology to modify the BCG vaccine and will guide the new vaccine through clinical trials. The license agreement grants Aeras exclusive rights for developing a TB vaccine. If a successful vaccine results from the use of this technology, then Aeras will manufacture the new vaccine at its facility in Rockville, Maryland. Vanderbilt retains rights to the technology as a delivery system for other uses. This could potentially include new vaccines or immunotherapies against other diseases from HIV and malaria to cancer.

The Vanderbilt technology, called proapoptotic BCG, is designed to weaken the BCG bacterium. It is a version of BCG with genetic modifications designed to inhibit the bacterium's ability to stop the programmed cell death of a patient's immune cells. These modifications are likely to result in a vaccine that provides better, longer-lasting protection against TB and may prevent progression to active TB among people with compromised immune systems. The financial terms are as follows:

- Grant: Aeras obtained an exclusive license in its field of use.
- Field of Use: Aeras has an exclusive license to the TB field; Vanderbilt retains rights in other fields.
- Payments/Royalties: The license is royalty bearing (including stacking terms) along with milestone payments.
- Patents: Patent costs paid by Aeras.

6.7 *Global Alliance for TB Drug Development—Bayer Healthcare AG*[37]

Moxifloxacin is an antibiotic first approved in 1999 and currently used in 104 countries to treat certain bacterial respiratory, skin, and intraabdominal infections. It has been used by more than 47 million patients worldwide. Moxifloxacin is generally well tolerated, but treatment may result in certain usually mild side effects, including nausea, diarrhea, and dizziness. In vitro and in vivo studies have demonstrated moxifloxacin activity against *Mycobacterium tuberculosis*. Investigators at Johns Hopkins discovered that substitution of moxifloxacin for isoniazid in the reduced treatment time (two months shorter in mice) of the TB treatment regimen. The treatment regimen included rifampin, pyrazinamide, and either moxifloxacin or isoniazid.

In October 2005, the TB Alliance and Bayer Healthcare AG announced a partnership to coordinate a global clinical development program to study the potential of moxifloxacin to shorten the standard six-month treatment of TB by two to three months. The trials will evaluate whether the substitution of moxifloxacin for one of the standard TB drugs (ethambutol or isoniazid) eliminates TB infection faster than the current standard therapy. If successful and approved by the respective regulatory agencies, a new, shorter regimen could be available in the next five years.

The Phase II/III clinical trial program spans four continents and will enroll close to 2,500 patients with TB. The trials will take place in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States, and Zambia. If the trials are successful, the partnership aims to register moxifloxacin for a TB indication. Upon regulatory approval, the partnership is committed to making it affordable and accessible in developing countries where TB patients need it most.

For this project, Bayer will donate moxifloxacin for each trial site and will cover the costs of regulatory filings; the TB Alliance will coordinate and help cover the costs of the trials, seeking to leverage support from the U.S. Centers for Disease Control and Prevention (CDC), the Orphan Products Development Center of the U.S. Food and Drug Administration, and the European and Developing Countries Clinical Trials Partnership. In May 2006, the TB Alliance received a US$104 million grant from the Bill and Melinda Gates Foundation. The grant will be used, in part, to fund Phase II and III trials of moxifloxacin with the goal of showing the efficacy of moxifloxacin in reducing TB treatment

times by two months by 2010. The financial terms for this development project are:

- Field of Use: Tuberculosis drugs.
- Payments/Royalties: Products will be made available in developing countries at cost, for use against tuberculosis.
- Patent strategy: Patents previously issued.

6.8 *International AIDS Vaccine Initiative—Neutralizing Antibody Consortium*

The mission of the International AIDS Vaccine Initiative (IAVI) is to ensure the development of safe, effective, accessible, preventive HIV/AIDS vaccines for use throughout the world. Central to IAVI's mission is to improve access to a vaccine for the developing world,[38] which requires speed of development, as well as availability and affordable pricing. IAVI uses a large portion of its resources to conduct R&D to design, manufacture, and test promising HIV/AIDS vaccine candidates.

In July 2002, IAVI announced the formation of the Neutralizing Antibody Consortium (NAC), a five-year, multimillion dollar research program to develop a preventative HIV/AIDS vaccine that fills a critical gap not addressed by most HIV/AIDS vaccines undergoing clinical trials. The original NAC consisted of four founding institutions. Today, the NAC includes an international group of 15 laboratories, funded by IAVI, representing academia, government, and not-for-profit research organizations. The financial terms for the NAC are:

- IAVI funds individual research work plans for NAC principal scientists; in some cases restricted grant monies are used for selected research projects. These carry special compliance terms that apply specifically to that project.
- IAVI manages intellectual property on behalf of the NAC. IAVI rights include:
  - option for exclusive license to program intellectual property in the field
  - option for nonexclusive license to background intellectual property
- IAVI pays for certain patent costs related to program inventions and background inventions.
- Predetermined sharing of revenues among all collaborators.
- Other provisions include diligence, governance, publications, patent management, and process for adding new members.

6.9 *Medicines for Malaria Venture (MMV)—GlaxoSmithKline (GSK)*

At the 2003, World Economic Forum's Africa Economic Summit in Durban, South Africa, Medicines for Malaria Venture (MMV) and GSK announced a joint portfolio of projects:

- Fab I—Fatty acid biosynthesis I
- Falcipains—Cysteine protease inhibition
- 4(1H)-pyridones—backups
- PDF—Peptide deformylase inhibitor [terminated in March 2005]

The main objective is to subsidize the socio-economic and public health benefit for the developing world. Any successful medicines discovered as a result of this initiative will be made available in endemic areas on a not-for-profit basis. Research work will take place at the GSK drug discovery unit in Tres Cantos, Spain, which GSK has dedicated to research on diseases of the developing world. The center has a team of 50 permanent staff with particular expertise in drug discovery. The Tres Cantos Center is fully integrated into the GSK R&D organization, which provides expertise and infrastructure for all aspects of drug discovery and development. GSK will contribute funding, staff with drug discovery expertise in malaria, and state-of-the-art facilities. MMV contributes funding for malaria drug discovery projects by subsidizing the employment of additional scientists to join the existing staff at Tres Cantos and expertise from its expert scientific advisory committee (ESAC).

6.10 *Harvard University—Medicine in Need*

In November 2006, Harvard announced that it would license a new aerosolized tuberculosis vaccine invented by Professor David Edwards to Medicine in Need (MEND), a Cambridge nonprofit founded by the inventor.[39] Sales to developing countries will be royalty free, while sales to developed countries will be royalty bearing,

but Harvard will return a large proportion of the royalties back to MEND. Edward's work was funded by a US$7.6 million grant from the Bill and Melinda Gates Foundation, which stipulated as part of the grant that Harvard would have to license the technology to MEND and that Harvard could not take royalties from MEND's sales to the developing world. The Gates Foundation has also used this strategy in its Grand Challenge Grants.

6.11 *Coley Pharmaceutical Group, Inc.—Gates Foundation*

Coley Pharmaceuticals Group, a publicly traded biotechnology company based in Wellesley, Massachusetts, has agreed to license VaxImmune to the Bill and Melinda Gates Foundation for use in conjunction with a vaccine for postinfection malaria. VaxImmune is a TLR9-agonist designed to enhance both antibody levels and potent killer T-cell immune response to infection or tumors. The agreement is a no-profit/no-loss arrangement, in which all clinical development is performed by the Institute for Tropical Diseases Research, funded by the Gates foundation, while Coley receives no royalties or other payments. Coley has partnered VaxImmune with GSK for cancer and infectious disease vaccines and with Novartis Vaccines and Diagnostics for infectious-disease applications. It will receive royalties on any commercial applications of the technology that emerge from the Gates foundation collaborations.[40]

6.12 *Unattributed transactions*

Various sources[41] quote royalty rates of no more than 3%–5% of sales for those companies that do insist on obtaining a financial return on sales of drugs to the poorest of the poor. Procurement costs for finished products are described as typically being at cost of production or cost of production plus 3%–5%, with agreements having not been reached when a margin of 15% over cost was demanded. However, what was not clear was how overhead, corporate costs, and cost of capital were allocated. At some point, there will need to be some incentive provided if private capital is to be utilized and for-profit entities are to become dependable suppliers, or alternatively the PPPs will need to provide the necessary investments for the construction of dedicated production facilities.

7. CONCLUSIONS: TOWARD APPROPRIATE VALUATION STRUCTURES

The comparisons above clearly show that the right valuation formula is to ask for the licensee(s) in developing countries to take over responsibility for future patent costs and to ask for no upfront fees, no milestone payments, and no running royalties. Any financial return to the university will be derived from opportunities in developed countries. Indeed, if a university's objective truly is to get drugs that have been discovered at rich universities in developed countries, using "other people's money," whether governmental or philanthropic, to the worlds' neediest people as cheaply as possible, then true leadership requires that those same universities not start off the process by putting their hands out and saying, "*We have to charge a royalty*."

Universities are under no obligation, under Bayh-Dole or any other law or regulation, to charge a royalty. The message communicated by asking for a royalty—even the modest rates suggested by the analysis above—would be inappropriate and inconsistent with the public mission of the university. Doing so would cost the moral high ground and weaken universities' ability to lead in this humanitarian endeavor.

Clearly, internal consensus between the research community, academic leadership, and technology transfer offices within the university is needed. The researchers who put their time and effort into developing a drug or vaccine to treat developing country diseases will certainly be happy with this approach, as Yale's experience with William Prusoff shows. The dean of the school of public health is a suitable avenue to the administration, if one is needed, as Amy Kapczynski also found at Yale. The development and public relations offices should be involved to ensure that the institution's objectives are properly portrayed and that the institution receives the appropriate recognition for its humanitarian efforts.

The technology transfer professional's negotiating skills will be called into play when negotiating for the rights and financial terms for any potential uses of the technology in developed countries and for spinout technologies. If there are none, it should be a simple negotiation, with indemnification provisions likely to be the most contentious issue. ■

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1 Novartis has decided to participate in both sectors and has recycled the name of one of its predecessor companies, Sandoz, to be the focus for this effort.

2 www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.

3 The first company to receive ANDA approval for a drug receives six months of coexclusivity after patent expiration with the patent holder. Prices come down fairly rapidly with this first entrant, but typically come down substantially further after six months when other companies can launch their own generic versions of the drug.

4 For example, Mylan, Teva, Watson, and Barr Labs.

5 Pearson M. 1969. *The Million Dollar Bugs*. Hudson Press: New York.

6 Lax E. 2004. *The Mold in Dr. Florey's Coat : The Story of the Penicillin Miracle*. John MacRae Books: New York.

7 Ryan F. 1993. *The Forgotten Plague: How the Battle Against Tuberculosis Was Won—and Lost*. Little, Brown: Boston.

8 Frenk J. 2006. Bridging the Divide: Global Lessons from Evidence-Based Health Policy in Mexico. *Lancet* 368: 954–61.

9 Moran M, AL Ropars, J Guzman, J Diaz and C Garrison. 2005. The New Landscape of Neglected Disease Drug Development. *London School of Economics and The Wellcome Trust*. September 2005. www.thegeorgeinstitute.org/shadomx/apps/fms/fmsdownload.cfm?file_uuid=8103EC91-AA42-C19E-182D-A6F3A789A7DC&siteName=iih.

10 UNICEF being The United Nations Children's Fund, UNDP the United Nations Development Program, and WHO the World Health Organization.

11 www.filariajournal.com/content/5/1/11/abstract.

12 aids.about.com/od/newlydiagnosed/a/hivtimeline.htm.

13 www.avert.org/origins.htm.

14 www.avert.org/his81_86.htm.

15 profiles.nlm.nih.gov/MV/Views/Exhibit/narrative/aids.html.

16 Deshpande R. 2006. AIDS in Brazil. Ricardo Reisen de Pinho. Harvard Business School Case 9-506-062. harvardbusinessonline.hbsp.harvard.edu/b02/en/home/index.jhtml?topicSection=gen.

17 Spar D. 2002. Life, Death, and Property Rights: The Pharmaceutical Industry Faces AIDS in Africa. Nicholas Bartlett. Harvard Business School Case 9-702-049, June 13, 2002, harvardbusinessonline.hbsp.harvard.edu/b02/en/home/index.jhtml?topicSection=gen.

18 Pfizer eventually withdrew.

19 Source: archive.salon.com/news/feature/2001/05/01/aids/print.html.

20 See, for example, Meeting the Challenges of Manufacturing and Delivering Affordable Vaccines. Remarks of Jean Stéphenne, president and general manager, GlaxoSmithKline Biologics, at BioVision 2005, Lyon, France.

21 Indeed, Yale reportedly may be in for more bad press over the successor to d4T. Yale announced in June 2006 that it had licensed ed4T, a new and improved version of d4T, to Tokyo-based Oncolys BioPharma. (www.thecrimson.com/article.aspx?ref=515702). However, according to Universities Allied for Essential Medicines, the license agreement does not contain a provision ensuring that developing world HIV patients will have access to the drug.

22 Brewster AL, AR Chapman and SA Hansen. 2005. Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation. *Innovation Strategy Today* 1 (3). www.biodevelopments.org/innovation/ist3.pdf.

23 See, for example, Salicrup LA, RF Harris and ML Rohrbaugh. 2005. Partnerships in Technology Transfer: An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to Worldwide Application. *IP Strategy Today* no. 12. www.biodevelopments.org/ip/ipst12.pdf.

24 For a comprehensive account of the emergence and impact of PPPs, see *supra* note 9.

25 Stevens A. 2003. Sources of Comparable Licensing Terms. In *Technology Transfer Practice Manual,* 2nd Edition. Association of University Technology Managers, Northbrook, Ill.

26 See, for example, Article 31.

27 Scherer FM and J Watal. 2002. *Post-TRIPS Options for Access to Patented Medicines in Developing Countries. Journal of International Economic Law* 5(4):913-939,

drawing on Working Group 4 of the Commission for Macroeconomics and Health of the World Trade Organization, 2001.

28 See *supra* note 25.

29 See also Outterson K. 2005. *Nonrival Access to Pharmaceutical Knowledge*. WHO Commission on Intellectual Property Rights, Innovation, & Public Health. 3 January.

30 www.essentialmedicine.org/EAL.pdf.

31 Verbatim from Fuhrmans V. 2002. A Hard Sale: Chiron and Non-Profit Group Agree on Drug-Development Deal. *Wall Street Journal* 1 February 2002. new.tballiance.org/newscenter/view-innews.php?id=482.

32 See supra note 9.

33 www.asbmb.org/ASBMB/site.nsf/web/88F1B8F34BE6C08885256CA300618731/$FILE/ASBMB+Today0402.pdf.

34 www.forbes.com/2003/09/12/cz_zm_0910oneworld.html.

35 www.tmgh.org/case-studies-treatment-for-malaria.php.

36 www.tmgh.org/case-studies-better-tuberculosis-vaccine.php.

37 www.tmgh.org/case-studies-tuberculosis.php.

38 www.tmgh.org/case-studies-aids-vaccine.php. The members of the NAC are: The Scripps Research Institute, the University of Pennsylvania School of Medicine, Weill Medical College of Cornell University, Dana Farber Cancer Institute, Harvard Medical School, University of Wisconsin, Center d'Immunologie de Marseille, the University of Oxford, University of Minnesota, The Children's Hospital of Philadelphia, Global Vaccines, Inc., Oregon Health & Science University, and the Dale and Betty Bumpers Vaccine Research Center of the National Institute of Allergy and Infectious Diseases.

39 www.thecrimson.com/article.aspx?ref=515702.

40 Arthur Krieg, CTO, Coley Pharmaceutical Group. Personal Communication.

41 See *supra* note 8.

Open Source Licensing

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ABSTRACT

This chapter provides an introduction to open source software licensing. The chapter seeks to demystify the concept of open source so that intellectual property (IP) owners and managers can decide whether an open source approach is worth pursuing. The chapter explains the principles of free and open source software licensing and outlines the decisions that an innovator must make when deciding which strategy to use for developing a new innovation. Also explained are the differences between open source and public domain, and between the uses of the terms copyleft and academic to describe open source licenses, as well as the incentives (financial and otherwise) for open source licensing. Finally, the author identifies important considerations regarding the possibilities for open source licensing in fields other than software development, particularly biomedicine and agricultural biotechnology.

1. INTRODUCTION

Open source software has had remarkable technological and commercial success. Since the late 1990s, many people have been interested in applying the principles of open source to other fields, including biomedicine and agriculture.

The term *open source* is sometimes used very broadly to mean any approach to intellectual asset management that entails a higher level of transparency, or greater access to information, than is usual in a proprietary setting. This broad use of the term is of little value to IP managers because it is too imprecise.

In fact, the only context in which the term *open source* has a generally accepted definition is in software development.[1] This chapter uses the term in as far as possible the same sense as it is used in the software context but suggests that the underlying IP management approach could be applied in other contexts.

Conventional software development is sometimes termed *cathedral building* because it proceeds according to the hierarchical directions of one or more software architects (the word *architect* is derived from words meaning "chief builder"). Conventional software is usually protected through IP rights, as a strategy to exclude some or all prospective users of the technology.

By contrast, open source software development projects, such as those that produced Linux, Apache, and BIND, are decentralized and self-organized. Open source software development is an evolutionary process: the contributions of self-selected project participants are subjected to trial-and-error testing in diverse use environments, and the resulting information influences further development. This mode of production has been termed "the bazaar" and is also known as *collective* or *commons-based peer production*.[2]

In order for open source software development to work, would-be users and developers must be authorized to access the source code. In

Hope J. 2007. Open Source Licensing. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

the conventional "proprietary" approach to software development, source code is not freely available for two reasons: (1) source code is treated as a trade secret and (2) the original expression contained in a program's source code is subject to copyright protection. To enable open source development, therefore, the software owner must (1) refrain from keeping the source code secret and (2) grant an IP license to others so that they have the legal right to access and manipulate copyright-protected aspects of the code.

Open source licensing should not, in theory, pose any antitrust problem (at least in jurisdictions where the relevant test takes into account substantive effects on competition), because its effects are fundamentally pro-competitive.[3]

2. WHAT IS *OPEN SOURCE*?

2.1 *The open source definition (OSD)*

An open source software license is one that conforms to the latest version of the open source definition (OSD), published on the Web site of the Open Source Initiative (OSI), a nonprofit corporation established in 1998 by a small group of programmers who wanted to promote the wider adoption of open source licenses.[4] Licenses that conform to the OSD are permitted to carry a registered certification mark.

A summary of the requirements of the OSD is that in order for a software license to be open source, licensees must be free 1) to use the software for any purpose whatsoever; 2) to make copies and distribute them without paying royalties to the licensor; 3) to prepare derivative works and distribute them, also without payment of royalties; 4) to access and use the source code; and 5) to use the open source software in combination with other software, including proprietary (that is, non-open source) software.[5] An open source license may not restrict the number of products a licensee is allowed to distribute, the identity or geographic location of the recipients, or the price the licensee asks them to pay. Optionally, these same guidelines may be stipulated to apply to certain improvements or other downstream uses of the original software.

The OSD's definition could be summed up even more concisely: in open source software licensing, anyone, anywhere, and for any purpose must be allowed to copy, modify, and distribute the software (either for free or for a fee) and, therefore, must be allowed full access to the software's source code.[6]

2.2 *The free software definition (FSD)*

The OSI is not the only de facto standard-setting body in the field of free and open source software licensing. Others include the Free Software Foundation (FSF)[7] and the Debian Linux community[8].

According to the FSF's Free Software Definition (FSD), software "freedom" is the freedom to use, copy, study, modify and redistribute both modified and unmodified copies of software programs, all without having to pay for or otherwise obtain specific permission. To give practical effect to this freedom the licensor must allow users access to the software's source code.[9]

Clearly, the FSD is very similar to the OSD. There are ongoing debates about the differences between what constitutes free software and open source software, but in fact the two are virtually identical: with very few exceptions, free software conforms to the OSD, and open source software conforms to the FSD.[10]

3. THE PROCESS OF DEVELOPING A LICENSING STRATEGY

Open source licensing is just one kind of IP strategy. Figure 1 depicts the process of choosing which licensing strategies (if any) to use.

The first thing to do when formulating an appropriate strategy for exploiting new technology is to make a careful cost-benefit analysis of all the possible avenues for development.

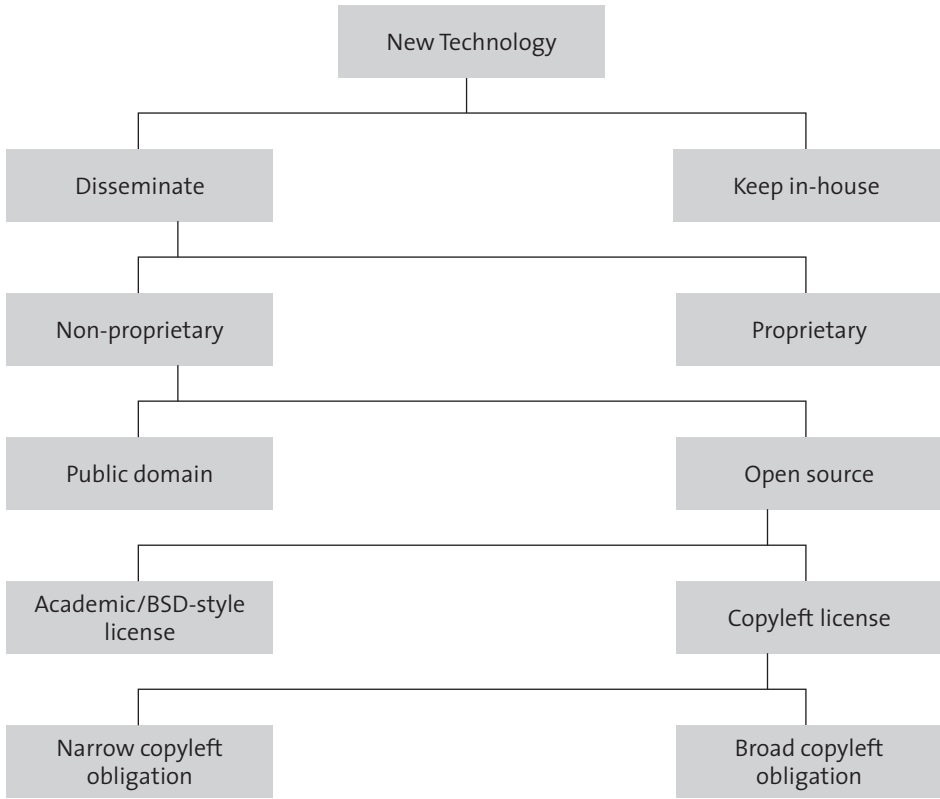
This analysis will require certain considerations:

- **The first decision**. If the technology is to be disseminated rather than kept in-house, resources must be committed to marketing the technology, demonstrating and improving its usefulness, and establishing it

within extended research and development networks.[11]

- **The second decision**. If an innovator decides to disseminate the technology, it is not always advantageous for him or her to restrict public access to it. Sometimes, an innovation can be freely offered to the public and still generate at least as much economic advantage for the innovator as would a proprietary strategy. Nonproprietary strategies can be more advantageous to the research community, society as a whole, and the innovator. Open source licensing generally creates fewer transaction costs and is inherently more transparent than a proprietary licensing strategy. The decision to follow a nonproprietary strategy does not have to be born out of altruism or ideology: it can instead be born out of healthy self-interest.
- **The third decision**. If an innovator decides on a nonproprietary strategy, the innovation can be licensed on an open source basis or placed in the public domain: that is, the innovator can refrain from obtaining any IP or other property rights at all. Licensing an innovation is costly and time-consuming and should be considered only if there is good reason to obtain or retain ownership of the technology.
- **The fourth decision**. After choosing an open source approach, an innovator must choose between an academic open source license and a copyleft-style license (both terms are defined in a later section). If the

Figure 1: Decision Tree to Determine the Type of License



main objective is to encourage widespread adoption of the technology in its current state, the more permissive academic license is likely to be preferable. If the main objective is to guarantee access for the innovator or others to improved versions of the technology, or to other innovations built upon it, a copyleft-style license is worth considering.

- **The fifth decision**. If the innovator decides on a copyleft-style license, the final decision must be how broad or narrow the copyright obligation is to be. The narrowness or broadness of a copyright obligation may be thought of as the reach of the copyleft "hook." Although the diagram depicts this decision as a binary one, in fact, possible formulations of copyleft obligations form a spectrum. The reach of the copyright hook should be dictated by the licensor's assessment of prospective licensees' incentives to contribute to ongoing development.

This remainder of this chapter will explore the nonproprietary options that are available to the innovator, with a special emphasis on the various types of open source licensing.

4. OPEN SOURCE VERSUS PUBLIC DOMAIN

Once an innovator has decided to disseminate his or her technology in a nonproprietary fashion, he or she must decide between open source licensing and placing the innovation in the public domain (also known as straightforward publication): that is, foregoing IP protection altogether.

4.1 *The advantages of public domain over open source*

The primary advantage of straightforward publication or dissemination of a new technology over an open source approach is that it does not require the innovator to obtain or maintain IP protection. Depending on the type of IP right, protecting IP can be costly in terms of time and resources. It also has the disadvantage of contributing to the proliferation of IP rights.

In some contexts, claiming ownership over an innovation may also create a negative effect with respect to ongoing collaborations. It may create ill will among prospective users and decrease the chances that a technology will be widely adopted or improved. Such negative effects are especially likely when the ownership claim is particularly broad (as in the case of the non-coding DNA sequence patents or junk DNA)[12] or when user-developers have a strong belief that the technology ought to be in the public domain (as in the case of human genome project sequence data).[13]

4.2 *The advantages of open source over public domain*

There are several circumstances in which an open source strategy might have advantages over a public domain approach as a way of encouraging the widespread adoption and ongoing development of an innovation.

One situation in which an open source approach may be useful is where inventors have automatic ownership rights over some part of the relevant technology. Some biological innovations incorporate tangible material components (such as cell lines or germplasm) that are owned by the inventor regardless of whether active efforts are made to protect the innovation. Similarly, software programs, data, or written protocols that are incorporated into biological innovations are automatically subject to copyright protection provided they meet statutory criteria. In such cases, a license may help to reduce the transaction costs of transferring the technology to other prospective users because the license clarifies the owner's intention to make the technology available on open source terms. (This is analogous to Creative Commons' objective of facilitating the dissemination of cultural material by helping copyright owners to specify which rights are reserved.)[14]

A second situation in which an open source license may be preferable to straightforward publication from the perspective of the innovator is a situation in which there is a proliferation of overlapping IP rights or the field of innovation is especially competitive or litigious. While even an open source license has the drawback of adding to the complexity of the IP landscape, failure to

assert ownership over a technology before making it available for public use sometimes means that someone else can patent the technology and pursue a proprietary exploitation strategy to the detriment of the innovator and other potential users. In this case, patenting followed by open source licensing of an innovation is a form of defensive disclosure that may be more reliable than other defensive disclosure mechanisms as a means of protecting against subsequent patent claims.

Third, IP ownership gives an innovator the right to set terms of use and exclude anyone who will not abide by those terms. For example, in a copyleft-style arrangement, follow-on innovators must make some improvements available to others on the same liberal terms as the initial innovation was made available to them. Another example is the litigation deterrent clause found in many licenses (both open source and proprietary), which terminates the licensee's rights if he or she sues the licensor (for example, for infringement of one of the licensee's patents).

Finally, IP rights may facilitate certain pathways to development even if they are licensed on open source terms. The existence of IP protection signals to potential investors that the innovator is disciplined and has financial backing and that the innovation is worth supporting.

4.3 *Combining proprietary licensing, open source, and public domain*

There is nothing to stop an open source licensor from offering a technology under both proprietary and open source licenses. This approach, known as dual licensing, generates a surprising amount of income for many open source software programmers, some of whose customers prefer, and are willing to pay for, a more conventional licensing arrangement. Thus, the commercial application of an open source license does leave some room for recovery of the costs of protecting the relevant IP.

It is possible to adopt a nonproprietary strategy at a relatively late stage in an innovation's life cycle, perhaps when the amount of proprietary licensing revenue the innovation generates begins to decline. In this case, granting an open source license to the innovation may be a sensible alternative to abandoning the patent altogether. In such circumstances the full cost of obtaining and maintaining IP protection has little bearing on the decision to go open source, because the majority of these costs have already been incurred.

5. INCENTIVES FOR OPEN SOURCE DEVELOPMENT

Why would any rational, self-interested IP owner decide to adopt an open source license? Many people think of open source licensing as an altruistic exercise, or alternatively, as a strategy pursued for the sake of purely personal rewards, such as fun or a sense of belonging to a community. This is an unnecessarily limited view.

5.1 *Direct financial incentives*

An open source license must permit the sharing and distribution of the technology without charging any royalty. In this context, a royalty is any ongoing payment that is linked to the use of the technology (for example, a percentage of profits on products generated using a technology, or a regular payment whose amount depends on the number of people who are given access to the technology), not a one-time payment. Therefore, although open source licensors cannot charge royalties, they can charge a one-time fee that is as high as the market will bear.[15]

Of course, the fact that an open source software license must guarantee its licensees' freedom to make copies of the licensed software and distribute them to others without having to make additional payments to the licensor means that the price of the technology tends to be driven down to the marginal cost of reproduction and distribution—for software, close to zero. Keep in mind that while the inexpensiveness of open source software *production* relative to conventional proprietary production is an inherent feature of the open source model, the low price of open source software to consumers (and hence the low rate of return to licensors in the form of license fees) is a consequence of market forces that may not exist with respect to other types of technology. For example, because the marginal cost of

reproduction and distribution may be quite high for technologies that are less highly codified than software or are embedded in tangible objects the production costs of which are sensitive to economies of scale, fewer distributors may come forward to compete with the original licensor, and licensees may be more willing to pay the licensor for extra "copies" of the technology than is the case in the software context.[16] This means that there may be more opportunities for a licensor to profit directly from the sale of non-software open source technologies.

5.2 *Indirect financial incentives*

Most of the incentives for open source licensing are indirect rather than direct. Sections 4.3 and 4.4 describe incentives relating to cost savings, productivity gains, and reputational capital. However, one of the most important effects of open source licensing is to expand the user base for a technology, thereby expanding the market for complementary goods and services.

There are several reasons why an open source license tends to increase user numbers. In the first place, a technology that is distributed according to open source terms is often more attractive to users because it is more affordable and available than its proprietary counterparts and because its availability is not dependent on any particular supply chain.

Next, open source technology is *malleable*. Licensees can make modifications to the technology and access the means for doing so. The malleable nature of the technology creates markets not just for the technology itself, but also for associated maintenance services, upgrades, and adjustments.

These market-expanding effects are especially pronounced for technologies with strong *network effects* (that is, technologies that become more valuable as more people adopt them, which in turn increases their popularity): this includes not only information and communication technologies but also many biomedical and agricultural technologies. For example, a microarray reader that displays data in a particular format becomes more useful if a number of scientists use the same reader: the uniformity of data output makes it easier to compare and verify data that originated in many different laboratories.

As the market expands, revenues from sales, one-off licenses, and dual licensing may be enough to offset the opportunity cost of adopting a nonproprietary licensing strategy. At the same time, the demand will increase for complementary products and services, including technology training, technical support, customization services, hardware or wetware supplies, proprietary data-analysis software, and so on. Many successful commercial open source software ventures turn a profit by providing complementary products and services. Perhaps the most striking example is that of IBM: a substantial investment in open source software production provides IBM with access to a better operating system that makes its primary commercial offering, server hardware, more valuable to consumers.

5.3 *Non-financial incentives for individual researchers*

Computer programmers are often motivated to contribute to open source software development by incentives that are not strictly monetary (though they can be translated into monetary rewards in the employment market): the possibility of enhanced personal reputation and the opportunity to learn new skills.[17]

At first glance, such nonmonetary benefits may seem irrelevant to the biomedical or agriculture fields, where decisions about research investments are commonly made at an institutional rather than an individual level. However, individual researchers in both of these fields can decide, to some extent, how and where they will direct their own or their laboratory's resources. Such self-determination is common for academic researchers, but is also evident in biotechnology and pharmaceutical companies, many of which allow staff to spend some designated fraction of their time on personal research projects in order to encourage creativity, increase job satisfaction, and, it is hoped, generate new commercial opportunities for the company.[18] Researchers with some creative freedom might decide to participate in open source development under appropriate funding and employment conditions. The

same is true for the many open source software developers who are not hobbyists but, instead, professionals whose contributions form part of their employment.[19]

5.4 *Institutional incentives*

5.4.1 *Intrainstitutional incentives*

It is to an organization's advantage to build a reputation for cutting-edge technological innovation, and to keep its researchers sharp by allowing them to participate in a range of projects, regardless of their projected commercial value. Furthermore, open source development encourages the development of a productive, collaborative environment.

5.4.2 *Interinstitutional incentives*

In both biomedicine and agriculture, the locus of innovation is often not the individual company or university but the network of diverse collaborations among organizations.[20] Open source licensing offers a way of sharing the costs and risk of technology development among many prospective users: in other words, open source development can be a form of precompetitive collaboration. As users and developers collaborate on a project, technological applications multiply and diversify, and robust and reliable tools are created. Bruce Perens, author of the OSD, points out that the same groups of companies often have a low rate of success of proprietary consortium software development but a high rate of success with large open source projects; he suggests that the inherent fairness of open source licensing encourages effective collaboration between parties with different interests.[21]

Open source licensing is not primarily a means of dealing with existing "anticommons tragedies," that is, bargaining failures among owners of multiple complementary IP assets.[22] Unless the technology in question is a killer app—a software term for any tool that renders obsolete all others in its class—the terms on which it is licensed, whether open source or otherwise, can have little impact on existing reach throughs, royalty-stacking provisions, and other restrictive licensing terms. Rather, open source is a means of pre-empting such tragedies by establishing a robust commons for basic or fundamental technologies whose value is likely to be enhanced by cumulative innovation. In situations where an anticommons problem already exists, nonproprietary strategies can have a beneficial tipping effect, because the greater the number of nonproprietary tools in any given tool kit, the greater the incentive of everyone in the field to invest in developing substitutes for the remaining proprietary technologies for the sake of achieving freedom to operate with the tool kit as a whole.

6. DIFFERENT TYPES OF OPEN SOURCE LICENSES

6.1 *Copyleft licenses*

A *copyleft*, or *reciprocal*, license allows the user to modify and redistribute a software program at will. The licensee's obligation under a copyleft license is to make relevant downstream technologies available to all comers (including the original licensor) under the same terms as provided by the original license. No one (including the original licensor and his or her licensees) obtains any special privilege regarding any next-generation technology, such as a right to preview any improvements or exclusive sublicensing rights to any improvements. The point of a copyleft license is to create an ever-growing pool of downstream innovations that remain freely accessible to all comers.[23]

However, a copyleft license is not always the best way for innovators to guarantee themselves access to future improvements in the technology. Instead, prospective licensors should carefully consider how they can best encourage licensees to contribute to a technology commons.

When deciding whether or not to use a copyleft license, the innovator should take into account the attitudes, needs, and constraints of prospective users, as well as the other tools that they are likely to use in conjunction with the technology. For example, if licensees use tools that are subject to proprietary intellectual property licenses, the conditions imposed by owners of that intellectual property may conflict with the copyleft obligation to make downstream

innovations freely available. Furthermore, it is possible to trigger a cycle of cumulative innovation even if users do not perfectly comply with the copyleft ideal, provided there is a critical mass of user-developers who do.

A copyleft-style obligation is probably necessary only if potential contributors are likely to be seriously put off by the existence of free riders, those who let others put in the time and money for research and development and then help themselves to the results. Even then, an innovator should take care to explain to his or her licensees why such an obligation is necessary. Under no circumstances should an open source license restrict licensees' freedom to take development in new directions, with or without the licensor's approval. The strength of open source is, after all, its ability to harness the creativity of diverse user-contributors who are allowed to work in relative freedom.

If it is decided to adopt a copyleft license, the licensor has two main ways of tailoring the license terms to maximize the incentives of prospective contributors. Not every modification, improvement, or new application of a technology that has been licensed on copyleft terms must be made available on those same terms. In the first place, only derivative works that are externally deployed—that is, sold or otherwise distributed outside the boundaries of the licensee's organization—are subject to the reciprocal obligation under a copyleft license.

Second, even if a downstream innovation is externally deployed, it still may not fall within the definition of improvements in a particular copyleft license, because different licenses have broader or narrower definitions. The only real check on the licensor's discretion with respect to the breadth of this definition, apart from the willingness of other contributors to accept the license terms, is the scope of the licensed intellectual property. A licensor who seeks to control that which he or she does not own may run afoul of competition laws.

In this connection, a trap for would-be copyleft-style licensors to be aware of is that an open source license must grant the licensee the freedom to create a new collaborative-development project based on previous contributions (a phenomenon known in the software industry as a code fork), for any reason at all.[24] The possibility of forking means that technologies can still be improved even if their initial innovators have lost interest in the technologies or have lost the capability to develop them. In practice, forking is rare, largely because it is difficult to persuade others to abandon the old project in order to start on a new one. It is often easier for dissenters to continue working on the original project and then invest some of their own resources adapting its output to their specific needs rather than abandon the original project altogether. However, in formulating the definition of improvements in a copyleft license, the licensor (or his or her agent) must avoid restricting the freedom to fork development.

Thus, the two most important aspects of a copyleft-style license are: (1) the definition of "improvements" (or an equivalent term) which determines which follow-on innovations must be licensed on the same terms as the initial licensed innovation; and (2) the definition of "external deployment" (or equivalent), which determines under which circumstances the aforementioned obligation must be fulfilled. These may be adjusted by the licensor to create a copyleft license that strikes the appropriate balance of incentives to contribute to any given project.

6.2 *Academic licenses*

Another type of open source license is the academic or BSD-style license (named after the Berkeley software distribution license, the oldest license in the OSI's list of approved licenses). These licenses do not require users to make externally deployed improvements available to the licensor on the same terms as the original technology; in some cases, the downstream user's only obligation is that he or she must give the innovator credit for the innovation. According to Larry Rosen, the difference between copyleft and academic open source licenses is that the former are employed by generous sharers of IP freedoms, whereas the latter are employed by generous donors of IP freedoms.[25]

An academic license can achieve some of the goals of open source as effectively as can a copyleft

license. Indeed, where the licensor's primary goal is to encourage widespread adoption of the initial innovation, an academic-style license may be more effective because a copyleft license could deter potential licensees who want to be able to commercialize their own improvements on a proprietary basis.

7. OPEN SOURCE IN FIELDS OTHER THAN SOFTWARE

Although most of the examples given here come from the software industry, the principles of open source can be applied to other fields as well. Open source technology could be especially useful in niche markets that are too small to be profitable for companies that make off-the-shelf, proprietary technologies. Importantly, open source technologies can be tailored to serve small agricultural and pharmaceutical markets in developing countries (where *small* may refer either to the numbers of potential users or the amount that potential users can afford to pay).

7.1 *Biological innovations*

Open source can have a place even in fields dominated by proprietary strategies, such as the life sciences. Open source tools are important—and growing ever more important—to life sciences research and development. Many of the most valuable and widely used enabling technologies in the field are bioinformatics software programs, licensed on terms that are open source in the strictest sense. A good starting point for readers interested in exploring the possibilities of open source software for biomedical and agricultural applications is the Web site of the Open Bioinformatics Foundation.[26]

What about open source licensing for non-software biotechnologies? Starting as early as 1999, a variety of life-sciences initiatives have consciously adopted one or more open source principles in attempts to overcome some of the challenges posed by an increasingly complex IP landscape. These initiatives include a Canadian proposal for a General Public License for plant germplasm,[27] a draft license (never adopted) for human genome project sequence data,[28] the data access policy of the international haplotype mapping (HapMap) project,[29] the Biobricks Foundation,[30] Tropical Diseases Initiative (TDI),[31] Science Commons,[32] and Biological Innovation for Open Society (BIOS).[33]

Many open source software licenses are drafted as generically as possible so that as many people as possible can use them, as templates, for as little cost as possible. It would be helpful, of course, if the life sciences had open source precedents or template licenses—or, for that matter, a voluntary licensing standard, equivalent to the OSD, or a set of best-practice guidelines. Such tools would not only help prospective licensees decide whether a biomedical or agricultural technology license is genuinely "open source"(thereby helping them judge whether it is likely to achieve the positive collaborative outcomes for which open source licensing is valued) but would also help prospective licensors set universally beneficial terms for technology transfer.

These tools, however, do not yet exist. In developing such tools, the biomedical and agricultural research and development communities could learn a lot from the experiences of software developers. However, it may turn out that biotechnology—which is a far more technologically diverse field than computer programming, and which relies on expensive, time-consuming, and complicated patents rather than automatic no-cost copyrights—simply does not lend itself to the use of template licenses.

Therefore, for the present, at least, IP managers should be wary of uncritically imitating existing attempts to formulate open source licenses for non-software technologies, both because these licenses are not generic enough to be appropriate in all contexts and because some may not truly embody the principles that make open source work. Instead, prospective licensors and their advisors should develop tailored strategies.

7.2 *Examples of open source in molecular diagnostics*

The following examples reveal how open source licensing could be advantageous in both the public and the private sector even outside the software context.

7.2.1 *Case #1: A nonprofit setting*

Suppose that a clinical scientist working in a not-for-profit setting (a university or hospital laboratory) discovers a genetic mutation that seems to correspond with the occurrence of an inherited disease in one of his or her patients' families. Using standard molecular biology tools, the scientist creates a diagnostic test and confirms the discovery. Imagine that the diagnostic test is patentable, but, because there are probably tens or hundreds of mutations associated with the disease, the new test will detect only a fraction of these mutations. As a result, the test has limited value.

Clearly, the utility of this diagnostic test—and hence the utility of the service the scientist's lab provides to patients, their families, and the community as a whole—would be enhanced if the new test could be combined with previously existing tests for other mutations associated with the same disease. The utility of the new test would also be enhanced by increased use: the more people who use the test, the more likely that systemic errors would be detected and corrected, and the greater would be the cost-effectiveness, for regulators, of enforcing best-practice standards for the test.

In this case, a copyleft-style open source license might be the most sensible way to protect the new genetic test. Such an approach would ensure that users do not have to pay license fees to subsequent developers in order to gain access to the most comprehensive version of the test.

7.2.2 *Case #2: A for-profit setting*

Suppose now that our hypothetical scientist works for a small company that operates on a mixed-revenue business model. Some of the company's revenue comes from the development and marketing of diagnostic tests for use in hospitals, physicians' offices, and in the home. More revenue comes from data analysis and contract research services. The rest of the revenue comes from licensing its collection of gene patents.

The inventor's company also conducts broad-ranging R&D activities that are economically important to the company in two ways. First, by developing and patenting new technologies, the company generates more revenue through patent licensing. Second, the company's research agenda enhances the company's reputation as a high-tech organization, which in turn attracts new customers. Because of its small size, the company's stand-alone research capacity is limited, so it makes a point of pooling resources with other research organizations. However, competition is fierce among small companies that want to forge alliances with the most desirable partners from industry and the nonprofit sector, so our imaginary company is always looking for ways to enhance its capacity for cutting-edge research and to advertise its excellent track record of scientific collaborations.

If the genetic test mentioned above were to be licensed under a copyleft-style license, the company would gain access to any new versions of the test—which are likely to be more reliable, easier to perform, and more comprehensive than the old ones—without having to pay exorbitant fees to other developers or having to deal with restrictive licensing terms. The better the test becomes and the cheaper it is for people to use, the larger the market will be for associated products and services (for example, test kits and genetic counseling). If the company is known as the producer of a cheap, effective test, the company's reputation will improve; the enhanced reputation, in turn, will lead to greater demand for its contract research services and, perhaps also, greater demand for access to the company's gene patents. Further, a better standing in the industry will make it easier for the company to attract and keep excellent employees and research partners. Meanwhile, the experience of leading an open source project would give the company a chance to acquire, and demonstrate, experience in collaborative research.

Note that although open source development makes sense for the two hypothetical cases outlined here, open source may not always be appropriate. There are no hard-and-fast rules about whether or not the benefits of an open source approach will outweigh the costs, so each situation must be evaluated on a case-by-case basis.

8. CONCLUSIONS

Much work remains to be done before open source licensing is fully integrated into the biomedical and agricultural spheres, and this chapter has done no more than scratch the surface of the topic. Ideally, those who are interested in exploring nonproprietary exploitation strategies in the life sciences will continue discussions that will eventually lead to the creation of open source standards and open source license templates. Until then, prospective licensors in the life sciences must be prepared to independently interpret the lessons of open source software licensing. ■

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1 Thanks to considerable scholarly attention in recent years, a broad consensus regarding the essential features of open source development is gradually emerging. A good starting point for interested readers is Demil B and X Lecocq. 2006. Neither Market nor Hierarchy nor Network: The Emergence of Bazaar Governance. *Organization Studies* 27:1447-1466.

2 See E.S. Raymond. 1998. The Cathedral and the Bazaar. *First Monday* 3(3); Benkler Y. 2002. Coase's Penguin, or, Linux and the Nature of the Firm. *Yale Law Journal* 112:369.

3 Feldman RC. 2004. The Open Source Biotechnology Movement: Is it Patent Misuse? *Minnesota Journal of Law, Science & Technology* 6(1):117-168; Boettinger, S. and Burk, D. 2004. Open Source Patenting. *Journal of International Biotechnology Law* 1:221.

4 The full text of the OSD is available online at www.opensource.org.

5 Rosen L. 2004. *Open Source Licensing: Software Freedom and Intellectual Property Law*. Prentice Hall: New Jersey. pp.8-11.

6 Rosen L., et al. 2003. Live from Silicon Valley, Views of Open Source Practitioners, p.39. In *Legal Issues Relating to Free and Open Source Software* (eds. B. Fitzgerald & G. Bassett), Volume 1 of *Essays in Technology Policy and Law*. Queensland University of Technology School of Law: Brisbane.

7 www.fsf.org/.

8 www.debian.org. For a history of free and open source software, see also Levy S. 2001. *Hackers: Heroes of the Computer Revolution*. Penguin: New York; Weber. 2004. *The Success of Open Source*. Harvard University Press: Cambridge, MA.

9 The free software definition is online at www.gnu.org/philosophy/free-sw.html.

10 For more information on "Debian-free licenses," see www.debian.org/legal.

11 For a discussion of this process in the context of the development of hybridoma technology, see Cambrosio A and P Keating. 1998. Monoclonal Antibodies: From Local to Extended Networks. In *Private Science: Biotechnology and the Rise of the Molecular Sciences* (ed. A Thackray). The Chemical Sciences in Society Series. University of Pennsylvania Press: Philadelphia. pp. 165–181

12 For a discussion on these, see, for example, Nottenburg C. 2004. Analysis of "Junk DNA" Patents. *Cougar Patent Law: Seattle and CAMBIA*. Canberra. lorac.typepad.com/patent_blog/files/simons_patents_analysisf.pdf.

13 According to Sir John Sulston, the possibility of alienating key collaborators was the main reason a copyleft-style license was not adopted for human genome project sequence data.

14 See Creative Commons' Web site, creativecommons.org.

15 In Larry Rosen's words: "[W]hatever they charge for, you only have to pay once." Larry Rosen, *Personal Communication*. March 2003.

16 *Codified* refers to the nature of the information incorporated into a technological artifact. Highly codified knowledge is organized and easily reproduced and transferred. Uncodified information, on the other hand, consists of undeveloped ideas and/or unarticulated know-how. Any biotechnology that includes living material is likely to be highly uncodified because living systems are so complex. Similarly, a laboratory technique that can only be reliably performed after hands-on training from an experienced practitioner is also uncodified.

17 For an empirically verified list of motivations to contribute to open source development, see Kim EE. 2003. *An Introduction to Open Source Communities*. Blue Oxen Associates. www.blueoxen.org/research/00007/BOA-00007.pdf.

18 Drews J. 1999. *In Quest of Tomorrow's Medicines: An Eminent Scientist Talks about the Pharmaceutical Industry, Biotechnology and the Future of Drug Research*. Springer-Verlag: New York. pp. 229–232.

19 See *supra* note 17.

20 Powell WW. 2001. Networks of Learning in Biotechnology: Opportunities and Constraints Associated with Relational Contracting in a Knowledge-Intensive Field. In *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (eds. RC Dreyfuss, D Zimmerman and H First). Oxford University Press: Oxford, U. K. pp. 251–266.

21 Perens B. 2005. The Emerging Economic Paradigm of Open Source. *First Monday. Special Issue #2: Open Source — 3 October 2005*. Online at firstmonday.org/issues/special10_10/perens/index.html.

22 Heller MA and S Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280: 698–701.

23 A copyleft license is formally similar to a *grant-back*, a type of license provision that in the patent context has sometimes been regarded with suspicion by competition authorities. See Boettiger S and D Burke. 2004. Open Source Patenting. *Journal of International Biotechnology Law* 1: 221. However, it is functionally distinct because it requires improvements to be made available on the same terms to all, thereby creating a level playing field between the initial licensor and follow-on innovators.

24 Bedell K. 2004. Open Letter to Sun from Eric Raymond. *O'Reilly ONLamp.com*, www.oreillynet.com/onlamp/blog/2004/11/open_letter_to_sun_from_eric_r.html.

25 See *supra*, note 5. p.104.

26 www.open-bio.org.

27 This proposal was developed by Tom Michaels, then of the Ontario Agricultural College, University of Guelph. A copy of the proposal is available from the author on request.

28 The proposal to publish genome sequence data under a copyleft-style license is described by the then-director of the Sanger Centre in Sulston J and G Ferry. 2002. *The Common Thread*. Random House: London. pp. 211–213.

29 For a post-case analysis of the HapMap data access policy, see Gitter D. 2007. Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases. *Houston Law Review* 43 (forthcoming).

30 Baker D. 2006. Building a Fab for Biology. *Scientific American* 294: 44–51; Endy D. 2005. Foundations for Engineering Biology. *Nature* 438: 449-453.

31 See Maurer S, et al. 2004. Finding Cures for Tropical Disease: Is Open Source the Answer? *Public Library of Science: Medicine* 1(3):e56. See also, the TDI Web site at www.tropicaldisease.org.

32 sciencecommons.org/.

33 Dennis C. 2004. Biologists Launch Open Source Movement. *Nature* 431:494.

Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries

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ABSTRACT

When public–sector organizations and public–private product development partnerships (PDPs) manage intellectual property (IP), they need to balance the commercial interests of private–sector manufacturers with the public sector's mission to obtain access to products at the lowest possible cost. An important tool for achieving this balance is the detailed definition of contractual milestones, which should clearly specify the terms for pricing to the public sector, territory and exclusivity, regulatory work, and time to market. Milestones should not, however, be cast in stone. Based on detailed analyses of market conditions, milestones need to remain adjustable throughout the life of the contract. When well defined, milestones can be used to ensure the availability of the most modern healthcare products to the developing world. After all, for the public sector, successful IP management is defined by how many poor people a product will reach, how easily it will be available to them, and who and how many will be able to afford the product. Accordingly, out-licensing intellectual property from public–sector-based organizations to private–sector partners requires the licensor to actively guard public–sector interests.

1. INTRODUCTION

When public–sector organizations and public–private product development partnerships (PDPs) manage intellectual property, they need to balance the commercial interests of private–sector manufacturers with the mission of the public–sector to provide access to products at the lowest possible cost. Many of the important inventions oriented toward public needs in healthcare and biotechnology result from R&D in public–sector research centers and international organizations. By adequately managing the resulting IP, the public–sector can benefit from its R&D investments by making the most modern healthcare products available to the developing world, eliminating significant barriers to access.

1.1 *The importance of contracts and milestones*

For parties entering into agreements of any kind, the primary assumption of contractual relationships is that the principal subject of their deal will be realized successfully. Obviously, this is not always a safe assumption, and when unforeseen events prevent the partners from reaching their goals, contracts differ considerably in the quality and substance of the remedies they provide. Too many contractual relations go sour because partners rush into agreements without carefully thinking about contingencies.

Without an early elaboration of contingency plans and crisis management, this honeymoon trap is why many contractual agreements contain unclear, foggy language and omit definitive, detailed, and enforceable conditions. Such conditions should address not only the contractual rights but also the obligations of each partner and the specific countermeasures to be

Oehler J. 2007. Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

taken should one party run into difficulties in fulfilling its part of the deal. Instead, "best efforts clauses" or provisions for consultations to solve problems case by case are used, so as not to spoil the initial enthusiasm of making the deal. When unforseen events occur, that can be a sure recipe for disaster, especially if the mechanisms to settle disputes over differing opinions about contractual performance are unclear.

A typical contract specifies the subject matter, the duration and terms, and the rights and obligations of each party under the agreement. Licensing agreements between two organizations identify, among many issues, the nature and scope of the intellectual property or product that is being licensed, the territorial grant to the licensee where the licensed product would be made available, and the financial obligations of the licensee.

A practical example is the use of technical know-how, or the results of scientific research, that represents the particular intellectual property of a licensor and is to be licensed out to a commercial company able to create a product from the intellectual property and distribute it to consumers and users. The interests of both parties in the arrangement are straightforward and mutually advantageous—it is a win-win situation. This ordinary, idealistic assumption prevails at the beginning of any licensing deal. All too often, however, reality thwarts the goals of the initial agreement. Planned goals are missed, or forecasts wrong, and the contractual partners are left with only a subset of the original targets.

Too often, the public sector forgets that the commercial interests of private-sector companies are oriented toward maximizing profitability. Accordingly, it should not be expected that private-sector businesses will automatically provide the best services to the public sector or that they will focus on the generation and use of intellectual property to maximize public–sector benefits. To prepare for situations when the original targets of a license agreement are delayed or not achieved, and to avoid situations when projected public–sector benefits are delayed or unrealized, it is good practice to establish *contractual milestones*. These govern the goals of the license contract and set incentives for keeping to timelines and performance targets. They encourage both the licensor and licensee(s) to focus resources on their efforts to perform as initially agreed.

But milestones should not be fixed or inflexible. They need to remain adjustable throughout the lifetime of a license contract because of potential changes in project development, the market environment, and other factors that cannot be completely anticipated. When it comes to the detailed specifications of individual milestones, it does not really matter if one is choosing an absolute or a relative goal, or which definition is finally settled upon. What matters is to get the commitment of the private–sector company to recognize public–sector targets. To do this, a working set of adequate milestones should be put in place, and periods for performance assessment of the private–sector contract partner should be defined. And when new, solid evidence requires a change of rules to keep both the product and the public sector's goals alive, both parties should be open to revisions. Such results-oriented milestones require intensive preparations, detailed knowledge of the processes related to developing and marketing the product, realistic forecasting of product potential, persistence in quantitative forecasting and establishing a master plan for the entire product roll-out, and a mission-driven mindset to establish optimum goals for the public sector.

Additionally, it is useful to spell out the level and conditions of fines (monetary or otherwise) to be paid when a partner does not fulfill its obligations. This should include a mechanism to prevent prolonged periods of quarreling over differing opinions and disagreements over performance. Otherwise, product development or marketing efforts could cease, which would ultimately hurt the public sector.

Most milestones cover:

- pricing to the public sector
- territory and exclusivity
- regulatory work and time-to-market
- royalties
- terms and termination of the license agreement

1.2 *Public–private partnerships: closing the medicines access gap in developing countries*

The role of ***public–private partnerships*** (PPPs), or, in the context of health, more and more frequently public-private product development partnerships (PDPs), as an innovative approach to the discovery, development, and distribution of health products, drugs, and vaccines for developing countries has been emphasized repeatedly in various publications. In fact, more than 90 PPPs have been established worldwide.[1] However, the accomplishments of PPPs/PDPs are rarely publicized, partly because most of these entities are relatively young. Half of these partnerships have been established since 1999. Since normal times to market range from no less than ten to around 12–15 years, on average, in a pharmaceutical R&D or healthcare environment, the time in existense of these partnerships has been relatively short. It is still possible to begin to gauge, however, the success of these ventures.

One example of a PDP is the Concept Foundation,[2] established in 1989 through the initiative and funding of the World Health Organization's Special Programme of Research, Development, and Research Training in Human Reproduction (WHO/HRP), the World Bank, and United Nations Population Fund (UNFPA), PATH/PIACT,[3] and The Rockefeller Foundation. The mission is "*to provide access to top quality reproductive-health products for developing countries at lowest possible prices in order to realize maximum public-sector benefits through the management of intellectual property and technology transfer for contraceptives and pharmaceuticals that otherwise would not be available to the public sector with the intended quality and prices.*" The Concept Foundation has accumulated extensive experience managing health technologies development and technology transfer in the pursuit of rolling out new technologies in the developing world.

Successful PPPs/PDPs are built on value propositions, from the public sector to the private sector, that take advantage of the inherent capabilities of the former. The public-sector IP manager should identify the capabilities that are relevant to a particular public–private partnership and turn these capabilities into specific value propositions that will help the private–sector partner realize its commercial goals. No potential benefit to the public sector, however, should be sacrificed. In this context, it is especially important to overcome the common phenomenon of further *marginalizing the poor* in the small and smallest countries of the developing world. Market attractiveness governs priorities in a commercial environment, but in a public–sector context, the poor in the smallest countries have the highest needs for accessing affordable products. As the experiences of the Concept Foundation reveal, the public sector successfully manages its intellectual property when it bridges these ostensibly opposing interests.

The R&D process for developing new drugs, vaccines, and diagnostics for diseases that afflict the poor is a crucial step toward ultimately eradicating these diseases. Many PPPs/PDPs concentrate their efforts on product development, and the largest product-development PPPs/PDPs have successfully raised (in combined figures) more than half a billion U.S. dollars in recent years to fund their R&D efforts. However, product delivery is an equally important, if not more decisive, factor for access to medicines, and most product-development PPPs/PDPs are not working to ensure that their products can be delivered to the local healthcare infrastructure. Indeed, product-development PPPs/PDPs have little experience with the downstream issues involved in bringing products to such markets.

But PPPs/PDPs face numerous downstream concerns associated with handling and financing the introduction and launch of new products including:

- adequacy of healthcare infrastructure
- disease surveillance
- compliance monitoring
- education and training of health workers and medical staff
- improving healthcare facilities
- physical distribution networks
- satisfactory supply volumes

- adequate volume forecasting
- minimizing product waste at the point of treatment

As is well known from experiences in the pharmaceutical industry, successful marketing and distribution of a new medicine is a significant, decisive part of its cost structure. While nobody would expect the need to create market demand (in other words, investing marketing dollars) for products to fight diseases of poverty (these markets exist!), huge investments are needed to compensate for the inability of the poorest regions to pay for both modern, effective products and for all downstream tasks related to effectively supplying and distributing these medicines. In addition, costs for surveillance programs to guarantee successful outreach to all who need treatment must be included. Product development public–private partnerships lack the experiences to address these downstream issues.

These efforts must include achieving the lowest possible manufacturing costs so that preferential pricing can be provided to public health services, establishing sustainable manufacturing with a continuous system for monitoring quality, and creating a business model that is financially attractive to private pharmaceutical companies thereby overcoming the expected poor returns of operating in public sector markets. The PPP/PDP business model of the Concept Foundation has helped to realize these goals. It takes into account the downstream issues surrounding product delivery and successfully utilizes contractual milestones to achieve the principal goal of closing the medical-product access gap in developing countries.

2. THE GREAT DIVIDE IN BUSINESS MODELS: INDUSTRY AND THE PUBLIC SECTOR

No matter how well public sector players think they understand industry, the discussion between the public sector and industry is a cross-cultural event. In such a cross-cultural environment, there is nothing more dangerous and conducive to misunderstandings than to *assume the obvious*, since what is obvious for a person with a public sector background may be different for a potential partner. Do not leave obligations and contractual performance to best efforts and common sense! It is much better for both partners to specify in writing exactly what the public sector wants to achieve with a commercial partner. The document should detail exactly when and how the objective will be achieved and specify penalties for failure to meet objectives. If the agreement specifies only best efforts and unspecified performance, disaster threatens!

To manage intellectual property for maximized benefits to the public sector, the expectations of the public sector to obtain products at the lowest possible prices, with excellent quality, and in sufficient quantities must be balanced with the expectations of private sector companies to generate a satisfactory rate of return.

Important value propositions for pharmaceutical companies are:

- **Save time to market.** An earlier market entry means higher market share opportunities for the company and, ultimately, more sales. Example: Pharmaceutical or clinical research, using an existing network of public sector institutions in parallel speeds the generation of results needed for drug regulatory approval by saving the lead time required to approach new, unfamiliar trial sites and train in GCP (good clinical practices).
- **Save resources.** Reduced need for internal company resources means a lower cost burden for the licensee and improves the bottom line. On the other hand, when investment levels are maintained, more parallel activities are possible with the same amount of resources, helping to increase the company's commercial output. Example: Existing public sector distribution networks, formal or informal, allow a product to reach a large public sector market very quickly without the costly build-up of a supply chain.
- **Save investments**. A reduced need for investments means better cash flow

utilization within the company, which is very important for investors.

Any plan for a value proposition must deal specifically with the nature of the partnership, and a successful proposal must present an authentic and actual value to a potential partner. These authentic, actual values must be based on the set of capabilities that the public sector organization can offer—this is precisely the platform for the creation of value—and based on what private sector partner needs could be met by the public sector. Such genuine values include the examples above: save time to market, save resources, and save investments. As these demonstrate, one must look behind the immediate and apparent face value of individual capabilities in the public sector to be able to identify and compose the true value of such contributions. Indeed, an authentic value proposition is more often composed of several contributions from various capabilities than a single value factor.

Understanding all the specific values when just beginning to approach potential licensing partners is essential—especially those values that drive an industry and are particularly important for the potential licensee. A detailed analysis of these values and their alignment with existing public sector capabilities helps to identify the value propositions that public sector organizations can offer their private sector partners.

3. THE MOST IMPORTANT MILESTONES

Maximizing public sector benefits through IP management has three key aspects:

1. definition of the geographic coverage for marketing the product (that is, territory)
2. the claim for product exclusivity by the private sector licensee
3. the definition of the preferred public sector price or other public sector benefit

These may seem very straightforward. It is easy to imagine that the partners in a license arrangement would agree on a set price for the product for public sector distribution, agree on the countries in which the product could be sold and that, as a result, the private sector company, as licensee, obtains the exclusive rights to marketing and sales of the product in this territory. However, in real life, this does not necessarily mean that public sector benefits have been maximized. Some key questions need to be answered:

- How well will we reach smaller countries with our product?
- How well will we reach rural populations in developing countries that normally remain underserved?
- Who will benefit from obtaining the product at a special public sector price?
- How can we ensure that we will obtain the product at prices affordable to public sector agencies?

The principal way to address these issues is to set contractual milestones that prevent the marginalization of the poor in smaller countries, regulate public sector access, and set the geographic coverage for all countries in a territory (even in countries and regions that are not interesting enough to generate sizeable returns on investments and would therefore normally not be served). Finally, there must be a clear framework for computing manufacturing costs, and this cost calculation must be available to the public sector partner.

Due to commercial pressures, putting the private sector and its commercial interests before those of the public sector is an inherent danger. Such prioritizing usually reflects attempts to simplify the private sector partner's participation because of fears about failing to make a deal. While simplifying agreements is good practice, establishing specific contractual milestones and clarifying them under the terms of an agreement are not necessarily complications. Success requires focusing on which areas to target and which issues to exclude. A tight focus will guarantee the simplicity of the provisions and regulations without overburdening an agreement.

When it comes to public sector benefits, simply making a product available at market prices or quickly placing it on the market does

not indicate progress. Success is instead defined by how many poor people the product will reach, how easily it will be available to them, and who and how many will be able to afford the product. The goal is to reduce morbidity and mortality. For the public sector, this is the ultimate aim of product development. The necessary achievements for obtaining this outcome need to be clearly specified as milestones in an agreement. We will next take a closer look at territory, exclusivity, and pricing.

3.1 *Territory and field-of-use*

A typical license agreement will specify the grant of the license. Language such as: "*LICENSOR grants COMPANY the rights to manufacture and sell the PRODUCT into the PRIVATE SECTOR and PUBLIC SECTOR markets of the TERRITORY*" is commonly used. The terms *LICENSOR*, *COMPANY, PRODUCT, PRIVATE SECTOR, PUBLIC SECTOR*, and *TERRITORY* are used according to the definitions in the introductory "Whereas" chapter to the agreement.[4]

Under this wording, the license grant is established as a right of the licensee to the product. However, the license grant does not specify the obligation to sell into the territory. This is a very important issue of practical IP management for public sector benefits. While it is reasonable to assume in the case of a one-product, home market manufacturer that the licensee will introduce the product into this (single) market, it is not necessarily true that a licensee will introduce the product into all markets of a multicountry territory, especially the public sector. This failure to reach all the desired markets may result from various factors that were not known or were underestimated when the license agreement was established.

Between the signing of a license agreement and the commercial roll-out of the product, a considerable period of time may be needed for product development, manufacturing scale-up, and regulatory approval. Depending on the capabilities of the licensee, this time period may well extend over several years. During this time, the company's business and the business environment may change significantly, and resources that originally were available for dealing with the product may have been partially redirected to other, possibly more profitable, products and projects. Markets that initially seemed attractive may have lost their appeal compared to other opportunities since recognized by the company.

Changes in the business environment and the focus of the business may affect the licensee's commitment to serve the public sector as originally envisioned for the entire area. To ensure availability and access to the product in the public sector's territory, it is only prudent to use the license grant to obligate the licensee to sell the product in that area—not just as a right of the licensee. This can be accomplished in various ways:

- By separating the grant of the *rights to manufacture the product* from the *obligation to sell the product into all countries of the territory* (Emphasis here should be on *all countries* in the territory.)
- By attaching milestones to the execution of the sales rights for the product (Only after showing defined success according to the milestones would the licensee be granted additional sales rights for other countries.)
- The rights of the public and private sector to sell the product could be dealt with in separate regulations that prioritize the public sector organization's goal of introducing the product into the public sector at a satisfactory level (to be defined by an adequate milestone) in one country, before additional rights to markets—public and private—in other countries would be granted. The license grant could specify, for example, the rights of a Brazilian manufacturer to produce and sell the product in Brazil, the home market, and the rights to sell it in other Latin American countries, once certain conditions are met. A wide range of options for these conditions are available and could be specified in the license agreement, such as:
  - **Market share.** licensee will gain the rights to sell into other countries after

establishing a market share of 20% in the specific market segment, as reported by IMS.[5]

- **Market position.** licensee will gain the rights to sell into other countries after positioning the product among the top-three products within its category in the Brazilian market, as measured by analyst reports.
- **Sales volume.** licensee will gain the rights to sell into other countries after an annual sales volume of five million units is realized in the Brazilian market, as measured by cumulative sales reports from distribution agents.
- **Public sector penetration.** licensee will gain the rights to sell into other countries after the total output/annual output into the public sector in Brazil has reached ten million units, as measured by procurement orders from public sector agencies.

In addition to the milestones for gaining the rights to sell in additional countries, the remaining countries in the licensed territory could be prioritized in order of importance for the licensee, and eventually the licensor as well. Each country on the list would then be characterized by individual milestones that the company must reach before it could sell in an additional country. These country priorities and milestone definitions should be set when signing the license agreement, with the option to revise the priorities and milestones after a certain period.

It is unwise to leave country priorities or milestone definitions open and uncovered for the sake of higher flexibility (for example, setting the next country priority shortly before reaching the last defined milestone in the actual country of activity or a similarly flexible model that postpones decision-making). Reaching consensus about country priorities and milestone definitions might become more and more difficult for the licensor and licensee, especially the closer the country of choice is to the bottom of the priority list. The licensee might then no longer desire to sell in a particular country, and especially to the public sector, due to various, possibly hidden, reasons. The company could walk away from its responsibilities to serve a particular country. In this case, the private sector company would not be violating the license agreement, since the milestones had not already been mutually defined and negotiations about new milestones had failed.

On the other hand, priorities and milestone definitions may change over time in a fast-moving business environment. Indeed, they might not be considered valid after several years into the lifetime of a license agreement. This is a common concern when it comes to defining priorities and milestones, especially among advocates of real-time implementation. Given the need to eventually define priorities and milestones, to protect public sector access to the product everywhere as far as possible, and to avoid the inherent dangers of leaving important parts of an agreement initially undefined pending a later mutual understanding, it is close to irresponsible to skip over these definitions and omit them from the initial version of the signed license agreement. One can provide for a regular update of the details of these conditions, when a changed environment requires them, for example, by calls for revisions. At that time, however, it would be up to the licensee to demonstrate the need for changes and to prepare a detailed proposal of what to change and how to change it. Unless the proposed changes bring up compelling reasons for the licensor, original priorities and milestones would prevail. The originally defined public sector goals would remain in force without alteration and the licensee would still be required to honor these goals.

Initially defining contractual priorities and detailed milestones is, of course, a painstaking process that requires intensive preparations to ensure that essential aspects of the public sector's objectives are not overlooked. This desk research and information collection is essential for adequately preparing license agreements that serve public sector interests. For initial negotiations between parties, the terms of a licensing agreement should be rolled-out in all related details, even though it may be difficult and

resource-intensive to formulate all of them. The tendency to postpone detailing specifications, or calls from the contract partner to omit the necessary detail in order to simplify and quickly reach an agreement is a trap. It does not allow the parties to establish the necessary framework for an efficient and effective public sector-oriented licensing arrangement. If it is impossible to reach an agreement on staggered priorities with detailed milestones in the beginning of the contract relationship, how can these differences be ironed out later?

3.2 *Exclusivity*

One of the first things that companies ask for is exclusivity. It is important to link such requests with specific milestones, such as:

- volume of sales reached in certain markets after a certain time period from launch or from the signing of the agreement
- level of market share reached against competition
- level of market share established in a new market segment, measured against the total product potential
- level of coverage of different regions in a large market or across different countries of a region
- latest product launch date into a market that will secure product/technology exclusivity for the company, in general, for a selected territory

Specifying penalties and fines for the licensee if these milestones are not reached is just as important as setting the specific milestones. The penalties could be:

- temporary increase of royalties on private sector sales until the milestone condition has been reached
- loss of exclusivity for the product or technology and conversion to a nonexclusive license, in general, or for a specific region
- loss of exclusivity and territory to a competitor
- payment of a fine, in a predefined amount, for failure to introduce a product into a country under exclusivity for the licensee.

It is good practice to evaluate the request for exclusivity with respect to the public sector benefits that a potential licensee could deliver. Again, it is unreasonable to expect that a private sector company would concentrate major resources on serving the public sector when there are no specific obligations in the license agreement or milestones are inadequate or undefined. Since the request for exclusivity is made to protect the commercial potential of a market place, the public-sector partner has the right in a quid pro quo to ensure the protection of public-sector needs. It is especially important for the public sector partner to understand what kind of resources—in terms of quality and quantity—the private sector company will make available and mobilize for the public sector segment of the exclusive territory. This understanding should be clearly stated in the license agreement.

3.3 *Pricing for the public sector*

A key issue for the public sector in developing countries is product affordability. Prices must ensure the widest possible availability. Prices, however, are calculated differently in the pharmaceutical industry than in the public sector.

Pharmaceutical companies commonly use a retrograde calculation scheme. They base product prices on the perceived purchasing power of the target segment in a market. Manufacturing costs are not a major factor for the price calculation. Overhead and marketing costs are usually higher than production costs and need to be well offset by product pricing. To a large extent, adequate product positioning into affluent markets determines achievable margins and operating profitability.

In contrast, the public sector mostly uses the cost-plus model for price determination. Manufacturing and organizational infrastructure contribute significantly to costs. Sales and marketing costs are kept at the lowest possible levels so as not to increase the product's price. A reasonable, but small, rate of operating profit is added on top of these costs to determine the product price. With the purchasing power of the public sector under severe limitations, a price

determination along the lines of a cost-plus model is the method of choice.

An effective license agreement needs to employ a detailed cost-calculation model. Its aim should be to understand all directly and indirectly attributed product costs that contribute to final cost. By applying the model and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for determining the lowest possible public sector price can be achieved. For indirect costs, it is necessary to find out if the cost burden on the product is fairly allocated. In the end, of course, private sector pricing of the product is entirely up to the discretion of the manufacturer and not a public sector concern.

It is good practice to mandate the annual submission of manufacturing cost reports and product cost-calculation details. Furthermore, the licensor should reserve the right to have these cost reports independently audited.

Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing, a definite timeline should be set to reach those levels. Adequate penalties should be in place to cover such cases. While a license agreement cannot be a tool to force a manufacturer to sell a product below cost, a detailed agreement based on the manufacturing cost-calculation model and the overall pricing structure for the product will eliminate related concerns.

The licensor should define which public sector organizations could obtain the product at the preferred price. For pharmaceutical products, it should be clearly defined whether these public sector organizations can be only ministries of health, government purchase organizations, public sector hospitals, and similar institutions or if nongovernmental agencies with charitable functions, social marketing organizations in a country, international organizations with a humanitarian mission, and other institutions are also potential beneficiaries. The license should define how these agencies and organizations would be informed about the availability of a preferred public sector price for the product.

3.4 *Regulatory work and time-to-market*

Pharmaceuticals are subject to drug regulatory approval by health authorities, and the time required for the regulatory approval process increases the time it takes for a product to reach a market. It is good practice to stipulate in the license agreement when the licensee must bring the product forward to registration. It is also best to specify within what time period after signing the license agreement the licensee has to forward a complete registration filing to the relevant authorities. For a multicountry territory, specifying the sequence of registration filings in the various countries and the maximum time allowed between individual filings is vital.

It is also advantageous to specify how much time may pass between registration approval and the product launch in the public sector. This prevents the unusual, but realistic, scenario in which a licensee sits on its rights and doesn't utilize them for the benefit of the public sector.

3.5 *Avoiding the marginalization of the poor in small countries*

For commercial companies, large markets dominate priorities and occupy the top spots of territorial ranking, while small countries regularly occupy the bottom. This is because market attractiveness rules priorities in a commercial environment. The needs of the poor and of public sector agencies in small countries are not normally attractive markets for companies that are expecting to generate sizeable commercial returns from their manufacturing and marketing efforts. A licensor must ensure that product access is not limited just to larger markets and that small countries will be covered in order to avoid further marginalizing the poor.

When it comes to the territorial grant of a license agreement aimed at maximizing public sector benefits, the licensor must thoroughly consider this particular issue. The prospect of substantial profits from product sales in the private markets of any territory is an important issue for deciding to award the licensee commercial advantages under the license agreement. However, the territorial grant must cover not only large countries and their sizeable private

markets—as main incentive that the public sector would be reached as well—but also small countries and their public sector markets that the private sector partner would not normally cover. An effective territorial grant must contain a mix of large and small markets to balance the commercial potentials for the licensee against the humanitarian needs of the public sector. Only the licensor can guard these public sector interests.

It is good practice, therefore, not to grant sales rights in large countries to a single licensee without including an obligation to serve the public sector and markets in the smallest countries. If a single licensee cannot cover all of a region's markets, the entire region should be appropriately segmented to ensure that two or more licensees each get a profitable share and that the public sector in the smallest countries will be served. As outlined above, this goal needs to be adequately supported by specific milestones.

The up-front definition of territorial milestones is often skipped, or neglected, to the public sector's disadvantage. One very common reason for this is that the primary needs of the public sector are spread over a wide territorial area and/or over a variety of minority groups in dire need of services. Satisfactory coverage requires detailing a multitude of distinctive priorities and characteristic milestone definitions, a burden squarely placed on the initial license partners—especially the licensor.

One strategy for expanding territories is for the licensor to generate sales to public sector agencies in countries that are not covered by the initial territory grant but that need the product very much. This approach has the following advantage: the licensee can focus on the obligations and related milestones under the license agreement without facing multiple targets, while the licensor serves public sector agencies outside the territory and potentially establishes other useful partnerships. If desired, this additional market may be assumed by the licensee.

Setting a quantitative goal for public sector sales needs special consideration. The licensor could use absolute or relative target figures. The market share percentage reached after a certain time from product launch is one good target figure. Other possibilities would be to 1) define the sales growth reached in the first years on the market or 2) to use the sales volume after one, three, or five years on the market to characterize the expected—and initially agreed upon—success rate. The licensor could specify, for example, that the product should be among the top-three products within the specific market segment in its third year of introduction.

In the private sector, competitiveness is an important factor for measuring the success of any product. Licensees need to achieve the highest levels of competitiveness in private sector markets in order to be able to reach their commercial objectives. This in turn would support a very competitive manufacturing cost structure, which ultimately would provide the public sector with the lowest possible cost. Measuring private market targets is therefore, also an adequate way to express public sector goals.

Another way to set milestones for performance in the public sector is to set sales volumes in the private and public sectors in relation to each other. A powerful milestone definition, for example, specifies that public sector sales reach 40% (or any other agreed upon ratio) of the sales volume for the private market within three years after product launch.

With respect to the availability of the product in the public sectors, it is essential to specify expected launch dates for the product. For example, the license agreement could stipulate that the product be made available in the public sector not later than two years after the signing of the agreement. Should a product require initial sales in the private market for any reason, an adequate requirement for public sector introduction could be "*not later than X years after private-sector launch.*" For multicountry territories, specific requirements for each country would need to be established and defined.

Remedies for unmet milestones need to be part of the license agreement. One effective remedy is to significantly increase royalties on private market sales when a milestone has not been reached.

4. CONCLUSIONS: TOUGH MILESTONES FOR A TOUGH INDUSTRY

Finally, some thoughts about milestones for the cautious few who feel uncomfortable with the idea of setting tough milestones in a tough industry. In a process-oriented sense, milestones represent and define the outcome of standard operating procedures (SOPs) for organizations that have voluntarily subjected themselves to certification procedures, such as ISO. Why should the public sector not also define such SOPs and specific outcomes for the important targets of a license agreement?

However, one of the underlying assumptions for everything outlined above is that milestones are not cast in stone. Milestones should be and need to remain adjustable throughout the lifetime of a license agreement to respond to changes in the project, changes in the market environment, and other factors that cannot be anticipated. When it comes to the detailed specifications of individual milestones, it does not really matter if one is choosing an absolute or a relative goal, or which definitions are finally selected. What matters is getting a private sector company to commit to accepting public sector targets. To accomplish this, it is important to have a working set of adequate milestones in place, to define review periods for performance assessment by the contract partner, and to be ready to be open to, and to accept, milestone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive.

Such result-oriented milestones require:

- intensive preparation
- detailed knowledge of processes related to product development and marketing
- detailed knowledge of markets
- realistic anticipation and forecasting of product potential
- persistence in quantitative forecasting and in establishing a master plan for the entire product roll-out
- a mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking

Finally, it is crucial to recognize that public–private partnerships are not a magic solution per se for tasks that have not been well specified! In this sense, public–private partnerships are a poor substitute for specific, well-defined targets. In fact, successful public–private partnerships are built upon specific, well-defined targets. ■

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1 See www.ippph.org for a complete list.

2 www.ConceptFoundation.org.

3 PIACT, the Program for the Introduction and Adaptation of Contraceptive Technology, is a predecessor of PATH.

4 For a broader discussion on field-of-use licensing, see the chapter 10.3, also in this *Handbook*, by SL Shotwell. Also, the chapter by M Olson, also in this *Handbook*.

5 IMS is an international company that publishes reports on pharmaceutical sales by conducting pharmacy audits and other means.

Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms

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ABSTRACT

This chapter reviews different forms of IP (intellectual property) "assembly" mechanisms (royalty-collection agencies, information clearinghouses, technology clearinghouses, open-source innovation clearinghouses, honest brokers, and other forms of facilitators, IP management services, IP commercialization agents, the services of merchant banks and venture capital enterprises, and patent pools). Emphasis is placed on patent pools, which are voluntary agreements between two or more patent owners to license one or more of their patents to one another or to third parties. Although there are many forms of patent pools, such arrangements fundamentally consist of the interchange (cross-licensing) of rights to essential patents by a number of entities, as well as an agreed framework for out-licensing the pooled intellectual property to each other and/or to third parties, including an agreed-pricing and royalty-sharing scheme.

There are both benefits and risks associated with patent pools. Benefits include greater ease with respect to resolving patent conflicts, making assembled patents in the pool available to others, and resolving disputes over blocking patents. Risks include antitrust liability. Under certain circumstances, patent pools have application in the area of humanitarian licensing as instruments of assembly of intellectual property.

1. INTRODUCTION

The importance of IP (intellectual property) "assembly" is becoming increasingly evident as the biotechnological components, both methods and materials, that are used in the R&D of agricultural and health innovations become more and more complex. The use of patent pools can be one way to achieve IP assembly. However, patent-pool formation is complex and often costly; it requires special economic, business, and legal considerations, and it is but one option to facilitate assembly and access.

One aspect of IP management is obtaining freedom to operate (FTO) for a given product in a given market.[1] Assembling intellectual property is therefore an essential step in innovation management. But having FTO alone does not bring a product to market, much less provide the product to the poor in developing countries. In this context, the value of patent pools must be carefully considered on a case-by-case basis, and, hence, the appropriateness of a patent pool for any given technological innovation will require careful analysis and consideration. This analysis will necessarily include legal, business, operational, and strategic considerations. Furthermore, it is important to remember that a patent pool simplifies the assembly of intellectual property, but does not in itself do much or necessarily lead to technology transfer or market access and distribution.

Before discussing patent pools in detail, the chapter will provide a brief overview of IP assembly options and mechanisms. This broader perspective will therefore place patent pools within

Krattiger A and SP Kowalski. 2007. Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

a context of available IP assembly tactics and explain the advantages and disadvantages of each.

2. IP ASSEMBLY: MECHANISMS AND OPTIONS IN PERSPECTIVE

A complex mix of factors drives technological innovation, but they essentially boil down to national policies, international agreements, and market dynamics. Innovation is the starting point for making inventions commercially and socially useful, but innovation alone will not lead to technological products that can produce goods or services. An invention must be assembled by putting together the patents and other forms of intellectual property from third parties. In-licensing is the best-known mechanism for intellectual property assembly, and patent pools are a complex form of licensing. But other mechanisms are also standard corporate approaches, including:

- mergers and acquisitions (M&As)
- strategic alliances (collaborations, joint ventures, corporate partnerships)
- licensing (principally IP bundles comprising an entire range of inventions required to practice, also called freedom to operate)

By itself, however, the assembly of IP will not make an invention commercially useful; many other steps are required, ranging from regulatory to the access of know-how. From a broader perspective, assembly and licensing can be facilitated through a range of mechanisms. These are summarized in Table 1. In the context of this *Handbook*, the range of mechanisms listed also include capacity-building services that more broadly deal with technology transfer.

2.1 *Royalty collection agencies*

In its simplest form, a license collection agency is a mechanism whereby one entity collects royalties on behalf of its members for a small fee. In this situation, the members make deals and set royalty rates, either bilaterally or multilaterally. The multilateral system is best known in the music business. Many restaurants and bars, for example, have jukeboxes with hundreds of CDs where customers insert money and select songs from individual CDs. Each time a song is played, a percentage of the revenue goes to the publisher of the CD and to the artist. In the United States, the American Society of Composers, Authors, and Publishers (ASCAP), composed of over 170,000 artists and publishers of every kind of music, protects the rights of its members by licensing and distributing royalties for the nondramatic public performances of their copyrighted works.[3] ASCAP makes giving and obtaining permission to perform music simple for both creators and users of music, and its licensees encompass all who want to perform copyrighted music publicly.

2.2 *Information clearinghouses*

The term *clearinghouse* derives from banking institutions and refers to the mechanism by which checks and bills are exchanged among member banks so that only the net balances need to be transferred in cash. Today, the term has much broader meaning and includes any mechanism whereby providers of goods, services, or information are matched. The CBD (Convention on Biological Diversity) clearinghouse[4] for biodiversity aims to promote and facilitate technical and scientific cooperation, develop a global mechanism for exchanging and integrating information on biodiversity, and develop the necessary human and technological network. Information clearinghouses also provide entry to a country's biotechnology (for example, Finland[5]), as do training clearinghouses that offer training for biotechnology technicians (for example, BioLink[6]), and industry links, updates, news, and job markets (for example, BioPortfolio[7]).

2.3 *Technology clearinghouses*

A comprehensive Web-based clearinghouse can lower the transaction costs and increase participation. In practice, however, such gains have not been realized with IP exchanges. This is because the applications specified in patents are highly heterogeneous, often difficult to define, and can only be valued after considerable experimentation and refinement has taken place and then only within the technological application.[8] However, IP exchanges are not very common. Few of them are complete enough to allow a

Table 1: Summary of IP Assembly Mechanisms and Options

Type of Mechanism or Service	Characteristics	Examples
Royalty collection agencies: Collection of royalties for a small fee by one entity on behalf of its members	Useful if licensing industries are already established; can be created by industry itself	American Society of Composers, Authors, and Publishers; British Society of Plant Breeders
Information clearinghouses: Broad term denoting a mechanism matching providers of goods, services, or info.	Useful for the exchange of specific information related to an activity or industry; does not facilitate tech transfer per se	BioBin, BINAS; portals to countries or industries biotech, training programs
Technology clearinghouses: 1. Web-based IP auctions and licensing, including business-to-business	Appropriate for general purpose technologies, platform technologies, bundles; limited ability to spread tech transfer further	Virtual trading floors, patent auctions
2. Public-sector initiatives dealing with training, good practices, and the bundling of technologies	Appropriate for development; furthers tech transfer	Public Intellectual Property Resource for Agriculture (PIPRA)
Open-source innovation clearinghouses: Web sites on which anyone can post ideas or inventions, and anyone is allowed to turn the ideas into products	Potentially appropriate for open-source licensing and diffusion of tangible research materials	Barry Nalebuff and Ian Ayres "Why Not?" or HalfBakery
Brokers and other forms of facilitators: Typically focused on creating public–private partnerships, providing "managed" tech transfer	Appropriate for charting new territory and bringing public and private actors closer	African Agricultural Technology Foundation (AATF); Global Alliance for Vaccines and Immunization (GAVI)

(Continued on Next Page)

Table 1 (continued)

Type of Mechanism or Service	Characteristics	Examples
IP management services: Comprises a wide range of entities, both public and private, assisting institutions in managing their IP assets	Good for addressing systemic issues; establishes new modes of interaction	Law firms, management consultants, global nonprofit entities (for example, MIHR), and academic training
IP commercialization agents: 1. Commercial entities dedicated to commercialization of third-party intellectual property	Highly effective business model; useful to learn from their experiences and adapt to serve nascent private sectors.	BTG Ltd.; certain specialized law firms
2. Mixed commercial and public-good objectives	Useful to learn from their experiences and adapt the model to other biotech sectors	Concept Foundation, for example
Integrated commercial services: A range of services for M&As, spinouts, including IP audits, business valuation, due diligence	There could be a need for a nonprofit merchant-bank-type institution to provide services to small/medium size enterprises	Merchant Banks; venture capital investment services
Patent pools: A voluntary agreement between two or more patent owners to license one or more of their patents to one another or third parties	Pooling unlikely to change the underlying structural barriers to technology transfer; difficult to establish because industry players have divergent strategic interests; in partial/modified form, effective for tech transfer	Internal, company-specific pools; portfolio pooling, cooperative pooling, third-party aggregations, forced pooling
Other public technology transfer and financing mechanisms	Range from education and training institutions, to consortia in health, and to certain specialized UN programs (including South–South transfers)	
Company-to-company arrangements: collaborations, joint ventures, strategic partnerships, and corporate partnering	Some of the most ubiquitous and efficient systems of technology transfer, rarely requiring public sector assistance; different government policies either encourage or thwart them	

Source: Krattiger.[2]

prospective licensee to assemble all the needed licenses to obtain freedom to operate (FTO). In addition, actually negotiating with a company often not only allows for cross-licensing but also for the transfer of know-how or trade secrets. And finally, IP owners typically use their patent portfolios as a strategic tool, a practice not conducive to wide licensing. Merely clicking on a Web link, downloading a standard license, and wiring money is rarely sufficient for technology transfer to occur.

The Public Intellectual Property Resource for Agriculture (PIPRA),[9] on the other hand, as a *managed IP exchange* initiative involving universities, foundations, and nonprofit research institutions, seeks to make agricultural technologies more easily available so that subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world can be more rapidly developed and distributed. The rationale for PIPRA is that intellectual property is often unwillingly encumbered. Universities, for example, typically grant worldwide exclusive licenses. Changing these licensing policies and retaining the rights for humanitarian uses in the developing world would make it much easier to transfer intellectual property and tangible property (TP) from universities to the developing world.

PIPRA brings together public sector institutions to collaborate and bundle their licensed and unlicensed technologies, as "shared technology packages," making the technologies more readily available to member institutions for commercial licensing or for designated humanitarian or special use. As part of this effort, a database of patented agricultural technologies is being developed to inform researchers about FTO, allowing them to modify their research plan to include more licensable technologies (IP and TP) or public ones. PIPRA is also currently exploring the creation of a patent pool.

2.4 *Open-source innovation clearinghouses*

One special category of clearing houses is worth mentioning, the open-source innovation clearinghouse. Consider a Web site initiated by two Harvard Business School professors, economist Barry Nalebuff and law professor Ian Ayres, to prove that innovation is a skill that can be taught. One hotly debated idea at the site in recent months is the so-called "reverse 900 number"—where telemarketers pay people to accept calls. Their system of innovation is growing on the Web[10] and deploys economics, game theory, psychology, and contract law to argue that innovation can be routinized and institutionalized.

Another Web initiative, called HalfBakery,[11] allows anyone to post ideas for innovative products and services. Anyone can turn the ideas into marketable products if they wish, without the need for licenses. The service quickly gained international fame when what may have appeared as "half baked ideas" were turned into commercially successful products, though none, as yet, in the area of health and agriculture.

This mechanism should not be confused with open-source licensing.[12] With software, open-source licensing is essentially the licensing of inventions without patent protection—the only requirement is that any licensee must agree to make available to others any improvements in the invention or technology. Applying this established mechanism of open source from software to biotechnology, where *source code* has no real equivalent, has not worked as yet. New terminology might be appropriate, such as *distributed, internet-based collaboration* or "non-proprietary peer-production of information-embedding goods."[13] One attempt to implement open source is the Biological Innovation for Open Society (BiOS).[14] Essentially, BiOS is a specific form of a patent license. It is really another way to describe a patent license with some novel terms. To what extent BiOS will foster innovation remains to be seen.

2.5 *Honest brokers and other forms of facilitators*

Honest broker is a term often used in peace negotiations but it has also been used by nonprofit organizations engaged in public–private partnership building. One institution that had its foundation as an honest broker is the International Service for the Acquisition of Agri-biotech Applications (ISAAA).[15] During the 1990s, it operated primarily as a facilitator, matching available technologies

to meet identified needs, brokering technologies, and building capacity by transferring knowledge and know-how between companies in developed countries and the public sector in developing countries. ISAAA addressed other constraints in biotechnology transfer, such as regulatory issues. In the last few years, the organization has shifted its strategy toward knowledge sharing.

A similar, more-recent institutional mechanism is the African Agricultural Technology Foundation (AATF).[16] Like PIPRA, AATF is emerging from a Rockefeller Foundation initiative. AATF recognizes that new and unique public–private partnerships are needed to remove many of the barriers that have prevented smallholder farmers in Africa from gaining access to existing agricultural technologies. Focusing on the creation of these public–private partnerships, it seeks to dramatically improve access to agricultural technologies, materials, and know-how, at the same time promoting efforts to create sustainable markets.

A similar organization in human health biotechnology is the Global Alliance for Vaccines and Immunization (GAVI).[17] Created in 1999, it functions as a broker for private and public sector entities committed to expanding the use of vaccines in the developing world. International organizations, governments, vaccine industry, research institutions, and major philanthropists collectively form a dedicated partnership serving the shared GAVI objectives. It includes as a subsidiary, or financial arm, the Vaccine Fund, which sponsors GAVI's objectives in poorer countries. The alliance also has programs to stimulate the vaccine industry to develop and supply vaccines that are vital to low-income countries. GAVI acts more at the product transfer level, whereas ISAAA and AATF function somewhat further upstream. ISAAA initially also aimed at charting new territory and creating models (which are more time consuming) rather than transferring large quantities of technologies.

2.6 *IP management services*

The best-known IP management services are law firms that specialize in patenting and licensing and management consultants, such as KPMG, the Boston Consulting Group, and Ernst & Young. These commercially oriented entities are discussed in the next section, but let us first focus on the nonprofit players in this field. A new organization headquartered in the United Kingdom, the Centre for the Management of IP in Health R&D (MIHR),[18] essentially acts as a service to public sector organizations in developing countries (and some private ones) to manage their intellectual property (in-house–generated, in-licensed, and to-be in-licensed) more authoritatively. It assumes that health programs that manage intellectual property well are more effective at mobilizing resources, technologies, and partners to deliver improved health care to the poor.

2.7 *IP commercialization agents*

Many types of "consulting" services fall broadly within this category, but only one institution is solely dedicated to the profitable commercialization of third-party intellectual property in the fields of health, medicine, and other biotechnologies: BTG Ltd.,[19] formerly known as the British Technology Group. Perhaps the world leader in commercializing novel technologies, BTG operates globally with a focus on Europe, North America, and Japan. The firm combines a strong commercial focus with a deep understanding of how to develop innovation, enhance intellectual property, and achieve critical development milestones. Clients include public research centers and global technology companies, from startups to multinational companies. It functions as a retainer for technology innovators, charging fees and sharing in revenues generated from its services.

In addition to services in several areas, the company seeks licenses for the technologies they manage. This includes assistance in seeking venture capital, the management of startups around platform technologies, and R&D funding to ensure that the technologies in BTG's portfolio become commercially viable. To accomplish this, BTG acquires or in-licenses promising technologies, assists in patent protection of inventions, forms alliances to advance inventions through an R&D phase, and develops technology marketing strategies. In effect, BTG pools

necessary technologies centered on the core innovations it manages, in order to increase the value of its portfolio. On the development side, the most prominent enterprise is the Concept Foundation,[20] headquartered in Thailand, which provides a mechanism to turn intellectual property, developed or owned by international organizations, into competitive and cost-effective products to be distributed at the lowest possible cost, especially into the public sector healthcare channels of developing countries. This intellectual property is typically owned in the form of data from medical research and clinical trials, data from pharmacological studies, manufacturing instructions, and so on. In some cases, the intellectual property owned by international organizations such as the World Health Organization (WHO) is enhanced through IP donations from pharmaceutical manufacturers earmarked for public sector healthcare services in the developing world. The licenses are negotiated by highly experienced foundation staff led by a former senior executive in pharmaceuticals.

2.8 *Merchant banks*

The term *merchant bank* was developed hundreds of years ago to describe well-financed organizations that sought high returns on their investments in return for predictable risk (which was also the original idea of a limited-liability company). Today's investment bank services include IP audits, business valuation, due diligence, and fairness opinions,[21] acting as a confidential advisor in preparing divestiture, managing the entire process of initial public offerings (IPOs), marketing divestitures, finding acquisition targets, structuring transactions, providing financing, facilitating financing, and refinancing existing debt.

Merchant Banks are essentially full-service centers for M&As, financial management, agreements, required government filings, antitrust issues, valuations, due diligence, and so on. Their services are crucial for any type of business, large or small.

2.9 *Other technology transfer mechanisms*

It would be negligent to fail to mention other types of technology transfer facilitators, ranging from education and training institutions (for example, universities across the world), to international agricultural research centers (for example, the CGIAR), to health consortia (for example, the Program for Appropriate Technology in Health [PATH]), or the many specialized UN programs. Company-to-company arrangements (including collaborations, joint ventures, strategic partnerships, and corporate partnering) are some of the most ubiquitous and efficient systems of technology transfer.

3. FOCUS ON PATENT POOLS

A patent pool is "*an interchange of patent rights by several companies. Either one or more of the patent owners, or some separate entity, has the right to license others under the pooled patents.*"[22] In essence, a patent pool is a voluntary agreement between two or more patent owners to license one or more of their patents to one another or to third parties. In other words, they are "*the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.*"[23] And further, "*The rationale for patent pools is simple: by reducing the number of necessary transactions and by simplifying patent landscapes, they can reduce transaction costs and facilitate technology transfers. Patent pools have the obvious but important advantage of considerably reducing the number of licences that need to be negotiated.*"[24]

Although there are many forms of patent pools, such an arrangement fundamentally consists of the interchange (cross-licensing) of rights to essential patents by a number of companies, as well as an agreed framework for out-licensing the pooled intellectual property to third parties, including an agreed-pricing and royalty-sharing scheme. Patentees can provide licenses directly to licensees, or licenses can be provided indirectly via a licensing entity that is specifically authorized to administer the patent pool.[25] "*A key difference between a patent pool and a cross-licensing agreement is that, in the former, the patent owners agree to license to third parties that do not themselves contribute patents to the pool.*"[26]

3.1 *The main pros and cons*

Patent pools are "*competitively beneficial in that they may help resolve patent conflicts, make assembled patents in the pool available to others, or resolve disputes over blocking patents. On the other hand, a patent pool is a horizontal agreement among competitors and carries the potential for abuse and as a cover for an anticompetitive cartel.*"[27] Hence, a patent pool, depending on how it is organized and implemented, represents a potential double-edged legal sword: able to cut through patent-thicket blockages to facilitate access to critical technological innovations, yet also potentially honed in such a way that antitrust issues arise. In other words, patent pools can facilitate access by overcoming IP obstacles via assembly of patents or can inhibit access via monopolization of intellectual property (complete with inequitable remunerations) and shielding of invalid patents.[28]

In addition, from a practical perspective, it is important to know what patent pools can, and cannot, facilitate. For example, patent pools serve the assembly of intellectual property, not the transfer of technologies per se. Although the U.S. Department of Justice (DOJ) along with the U.S. Federal Trade Commission (FTC) have observed that "*by promoting the dissemination of technology, cross-licensing and pooling arrangement are often procompetitive,*" it is critical to understand that, in the context of technology transfer and collaboration with developing country partners, patent pools would *mainly assist with licensing intellectual property*. That is, such developing countries would not necessarily benefit equally from sharing know-how, show-how, and trade secrets. Hence, patent pools can serve certain purposes and confer benefits, but they are not an IP management panacea.

Still, a patent pool can have advantages: intellectual property can be licensed through an efficient one-stop shop, stacking licenses can be eliminated, patent litigation can be averted, and institutionalized exchanges of otherwise proprietary know-how (trade secrets) can be facilitated.[29] Significant research and administrative costs would decrease dramatically. Speed and efficiency would be greatly increased. A patent pool is an IP management tactic that can have a significant positive affect on facilitating access to innovations, yet, it is important to recognize that a pool may not be the only way to achieve these objectives, and that, in the overall context of best practices in IP management, there may be other equally effective approaches.

Patent pooling has been more focused in the realm of DVD technologies, where it makes sense to generate revenue through sales and not licensing. Such patent pools help to clear blocking positions. But with regard to patent pools for public-health initiatives, it appears that there is less likelihood that companies will give up their exclusive IP rights, depending, of course, on the technologies under consideration. This is because pools tend to arise organically because the owners of intellectual property are mutually stymied; this, for example, has not yet happened for vaccines. The technology is not at the same level of maturity as in the DVD industry. Patent pools are especially useful for developing industry standards. Hence, although patent pools have been successfully implemented in various industries (notably electronics), their application to health and agriculture may still be, relatively speaking, premature. The pros and cons are summarized in Table 2.

3.2 *Organization and establishment*

Organizing and establishing a patent pool is not a simple matter.[30] It is a long, complex, multistep process, with many technical, legal, and business challenges. It therefore requires the interdisciplinary coordination of efforts by attorneys, scientists, business professionals, and other experts. Setting up a successful patent pool therefore requires organization and planning, based on sound information and solid analysis. These conditions having been met, the operational, business and legal aspects of the pool can be effectively managed and successfully executed.

A ten-step checklist for setting up a patent pool would include the following considerations:

1. Determining the validity of the patents to be pooled
2. Determining the essentiality of the patents being considered for inclusion in the pool
3. Patent analysis by an independent expert

4. Nonexclusive licenses to the pool
5. Licensees must be free to develop and use alternative technologies
6. Grant-back licensing provisions, from licensees to licensors, on improvements to essential patents and with reasonable terms, should be available on a nonexclusive basis
7. Royalties should be distributed among the licensors according to a formula set forth in the patent pool agreement
8. Royalties paid to the pool by licensees should be fair, reasonable, and nondiscriminatory
9. Sensitive business information must be safeguarded
10. Appropriate dispute resolutions, preferably, independent and neutral, should be part of the patent-pool agreement

A ten-step procedure for setting up a patent pool would include the following activities:

1. Observation of a potential patent thicket that could be overcome by an appropriately structured patent pool
2. Patent and scientific experts identify essential technologies
3. Patent experts identify patents and patentees
4. Working group set up by counsel
5. Initial agreement among patentees to move forward with pool development
6. Further evaluation of patents by both scientists and patent experts
7. Agreement on patent-pool conditions
8. Signing of patent-pool consortium agreement
9. Antitrust analysis and evaluation as per the jurisdictions under consideration (for example, the United States, Europe, and Japan)
10. Execution of patent-pool agreement

Patent pools are set up by the patent holders, who function both as shareholders of the pool and also as financiers of the designated licensing authority (if the patentees themselves do not function as the actual licensors). The patent holders,

Table 2: Summary and the Pros and Cons of Patent Pools

Pros	Cons
Integrates complementary technologies	Difficult to agree on the value of individual patents contributed to a pool
Reduces transaction costs	Complex to set up and avoid antitrust problems (collusion and price fixing)
Clears blocking positions	May inflate licensing costs through nonblocking or unnecessary patents
Avoids costly infringement litigation	Complex when many patents are under litigation, as is the case with biotechnology
Promotes the dissemination of technology	May shield invalid patents and thus prevent much technology from entering the public domain
Levels the playing field	

therefore, establish and retain authority over the licensing provisions.[31]

3.3 *Examples of pools*

One of the first such patent pools was created for the manufacturing of sewing machines in the mid-19th century.[32] Other examples of early patent pools include aircraft manufacturing, glass manufacturing, and radio technology. In each case, the pool contributed significantly to industry standards (for example, radio waves). More recently, patent pools were created to enable standard settings in DVDs, video games, and MPEG2 video-compression technology. Interestingly, private and public sector participants formed the latter in 1997: Columbia University, Fujitsu, General Instrument, Lucent, Matshushita, Mitsubishi, Philips, and Sony.

Typically, however, patent pools are constituted by members who each contribute patents in their respective fields. Whether or not developing country institutions will qualify to become members of patent pools will, naturally, depend on their respective potential contributions.

The following types of patent pools exist today:

- **internal, company specific.** For example, DuPont combining technologies through internal development or Syngenta complementing its internal portfolio with outside technology through licensing and M&As; critical challenge is to keep internal innovation ongoing and tightly managed
- **portfolio pooling**. Internal technology supplemented with third-party technologies, for example, Microsoft; critical challenge is to have a dynamic team handling in-licensing and aligning strategies closely with the overall corporate strategy
- **cooperative pooling.** Companies agree to combine their technologies and allow them to be managed by a separate entity, typically for standard-setting purposes; critical challenge is to avoid antitrust issues
- **third-party aggregations.** For example, strategy practiced by BTG Ltd.; critical challenge is to work around antistacking provisions that are very common in biotechnology licenses
- **forced pooling.** For example, rarely enforced compulsory licensing and the pooling forced by the U.S. government shortly after the radio was invented

3.4 *Patent pools in biotechnology*

In biotechnology, unlike in much of the electronics industry, standard setting is not really an issue, which may explain why patent pools have not been necessary for the biotechnology industry to commercialize products (for example, in the development of drugs and vaccines). Nonetheless, as the biotechnology industry continues to grow and mature, and with specific sectors becoming commercially focused, there may be fundamental challenges that can be effectively addressed via patent pooling.

For example, the issue of "research tools" in the life sciences has led to a call for patent pooling in the U.S. companies, and institutions involved in biotechnology research are encountering widespread delays due to the near-universal patenting of research techniques that were traditionally available in the public domain. Uncertainty over the prospective costs of licenses, royalty stacking that creates uncompetitive costs, delays in obtaining licenses, and the differing definitions of *pure research* versus *product development* across different territories are all inhibiting biotechnology R&D in many areas.

Similarly, one of the biggest public concerns voiced against the PTO for its practice of granting of patents for inventions in biotechnology, particularly in genomics, is the difficulty of accessing patented inventions for basic biological research and R&D. One solution to this constraint is to form patent pools, a mechanism successfully implemented by other industries.

In a rapidly changing field such as biotechnology, patent pools can have significant procompetitive effects and may improve an industry's ability to survive. For developing countries, patent pools may eventually become even more important because companies can easily obtain the licenses required to practice a particular technology, which reduces transaction costs and facilitates the rapid deployment of new applications in health and agriculture. Hence, there is no reason

that a novel type of patent pool, centered on preferential licensing terms to developing countries, could not be established.

Still, when considered from the perspective of the overall biotechnology industry, while patent pools may be very useful for assembling IP related to platform technologies that need to establish industry-wide standards (for example, DVD, MP3), the value of patent pooling is much less when industry interests are not aligned (still maturing industries), which, indeed, is the general case with biotechnology. Hence, in the context of R&D in many biotechnological applications, for example, with respect to vaccines—an evolving field with no platform and with no technology clearly in the lead—industry interests can hardly be considered aligned. Indeed, if a technology has not matured to the stage where industry standards can even be contemplated, then a patent pool would likely not be the favored option. At these earlier stages in the R&D of innovative technologies, few companies will have an interest in giving their rivals preferential access to their technologies. Companies also typically become cautious about antitrust issues when a patent pool is suggested, which might also hinder participation.

As an illustrative example of the current situation with (at least most of) the biotechnology industry and the potential for using patent pools, Gaulé draws our attention to the recent SARS outbreak:

Shortly after the severe acute respiratory syndrome (SARS) outbreak in February 2003, patent applications covering sequences of the genome of the SARS coronavirus were filed by several research teams around the globe. Some have argued that this may result in a complex, uncertain IP situation that could delay the development of SARS vaccines and diagnostic tools. As a result, the four parties known to own key patent applications (CDC) have expressed their willingness to form a patent pool and enable wide access to the SARS genome. But consider the differences between the SARS patent pool and the consumer electronics pools. The SARS patent pool will not be in an industry characterized by all-important network effects or be closely linked to a standard. For the moment, the licensors are not vertically integrated firms but universities and public institutions, and so there will be far fewer licensees. Most importantly, however, the commercial products in which the licensed technology will be embedded do not yet exist and will be developed by the licensees after extensive R&D efforts. Therefore, the licensing policy of the SARS patent pool might be quite different from other modern patent pools.[33]

However, the use of patent pools in biotechnology will likely increase as sectors of the industry mature into focused, identifiable technologies and products/services (as has been the case in the electronics industry). One area where this appears to be the case is diagnostic genetics, that is, disease-specific (for example, breast cancer and cystic fibrosis) diagnostics. This indeed appears to be an example of a rapidly emerging area of the biotechnology industry where patent pools might be applicable and advantageous. Unlike the general area of genomics, which is broadly diverse, diagnostic genetics is commercially focused on identified diseases with clear industry standards (mutations for analysis), and the players in the field share common goals. Hence, patent pools, narrowly constructed to address the diagnosis of specific polymutational diseases (for example, cystic fibrosis), could have great utility in overcoming IP thickets that inhibit access to advances in genetic diagnostics.[34]

Those who advocate patent pools as a solution to a general problem with assembling intellectual property related to biotechnological advances in health and agriculture should keep in mind that they embody many challenges; for example, in addition to the presence, or lack thereof, of industry standards, patent pools are expensive to establish and maintain. Hence, unless a given technology reaches a certain economic threshold, there is no financial incentive to establish a patent pool. The economic feasibility of a pool is determined by:

- number of pool participants
- number of patents held by each pool participant
- likelihood of a patent being useful for a given platform
- number of patents required to assemble a viable platform
- market value of the assembled platform

- cost to assemble and maintain the pool

As the biotechnology industry continues to grow and mature, the applicability of patent pools will also likely increase.

3.5 *Legal concerns*

One reason why patent pools are often approached with caution is because U.S. antitrust law has the reputation for precariously situating patent pools on the borderline between allowed monopolies and antitrust violations. Although the legalities of forming patent pools exceed the scope of this chapter, it is worth noting that the U.S. Department of Justice (DOJ) along with the U.S. Federal Trade Commission (FTC) have published guidelines for patent pool applications and require an opportunity to review applications for them.[35]

The PTO has summarized the DOJ/FTC patent pooling antitrust guidelines, and this serves as a concise template for understanding the potential antitrust implications of patent pools.[36] When making antitrust determinations, courts consider these guidelines as part of a multifactor weighing "rule of reason" analysis.[37] What follows is a brief excerpt from the PTO paper.

Since 1979, the FTC has had a similar procedure, in which businesses may seek FTC advisory opinions concerning proposed business practices. These procedures led to Justice Department and FTC policies in the IP licensing area, and in 1995, these agencies issued Antitrust Guidelines for the Licensing of Intellectual Property, *"IP Guidelines," which sets forth their enforcement policies in this area. The IP Guidelines specifically address pooling arrangements involving IP owners and their rights.*

In particular, the IP Guidelines state that IP pooling is procompetitive when it:

- integrates complementary technologies
- reduces transaction costs
- clears blocking positions
- avoids costly infringement litigation
- promotes the dissemination of technology

The IP Guidelines also discuss that excluding firms from an IP pool may be anticompetitive in these circumstances:

- The excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies.
- The pool participants collectively possess market power in the relevant market.
- The limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies.

Anticompetitive effects may also occur if the pooling arrangement deters or discourages participants from engaging in research and development that is more likely when the arrangement includes a large fraction of the potential research and development in an innovation market.

The DOJ has applied these guidelines in considering and approving three proposed patent pools. Its first review set forth the following additional guidelines:

- The patents in the pool must be valid and not expired.
- These can be no aggregation of competitive technologies and setting a single price for them.
- An independent expert should be used to determine whether a patent is essential to complement technologies in the pool.
- The pool agreement must not disadvantage competitors in downstream product markets.
- The pool participants must not collude on prices outside the scope of the pool, for example, on downstream products.

Currently, the guidelines have been "collapsed" into the following two overarching questions:

1. Whether the proposed licensing program is likely to integrate complementary patent rights

And if so:

2. Whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program

4. CONCLUSIONS

Patent pools have received much attention in recent years as a possible solution to the patent

thicket. This review shows that patent pools are indeed one possible option, but others should also be considered. Organizing and establishing a patent pool is not a simple matter. It is a long, complex, multistep process, with many technical, legal, and business challenges involving the interdisciplinary coordination of efforts by attorneys, scientists, business professionals, and other experts. Setting up a successful patent pool therefore requires organization and planning, based on sound information and solid analysis.

As procompetitive arrangements, patent pools are aimed at IP assembly. They seek to resolve patent conflicts (reducing litigation), to settle disputes over blocking patents (accelerating product development and FTO), and to facilitate arrangements for licensing patents in the pool to outside members (accelerating the setting of standards and reducing licensing transaction costs). They exploit economies of scale by integrating the technical complementarities of the pool members.

From a legal perspective, pools require careful antitrust considerations to avoid potential, perceived, or real anticompetitive behavior by pool members or, more importantly, by the pool itself. From an operational perspective, only essential patents can be included in a pool. And finally, from a business perspective, the interests of the various IP holders need to be aligned in order to bring them to the table (pools are invariably voluntary arrangements). ■

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SECTION 3

The Policy and Legal Environment for Innovation

The Courts and Innovation

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ABSTRACT

Established and enforceable rules of law can provide just and expeditious resolution of the disputes that are inevitable in vigorous commerce. But in the rapidly evolving subject matter of biotechnology, this science can bring to court issues for which there is no precedent and about which there is no consensus. The rule of law, however, is vibrant, adapting to the evolving contexts of science and technology. In today's era of rapid technological change, jurisprudence provides the stability of the law, while reflecting the social implications of the science. But the scientific and technologic issues of today, such as arise in IP disputes, must also be correctly decided to promote a uniform and predictable application of the law that promotes commercial stability adequate to support industrial innovation and the national interest.

1. INTRODUCTION

The role of courts in technology development, protection, transfer, and commercialization, in biotechnology as in all fields, is a combination of the traditional role of courts in dispute resolution and the common-law role of courts in the evolution of law. In a national and world economy that is increasingly technology based and yet governed by jurisprudence reflecting cultural norms, new fields of science and technology propel the courts into proceedings and decisions of economic and societal impact.

With respect to commerce and trade, legal systems have been described as having three missions. The first is to establish the rights and rules of property ownership, including intellectual property (IP). The second is to protect property rights from illegal disposition by guarding against civil wrongs and crimes. The third is to provide and enforce the rules of exchanges and transfers of property: the laws of contracts and sales and competition. In addition, legal systems establish rules for entering and leaving commercial activity, such as corporate law and bankruptcy law, and rules that promote competition and innovation, such as antitrust and IP law. In the development, management, and transfer of technology, effective legal systems provide stability and predictability of national and international force. This concept is globally applicable: strengthening the rule of law has broad-ranging implications for every country and organization. In regard to IP laws, which partake of so many interrelated policies, understanding how the courts balance conflicting policies can provide useful guidance to business, technology managers, and scientists.

Litigation in the fields of today's biological advances takes us to the edge, not only of science, but also of conflicting policies—often at the limit of judicial experience. Justice Holmes said, "The life of the law has not been logic: it has been experience." Human experience absorbed science and technology into the common law and its basic concepts of property, human responsibility, and fairness. But litigation of disputes concerning

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science and technology is bringing new challenges to the search for justice through truth—the foundation of judicial systems.

Judges do not create national policy or industrial policy; such policy finds its origins in the cultures of nations, and its sustenance in the laws of nations. Yet policy comprehension is essential to judicial decisions. When technology and biology are involved, then the jurisprudential overview (as well as the decision of individual cases) can affect the nation's economy and the public interest. It will additionally have an even broader global impact. This *Handbook* arises from the premise that developing the products of science and technology is of profound public benefit, a benefit that requires both scientific and industrial participation. This is a many-faceted concept, yet today we exist in an era of such pervasive scientific and technological advance that the development of these benefits, and their movement into commerce and among nations, warrant our most concerned efforts.

2. THE COURTS AND TECHNOLOGIC ADVANCE

The courts implement the rules by which society chooses to be governed. A reliable mechanism of dispute resolution eases the path to sustainable technologic advance, economic growth, and ensuing public benefit. Established and enforceable rules of law can provide just and expeditious resolution of the disputes that are inevitable in vigorous commerce. In the rapidly evolving subject matter of biotechnology, this science can bring to court issues for which there is no precedent and about which there is no consensus. In such areas, legal issues arising from developments in science and technology often reach the courts for primary resolution, and the decision can affect both economic and technologic advance.

An example is seen in the U.S. Supreme Court's decision in the *Chakrabarty* case in 1980,[1] when despite predictions of the dire consequences of authorizing patents on *life forms*, the Court opened the nation's economy to industrial biotechnology, enabling commercialization of this nascent field, to the human benefit that is today bearing fruit. The growth of the biotech industry is a testament to judicial vision, for the U.S. Patent Office had refused to patent Dr. Chakrabarty's modified bacterium that was designed to digest oil spills. It was the Court of Customs and Patent Appeals and the Supreme Court that held otherwise.

Another example is seen in the U.S. Court of Appeals for the Federal Circuit, created for the purpose of revitalizing technologic innovation in a faltering economy. The industrial and scientific communities had recognized that national policy, as implemented in the courts, was inadequately supporting industrial innovation, a failure attributed to an inadequate understanding of the relationships among scientific research, technologic advance, and commercial investment. The adverse effects included a negative balance of trade, retrenchments in industrial R&D, mass layoffs of scientists and engineers, sparse capital formation, stagnation in productivity, and loss of international competitiveness.

Judicial misunderstanding of the system of patents and its purposes and processes was a primary problem. As a result, patents were not viewed as reliable support for commercial investment, for they could be litigated in circuit after circuit until they fell. And the Justice Department's "nine no-no's" of patent licensing were a further disincentive to technology transfer. During the economic recession of the late 1970s, the retrenchment of investment in new technologies was so severe that dramatic remedies were accepted—including the first major change in the federal judicial structure in a hundred years.[2]

Thus the federal judicial system was restructured to provide a national appellate court that would receive all patent appeals throughout the nation, whether from the district courts, the International Trade Commission, or the Patent Office.[3] The hope was that a single appellate court would better understand, and correct, the policy misperceptions that had led to a judge-made reduction of the patent incentive for investment in technologic advance. The goal was a uniform and predictable application of the law that would promote commercial stability adequate to support industrial innovation. The change was not without vigorous controversy, but it was implemented

with the congressional leadership of Wisconsin Representative Robert W. Kastenmeier and senators Robert Dole and Patrick Leahy. It was an extraordinary and creative action to change the nation's court system as an incentive to technologic advance. And the effect of this juridical change was dramatic, as entrepreneurial business as well as established industry returned to developing new and improved technological products.

The change in industrial activity based on a strengthened patent incentive surpassed the most optimistic expectations. One rarely sees so direct a relationship between judicial structure and commercial vigor.

3. THE EVOLVING PATENT JURISPRUDENCE

The legal framework of technology movement into public availability through market forces partakes primarily of the law governing all commerce. As for all laws, the overarching consideration is the national interest. Patent law is designed to serve as an incentive to promote technologic research and industrial commercialization, not only to bring to the public the benefits and conveniences of new technologies, but also to achieve a vigorous combination of industrial products and employment and trade. These societal and economic policies undergird the laws of intellectual property.

Starting about two decades ago, the U.S. Court of Appeals for the Federal Circuit methodically undertook to restore the patent law to the legal mainstream. In decisions applying across all areas of technology, the court implemented the patent statute and revived dormant legal principles. Some examples are the rulings that

- summary judgment is as available in patent cases as in any other
- consent judgments and settlement agreements in patent cases are not contrary to public policy
- an assignor can be estopped from challenging the validity of an assigned patent, as others are estopped who transfer property for value
- infringement is a wrong and subject to remedy like other torts
- the measure of damages is to make the injured party whole, as for other torts
- patents are presumed valid, as the statute requires
- proof of inequitable conduct in patent prosecution requires both materiality and deceptive intent
- preliminary injunctions in patent cases are decided on the same criteria as in other fields (as recently clarified by the Supreme Court[4])

The court, in its first years, developed objective standards for determination of obviousness (this topic is at present under review by the Supreme Court), applied the same law to the Patent Office and to the courts, eliminated appellate forum shopping, and generally restored the effectiveness of the patent system as support for industrial innovation. Much media attention was given to the "new strength" of patents.

Subsequent decisions of the Federal Circuit and the Supreme Court were geared toward refining the law and adding precision, for many decisions depend more on the science and technology than on the letter of the law. To this end, the court adjusted the roles of judge and jury in interpreting patents. The *Markman*[5] case, assigning the interpretation of patent claims to the judge instead of the jury, has affected trial procedures as well as the content and interpretation of patents. This decision and its implementation are still not free of controversy. Another controversial decision, *Festo,*[6] reduced the patentee's access to unclaimed technological equivalents, generally limiting patentees to what they actually described. The main emphasis of these decisions is the enhancement of predictability of patent scope, an emphasis that has led to requiring more technical description by the inventor and often more development of the inventive subject matter. The balance between a rigorous-notice function of patent claims and the cost of protecting the innovator against imitators who use the inventive concept but manage to skirt the claims warrants an objective evaluation of the benefits and obstacles presented by this direction of the law, as the interested communities seek the optimum policy and its legal implementation.

New issues of law are constantly arising, for developments in biological science and their application present factual situations that do not easily fit into precedent, such as questions of patentable subject matter, or the nature and conduct of scientific research. Such questions reach the courts when disputes arise; as, depending on the facts of the case, the courts try to implement the law in line with statute, precedent, and a judicial balance of practical economics, research incentive, and fairness. With each judicial decision, precedent adds its weight to one or another competing policy, for there are many facets to the legal and economic theory of intellectual property. For example, some theorists see patents primarily as an economic tool; some as founded on principles of natural right and fairness. Some are concerned lest the patent law impede the flow of ideas and knowledge; others suggest that without patents, fewer ideas and less knowledge would be generated, and even less used for public benefit. Much of the controversy concerning the role of patents arises, I believe, from vested interests that emphasize one or another of the purposes and uses of patent systems, as the courts apply a one-law-fits-all structure to service the public and national interests.

4. ADJUDICATING ISSUES OF SCIENCE AND TECHNOLOGY

Judicial interpretation and application of every aspect of IP law is challenged by the complexity of science and technology. In Thomas Jefferson's day, an educated person could understand every known technological aspect of life. Today we litigate questions whose scientific framework strains even persons within the corresponding discipline. These include the classical areas of technological applications of law, such as medical causation and product liability, as well as environmental issues and patent infringement; these questions also include new issues of constitutional and personal and commercial rights that flow from new scientific knowledge and its applications.

The scientific issues in litigation are rarely straightforward, and they tend to fall in incompletely explored areas and are often intermingled with policy concerns. The ongoing scientific advances in biology and genetics come to court in many guises: there are issues of criminal behavior, employment, insurance, and medical and product liability, as well as intellectual property. No matter how finely tuned a judge's judicial intuition, no matter how wise and benevolent, cases that turn on findings of science or technology cannot always be decided using the judge's traditional tools of reasoned analysis, an instinct for credibility, and worldly experience.

How then can the truths of science and technology be found in the courtroom? The just resolution of issues that turn on such findings presents a profound challenge to the administration of justice. Despite this concern, most judges prefer not to depart from the procedures of the adversary system—not as a matter of principle but of experience. Judges learn that not all scientific questions have clear answers; we have learned that scientific truth is often a matter of the honest but divergent viewpoints of scientist witnesses and that many of the questions of science and technology that come to court do not have a firm answer. Scientific facts are not like the traditional facts of lawsuits, based on the human components of recollection and credibility. In traditional judicial fact finding there are gradations of truth or falsity, questions of weight and value of evidence. What judges call "facts" are matters on which there is a difference of opinion, while scientific facts are supposed to be objective and absolute. The problem is that for issues in litigation the scientific answer is often unknown at the time of the lawsuit. By requiring the judge to decide questions that the scientists have not decided—and perhaps cannot decide—on the present state of knowledge, the side with the burden of proof simply is penalized.

Yet there is a natural partnership between jurisprudence and science, for both enhance our understanding of natural law. Both the law, and the science it deals with, progress along irregular pathways, via incremental steps in diverse directions, sometimes with false starts and often encountering dead ends, building on the past until the present presents a coherent and stable body of knowledge. Justice Felix Frankfurter called the decision-making process the "correlation of

imponderables," a term never more apt than in the evolving fields of biotechnology.

The rule of law is vibrant, adapting to the evolving contexts of science and technology. In today's era of rapid technological change, jurisprudence provides the stability of the law, while reflecting the social implications of the science. But the scientific and technologic issues of today, such as arise in IP disputes, must also be correctly decided.

For determining the reliability of scientific and technologic evidence, the Supreme Court has exhorted judges to apply the same standards as the scientific community. That is not easy, for although judges can readily understand the methodology of science, it is the science itself that is daunting. Habits of logical thinking, precision of reasoning, are common to science and law, each an elegant intellectual blend of theory and testing that leads the mind through complexity. Although as judges we do not test our theories in the laboratory, we do test them against the accumulated knowledge and wisdom of the past. This is the tradition and strength of the common law, as it continually adapts and is usefully and effectively applied to the new biology.

5. WHAT ABOUT THE FUTURE?

A major problem in judicial decision-making is how to achieve practical justice for the high-tech, science-based issues of today's disputes. The problem goes beyond the laws of intellectual property, for many issues that reach the courts (for example, in environmental law, communications technology, product liability, forensics and other criminal issues) turn on questions of science and technology of a complexity that did not exist even a few years ago. These issues require full access to the rule of law, with its protection of the public interest and private rights, its safeguards to litigants, its concern for legislative intent, its openness, its checks and balances. Its justice.

The rule of law contemplates a living law, adapting to changing contexts while benefiting from the experience of the past. Judges must understand the social and economic fabric of the statutes and precedent that we apply. It is essential to preserve a stable jurisprudence, lest we build uncertainty into areas whose strengths lie in their reliability. Yet new questions are constantly arising, or old questions in new contexts, such as the question of whether there is, or should be, a research exception to the use of another's patented invention. No one really worried about that question until science, particularly biological science, reached the stage where the boundary between basic and applied research was blurred or lost.

For the new biology, in general the law has lagged the science. Law usually lags social change. The evolution may be too slow for the enlarging issues of biology and genetics, as well as the developing issues of biodiversity and agri-biotechnology. As we ponder the legal and policy aspects of these new sciences (for example, with respect to advances in genetic science), constitutional principles arise. Is the preservation of human diversity—including the sick, or the ugly, or the moronic—a constitutional question? Justice Holmes is still criticized for ruling that "three generations of imbeciles is enough."[7] Would he be criticized for ordering remedy in the womb—or for denying such remedy? The cases in court often inspire thinking about the foundations of the law, as well as the historical and social and economic policies of the law.

Disputes arising in the biological sciences are likely to encounter the uncertainties of this jurisprudence, for the new biology raises new issues in the context of commerce and the interaction of public and private interests. I encourage you who are engaged in the creation and dissemination of these sciences to think about what the law should be, so that together we may seek the optimum legal framework for today's and tomorrow's scientific and technologic advances. ■

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1 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

2 The Bayh-Dole Act, discussed elsewhere in this *Handbook*, was also implemented at this time, as part of the larger purpose of revitalizing commercial development of the products of academic science.

See also, in this *Handbook*, chapter 3.3 by GD Graff and chapter 3.2 by R Nugent and J Keusch.

3 This patent-related jurisdiction was initially about 12% of the Federal Circuit's assignment, for the plan was to assure diversity and breadth of experience and responsibility. The number of patent-related cases has since increased, but they are still a minority of the court's assignment, which includes claims against the government, childhood vaccine injury cases, tax cases, Native American claims, veterans appeals, Fifth Amendment property takings, international trade and customs cases, and several other areas of national appellate jurisdiction.

4 *eBay v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

5 *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

6 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

7 *Buck v. Bell*, 274 US 200 (1927).

Global Health: Lessons from Bayh-Dole

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ABSTRACT

Public sector institutions help deliver public health goods. By extension, universities that receive public research funds must deliver a benefit to the public that goes beyond licensing a discovery to the private sector for development. In the United States, 25 years of experience with the Bayh-Dole Act, which governs the use of intellectual property (IP) derived from public research, offers both lessons and warnings for developing countries currently establishing their own IP systems. Bayh-Dole successfully created a large body of IP from publicly funded research. Absent a strong profit motive for the private sector, however, the Act has been much less successful at producing public goods for health. Current practice undervalues the "public benefit" aspect of the mandate, especially for the poor. Possible ways to address this mandate would be for public sector entities (and their academic partners in the biomedical sciences) to invest some of their earnings from licensing publicly funded discoveries into programs for neglected diseases of the poor. IP rights from public funded research could also be leveraged in negotiating licensing agreements with the private sector to address these neglected diseases. IP laws and institutions should be designed to encourage such sharing. The public and academic research sectors should also seek a new compact with the private sector aimed at reducing the burden of disease affecting the poor.

1. INTRODUCTION

In the past 50 years, the intensity of research and the pace of discovery in the biomedical and health fields have accelerated dramatically in the United States, in both the public and private sectors. As a result, the number of safe and effective drugs, vaccines, and medical devices for a broad range of illnesses and conditions has skyrocketed. But current laws and practices may mismeasure the benefits of publicly funded health research by relying too closely on a private sector yardstick. Furthermore, in an increasingly global world—where the risk of disease and the benefits of research can come from any corner—the society that benefits from public sector health investment should be the global society. The "public benefit" aspect of U.S. federal research investments should thus include the poor in societies inside as well as outside of the United States, and IP laws and practices should be changed to enhance the benefit of our investments.

Out of an estimated US$106 billion in health R&D expenditures globally, about 50% is estimated to come from public sources.[1] In the United States, most public funding of biomedical and behavioral research is through the National Institutes of Health (NIH), whose spending on research is approximately US$28 billion in 2006. Those numbers dwarf the amount of public research funding in developing countries, but developing country R&D investment will continue to grow, along with IP derived from it. As IP systems evolve in developing countries, they should avoid or reduce barriers to the development of health and medical products for the poor.

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Only in the past decade has global attention focused on the health needs of poor and marginalized populations in developing countries.[2] This new attention has opened to public view the system of protections for IP and trade embodied in national rules and in the global Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Moreover, recent debates over access to drugs for low-income populations in developing countries have highlighted the controversies found in the often arcane details of the patent system and IP laws.[3] The media often portray these debates as a struggle between rich and poor countries, big drug companies and sick people, or insensitive bureaucracies and caring relief organizations. While such portrayals may gain the attention of the public and of policy-makers, they at best oversimplify and at worst obscure the true nature of the problems, and thus create further barriers to finding solutions.

The economic, legal, and policy arrangements that move innovation from research labs to consumers are the same ones that erect barriers between those same labs and the poor. The main economic barrier is the high cost of developing a product from a basic discovery. The main legal barrier is a complex ownership system, one that goes too far in protecting the interests of those who invest in research and development. Finally, there is a policy barrier: the inability to balance the competing interests of the scientific community, consumers, and industrial development, all of which vie for advantage in the increasingly lucrative world of health care products. As IP systems evolve in developing countries, they should avoid repeating mistakes and act to reduce barriers to development of health and medical products for the poor.

This chapter outlines several ways that public and university decision makers can reorient their IP strategies to remove these barriers. It first considers the rationale for government investment in biomedical research, and then explains what kind of public benefits should be expected from that investment. The chapter then examines the key U.S. laws governing technology transfer from federally funded research and provides a synopsis of the legislative context of their passage. Some creative options for extending the benefits of biomedical research to poor countries or global beneficiaries are then proposed for the public sector and universities. A few of these options could also be adopted by developing-country research funders and universities.

Indeed, there are several ways for public institutions to increase the resources and tools devoted to public health needs in the developing world. At the upstream end, public institutions could direct funds toward research in developing countries and their diseases; they could also partner with private and nonprofit entities wishing to do the same. At the downstream end public institutions could directly render assistance to developing country institutions in building research capacity, provide products to users in poor countries, reduce barriers to the transfer of technology, or partner with industry and academia to expedite the development of products from research. Most of these steps also apply to fields outside of health and medicine.

2. PUBLIC SECTOR INVESTMENT IN HEALTH RESEARCH

It is generally acknowledged that publicly supported basic research invaluably contributes to the development of new medical technologies. Creating such benefits is part of the mission of the U.S. National Institutes of Health (NIH). Moreover, the U.S. Congress and the NIH leadership recognize the direct connection between global health improvement and the health and well being of U.S. citizens. Public research agencies, such as the NIH, have a clear commitment from Congress to provide global benefits from their research. NIH has therefore allocated some of its resources for research and research training related to specific developing country health needs (for example, HIV/AIDS, tuberculosis, malaria, tobacco-related illness, cognitive development, and others). It has also advanced such efforts through technology transfer negotiations with private companies developing the discoveries of NIH laboratories.

It is worth emphasizing that about 90% of NIH research funds support extramural research,

the vast majority in universities. Control of technology from that research was placed in the hands of universities by the Bayh-Dole Act of 1980. Therefore, by far the greatest impact of any innovation in intellectual property (IP) management comes from decisions made by university presidents and their technology transfer officials. They determine how IP derived from publicly supported research is used. Most of the following suggestions are meant for their special consideration. Similar arrangements, of course, could be adapted in developing countries.

2.1 *Rationale for public sector investment in biomedical research*

Several arguments have been put forth to justify the government's role in funding research. Although this discussion mostly focuses on biomedical research, the same arguments apply to other sectors. First, funding basic research is a classic example of the role of the government to provide public goods, as applications for health are built on the foundation of fundamental knowledge. Because the market typically underinvests in fundamental knowledge creation and utilization, government support of basic biomedical and health research is an efficient use of society's resources. Furthermore, it is important that the public sector continues to invest lest the increasing expenditures of the private sector unduly control access to basic knowledge. The fruits of publicly funded research—whether in genomics, developmental biology, aging, emerging infectious diseases, molecular virology, cancer, or other fields of science—benefit the public in many ways. These benefits are delivered, not only in the form of new medical technologies, but also in ways unspecified and unforeseen. An example of the latter is the NIH's investment in basic retrovirology, which paved the way for an early understanding of the nature of HIV.

Second, public funding of research ensures that data is available to scientists at the earliest possible time. Academic research careers depend on research productivity, often expressed as the "publish or perish" dictum. Publicly funded research discoveries are often placed immediately in the public domain through presentations, publication, and professional networks. Privately funded researchers, however, are under no obligation to make their findings available to other researchers or to the public and indeed may in some instances be prevented from doing so by company policies.[4] This difference is illustrated in the approaches of the publicly funded human genome project and the privately funded sequencing research. The former placed the data in the public realm in real time via the Internet, whereas the latter did not—though the private sector could still benefit from the publicly funded program's findings.

Third, publicly supported research can fill knowledge gaps not addressed by private industry. Because the public sector is based on incentives other than the profit motive, government research can set priorities based on society's needs, scientific promise, and other factors that—when no market for a product exists—are not of paramount concern to the private sector. Therefore, the choice of whether to develop new ideas into products is largely left up to the private sector. The implication of this is that technology development from public research by and large gets rationed according to the priorities of the private sector, typically from a "return on investment" perspective. Admittedly, there are tensions across these public and private sector interests. However, in the United States these divergent paradigms are sorted out through a multi-agent lobbying and vetting process that occasionally produces disagreement but is generally accessible and transparent.

One important consequence of this third point is that publicly funded research can address fundamental questions without undo concern for the immediacy of its application. When patents are derived from federally supported science they are in fact generally for early-stage technology—often processes and materials to be used by other researchers.[5] Rarely does a discovery occur in federal labs that does not require years of additional funding to enter into the market. This is why public and private investments in biomedical research are mutually dependent: a public sector invention is usually brought to market by private sector product development. Still, inherent in this relationship is the reservation of the choice of

whether to develop new ideas into products being largely left up to the private sector. The implication of this is that technology development from public research gets rationed according to the priorities of the private sector.

2.2 *Balancing public and private research investment*

The synergistic relationship between the public and private sectors is generally highly efficient and productive; however, the potential of this arrangement to create public goods from the investment of the public sector is by no means certain. In principle, the case can be made that beyond the support for the research itself, public agencies have a role to ensure that the benefits of basic research get delivered to the public. How it can best carry out this role, however, is not obvious. Under current arrangements, the public sector has limited capacity and experience in the downstream steps of developing and delivering products to consumer markets. These steps are not only costly but are also not aligned with the public sector's comparative advantage.

The public sector, therefore, requires two kinds of investment: one enhances private sector investment by supporting basic research that will eventually lead to private sector product development; the other augments the private sector by investing in those areas that are unattractive for private sector investment. Both avenues are essential for the public sector to pursue, and shifting public health needs require the frequent rebalancing of priorities.

The conundrum for public research agencies is that however large their public funding may appear, their resources are still limited relative to scientific opportunity. They must prioritize research investments and are often unable to take a technology far enough to determine how much public benefit might be derived from the full, vigorous exploration of its potential. The cost of fully developing a new technology is great, and the rate of attrition—explorations that end without a product or a profit—is very high.[6]

This underlies the crucial concern that some explorations end prematurely because the estimated market is too small to justify the needed up-front investments. In the health sciences, this may be particularly true of research for products that target diseases of the poor or of developing nations (for example, tropical and parasitic diseases) or that are more appropriate for delivery and application in developing country health systems. One hopeful note in the past five years has been the substantial expansion in R&D investment in neglected diseases of the poor via public/private partnerships (PPPs): between 2000 and 2004, R&D expenditures from public/industry nonprofit partnerships grew from US$23 million to US$44 million per year.[7]

To help balance the above interests, the NIH has created guidelines for sharing research tools.[8] It is also tracking inventions produced from NIH investments that result in therapeutic drugs or vaccines. FDA-approved therapeutic drugs and vaccines developed with technologies from the intramural research programs at NIH are reported on the NIH Web site.[9] Eventually this system will document the public health outcomes of any commercial technology developed with NIH support. These steps may be worth emulating as developing countries establish their own systems for tracking the results of their research investments. But while this system will produce valuable information about the benefits of research investments, it is still an a posteriori exercise.

3. IP LAWS AND PUBLIC RESEARCH INVESTMENT

A successful research endeavor creates IP, but when does this ownership enhance the public good? The status and ownership of IP derived from government-funded research in the United States is framed by a series of public laws that establish the current principles and procedures used by the U.S. government and its private partners. For purposes of this discussion, the most important laws date from a quarter-century ago, although the laws have been amended and enhanced in minor ways since then. These are the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) pertaining to intramural research in government laboratories, and the Bayh-Dole Act (officially Amendments to the Patent and Trademark Act,

P.L. 96-517), pertaining to extramural research outside of government laboratories.[10] Both Acts were passed in 1980 to stimulate greater use of technologies developed through government support. Their legislative history is instructive for understanding the public benefit the laws were designed to create.

3.1 *History of Bayh-Dole and Stevenson-Wydler acts*

In the mid-1970s, Congress became concerned about the failure to use federally owned patents to encourage product development stemming from federally funded R&D. At the time, only 5% of the 28,000 patents retained by the U.S. government had been licensed for use, whereas 25%–30% of industry patents were being applied.[11] These circumstances prompted Congress to inquire into how federal research was transformed into usable technology. Congress concluded that the barriers were too great and the incentives too small for academia or the private sector to develop technology from the patents produced with government research support. At the time, there was no discussion about public sector involvement in downstream activities.

The main barrier to the use of federally patented technology was believed to rest with the unwillingness of the responsible agencies to grant exclusive licenses for companies to use the patented technology and invest in product development. An exclusive license would allow one company to have a monopoly in the invention produced with government funds as an incentive to develop and test the product. Companies complained also that even the attempt to obtain nonexclusive licensing was an excruciatingly slow process. Federal agencies imposed many paperwork requirements and other burdens on their licensees in an apparent effort to protect the public's interest in the invention. It became clear to Congress that private companies would not accept the risk and expense of developing technology for the marketplace without some exclusive rights and without a more streamlined way to obtain patent rights across agencies.[12]

The Bayh-Dole and Stevenson-Wydler acts were intended to rectify this situation. They did this by creating a uniform licensing system for all federal agencies, reducing the steps needed to grant licenses, and providing incentives for industry to invest risk capital in product commercialization from federal patents. Most importantly, Bayh-Dole allowed universities and small-business government contractors to receive title to inventions derived from government support, rather than the prior arrangement in which government was the sole holder of the patent. It also allowed the grantees and contractors to license the technology developed under these patents for use by small business and private industry.[13] The Stevenson-Wydler Act effectively allowed federal labs conducting intramural research to exercise the same privileges.

The effect of these new statutes was to transfer the ownership of IP and the benefits derived from it. They allowed companies to license and develop products based on the discoveries of federally funded university research with full legal protection from competition. According to the Congressional Research Service, "*Proponents of this approach contend that these benefits are more important than the initial cost of the technology to the government or any potential unfair advantage one company may have over another in their dealings with the federal departments and agencies*."[14]

Interestingly, the Bayh-Dole legislation initially proposed a formula for repayment to the taxpayers of the government investment when a patent yielded commercialized technology. This provision was dropped in the final stages of passage because of disagreements over technical aspects of the repayment mechanisms.[15] While the legislative history demonstrates that there was widespread acceptance of the principle of a rightful return to the public from private sector use of publicly funded technology, it was the details of implementation that ultimately defeated its inclusion in the bill.[16]

Nonetheless, the legislation was passed with several clauses intended to ensure that the monopoly powers granted to patent holders and licensees would not be abused. These clauses have been the subject of much debate among IP specialists and are a cause of anxiety for the private sector, which is concerned about when and with

what justification they would be invoked by the government. The legislation expressed Congress's view that the use of discoveries from federal research to improve health was clearly in the public interest, even if it must be carried out by government action.

The Bayh-Dole law states the intention "*to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions…*"[17] The means to achieve that goal were codified in the following provisions that reserve certain rights for the government:

- The right to a nonexclusive, nontransferable, irrevocable, paid-up license to practice for or on behalf of the United States throughout the world.[18]
- "March-in" rights that enable the government to require the licensee or patent holder to grant use rights to another user with due compensation under special circumstances. The special circumstances envisioned in this clause refer to lack of use within an agreed-upon time frame or special health or safety needs that are not being met by the licensee or patent holder.[19]

The first clause, allowing government use of the technology, has been narrowly interpreted to refer only to a true government purpose. This interpretation has not been fully litigated and therefore it is likely that private pharmaceutical companies remain concerned that changes in its interpretation could expand to threaten their economic interests. This provision could theoretically allow the government to practice the technology—or contract with a third party to have the technology practiced—for authorized government purposes. Because the mission of the NIH is "*to secure, develop and maintain, distribute and support the development and maintenance of resources needed for research,"* some have suggested that there appears to be a limited scope for NIH action in this regard.[20] However, the Department of Health and Human Services might, due to its public health mission, have a clearer justification to invoke the government-use clause in pursuit of its mission.

The second clause, the so-called march-in right of government, has attracted greater attention and has been more extensively explored. It has been formally tested just once, in a case in which the NIH declined to initiate march-in proceedings, thereby disallowing the petitioner use of the technology.[21] This test case provided the opportunity for both the government and affected parties (who were primarily third-party recipients of government research funds or prospective licensees) to indicate their views on how restrictive the march-in rights should be.[22] The debate centered on questions of what constituted timely delivery and how critical the public health or safety need had to be to in order to warrant government action. The voluminous record produced for this petition demonstrated that universities and industry were extremely concerned that the march-in provision would undermine licensing rights under Bayh-Dole. It also demonstrated that petitions for march in would prompt a full-blown legal procedure, imposing both time and financial costs on any potential petitioner.

3.2 *Twenty-five years after Bayh-Dole and Stevenson-Wydler*

The laws that govern the disposition and use of technology derived from U.S. government investment in health R&D must be judged first and foremost by how well they have met their original legislative intent. Assessments of the impacts of the Bayh-Dole Act and related legislation suggest that the laws performed as Congress intended.[23] Most independent analyses have concluded that the acts greatly increased technology transfer from researchers to private industry in the biomedical sciences, improved the governmental patenting and licensing process, and made available to the public products that improve their health and well being.[24] Thus, the goal of greater private sector utilization of the research output by federally funded scientists seems to have been achieved.[25]

Simultaneously, research universities experienced significant upheavals as agendas and researcher time focused more and more on revenue

opportunities. In the two and a half decades since passage of the Bayh-Dole Act, the major U.S. research universities have developed highly proficient offices of technology transfer, staffed by professionals who deal with patents and licensing. Through this infrastructure, these universities have come to expect financial rewards from their research efforts in the form of royalties and fees from patents and licenses. In the eyes of some university officials, this income flow is justified as partial compensation for the costs incurred during the conduct of federally supported research—an enterprise most universities believe costs them more than the infrastructure support provided with federal grants.

Yet there is no guarantee of financial returns from research, and most universities have long operated without this extra income. They still do, albeit there are consequences on investments in expansions of faculty and facilities. The intent of Bayh-Dole was not to produce supplemental revenue streams to universities. Rather, it was to engender innovation and increase the use of technology for economic development. Universities do accept their responsibilities to contribute to the public good, but these have generally focused first on university, state, and national health issues, in that order. Most universities have either not addressed or achieved a balance between entrepreneurship and the generation, use, and dissemination of knowledge for the public good.

Recent analysis concludes that, although more university technology transfer operations have become profitable over time, many universities do not earn profits from licensing the results of research.[26] The occasional blockbuster technology has produced large royalties for a few universities holding patent rights, and some others generate a few million dollars annually. Most universities, however, are still barely in the technology development business. Out of almost 1,500 licenses executed during 2004, only 1.5% (67) generated more than US$1 million in revenues. In 2004, US$1.4 billion in earnings from licenses and US$1.2 billion in royalties was reported by the 196 U.S. institutions that responded to an annual survey of university research technology offices. The survey respondents reported about US$41 billion in research expenditures for the same year, and over 10,000 new patent applications filed.[27]

Much has changed in the 25 years since the Bayh-Dole and Stevenson-Wydler acts were passed. Not the least of these changes is an increasing concern for global health, a concern arising from a recognition that the health issues of poor country populations and the U.S. population are connected, as are the health of poor country populations and their economic and social prospects. For example, the devastating impact of HIV/AIDS and the limited use in impoverished developing countries of technological advances for diagnosis and management of this infection and its complications is very much in the news today. As a consequence, many countries are trying to figure out how to deliver health technology to poor and technologically marginalized populations. In the process, questions are being raised about the balance of interests between the use of new technology to reduce threats to health and the ownership rights to that technology.

3.3 *Current debates*

The obligations to a larger, more global public—and the rights of this public—are raising critical questions: just who is the public and what return on the investment is due the public? Debate continues about how to ensure the availability of effective treatments to all in need while ensuring that research partnerships with industry remain viable and productive. Public research and research funding agencies such as NIH, the academic community, and industry will be challenged to consider how to interpret and apply IP laws and regulations in the context of how a patent or a license, granted or denied, will affect the public good. Not only are economic, legal, and policy issues involved, but there are also complex ethical and social considerations created by decisions to apply IP laws.

The controversial nature of IP for biomedical research is illustrated in public debate and in proposals in recent sessions of the U.S. Congress:[28]

- disputes over competing claims to IP developed under government/industry ventures

- delays in negotiating Cooperative Research and Development Agreements [CRADAs] because of issues related to dispensation of IP
- controversies over the rights of drug companies to set prices on drugs developed in part with federal funding
- uncertainties due to the increasing mix of funding sources among government, foundations and the private sector, and the portion of IP that represents the public good return
- problems obtaining technologies for research developed in the private sector for use in federal laboratories (A more general problem of access to research tools has not been considered by Congress.)

This list of issues is not exhaustive and raises more questions than answers. Moreover, each could be—and indeed most have been—the subject of a rousing debate and the occasion for a flurry of letters, testimony, articles, op-ed pieces, and books. One place to start searching for ways to increase the return to the public—both global and U.S.—of the public investment in research is to review the arrangements currently or potentially in use to deliver these benefits.

4. THE PUBLIC SECTOR AND GLOBAL HEALTH RESEARCH

There are several ways that government research funders can increase the resources and tools devoted to the public health needs of the developing world. At the upstream end they can direct funds toward research on specific diseases; they can also partner with private and nonprofit entities wishing to do the same. At the downstream end they can directly provide products to users in poor countries, reduce barriers to the transfer of technology, or partner with industry and academia to expedite the development of products from research. Some of these steps could be adopted by academic recipients of public funds, especially those that actively develop IP ownership derived from public research funds.

The following specific actions could be taken by public funders and their academic and private sector partners to increase global public goods for health. Many of these actions could also be adapted, by implementing IP rules and procedures, for use in developing countries.

4.1 *Action within the research enterprise*

Strengthen capacity for research in developing world. Increasing funding for research in developing countries is, if sustained, one of the most direct ways to create a global benefit and ultimately increase access to the results of scientific research for the world's poor. Such funding can also lead to collaborations between developed and developing country scientists, creating more sustainable research environments and the opportunity for human capacity building and research infrastructure development.

Government research awards can contain provisions requiring researchers to train developing country scientists in these highly successful laboratories. In the health sciences, for example, a portion of the royalties from the NIH intramural program is returned to the lab that discovers and invents new technology—this also applies to university labs that produce patentable inventions. These funds could be devoted to training new scientists. In addition, the same opportunities could be provided in developing countries.

Academic/industry partnerships. Both within and apart from the university research environment, the relative importance of private sector funding has increased. Private companies are now estimated to spend three times as much on biomedical research as the NIH, most of it within their own research laboratories.[29] However, industry-funded university research is also growing. It is unclear how involved industry is in academic biomedical research at present, although one source indicates that a small portion of private R&D (about 12%) is conducted within U.S. academic institutions.[30] Whatever the magnitude of industry's involvement, it is large enough to possibly blur the distinction between the objectives of universities and private industry, and it has caused some to question university motives for carrying out research.[31]

The nature of science and its conduct has also changed since Bayh-Dole was instituted.

Few academic or public research organizations have the particular combination of scientific know-how, application tools, and commercialization potential that it takes to turn ideas into real deliverable products. Public/private partnerships are increasingly looked to as the mode of operation for future biomedical research that rapidly develops products. Nowadays, the complementary human capital and financial resources of the public sector, academia, and industry are all needed to bring scientific inquiry to fruition. The power of the Gates Foundation to influence this process is a major new force shaping this landscape.

In recent years, new approaches have been devised to sweeten the pot and bring new players into the development of health technologies for the poor. These include public/private partnerships such as MIHR (Centre for the Management of Intellectual Property in Health R & D,) established in 2002 precisely to address public sector needs in IP management. It provides a forum for multiple public and private entities to improve the management of health IP for the benefit of developing countries through information exchange, training, defining best practices in licensing, and help in developing norms for IP management.[32] MIHR is working with developing countries to help them bridge the gaps between what the public and private sectors can provide in addressing global health needs.[33]

Many universities prominent in health research are also seeking to balance their financial objectives, their charge to advance scientific discovery, and their dissemination of the benefits of those discoveries to the public. Universities in both developed and developing countries could explore how to create research partnerships with one another and with the private sector that achieve a public benefit goal, while still meeting the profit motive of private companies.

4.2 *Technology transfer options*

The evolution of technology transfer practices since Bayh-Dole has placed public sector institutions and research universities in a difficult position. The delicate balancing of their scientific interests, their responsibilities to the public, and their need to maintain a competitive position vis-a-vis the private sector to retain expertise has been jarred repeatedly in the past few years. Developing country institutions are particularly challenged by the lure of greater research opportunities and higher salaries and benefits for their top and young scientists in the U.S.

The following list suggests how public investment can use technology transfer more effectively to create global public-health goods. The list also makes the important point that all possibilities should be open to discussion among committed and interested parties—including policy-makers and research leaders in the developing world. Many of the suggestions are derived from NIH experiences, but they could be applied far more widely. Most importantly, the engagement and involvement of all stakeholders is essential, without this it will be impossible to change current operating principles. Change will not be accomplished by fiat.

1. A straightforward way to deliver social dividends from research is to write provisions into licensing agreements. On an ad hoc basis, NIH has incorporated voluntary provisions for public benefits into license agreements with private industry. As a result, many licenses granted by NIH include a public benefit of some sort.[34] The types of public benefits called for in these purely voluntary arrangements include educational Web sites, product donations, and drug delivery to needy communities. The initiative has been palatable because no specific level of benefit or outcomes is requested in the license provisions. It appears, however, that the public benefit delivered through this approach has been, at best, modest.

   Public-benefit provisions in licensing agreements could state a specific aim to benefit poor countries. Both publicly funded research agencies and university technology transfer offices could increase the use of such provisions. If employed in developing country licensing agreements, the provisions could ensure the delivery of drugs or technologies to the poor by whatever direct mechanism the

commercial partner prefers (for example, drug donations or reduced prices), or even indirectly through a nonprofit organization. For instance, a reasonable proportion (however difficult it is to determine the meaning of *reasonable*) of the royalties to a university from the license would be placed within a foundation established to support global public-health goods. It is necessary to recognize that the funds available for diversion are meager, if they exist at all, at most universities.

2. The private sector lacks interest in many available technologies because of its perceived lack of profitability. Therefore, ways to increase profitability need to be explored. One method open to the public sector and academic institutions is to bundle technologies developed in their laboratories. This would require companies to license another, less profitable technology for development in order to obtain a license for more lucrative technologies. This is consistent with the paramount aim of the Bayh-Dole Act to get technologies used.

So far in the United States, there have been few takers for this type of arrangement, and its impact will likely be small. The argument is that bundling may help license less-attractive technologies, although it will not make them more profitable for companies to develop. However, in a developing country setting, the economics of bundling may be different. For instance, if the public institution can help identify a large buyer to take the initial output, a profitability threshold might be reached if the price from the bulk purchaser met minimum average cost of production at the appropriate scale. A private company wishing to expand its capacity in a developing country could anticipate potential profits.[35] Merck reached such a level when it chose to produce recombinant hepatitis B antigens in China for that market. It even built a state-of-the-art plant to produce vaccine. This led to widespread use of the vaccine in China and a foothold for the company in the country—a win-win situation.

The economics of bringing products to market in developing countries differs from those in developed countries.[36] Human clinical trials are the most costly phase of product development; this phase is also when most experimental technologies fail. Developing countries have the opportunity to streamline procedures for carrying out clinical trials, including establishing more rational and less time-consuming institutional review board (IRB) processes. Other components of the R&D process that generally cost less in developing countries are legal, marketing, and regulatory fees. Also, the medical research companies in developing countries may be more willing to take risks than are those companies in the United States. Moreover, both companies and their government regulators may be more strongly motivated by the clear, urgent need for improved diagnostics and therapeutics.

Developing country markets can also be segmented: the technology could be provided at low or no cost to the poorest countries through a subsidy mechanism (market *pull*), at a sustained rather than reduced price in middle-income developing countries, and at a higher price as the market develops. Such an arrangement would be consistent with economic theory, in which price discrimination can increase market efficiency and equity.[37] It actually resembles the pricing methods that pharmaceutical companies currently use in developed country markets and could make some technologies suddenly more financially attractive. For this approach to work, measures must be taken to ensure that there is no parallel importation or smuggling from the low price to the higher price nations. This is a difficult goal, but one that might be expedited through TRIPS to allow trade in generics among developing countries.

A variant of this approach would be for technology transfer offices (TTOs) to

work more with nonprofit organizations to deliver technology, instead of seeking commercial avenues. NIH currently uses CRADAs to work with the World Health Organization (WHO) and nongovernmental organizations (NGOs) (for example, PATH) to move malaria drugs and other less-profitable technologies into use. The overriding concern for a CRADA is whether the organization can carry out the necessary R&D to develop a product. The current fully capitalized cost (including post-approval R&D costs) to the private sector to develop one drug is estimated to be nearly US$900 million. And with more than eight years required for the clinical and approval phases of development alone, nonprofit organizations just do not have the capacity to sustain such an investment.[38] However, as already noted, it is extremely difficult to make such estimates because the necessary information is not in the public domain; it is likely that goals can be achieved at much lower cost in developing countries , and this can be put to the test.

3. In an effort to increase the licensing of vaccine technology in selected developing countries, the NIH is now requiring companies seeking to license NIH technology to produce a plan to market the technology in developing countries within two years of regulatory agency approval. They can either opt to deliver the product themselves or initiate a joint venture with another company. The goal is to use the potential profits from sales in developed countries to encourage companies to manufacture for the developing world at or near cost, although the expense of adding manufacturing capacity or the opportunity cost of shifting existing production to this product should be factored in. Another way to achieve access and affordability for the poor is by manufacturing in developing countries at lower cost than in the United States.[39] This sort of a tie-in is difficult to accomplish from the United States, but a developing country government could arrange it much more easily.
4. Delivering technologies for developing country use through multiple-use licensing is too rarely used. This approach identifies and licenses basic technology for specific fields of use (for example, a cancer vaccine) and requires the same (or another) company to do parallel development of the same technology for another field of use (for instance, an HIV vaccine). In the existing regulatory framework, an expansion of this approach would require renegotiating existing licensing agreements and would certainly be strongly resisted by licensees. However, in an open playing field such as exists in some developing countries, it could become common.
5. A radical approach open to the U.S. government but not to universities is to exert march-in rights on already-licensed NIH-derived technology to meet special health or safety needs that are not being satisfied. This option, referred to as compulsory licensing, should be retained by developing country governments in case of public health emergency—and it should be used when necessary, and never frivolously.
6. Finally, all activities—from early-stage development to manufacture and distribution—could theoretically be performed by a government agency, university, or contractor. For instance, government research institutions could move their own involvement further down the development pipeline to include whatever steps would be needed to get the product ready for uptake by a private or nonprofit entity. Although this is clearly not a priority for a research agency such as NIH, there are already some programs to develop medications at NIH instead of relying on the private sector. It is worth emphasizing that, within the context of the Bayh-Dole Act in the United States, by far the greatest impact from IP innovations will come from decisions made by university presidents and their technology transfer officials. They control how IP

derived from publicly supported research is used.

If universities decide to adopt any of these options, the decision, in our view, should come from a consultative process among all interested parties, including public research agencies, developing country representatives, potential funding partners, and industry. Universities and their faculties would have to embrace the moral and social imperative of enhanced delivery mechanisms and become full partners in the means selected to achieve them. Because most of the relevant technology is developed by a small subset of research-intensive universities, it would not be necessary to bring all universities on board; instead, a focus on the leaders would establish standards that others could follow. The process would be strengthened if developing countries joined and were led, for example, by a multinational organization such as the Inter-Academy Medical Panel.

5. CONCLUSION

5.1 *Considerations for senior policy-makers*

Economic development, drugs for the poor, breakthrough technologies for the world's most common diseases, and scientific advances for treating tropical diseases are legitimate social goals for all nations. But these goals vie for limited financial and expert resources and are not always compatible with each other. Policy-makers must ensure that the public's investment in research is rewarded. A system should spur economic development and creative innovation, as was the intent of the Bayh-Dole Act. Just as importantly, the IP system should clearly articulate and codify an overarching social goal.

It is understood that subsidies to research universities in the form of indirect costs in grants funded by the government may not cover the actual cost of supporting research infrastructure, and that industry risks capital in R&D for products that fail somewhere along the path, and that this has implications in terms of fiduciary responsibility to stockholders due a return on investment for success in product development. None-the-less, policy-makers should insist that, as a condition of receiving the protections of patents and licensing, companies and universities must pay some "dividend" back to the public. This dividend could be indirect and used to support further research to address needs the market alone does not satisfy. Further, policy-makers should retain the government's right to exercise a technology license on behalf of the public, as well as full march-in rights. The government should be prepared to exercise these rights in the event of a real public-health emergency or in the event that the private sector licensee fails to develop or bring to market a product that has potential public benefit. The government must accept its responsibility to ensure that the public's investment pays returns to the public. As it turns out, the option for government action itself will likely provide companies with a strong incentive to make products available in the market. Government should also embrace principles of segmented markets and tiered pricing for vulnerable populations in the U.S. and abroad—the poor, the elderly and the vulnerable in particular. In this way, the government accepts its responsibility to ensure that the public investment pays returns.

5.2 *For presidents of universities*

In their approach to IP laws, the academic community is faced with complex ethical and social issues. If partnerships are to promote research that leads to global benefits, there should be agreements that explicitly commit all of the partners to this goal at the outset. Creative financing and IP sharing arrangements will have to be developed. And scientists will need to prioritize the delivery of global benefits. Similarly, university officials will have to fully embrace the larger role of universities in society and in the global community. Leadership must come from the very top of the institution, for example valuing applied research and including the creation of global public goods among the criteria for academic advancement.

Many universities prominent in health research are seeking to balance their financial objectives, their commitment to scientific discovery, and the dissemination of benefits to the public. PIIPA (Public Interest Intellectual Property Advisors) is one example of how U.S. universities can use their stock-in-trade to serve the global public need by offering expertise and training.[40] PIIPA is a newly formed consortium of universities and companies that provides pro bono legal and professional assistance about IP issues to entities in developing countries, including governments and universities.

There are many ways that universities can help meet global public health needs. They can include including public benefit clauses in their licenses to the private sector, investing part of their royalty stream in a foundation, ensuring that returns to the university itself are used in part to support capacity building and applied research of global relevance, establishing an "ethical" investment fund,[41] licensing technologies to nonprofits or others who would develop and manufacture for poor countries, or bundling technologies to encourage the development of medicines aimed at diseases of the poor. Research universities or public funding agencies could unilaterally adopt any or all of these options, but a multilateral approach would have far greater public awareness and public health impacts. Ideally, this approach would be an international, multi-institutional effort.

5.3 *For the technology transfer officer*

The job of the TTO is to create the incentives needed to move discovery into the product development arena, motivating academic researchers not by the sole promise of high profits—which rarely appear—but by applying royalty toward the support of research in the inventor's laboratory, and by balancing some financial reward to the inventor with the satisfaction of seeing his or her work used for public benefit. Although not the responsibility of the technology transfer officer, the latter can become so. This will require creating opportunities for various forms of licensing (including exclusive licensing where appropriate, but a nonexclusive license should be insisted upon if that is likely to move a promising technology to market sooner), maintaining a very low paperwork and expense burden for private (including nonprofit) companies wishing to license government-funded technology and insisting on explicit public-benefit clauses. Technology transfer officers should report such efforts and their potential impact to the President him/herself.

5.4 *For a university scientist*

Individual researchers in the United States have established product development companies in large numbers, and developing country research scientists and their institutions will feel pressure to do the same. When considering a research collaboration with a scientist from the United States, developing country scientists should be certain that they receive equitable treatment in whatever IP ownership arrangements are made. While IP protection is often necessary to convince industry to move discovery into product development, something neither academia nor government, for that matter, do with distinction, not every discovery should or need be protected. Scientists should be capable of participating in these discussions. Developing country scientists should also resist the excessive protections that are sometimes placed on research output in the United States—protections that delay and sometimes prevent discoveries from being published and shared in the scientific community. It is very important for developing country researchers to get the professional exposure and opportunities that scientific publication can offer. Narrow-minded efforts to establish property rights can inhibit those benefits.

5.5 *A global vision*

Creating and delivering global public health goods is much more difficult than creating and delivering national public health goods. Yet we are committed, in the words of Tennyson, "*to strive, to seek, to find, and not to yield*." To change the current reality will require a coalition of university officials, government, industry, foundations, and NGOs to identify priorities and opportunities and then collectively carry them out.

Although IP has clearly spurred the development of technologies that promote the public health of wealthier nations, the impact of IP in promoting global public health goods is mixed at best. Although the fundamental premise of IP protection—that it acts as a spur to innovation and a reward for risk-taking—applies equally to all industries, some characteristics of the health care industry set it apart from other fields where IP is important. Quite simply, in health care, the outcomes of technology development and its availability are matters of life and death.

In 2002, *The Economist* observed "*Rich countries should accept that considerations of how IP rights affect poor countries are not just a concern of overseas aid agencies but play a part in broader trade and economic relations too*."[42] This chapter builds upon the truth of that insight. Indeed, if Bayh-Dole were being debated today, then surely the economic development objectives at the core of the legislation would take on a much broader meaning. ■

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1 Global Forum for Health Research. 2006; Monitoring Financial Flows for Health Research 2005. Global Forum for Health Research: Geneva. www.GlobalForumHealth.org.

2 This attention has been prompted significantly by the World Bank's publication of *Investing in Health*, which was the World Development Report of 1993 (World Bank. 1993. *Investing in Health*. World Development Report 1993. The World Bank: Washington, DC). The concern has been reinforced by the expanded activities of the Bill and Melinda Gates Foundation for global public health, as well as the development of many other partnerships for public health.

3 See extensive media coverage in 2001 of the South Africa AIDS drug controversy, Brazil's decision to issue compulsory licenses for AIDS drugs, and the stalemate subsequent to the November 2001 WTO meeting in Doha, Qatar, over drug access in public health emergencies.

4 Thursby and Thursby report that 27% of university research licensed by industry allows for prepublication deletion of information from research papers; 44% of them allow for publication delays of about 4 months, on average (see Thursby J and M Thursby. 2003. Intellectual Property, University Licensing and the Bayh-Dole Act. *Science* 301: 1052).

5 Seventy-five percent of licensed inventions from universities are "proof of concept" (see Jensen R and M Thursby. 1998. *Proofs and Prototypes for Sale: The Tale of University Licensing*. National Bureau of Economic Research: Cambridge, MA). This means that most university inventions are at an early stage of development at time of license and require further involvement from the inventor to reach the commercial stage.

6 One rule of thumb is that one of 5,000 drug candidates discovered in labs will be commercialized, *Business Week*, July 9, 2001. p. 96.

7 Moran M and J Guzman. 2005. *Drug R&D for Neglected Diseases: Are Public Funds Appropriately Distributed?* chap. 2. Global Forum For Health Research: Geneva.

8 Nass S and B Stillman (eds). 2003. *Large-Scale Biomedical Science: Exploring Strategies for Future Research*. National Academies of Science, Washington, DC. p. 168.

9 ott.od.nih.gov/about_nih/fda_approved_products.html.

10 Stevenson-Wydler established technology transfer as a federal agency mission, creating rules by which federal agencies could license discoveries for commercial use and receive royalties and fees. Bayh-Dole extended these powers to other organizations performing federally sponsored research, including universities. See Congressional Research Service (various) and *supra* note 11 for further details about federal patent law.

11 U.S. General Accounting Office. 1998. Technology Transfer, Administration of the Bayh-Dole Act by Research Universities. *RCED* 98-126, Washington, DC. p. 3.

12 Ibid.

13 A 1983 presidential directive extended licensing rights to large businesses.

14 CRS. 2000a. Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act. RL30320, December 11. Congressional Research Service: Washington, DC. p. 11.

15 National Institutes of Health. 2001. NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests Are Protected. NIH, Washington, DC. p. 10. www.nih.gov/news/070101wyden.htm.

16 Prompted by persistent Congressional concerns about returns to taxpayers from federal research, NIH later attempted to impose a policy of "reasonable pricing" on the technology developed from certain types of federal research. The private sector refused to comply with this arrangement and it was eventually dropped. Reference is made to NIH Cooperative Research and Development Agreements (CRADAs); see *supra* note 15 for discussion.

17 35 U.S.C. § 202.

18 35 U.S.C. § 202(c)(4). Exclusivity grants the licensee the sole right to use the IP, which serves essentially as a monopoly. Nonexclusive rights allow the grantee to use the IP, but they do not provide the right to be the only user.

19 35 U.S.C. §.203(1).

20 McGarey B and A Levey. 1999. Patents, Products and Public Health: An Analysis of the CellPro March-In Petition. *Berkeley Technology Law Journal* 14(3): 1114.

21 CellPro Petition to DHHS, March 3, 1997, cited and discussed in McGarey and Levey (see *supra* note 20). CellPro petitioned for a license to practice a stem-cell separation technique developed by a researcher at Johns Hopkins University. CellPro had not been able to negotiate a license agreement with Johns Hopkins or the existing licensee but had used the technology. It was found guilty of willful infringement on the Johns Hopkins patent. CellPro argued in its petition for government march in that Johns Hopkins and the licensee had failed to commercialize the technology in a timely fashion and that public health and safety needs were not being met. The NIH rejected both grounds of the petition. More recently, NIH was petitioned in 2004 to march in due to steep price increases imposed by Abbott Labs on ritonavir, an HIV/AIDS drug developed in part from public funds. NIH declined the petitioner's request. www.aamc.org/advocacy/library/washhigh/2004/060404/_4.htm.

22 Both the timeliness clause and the public health and safety clause were tested in the CellPro case.

23 National Academy of Science. 2001. Board on Science, Technology, and Economic Policy; Committee on Intellectual Property Rights in the Knowledge-Based Economy, Workshop and Related Papers. April. NAS: Washington, DC www7.nationalacademies.org/step/STEP_Projects_Intellectual_Property_Rights.html.

24 CRS. 2000b. R&D Partnerships and Intellectual Property: Implications for U.S. Policy. 98-862 STM, Updated December 6. Congressional Research Service: Washington DC. p. 11.

25 See *supra* note 4.

26 See *supra* note 4.

27 AUTM 2005. AUTM Licensing Survey™: FY 2004. Association of University Technology Managers: Northbrook, IL. www.autm.net. Note that figures include royalties and fees from all patents and licenses. In comparison, NIH royalties from intramural licensing were US$52 million in fiscal year 2000.

28 See *supra* note 24.

29 Goldberg R. 2001. In Changing Times, NIH, NSF Look Outdated. *Trendspotter* (May). www.genomeweb.com. This includes product development expenditures.

30 Blumenthal MD and M David. 1995. Capitalizing on Public Sector Research Investments: The Case of Academic-Industry Relationships in the Biomedical Sciences. Presented at NIH Economics Roundtable on Biomedical Research: Bethesda, October 19.

31 See for example: Bok D. 2002. *The Commercialization of Higher Education*. Princeton University Press: Princeton, NJ; Kennedy D. 2005. Bayh-Dole: Almost 25. *Science* 307: 1375; Krimsky S. 2003. *Science in the Private Interest*. Rowman & Littlefield: Lanham, MD.

32 Mission statement and partners in MIHR can be viewed at www.mihr.org.

33 See also Widdus R and K White. 2004. Combating Diseases Associated with Poverty: Financing Strategies Associated with Public Health and the Potential Role of Public/Private Partnerships. The Initiative on Public/Private Partnerships for Health, Global Forum for Health Research: Geneva.

34 Ted Roumel, former deputy director of OTT/NIH. Personal communication, June 2001.

35 It is important to note that many existing purchase arrangements through WHO and nonprofits are on off-patent medicine and technology. Thus, the bulk purchase through a competitive bidding process by WHO for TB drugs allowed a 30% lower unit price through the purchase of generic drugs from manufacturers based in The Netherlands and India (*The New York Times*, June 22, 2001).

36 Light D. 2005. Basic Research Funds to Discover Important New Drugs: Who Contributes How Much? chap. 3 in Global Forum for Health Research: Geneva.

37 Efficiency is maximized with an arrangement of perfect price discrimination (in which each buyer pays his maximum price), but can also be improved by using block pricing according to the willingness to pay of different market segments. This pricing scheme is referred to as Ramsey pricing.

38 Tufts Center for the Study of Drug Development. *Outlook 2004*. csdd.tufts.edu/InfoServices.

39 The domestic manufacturing requirement in the law can be waived and applies only to U.S. sales.

40 For information about PIIPA, see www.piipa.org and Gollin M. 2003. Answering the Call: Public Interest Intellectual Property Advisers. Paper presented at the Biodiversity and Biotechnology Conference, Washington University School of Law, St. Louis, MO, April 4–6, 2003.

41 Ethical investment funds or other financial tools are recommended among the "Top 10 Biotechnology" approaches for improving global health by a commission of the Joint Center for Bioethics at the University of Toronto (see Daar AS, H Thorsteinsdottir, DK Martin, AC Smith and PA Singer. 2002. Top Ten Biotechnologies for Improving Health in Developing Countries. *Nature Genetics* 32: 229–32).

42 *The Economist*. 2002. September 14. p. 14.

Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies

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ABSTRACT

Seeking to drive economic growth within the knowledge economy, governments have increasingly sought to commercialize the results of publicly funded research. The ability to use intellectual property (IP) as a tool to encourage and facilitate commercialization hinges on three fundamental policy concerns: protection, ownership, and management capacity. This chapter surveys the policies and practices across an array of emerging and developing economies, including Argentina, Brazil, Chile, China, Ethiopia, India, Indonesia, Jordan, Kenya, Malaysia, Mexico, the Philippines, Poland, Russia, South Africa, Tanzania, Uganda, and Vietnam. In regard to the availability of intellectual property protections, the survey finds that countries can logically be sorted into three tiers. The first tier contains the most innovative countries, those with an active intellectual property system used vigorously by domestic patentees. The second tier consists of countries actively seeking to become more innovative, with intellectual property systems that are only beginning to be used by domestic patentees. The third-tier countries are those with limited or nascent intellectual property systems and virtually no domestic patentees. Almost all first tier innovative countries, about half of second-tier countries, and no third-tier countries have formally addressed the question of intellectual property ownership through national policy. Among those that have, however, the survey finds a wide range of policy approaches used to address the question of intellectual property ownership, including patent law, labor law, government procurement or contract law, and laws governing national R&D or innovation systems, as well as rulings by ministries of science and technology or ministries of higher education. With regard to institutional intellectual property management capacity, the survey finds a very broad range of sophistication and expertise, both across and within countries of all three tiers. Higher capacities for institutional intellectual property management appear to be more closely associated with levels of R&D expenditure than with the existence or absence of national policies that allow or encourage institutional ownership. The implication is that intellectual property management at the institutional level grows in tandem with strong R&D and the capacity for the local economy to commercialize the technology.

1. INTRODUCTION

As governments in countries with emerging and developing economies confront the issues of globalization and technological advance, many have focused on how domestic universities and research institutes can promote economic growth by supporting and seeding innovation in the private sector. Such institutions have traditionally served two core missions: to educate the elites of the workforce and to conduct applied or adaptive research to address domestic economic and social needs. Institutions in developing countries are also often concerned with carving out a place for the country within the global scientific community.

Increasingly, government officials in developing countries are under pressure to democratize higher education and fund a broader range of research and development priorities. At the

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same time, commercializing innovation is being emphasized as a core mission of publicly funded research. To advance this mission, the tools of patenting, technology transfer, and venture creation are increasingly deployed. Indeed, in countries like China and India, student numbers are swelling, rates of publication in prestigious international journals are climbing, academic patents are growing, and the number of start-up companies is increasing. Like other areas of development policy, academic innovation may be an area in which developing countries can leapfrog directly to the standards and practices of the knowledge economy.

National systems of innovation are not made overnight; they evolve over generations. Those economies that are today actively seeking to expand the private economic impact of their publicly funded R&D are building upon the legacies of past investment in their institutions and in the human capital that is the very source of innovation. Today's challenge is to adapt the policy environment to improve the social rate of return on those investments. This can be achieved by increasing the flow of technologies into the private sector. It is therefore important to understand how technology transfer from universities and public research institutions is affected by national policies. The three fundamental policy questions that any country must answer are:

1. To what extent are intellectual property (IP) protections available?
2. To whom can/should the ownership of those property rights be assigned? (To the government or third-party sponsor of the research? To the institution where the work was conducted, or to the individual inventor?)
3. What capacity, in the form of dedicated infrastructure, programs, or other resources, will be provided to identify, protect, and commercialize new technologies and to support industrial development and technology-based entrepreneurship activities?

IP is just one part of an economy's system of innovation. The research base, the legal IP regime, and the institutional infrastructure all co-evolve in a synergistic process with each part supporting, and supported by, the others, just as the different parts of an ecosystem co-evolve. This chapter provides brief sketches of the national policies governing university and public sector technology transfer by means of intellectual property, looking at how the three basic policy questions have been addressed around the world. From these observations, we can distill general trends in legislative, regulatory, and institutional reforms from around the world.

2. PRIMARY AREAS OF POLICY AFFECTING TECHNOLOGY TRANSFER

2.1 *Availability of IP protection*

The first policy question is whether private-property rights can be claimed over the intangible results of research. This issue is governed by a country's intellectual or industrial property laws. Some degree of global standardization has been achieved through multilateral agreements. The Paris Convention of 1883 ensures that foreign inventors from signatory countries are treated as nationals. The Patent Cooperation Treaty (PCT) of 1970 provides a common patent application clearinghouse for inventors wishing to file for patents in multiple countries. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) of the WTO, adopted in 1994 and entered into force in 1995, stipulates minimum IP standards for members of the WTO. In addition, provisions or conditions for IP protection are often the subject of bilateral trade agreements. Influential centers of trade such as the United States and the European Union exert a harmonizing influence on the national policies of trade partners with whom they have concluded bilateral trade agreements. These trade leaders often set standards for IP protection that are even higher than the conditions set forth in TRIPS. In the specific area of newly bred plant varieties, the Union for the Protection of New Plant Varieties (UPOV) Convention, adopted in 1961 and revised in 1972, 1978, and 1991, has established international standards for plant variety protection (PVP). Each revision of the

treaty outlined increasing levels of protection that countries can decide to adopt.

Even if domestic IP rights are not available for a newly invented technology, the inventor does have the option of filing in other countries where IP rights may be granted. It is common for inventors around the world to minimally file in the major triad of the United States, Europe, and Japan.

2.2 *Ownership of intellectual property*

The second policy question concerns the locus of ownership of intellectual property that results from work done at publicly funded organizations. Legislative reforms have been introduced in many countries seeking to systematize and promote the commercialization of technologies. Many of these efforts have taken inspiration from the experience of the United States under the Bayh-Dole Act of 1980, which harmonized the variety of U.S. government agency IP ownership policies. The Bayh-Dole Act specifically focused on the rules concerning the disposition of IP rights over inventions that result from federally funded research. It effectively limited the government's role in ownership, vesting ownership rights to the organization where the invention is made, along with responsibilities and conditions for how the intellectual property is to be managed. It is possible, however, for other areas of law, including patent law and labor law, to shape how universities manage intellectual property.[1]

2.2.1 *IP, industrial property, or patent laws and regulations*

IP or patent law often provides conditions for the disposition of patent rights between the individual inventor, the institution that employs him or her, and a designated assignee of the rights, which can be either the employing institution or a third party.

2.2.2 *Labor or employment laws and regulations*

Employment laws and regulations can stipulate the privileges, rights, and responsibilities of employees, including the disposition of rights to inventions made during the course of employment. These commonly specify that inventions made in the natural course of employment are to become the property of the employer, although conditions may be put in place, such as requiring additional compensation for the employee-inventor. In some countries, particularly in continental Europe and Scandinavia, an exemption to labor law has been historically granted to university faculty, dubbed the "professor's exemption." This exemption gives faculty the right to take ownership over any intellectual property resulting from the research they conduct at the university.

2.2.3 *Laws of funded or contracted research*

Government funds or contracts, including those granted for the conduct of research, often carry requirements for the recipients of those funds or for the parties to that contract. In some (increasingly rare) cases, a government may explicitly require that the results of research funded by the government be made freely available to the public, thus prohibiting any private IP claims. In other cases, a government may itself take ownership of IP rights over the results of research. Alternatively, a government may choose to devolve the rights of ownership, either to the institution that hosted the research or to the individual inventor. The primary justification of the latter two policies is that putting the IP rights into the hands of the host institution or the inventor properly aligns private economic incentives to encourage inventions and entrepreneurial activity. The premise is that economic activity governed by the market will better serve the economy and consumers—while at the same time generating rewards and incentives for institutions and researchers based on the actual market impact of their contribution.

2.2.4 *Laws and regulations of the national R&D system*

Governments in many countries are taking specific steps to develop national innovation or R&D systems supported by an integrated set of policies covering the creation of new research institutions, increased research funding, management of human resources, and the provision of grants and subsidies. These policies might include tax incentives for industry R&D and institutions along

with funds to support venture investment and entrepreneurship. As part of the integrated policy, there may be rules for the provenance of intellectual property created within the national system.

2.2.5 *Ownership questions in the absence of domestic policies*

In cases when IP rights are not available in an inventor's home country, the question of ownership may still arise, in particular the ownership of available foreign IP rights, whether it be by the individual inventor, their government, their employing institution, or a third-party assignee.

Importantly, in the absence of laws specifically enabling or restricting ownership of intellectual property, universities and public research institutions are free to establish their own policies and practices. This is the situation in many countries, including developed countries such as the U.K. Such openness can allow a research institution greater IP management flexibility. On the other hand, the lack of a specific national policy on IP ownership often indicates a lack of coordination or transparency.

2.3 *IP management capacities*

The third fundamental policy question concerns the provision for IP management and technology commercialization. Merely providing for the existence of private-property rights over intellectual assets is not enough. Public institutions need more than rights to own intellectual assets; they need to develop the infrastructure and expertise required to manage these intellectual assets and engage in productive commercial relationships with private companies and investors. Even in high-income countries such as the United States, institutional developments took a decade or more to spread through universities. While universities were left to create infrastructure and expertise on their own in the United States, many other countries have pursued policies that range from providing subsidies to universities to set up technology transfer offices (TTOs)—Denmark is a good example—to establishing national networks or central offices to coordinate and assist universities in developing their technology transfer operations (such as Chile).[2]

While national laws and regulations provide a legal framework within which universities and public research institutes operate, these are ultimately implemented by the staff dedicated to the management of technology commercialization. Institutional policies can be slow to take shape, and dedicating resources, establishing offices, and deploying staff takes time and commitment. However, while universities develop or adapt formal policies, rules, and regulations, the informal norms and practices within the academic culture are equally crucial. Once policies and capacity are established at the institutional level, an effective IP management program can take up to ten years to develop and mature into a self-sustaining enterprise that is supported by the academic community. These capacity developments are often most visible in the creation of offices or units for IP management, technology transfer, or commercialization, and in the volume of patents, licensing deals, or spinouts coming from the public sector.

3. CURRENT POLICIES IN EMERGING ECONOMIES

3.1 *Argentina*

IP protection. Argentina's current patent law, the Law on Patents and Utility Models No. 24.481 was adopted in 1995, amended by Law No. 24.572 in 1995, and harmonized in 1996 by Executive Decree No. 260.96. Argentina joined the WTO and became signatory to TRIPS in 1995, which entered into force in Argentina on 1 January 2000.[3, 4] Under Article 100 of the new Law on Patents, pharmaceutical products became patentable as of 2000 (with patent applications accepted as of 1995). Article 6 of the new Law on Patents, however, clearly stipulates that plants, animals, and indeed "*all classes of living materials and substances existing in nature*" cannot be patented. Article 7 reinforces this, excluding from patentability "*the totality of biological and genetic material existing in nature…*"[5] Patents are administered by the Instituto Nacional de la Propiedad Industrial (INPI).[6]

Plant varieties are protected in Argentina under the 1973 Law No. 20.247 on Seed and

Phytogenetical Creation (the Plant Varieties Law). Argentina joined UPOV in 1994, as enacted by Law No. 24.376 on the Protection New Varieties of Plants.[7, 8]

In 2004, the National Agency of Scientific and Technologic Promotion announced an initiative to help researchers, both in industry and government laboratories, to pay for foreign patent filings, in an effort to boost the rate of domestic patenting (in many jurisdictions, domestic filing is a prerequisite for foreign filing). In 2000, 145 patents issued by Argentina went to residents of Argentina, while 1,442 went to foreign residents.[9]

Ownership. The 1990 Law on the Promotion of Technological Innovation No. 23.877 and the 1995 Law on Higher Education No. 24.521 provided certain conditions for institutional ownership and transfer of intellectual property resulting from the work of researchers.[10] The 1990 law allows national research institutions to establish or outsource TTOs, but leaves the question of internal distribution of income up to institutional policy. It allows for researchers to receive income beyond their government salaries from technology commercialization activities. The law also provides for government funding of TTOs for collaborations with (preferably small) businesses and establishes a fund for this purpose. In the 1995 law, Article 59 establishes the financial autonomy of national universities and their right to seek additional sources of revenue from the provision of services, products, contributions, fees charged, and any other resources, including technology transfer and commercialization. The law also allows national universities to form or own corporations.[11]

However, the 1995 Law on Patents and Utility Models (24.481, modified by 24.572) established that the ownership of inventions made by employees in the course of their jobs goes to the employer, in most cases. But the law also requires the distribution of a share of the income to the inventor, and for researchers at national universities, it, in effect, gives joint ownership to the university and the centralized agency CONICET (Consejo Nacional de Investigaciones Cientificas y Tecnicas), which manages employment and pays salaries for most university-based scientists in the country. TTOs of individual institutions may establish individual agreements with CONICET for the assignment and management of particular inventions. CONICET does not, however, have a general policy on handling joint inventions.[12]

Institutional capacities. As a result of ownership laws, there is both some IP management and coordination capacity at the government level. TTOs exist at some universities, and IP management is also contracted out to third-party management companies or centers. Among the most developed programs are:[13]

- University of Quilmes
- University of Cordoba
- University of Litoral
- Inis Biotech (the TTO for Instituto Leloir)
- Some capacity for IP management is centralized at CONICET, within its Directive for Science and Technology Links (Dirección de Vinculación Científico Tecnológica). This lists on its Web site more than 60 patents registered in Argentina, 12 registered in other Latin American countries, and four registered in the European Union, the United States, and Canada[14]
- The Constituyentes Technology Pole (Polo Tecnológico Constituyentes) was created in 1997 to facilitate technology transfer for several research institutions, including the National University of General San Martín (UNSAM), the Atomic Energy Commission, (Cómision Nacional de Energia Atómica - CNEA), and the National Institute of Industrial Technology (Instituto Nacional de Tecnología Industrial - INTI)

The Secretary of University Policies, which is part of the Ministry of Education, has established a Technology Network (Red de Vinculacion Tecnologica) that holds meetings and provides general information. Its main mission is to maintain professional networks.

3.2 *Brazil*

IP protection. Brazil has a long history of IP rights, having first introduced a system of protection in

1809. Brazil was also an original signatory to the Paris Convention in 1884. Beginning in the 1950s, Brazil pursued an aggressive science and technology policy designed in part to engender economic development under an import-substitution development policy. The previous Industrial Property Code (Law No. 5.772), dating from 1971, supported this policy by excluding patent protection for certain areas of technology, such as pharmaceuticals and chemicals. Following political and economic reforms, IP laws changed significantly in the 1990s. Brazil became a founding member of WTO and thus a signatory to the TRIPS Agreement in January 1995. The Law on Industrial Property No. 9.279 of 1996 entered into force in May 1997 to implement TRIPS. It has since been amended several times. Patents are administered in Brazil by the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial - INPI).[15] Article 10 of the Law on Industrial Property excludes from patentability materials existing in nature: "all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and natural biological processes."[16, 17]

Plant varieties are protected under Law No. 9.456, adopted in April 1997, and implemented by Decree No. 2.366, in November 1997. They are also protected by the Ordinances of the Ministry of Agriculture No. 503, in December 1997, and No. 8, in June 1999. Brazil has been a member of UPOV since May 1999.[18]

In 2002, Brazil issued 666 patents to residents of Brazil and 1,366 to foreign residents.[19]

Ownership. For purposes of invention ownership, researchers at universities and public research institutes are not considered, under Brazilian law, to be different from other kinds of employees. The Law on Industrial Property gives inventors the right to apply for a patent, but gives employers the right to ownership of an invention by an employee that is "hired to invent," according to the terms of their employment contract. The law thus differentiates between inventions made in the course of employed work, inventions made separately from employed work (free inventions), and inventions that combine both (mixed inventions). Universities thus need to establish the type of inventions on a case-by-case basis and can take title to those made in the course of employed work. According to Article 93 of the Law on Industrial Property and spelled out in Presidential Decree No. 2.553, of April 1998, inventors who are employees in public institutions are to receive remuneration from the income created by the patent, as an incentive or bonus for inventing. The exact share to be distributed is left to institutional policy, but is not to exceed one-third of the value of the invention. Terms of IP ownership and revenue sharing are further spelled out in implementing orders of the Ministry of Science and Technology, No. 88, of 1998, and the Ministry of Education and Sport (No. 322 of April 1998).[20]

Institutional capacities. As early as 1982, under the former military regime, a central office for technological innovation was established at the National Council for Scientific and Technological Development to promote innovation at universities and encourage technology transfer to Brazilian industry. Thereafter, 12 Technological Innovation Centers were established at Brazilian universities to protect intellectual property and facilitate the university–industry interface. Today, more than 30 universities and research institutes operate TTOs.[21] Among the largest and most experienced are:

- the Agency for Innovation at Unicamp (Inova Unicamp)[22] at the State University of Campinas (Unicamp)[23]
- the USP Agency for Innovation (Agência USP de Inovação)[24] at the University of Sao Paolo
- the Brazilian Agricultural Research Corporation (Empresa Brasileira de Pesquisa Agropecuária - EMBRAPA),[25] which adopted an institutional IP policy in 1996 and opened its IP Secretariat in 1998 to handle intellectual property and technology transfer[26]
- the Technology Development Support Center (Centro de Apoio ao Desenvolvimento Tecnológico - CDT), created in 1989 at the University of Brasília, and among the

earliest university centers for technology transfer [27, 28]

- the Secretariat for Technology Development (Secretaria de Desenvolvimento Tecnológico - Sedetec) at the Federal University of Rio Grande do Sul, formed by merging the operations of a TTO and an incubator network in 2000[29]

Patenting by Brazilian public sector institutions has grown dramatically. In 2003, the top seven universities plus EMBRAPA received 153 patents in just one year.[30] In contrast, over the 15 years between 1980 and 1995, all Brazilian universities and EMBRAPA received just 264 patents combined.[31]

3.3 *Chile*

IP protection. IP protection over technological inventions in Chile is based upon the Industrial Property Law (No. 19.039) of 1991. A 2005 modification (No. 19.996) brings Chilean law into line with the minimum requirements in TRIPS and the IP requirements in the bilateral free-trade agreements concluded with the United States and the European Union. Chile has been a member of the WTO and a signatory to TRIPS since 1995. However, Chile is not a member of the PCT. In Chile, patents are administered by the Department of Industrial Property. [32, 33, 34]
Plant varieties are protected in Chile under the Rights of Breeders of New Varieties of Plants (No 19.342) of April 1997. Chile joined UPOV in 1996.

In 2000, Chile granted 32 patents to residents of Chile and 569 to foreign residents.

Ownership. The Industrial Property Law (No. 19.039) regulates the ownership of intellectual property resulting from work conducted under contract or employment. A section specifically on universities stipulates that IP rights derived from the work of university employees belong to the university or its designee, since that inventive or creative work is understood to be part of the job obligation. However, certain limitations on the assignment of IP ownership are set by workers' rights provisions in Chilean labor law, namely that universities cannot ask employees to completely waive the portion of IP rights due to them as inventors. Major Chilean research funding sources (such as FONDEF and CONICYT) now require IP protection of results by those organizations receiving funding, including universities.[35]

Institutional capacities. Among leading Chilean organizations with an organizational capacity for IP management are:

- University of Concepción, with its Center for Industrial Property (Unidad de Propriedad Industrial)[36]
- In 2003, the University of Chile formed the Central Commission for Industrial Property (Comisión Central de Propiedad Industrial)[37]
- Fundación Chile, which coordinates innovation and entrepreneurship projects based upon Chilean R&D, provides expertise and resources for IP management[38]
- NEOS, a consulting company located in Santiago, provides professional IP services for universities in Chile[39]

3.4 *China*

IP protection. IP law is widely viewed in China as a western import, with a first patent law adopted relatively recently in 1984 and a copyright law adopted in 1990. While protection and enforcement under these has been of ongoing concern for outsiders, the internal political climate has been shaped by the desire to join WTO and the growing prowess of Chinese companies in science and technology. It is largely these internal forces that led to the strengthening of the patent law in 1992 and in 2001.

New plant varieties are protected under the Regulation on the Protection of New Plant Varieties, implemented in 1997. China joined UPOV in 1999.[40]

In 2004, China granted 18,241 patents to residents of China and 31,119 patents to foreign residents.[41]

Ownership. As early as 1985, just five years after Bayh-Dole passed in the United States, provisional regulations issued by the State Council on Technology Transfer gave Chinese universities the right to manage and use the inventions

of university researchers, even though ownership formally remained with the State.[42] The government, however, has only recently encouraged universities to assert such rights. China adopted its Act for Promotion of Technology Transfer in 1996, later reinforced by the Decision on Reinforcing Technological Innovation and Realizing Industrialization of the State Council in 1999 and by the Opinion on Exerting the Role of Universities in Science and Technological Innovation issued jointly by the Ministry of Education and the Ministry of Science and Technology in 2002.[43] The latter is often called the "Chinese Bayh-Dole Act." In 2003, the Ministry of Education again clarified the rights of IP ownership by institutions undertaking research sponsored by the government in its Key Points on Promoting Science and Technology of Universities.[44]

Institutional capacities. Internal organizational capacity for IP management is most readily found at leading universities, such as:

- Tsinghua University, with probably the most well-developed university TTO in China[45]
- Beijing University

The number of patent applications from across the full range of Chinese universities is significant. It quadrupled in the four years from 1999 (with 988 applications) to 2002 (with 4,282 applications).[46] For comparison, U.S. universities reported total patent applications increasing less than two fold between 1999 (with 8,457 applications) and 2002 (with 12,222 applications).[47] However, some caution should be taken in interpreting these figures, since the practice of patenting by Chinese academics appears to have been adopted as something of a proxy for published research. In fact, inventorship on patents is widely admitted as a criterion for academic promotion. Significantly, far fewer Chinese university patents are being licensed or commercialized. Still, Tsinghua University reports having spun off more than 38 companies, generating annual sales of US$1.8 billion and actively incubating more than 200 companies at the Tsinghua Science Park during 2003 alone.[48]

3.5 *Ethiopia*

IP protection. Ethiopia is an example of a country still largely outside of the global IP system. Ethiopia has a basic patent code, created in 1995 by Proclamation No. 123 Concerning Inventions, Minor Inventions, and Industrial Designs, and instituted in 1997 by Regulation No. 12. The stated purpose is to encourage local innovation (mostly minor adaptations of existing technologies) and transfer in foreign technologies. The proclamation precludes the patenting of plants, animals, and essentially biological processes.[49] The country is an observer but not a signatory to WTO, and is thus not bound to compliance with TRIPS. Ethiopia protects copyright under its civil code.[50]

PVP was introduced in February 2006 by Proclamation No. 481, Plant Breeder's Rights.[51]

In 2000, the Ethiopian Intellectual Property Office received just seven patent applications and granted just one, to a foreign resident. In the same year it granted 19 industrial designs, 12 to residents of Ethiopia and seven to foreign residents.[52]

Ownership. There is no national framework and an apparent lack of clarity or transparency about the terms and conditions under which public research institution or individual inventors might be owners of any IP rights.

Institutional capacities. The largest research organizations in the life sciences are Addis Ababa University, Alemaya University, the Ethiopian Health and Nutrition Research Center, the Ethiopian Agricultural Research Organization, the National Veterinary Institute, and the International Livestock Research Institute (ILRI), all producing locally or regionally marketable research results. Only the Ethiopian Agricultural Research Organization has an IP unit in formation. The rest have no IP management units, and their scientists and staff have a very low level of awareness and knowledge about IP rights. The Ethiopian Intellectual Property Office has received only a handful of patent applications from university researchers in Ethiopia, (primarily in agriculture, pharmaceuticals, and mechanics) and only one from the Ethiopian Agricultural Research Organization.[53]

3.6 *India*

IP protection. India's history with IP law is deeper than that of many developing countries. The first patent law was adopted in 1856, and by 1911 Indian patent law conformed to the standards of developed countries. Copyright, trade secrecy, and design laws have been in place equally as long. However, patent law was relaxed in 1970 under the import-substitution industrial policy, which encouraged economic development through the reverse engineering of western technologies. Since adopting market-oriented reforms and seeking WTO membership in the 1990s, reform in IP law has been rapid. India joined the WTO and became signatory to TRIPS in 1995. Patent law was strengthened in 1999 and again in 2002 to become compliant with TRIPS.[54] Legislation that passed in 2005 reinstated the patenting of pharmaceutical compounds, reversing legislation from 1970 that limited patenting to the processes for the manufacture of pharmaceuticals.[55] Today, an elite cadre of Indian pharmaceutical companies has emerged with the capacity to engage in globally competitive R&D, significantly influencing India's internal IP policy debate.

Plant varieties are covered by the Protection of Plant Varieties and Farmers' Rights Act of 2001.[56] India has not joined UPOV.

In 2004, India granted 851 patents to residents of India and 1,466 to foreign residents.[57]

Ownership. In 2000, the Ministry of Science and Technology issued a ruling that gave title to intellectual property to those institutions that receive funding from the Ministry. While this is not a legislated policy, it signaled a milestone in an ongoing trend of shifting technology transfer activities away from the government to research institutions. This trend has been underway since at least 1995.[58]

Institutional capacities. The bulk of intellectual property and technology transfer expertise in the public sector remains located in government agencies, particularly in the Council for Scientific and Industrial Research (CSIR), the Department of Science and Technology (DST), and the Department of Biotechnology (DBT). The Ministry of Science and Technology, the Indian Council of Medical Research (ICMR), and the National Research and Development Council (NRDC) are also involved in technology transfer activities.[59]

Most academic intuitions still lack IP management capacity, with the exception of the leading Indian Institutes of Technology (IITs) and a few other universities. TTOs or centers are now found at:

- IIT New Delhi
- IIT Bombay
- IIT Kharagpur
- IIT Kanpur
- IIT Guwahati
- IIT Roorkee
- IIT Chennai
- Delhi University
- Govind Ballabh Pant University of Agriculture & Technology, Pant Nagar
- Bidhan Chandra Krishi Vishwavidyalaya
- Jadavpur University[60]

Only a small portion of the 277 Indian universities listed by the Association of Indian Universities have functioning TTOs.[61] In April 2005, a professional association for technology transfer was launched—the Society for Technology Management (STEM).[62] In April 2006, the Minister of Science and Technology announced plans to set up an Indian Institute for Intellectual Property Management.[63]

3.7 *Indonesia*

IP protection. Intellectual property is a relatively new concept in Indonesia. Indonesia signed the Paris Convention in 1950. It joined WIPO in 1979. Industrial Designs were introduced by Law No. 5, Concerning Industry, in 1984. Patents were introduced by Law No. 6, Patent Law, in 1989 and amended by Law No. 13 in 1997. Indonesia has been a member of WTO and a signatory to TRIPS since 1995.[64, 65]

In Indonesia, a plant variety can be protected by a patent if it fulfils the basic requirements for patentability. In addition, in 2001 the Indonesian parliament passed a Plant Variety Protection Act, based on the UPOV 1991 standards, to establish a PVP system.[66] Indonesia has, however, not joined UPOV.

In 1996, Indonesia granted 16 patents to residents of Indonesia and 615 to foreign residents.[67] In 2003, however, Indonesia granted 2,902 patents, including both residents and nonresidents.[68]

Ownership. The 2002 Law No. 18, titled National Systems for Research, Development, and Application of Technology, stipulates that institutions and universities in Indonesia should establish units for IP management and that they may use the income derived from the exploitation of intellectual property.[69]

Institutional capacities. There are now, at least nominally, over 90 IP management units at institutes and universities throughout Indonesia. Leading centers of public sector IP management include:

- more than 30 research institutes of the Agency for Agricultural Research and Development (AARD) have their technology transfer needs handled by Kekayaan Intellectual dan Alich Teknologi (KIAT), established in 1999
- Indonesian Institute of Science (LIPI)
- University of Indonesia
- Bandung Institute of Technology
- Bogor Agricultural University (IPB)[70]

3.8 *Jordan*

IP protection. Jordan joined the WTO in 1999, as the 136th member of the WTO. It became a member and signatory to TRIPS in April 2000. The Patents of Invention Law No. 32 was adopted in 1999. In 2001, Jordan signed the U.S.-Jordan Free Trade Agreement, which led to further IP reforms. Patents are issued by the Industrial Property Protection Directorate (IPPD) of the Ministry of Industry and Trade.[71, 72, 73]

Plant varieties are protected under the Plant Varieties Law No. 24 of 2000. Jordan acceded to UPOV in October 2004.

In 2004, Jordan granted four patents to residents of Jordan and 56 patents to foreign residents.

Ownership. Jordanian law is flexible in its approach to commercializing technology developed in public sector institutions. Currently, a high-level comprehensive review is underway of all relevant legislation and supporting regulations to outline areas that could be improved by an explicit act promoting commercialization. This legal and regulatory review will lead to specific improvements in their technology transfer infrastructure.[74]

Institutional capacities. Few universities or research organizations have had time to adapt to the new IP legislation, and thus far only the Royal Scientific Society, the premier government research institution, reports having established its Technology Transfer Centre.[75]

3.9 *Kenya*

IP protection. The application of IP regimes is not deeply rooted in the history of Kenya or in other countries of eastern Africa, and the country has typically responded to colonial influence or international developments. Kenya first introduced its Patent Registration Ordinance in 1914, which was modeled and dependent upon the British system. However, the Industrial Property Act of 1989 established the first independent patent system in Kenya. Kenya joined the WTO and became signatory to TRIPS in 1995. The 1989 Act was superseded by the Industrial Property Act of 2001, which set up the Kenya Industrial Property Institute (KIPI)[76] as an autonomous office to administer patents, utility models, trademarks, and service marks. Section 26 of the Industrial Property Act includes standard TRIPS exemptions from patentability: methods for treatment of human or animal, diagnostic methods, any drugs or compounds necessary to combat threats to public health, and plant varieties.[77]

PVP was established in 1972 by the Seeds and Plant Varieties Act and implemented under the Seeds and Plant Varieties Regulations of 1994. Kenya acceded to UPOV in 1999 under the terms of the 1978 Act. PVP is administered by the Kenya Plant Health Inspectorate Service (KEPHIS), under the Ministry of Agriculture and Rural Development.[78]

In 2001, Kenya granted no patents to residents of Kenya and 33 patents to foreign residents. That year just two applications were received from residents of Kenya.[79]

Ownership. A national policy for IP ownership, beyond that stipulated in the employment and inventorship clauses of the *Industrial Property Act,* is largely irrelevant because public sector research institutions make up most of the R&D infrastructure in Kenya. Many were founded with a mandate for conducting innovation and product development, since R&D is almost nonexistent in the private sector. Thus, public institutions are neither prohibited nor mandated to take ownership; they are left to themselves to adopt institutional policies and capacities to assert ownership, as long as the institutions operate according to the basic requirements of national IP law.

Institutional capacities. The development of institutional IP management capacity has been motivated partly by reports that the University of Nairobi, the premier university in Kenya, has had to forego IP rights for some innovations due to a lack of clear policy and structures. These innovations included a fermented milk product, a beer product, a disease-resistant pea variety, a pesticide compound, a database of medicinal plants, and a potential AIDS vaccine.[80] The following research institutions are currently engaged in developing IP policies and creating IP offices:

- University of Nairobi has recently adopted an IP policy that establishes an internal TTO.[81]
- Moi University has established Moi University Holdings Ltd., a fully owned subsidiary with a TTO to manage the university's intellectual property.[82]
- Jomo Kenyatta University of Agriculture and Technology (JKUAT) has drafted an IP policy and employs one IP manager.
- At Kenya Agricultural Research Institute (KARI) a legal officer manages intellectual property.
- The International Livestock Research Institute (ILRI) adopted an IP policy in 1998 and has an IP office at its Nairobi center.[83, 84, 85]

3.10 *Malaysia*

IP protection. Malaysia instituted a range of IP laws in the 1980s, including the Patents Act of 1983 (Act No. 291). The Patents Act has been amended several times, both before and after Malaysia joined the WTO and signed TRIPS in 1995. The Patents Act excludes from patentability the same life-science subject matter excluded in TRIPS, including plant and animal varieties, essentially biological processes, and methods of medical diagnosis and treatment. Since the 1983 Act, Malaysia has allowed product patents on pharmaceutical and agricultural chemical compounds. The Intellectual Property Corporation of Malaysia Act of 2002 (Act No. 617) established the Intellectual Property Corporation of Malaysia as the new patent office. Malaysia joined the PCT in August 2006.[86]

The Protection of New Plant Varieties Act of 2004 (Act No. 634) is largely compliant with UPOV, even though Malaysia has not yet joined UPOV.[87]

In 2003, Malaysia granted 31 patents to residents of Malaysia and 1,542 patents to foreign residents.[88]

Ownership. Under the Patent Act of 1983, employers, including publicly funded research institutions, are the rightful owners of intellectual property created by employees in the course of employment. However, there have been recent ministerial examinations of IP ownership issues in cases where government funding is involved. In 2003, the government announced the Second National Science and Technology Policy, which included the following clauses:

- "*to promote adoption of sound research management practices including intellectual property management and commercialisation of research outputs in all PRIs [public research institutes] and universities.*"
- "*to enhance the management of intellectual property rights including patent advisory and other services.*"
- "*to review existing legislation or to develop new legislation related to policy.*"[89]

In 2004, Malaysia's Ministry of Science, Technology, and Innovation (MOSTI), at the prompting of the prime minister, began a review of incentive systems to attract and retain Malaysian scientists, including the availability of R&D facilities, financial assistance, and venture capital.[90]

The Ministry also considered IP policy options similar to those in the United States under the Bayh-Dole Act.[91] The government then indicated that it would instead pursue a policy of three-way IP rights sharing: the government, research institute, and inventor would all jointly own research results.[92] In a March 2006 announcement, the head of MOSTI announced, "*research work undertaken with government grants should be jointly owned by the Government, the respective university, as well as the scientists involved.*"[93]

Institutional capacities. Most universities and institutes established their internal IP policies under the Patent Act of 1983, asserting institutional ownership of inventions made by employees and managing them accordingly. Currently, 17 out of the 45 or so universities in Malaysia have established TTOs.[94] IP management offices found at leading universities and research institutes include:

- University of Malaya's Technology Transfer and Commercialization Unit (UPTK) was founded in 1998 as part of the university administration, but in 2001 it was transferred to the university's Institute of Research Management and Consultancy (IPPP), which handles the full range of research interactions with industry.
- At Universiti Sains Malaysia (USM), the Research Creativity and Management Office (RCMO) handles many issues related to R&D relations with industry, including IP marketing.[95] Some aspects of patenting and commercialization are also handled by the Corporate and Sustainable Development Division (BPLK).[96]
- Univeristi Teknologi Malaysia (UTM) is the premier engineering institute in Malaysia. In 1993, the university created a Bureau of Innovation and Consultancy to promote technology commercialization within its Research and Consultancy Unit, which has managed research relations with industry since 1981.[97]
- Universiti Malaysia Sarawak (UNIMAS) has recently established the new Intellectual Property and Commercialization Unit (IPMCU) within the university's Research and Innovation Management Centre (RIMC), which was formed in 2005 out of the previous Research Management Unit established in 2003.[98] Some IP commercialization services are also offered by the Centre for Technology Transfer and Consultancy (CTTC), formed in 1993 to facilitate collaboration between university experts and local industry.[99]
- The Malaysian Palm Oil Board (MPOB) has been one of the most successful organizations in the country in using intellectual property to commercialize technology.[100] MPOB offers an extensive list of technologies available for transfer and commercialization, with licensing managed by the Licensing and Enforcement Division.[101, 102, 103]
- The Malaysian Agriculture Research and Development Institute (MARDI) has a sizable technology transfer and commercialization unit and list of technologies available for transfer and commercialization.[104, 105]

3.11 *Mexico*

IP protection. Mexican patent law has been in place since the early 1800s. Today, intellectual property protection is governed under the Industrial Property Law, adopted in 1994 and amended in 1997 and 1999.[106] Mexico joined the WTO and signed TRIPS in 1995. Mexico's Industrial Property Law excludes from patentability any essential biological process for the production, reproduction, and propagation of plants and animals; biological and genetic materials as found in nature; animal species; the human body and its living components; and plant varieties.[107] Patents are administered by the Mexican Institute for Industrial Property (Instituto Mexicano de la Propriedad Industrial).[108]

Mexico protects plant varieties through the 1997 Federal Law on Plant Varieties (Ley Federal de Variedades Vegetales), under regulations implemented in 2000 by the Ministry of Agriculture. Mexico joined UPOV in 1997, but joined under the terms of the 1978 Act.[109]

In 2004, Mexico granted 162 patents to residents of Mexico and 6,677 patents to foreign residents.[110]

Ownership. In Mexico, Article 163 of the Federal Labor Law (Ley Federal del Trabajo), adopted in 1970 and reformed in 1998, governs the ownership of inventions made by employees.[111] The law indicates that results of research are owned by the employer, who has the right to exploit patents. The employee, however, is to be given additional compensation, and in some cases the right of ownership. In all cases, the employee's name is listed as inventor. The Industrial Property Law, Article 14, reflects these protections of the employee. The 2002 Law of the National Council of Science and Technology (Ley de Ciencia y Tecnología), Articles 47–59, discusses invention ownership in cases where the national science council (CONACYT) finances research and development in universities or any other nongovernmental organizations and in the 60 or so public research institutes and agricultural R&D centers in Mexico. In both cases, the ownership of the results is determined according to the policies of the organization where the research is carried out. Many organizations, like universities and large companies, have policies that indicate that the ownership of research results goes to the institution, but in most cases the inventor will get some share of the financial benefits. Usually in the case of universities, the researchers are named as the inventors on the patent but sign full ownership rights over to the university. Within universities, the distribution of benefits follows the terms of an internal agreement or institutional policies.[112]

Institutional capacities. Development of institutional IP policies and discrete offices of IP management is minimal, but includes the following:

- At the National Autonomous University of Mexico (UNAM), the General Counsel's Office oversees IP policy and management. However, according to a critique in *Nature Biotechnology*, "*there is no support, even at the university level, for patenting: the level of technology transfer is low… UNAM has neither sufficiently trained personnel, nor, apparently, the interest to fight for its share on the patents.*"[113]
- Instituto Tecnológico de Estudios Superiores de Monterrey (ITESM) has engaged in several projects involving technology transfer in aerospace and expert systems engineering
- CINVESTAV is engaged in a number of biotechnology projects and has mediated transfers of proprietary biotechnologies.

3.12 *Philippines*

IP protection. IP protection has a somewhat deeper history in the Philippines than in some of its neighboring Asian countries. After achieving independence from the United States in 1946 at the end of World War II, the Philippines provided for the protection of inventions, utility models, and industrial designs under the Republic Act (No. 165) of 1947. Borrowing heavily from U.S. patent law, it provided 17 years of protection from the date the patent is granted and recognized priority based on "first to invent." The Philippines joined the WTO at its founding in 1995 and became a signatory to TRIPS. IP law was brought into compliance with TRIPS provisions in 1998 with Republic Act (No. 8293), the Intellectual Property Code of the Philippines. This changed patent terms to 20 years from date of filing and recognized priority based on first to file. The Act also created the Intellectual Property Office of the Philippines. In accordance with TRIPS provisions, the Act treats as non-patentable plants, animals, and essentially biological processes for the production of plants and animals.[114]

Republic Act (No. 9168) of 2002, titled Act to Provide Protection to New Plant Varieties, provides for sui generis protection of plant varieties and established the National Plant Variety Protection Board. The Philippines is not a member of UPOV.[115]

In 2003, the Intellectual Property Office of the Philippines granted 11 patents to residents of the Philippines and 1,160 patents to nonresidents.[116]

Ownership. The Philippines has no enabling legislation to give ownership of inventions to universities or research institutes, effectively leaving them free to develop their own institutional IP ownership policies.

Institutional capacities. Policies and offices for IP management are being developed both centrally and at leading research institutions:

- The Department of Science and Technology (DOST) has developed IP guidelines and the Technology Application and Promotion Institute (TAPI) to provide centralized services in technology transfer for pubic institutions.[117]
- A central University Intellectual Property Office (UIPO) for the University of the Philippines was established in 1997 to coordinate offices at its six semiautonomous campuses.[118, 119]
- IP and technology transfer needs of faculty at the University of the Philippines, Diliman campus, is served by an intellectual property section within the Research Dissemination and Utilization Office (RDUO) of the Office of the Vice Chancellor for Research and Development.
- The University of the Philippines, Manila, the main medical research university, has an intellectual property rights office in the Office of the Vice Chancellor for Research.
- The University of the Philippines, Los Baños, has an intellectual property rights office in the Office of the Vice Chancellor for Research and Extension.
- The Philippine Rice Research Institute (PhilRice) of the Department of Agriculture created a TTO in 2004.
- The International Rice Research Institute (IRRI) adopted an IP policy in 1994 that specifies that IP protection will only be used selectively to serve the needs of farmers in developing countries. IRRI coordinates intellectual property for some biotech projects for other institutions with which it partners.

Thus far, only a few dozen patents have issued to public sector institutions in the Philippines.[120]

3.13 *Poland*

IP protection. Poland's IP system is relatively mature, with the Polish Patent Office formed in 1918. However, the intervening years of socialist government had some effects, with Poland joining the PCT only in 1990. Poland became a signatory to TRIPS along with WTO membership in 1995. The Industrial Property Law of 2000 (in force since August 2001) brought Polish patents and trademark law into compliance with TRIPS, and its amendment in 2002 brought Polish law into harmony with E.U. directives on biotechnology intellectual property, including patentability of biological materials, methods, and uses.[121]

The Law on Seed Industry of 1995 conforms to UPOV, of which Poland has been a member since 1989.[122]

In 2004, Poland granted 778 patents to residents of Poland and 1,016 to foreign residents.[123]

Ownership. The Industrial Property Law, Article 11(3) stipulates that an employer or a contractor is the rightful owner of an invention produced under work for hire or contract, unless otherwise agreed upon by the parties involved. This gives universities flexibility to arrange for ownership through terms of employment and research agreements.[124] In recent years the Polish government has been shifting R&D spending away from relatively inefficient industry research institutes and state-owned companies and toward universities.[125] This shift in funding, however, has not been accompanied by any new policy specifically affirming or denying institutional ownership of IP rights resulting from research conducted with state funds.

Institutional capacities. In practice, universities own the intellectual property resulting from research they conduct.[126] IP management offices in Poland are still developing and are found mostly at the leading universities, including:

- The Wroclaw Center for Technology Transfer (WCTT) formed in 1995 at the University of Wroclaw.[127]
- The Technology Transfer Center (Centrum Transferu Technologii - CTT) formed in 1997 at the Cracow University of Technology.
- The Centre of Innovation, Technology Transfer, and University Development

(CITTRU), formed in 2003 at Jagiellonian University.[128]

- The Technology Accelerator and the Innovation Center at the University of Lodz[129] formed in 2003 through a mentoring collaboration involving technology commercialization and entrepreneurship established between the University of Texas at Austin and the University of Lodz. This was an offset commitment under an agreement between Lockheed Martin and the Polish Government for the purchase of F-16 fighters.
- Poland has four regional Innovation Relay Centres (IRCs) hosted at university technology centers, such as the IRC South Poland, which is coordinated by the CTT at Cracow University of Technology.[130] The IRC Network was established by the European Commission in 1995 and now consists of 71 regional centers throughout Europe. It seeks to support innovation and transnational technology cooperation through coordinated activities and a common technology database.

3.14 *Russia*

IP protection. Russia has a history of intellectual property that dates to the time of the czars. The first patent law was adopted in 1812, and then reformed in 1896.[131] During the Soviet period, the State effectively exercised monopoly power over all technological innovations, including those arising from universities and research institutes, with a Committee on Inventions and Discoveries issuing authorship certificates to inventors.[132] In 1991, the U.S.S.R. Law on Inventions radically departed from the Soviet system, creating a form of patent protection that gave exclusive rights of ownership to inventors. In 1992, following the establishment of the Russian Federation, a range of IP legislation was adopted, including the Patent Law of 1992. The Committee for Patents and Trademarks was created, and in 1996 it was changed to the current Federal Service for Intellectual Property, Patents, and Trademarks or ROSPATENT.[133] In 2003, the Patent Law was amended to bring it into alignment with the provisions of TRIPS.[134] As of 2006, the Russian Federation is still only an observer to the WTO and is thus not bound to compliance with TRIPS.

The Russian Federation provides for PVP under the Law on Protection of Achievements in Plant Breeding, adopted in 1992 when the range of new IP legislation was introduced. In 1998, Russia became a member of UPOV under the terms of the 1991 Act.[135]

In 2005, Russia issued 19,447 patents to residents of Russia and 3,943 to foreign residents.[136]

Ownership. Attempts were first made to clarify the question of ownership by public research organizations in 1998 with the Decree of the President No. 863 "*On state policy for the introduction of the results of scientific and technological activity and objects of intellectual property into economic turnover,*" and implemented in 1999 by Resolution No. 982 "*On the use of the results of scientific and technological activity.*"[137, 138] While stating in principle that a research organization might take IP rights over inventions made under work funded by the federal budget, in effect, the policies gave the Russian government first right to any intellectual property by giving the government rights to any military, dual-use, or other technologies deemed "*of use to the State,*" and by requiring all inventions made under federal funding to be recorded with the federal government. These conditions meant that very few publicly funded inventions were reported and that few patents were sought through official channels.[139] A fundamental shift in the government's position, which provided clarity over the rights of the organization conducting the research, only came about in the 2003 revision of the Patent Law. Article 9 states that the right to patent an invention created under state funding belongs to the contracted research organization, unless the research agreement specifies that the right belongs to the government.[140]

Institutional capacities. Despite the State centralization and lack of formal IP rights under the Soviet system, some attention was paid to developing mechanisms for the administrative management of technology transfer at the institutional level. While technology transfers were free of charge, they did occur between public research

organizations and state companies in the Soviet Union and in other Soviet bloc nations.

As a result, a significant number of universities and research institutes today have well-developed technology transfer policies and offices in place. In addition, a number of private, third-party companies and centers have emerged to coordinate technology transfer services for multiple clients, including universities, institutes, and companies, within particular regions or particular fields of technology. Leading examples include:

- the intellectual property and technology transfer department of the St. Petersburg State University, founded in 1967 as the Patent and Licensing Department (PLD) of the university[141]
- the Puschino Center for Technology Transfer of the Puschino Scientific Center[142]
- the Innovation and Technology Center of the University of Nizhny Novgorod[143]
- the Patent Service Center of the Saratov State University[144]
- the Obninsk Center for Science and Technology, which manages technology transfer and business development projects for the Institute of Physics and Power Engineering (IPPE), as well as for R&D centers in the Russian Ministry of Atomic Energy and the Russian Ministry of Science and Technology. [145]
- the Urals Regional Technology Transfer Center [146]
- the Southern Center for Technology Transfer [147]

In 2005, a professional association for technology transfer was launched in Russia and other former Soviet republics, called the Eurasian Association of Technological Transfer Managers (EATTM).[148]

3.15 *South Africa*

IP protection. IP law in South Africa historically derives from U.K. law. South Africa's first Patents Act (No. 37) of 1952 was modeled on the British Patents Act of 1949.[149] It was superseded by the Patents Act No. 57 of 1978, which is in force today, though amended at least eight times.[150] South Africa signed the TRIPS agreement in 1995. Patent Amendment Act No. 58 of 2002 was largely responsible for bringing the provisions of the Patents Act into line with TRIPS requirements. The Act excludes from patentability "any variety of animal or plant or any essentially biological process for the production of animals or plants."[151] Patents in South Africa are administered by the Companies and Intellectual Property Registration Office (CIPRO).[152]

Plant varieties are protected in South Africa under the Plant Breeder's Rights Act No. 15 of 1976. South Africa became a member of UPOV in 1977 and still adheres to the 1978 Act.

In 1995, the last year in which data was reported to WIPO, 5,549 patent applications were received from residents of South Africa, and 5,501 patent applications were received from foreign residents.[153]

Ownership. The patent law of South Africa contains IP ownership terms typical of many countries, but it does not detail public sector employers' rights of ownership or provide terms for publicly funded research.[154] However, a national policy for the ownership of patent rights by public research organizations is currently in development.[155] In the absence of such policies, the question of ownership has historically been shaped by institutional IP policies. But these are not uniform across or within institutions. While most universities prefer to take ownership of intellectual property whenever possible, a relatively high level of their research funding (about 58%) comes from industry contracts, which typically stipulate industry control of IP rights resulting from the funded project.[156] As a result, most universities maintain flexible policies and relinquish ownership of intellectual property as needed to obtain industry research funding.[157]

The National R&D Strategy of 2002 contained language recommending improved protection and commercialization of intellectual property from public research.[158]

In 2006, draft legislation embodying these recommendations was proposed: the Framework for Intellectual Property Rights from Publicly Financed Research. The Framework is largely modeled on the U.S. Bayh-Dole Act. It seeks to

unify IP policies across different government agencies that fund R&D and gives primary rights and responsibilities over intellectual property to the funded research organization. The draft legislation also retains certain privileges for the government to use protected technologies and gives preference for licensing to domestic companies.[159]

Institutional capacities. In order to support their important funding relationships with industry, a cadre of elite research universities in South Africa has developed significant IP policies and internal capacities for IP management. These include:[160]

- University of Stellenbosch has a technology transfer officer in the Office of Research and has established Unistel, a wholly owned subsidiary, to commercialize research through start-up companies.
- University of Cape Town (UCT) has a well-developed IP policy and an office called UCT Innovation with a staff that handles a range of activities, including management of research contracts, protection of intellectual property, and technology commercialization and entrepreneurship.
- University of Pretoria and the Council for Scientific and Industrial Research (CSIR), the national research agency, have collaborated to form a private company, the Southern Educational Regional Alliance (SERA) Ltd., to handle licensing and commercialization for both institutions.
- The South African Medical Research Council has a technology commercialization unit called the MRC Innovation Centre.[161]

With the pending advent of the Framework, the government has also proposed a centralized office, the Innovation Fund Commercialization Office (IFCO), to assist public institutions with IP management and to help cover some of the costs associated with IP protection.[162]

In 2002 a regional association for technology transfer professionals was launched, called the Southern African Research and Innovation Managers (SARIMA).[163]

3.16 *Tanzania*

IP protection. Like other east African countries, Tanzania inherited a colonial IP system from the U.K., including the Patent Registration Ordinance 217 of 1931. The patent ordinance was superseded by the Patent Act No. 1, adopted in 1987 and implemented in 1994. Tanzania joined the WTO and became signatory to TRIPS in 1995, but under the terms for developing countries it had until 2006 to become fully compliant with its provisions. In 1997, under the Government Executive Agencies Act No. 30, the Business Registrations and Licensing Agency (BRELA) was established to administer industrial property. Tanzania has been a member of the African Regional Industrial Property Organization (ARIPO) since 1983.[164, 165]

Tanzania is not a member of UPOV, but in compliance with its obligations under TRIPS, it adopted the Plant Breeder's Right Act No. 22 in 2002 to provide protection for new plant varieties.[166]

In 1989, the last year for which data were reported, Tanzania granted 23 patents, all to foreign residents.[167]

Ownership. Similar to other African nations, the Patent Act serves as the policy for IP ownership. Public sector research institutions make up most of the R&D infrastructure in Tanzania; private sector R&D is almost nonexistent. The public institutions are neither specifically prohibited nor mandated by law to take ownership, but are left to adopt institutional policies and capacities to assert any ownership under the terms of national IP law.

Institutional capacities. Several of the leading universities and research institutes have taken the first steps to establish institutional IP policies and are just beginning to set up IP management offices:[168]

- Sokoine University of Agriculture, the first institution in Tanzania to develop an institutional IP policy, adopted in December 2003
- Dar es Salaam Institute of Technology
- Tanzania Industry Research and Development Organization
- Tropical Pesticides Research Institute

3.17 *Uganda*

IP protection. After independence in 1962, Uganda maintained a patent system inherited from the U.K. until the Patents Statue No. 10 was adopted in 1991. Subsequently, the Patents Act, Chapter 216 was passed and regulations were implemented in 1993. Section 3 created the Office of the Registrar of Patents and a patent registry office to administer the granting of patents. Uganda was a founding member of the WTO and became signatory to TRIPS in 1995. The Patents Amendment Act No. 7 of 2002 brought Uganda into the PCT mechanism, but Uganda is still developing legislation to bring patent law into full compliance with TRIPS. Uganda has been a member of the African Regional Industrial Property Organization (ARIPO) since 1978.[169, 170]

Although not a member of UPOV, Uganda is a member of the Organization of African Unity (OAU), which has advocated a separate set of standards for PVP in African countries. Uganda passed the Agricultural Seeds and Plants Act in 1994 to provide for the registration of new plant varieties.

In 2001, Uganda granted no patents to residents of Uganda and 34 patents to foreign residents. That year only two patent applications were received from residents of Uganda.[171]

Ownership. No specific requirements, constraints, or distinctions are made in Ugandan law regarding the ownership of intellectual property by public sector research institutions or ownership of intellectual property from work funded by the Ugandan government. As such, universities and research institutes are left to adopt institutional policies and capacities to assert IP ownership under the terms of national IP law.

Institutional capacities. IP management in Ugandan institutions is, at best, embryonic, with the following developments reported for the country's leading research institutions:[172]

- The Uganda National Council for Science and Technology (UNCST) has plans to develop an IP management policy and office that could serve as a central advisor on IP management issues for R&D institutions that lack such capacity.
- The Ugandan Industrial Research Institute, which is very active in collaborating with local industry, has a single liaison officer in charge of IP issues.
- Makerere University, the oldest and largest university in Uganda, has no IP management policy or office.

3.18 *Vietnam*

IP protection. Chapter II of Part Six of the Civil Code of 1995, on intellectual property and technology transfer, covers industrial property and was the first legislation to introduce IP protections and include basic TRIPS provisions. Decree No. 63/CP of the Government, promulgated in October 1996, contained detailed regulations concerning Industrial Property.[173] Enacted in November 2005 and entered into force in July 2006, the new Intellectual Property Law has introduced comprehensive TRIPS-compliant IP standards, with the decrees and circulars needed to implement this law likely to be out by the end of 2006.[174] Vietnam entered into a bilateral free trade agreement with the United States in 2004, which obliges it to protect U.S. intellectual property. Vietnam also joined the WTO in December 2006, bringing with it the formal commitment to comply with TRIPS obligations.

Vietnam introduced PVP in 1995. However, only the new Ordinance on Plant Varieties of March 2004 made it a workable system. PVP is also included in the new Intellectual Property Law of 2006. Vietnam's membership in UPOV is slated for late 2006.[175]

In 2005, Vietnam issued 17 patents to residents of Vietnam and 756 to foreign residents.[176] So far, only about 14 instances of PVP have been granted in Vietnam, almost all going to foreign entities. There are currently 18 new applications for PVP, with some coming from domestic companies and universities.[177]

Ownership. In general, property rights are still weak in Vietnam. There are few mechanisms in Vietnam to clarify and ensure the rights of ownership over technology created at universities and research institutes.[178] The situation is further complicated because, despite

increasing autonomy, universities are still in many respects regarded as part of the State apparatus.[179] Industry is also still in the process of being privatized, and in most cases the State still holds a large minority stake in, if not outright control of, private companies.

Institutional capacities. Currently, university researchers and administrators in Vietnam do not have much understanding of intellectual property. Their organizations largely lack IP management capacity, although some are beginning to seek patents and plant variety protections. Leading research institutions in the life sciences are beginning to orient toward intellectual property as a tool for technology transfer. These institutions include:

- The Institute for Biotechnology of the Vietnam Academy of Science and Technology, which does not yet have a formally adopted IP policy, has registered about 20 patents. Inventions and royalty distributions are decided on a case-by-case basis.
- Hanoi Agricultural University's Science Management Office has handled IP issues for its researchers. Estimates are that university faculty members have registered three or four patents and six to seven trademarks, largely on new crop varieties.[180]
- The Institute of Agricultural Genetics of the Ministry of Agriculture and Rural Development states that technology transfer is an important goal of new research projects, particularly technology transfer to farmers, but it has not registered intellectual property over any inventions.
- The University of Technology of Hanoi: In the last five years, 20 of the leading technical and agricultural universities in Vietnam have signed 13,000 contracts worth VND 1,188 billion (approximately US$74 million). From 2000 to 2004, 22 Technology and Equipment Fairs, called Techmarts, were held in Vietnam, through which universities and research institutes sold more than 2,000 technology contracts worth up to VND 4,000 billion (approximately US$250 million).[181]

4. TRENDS AND CONCLUSIONS

The 18 countries examined above provide a representative cross-sampling of emerging and developing economies. They represent an enormously broad cultural, social, and economic landscape. Still, trends are discernable in the three areas reviewed: the availability of IP protections, the ownership of intellectual property over publicly funded research, and the institutional exercise of IP rights.

4.1 *Trends in IP protection*

Trends in the availability of IP rights follow several fundamental determinants. The first is the domestic science and technology capacity in the public and private sector and the level of economic development, both of which serve to drive the formation of IP policies and the use of the IP system by residents. A second and somewhat correlated determinant is the history of IP laws within the country; this factor is more difficult to measure than the first. Some countries have had systems in place for over a century, particularly in Europe (Russia and Poland) and those that were major European, and particularly British, colonies (India and South Africa). This leaves a legacy of IP practices, even if IP rights have not been extensively used or enforced. Third, national agreements, in particular TRIPS and UPOV, have driven IP legislation in virtually every country reviewed.

Roughly three tiers emerge when gauging the robustness of domestic IP systems (Table 1). The first tier consists of a handful of countries that have functioning IP policies and institutions, along with substantial numbers of domestic patent applications. These countries include the most-advanced innovators among emerging and developing economies, such as Brazil, China, India, and Russia.

These countries all generate something in the range of 3,000 to 30,000 science and engineering articles per year. Their national patent offices grant 1,000 to 30,000 patents per year. Crucially, residents account for at least 50% of patent recipients, signifying a significant level of domestic innovation that is generated by national IP systems.

Table 1: Determinants and Indicators of the Status of National IP Systems

	Country	Per capita GDP by PPP, 2005[182]	Number of science & engineering articles, 2003[183]	Number of globally top-ranked universities[184]	Date of first patent law	Date joined TRIPS	Date(s) patent law amended for TRIPS compliance	Date of PVP law	Date joined UPOV	Patents to residents/ patents to foreigners (yr)	Ratio of resident to foreign
	United States	**41,399**	**211,233**	**168**	**1789**	**1995**	**-**	**1930**	**1981**	**84,271/80,020 (2004)**	**1.05**
TIER 1	Russia	11,041	15,782	2	1812	-	2003	1992	1998	19,447/3,943 (2005)	4.93
	China	7,198	29,186	8	1984	2001	1992, 2001	1997	1999	18,241/31,119 (2004)	0.59
	South Africa	12,161	2,364	4	▸1925	1995	2002	1976	1977	5549[a]/5501[a] (1995)	1.01
	Poland	12,994	6,770	3	▸1925	1995	2000	1995	1989	778/1,016 (2004)	0.77
	India	3,320	12,774	3	1856	1995	1999, 2002	2001	-	851/1,466 (2004)	0.58
	Brazil	8,560	8,684	4	1809	1995	1996–1997	1997	1999	666/1,366 (2002)	0.49
TIER 2	Argentina	14,108	3,086	1	▸1875	1995	1996–2001	1973	1994	145/1,442 (2000)	0.10
	Mexico	10,186	3,747	1	▸1850	1995	1997,1999	1997	1997	162/6,677 (2004)	0.02
	Chile	11,936	1,500	1	▸1850	1995	2005	1997	1996	32/569 (2000)	0.06
	Indonesia	4,459	178	0	1989	1995	1997	2001	-	16/615 (1996)	0.03
	Malaysia	11,201	520	2	1983	1995	2000	2004	-	31/1,542 (2003)	0.02
	Jordan	5,095	263	0	1999	1999	1999, 2001	2000	2004	4/56 (2004)	0.07
	Vietnam	3,025	216	0	1995	2006	2005	2004	2006	17/756 (2005)	0.02
	Philippines	4,923	179	0	1947	1995	1998	2002	-	16/1,437 (2004)	0.01
TIER 3	Ethiopia	823	99	0	1995	-	-	2006	-	0/1 (2000)	0.00
	Kenya	1,445	258	0	1914	1995	2001	1972	1999	0/33 (2001)	0.00
	Tanzania	723	86	0	1931	1995	-	2002	-	0/23 (1989)	0.00
	Uganda	1,501	90	0	▸1950	1995	-	1994	-	0/34 (2001)	0.00

[a] Patent applications filed.

The second tier contains the bulk of middle-income countries that have recently developed or improved their IP policies but that still grant most of their patents to foreigners. These include countries like Argentina, Indonesia, Malaysia, and Mexico. These countries have some research capacity, evidenced by the generation of 300 to 3,000 science and engineering articles per year. Their national patent offices are functioning, granting several hundred to several thousand patents per year. Crucially, however, domestic inventors are receiving less than 10% as many patents as foreigner applicants. Thus, the patent system is primarily being used to protect imported technologies. Still, companies and governments are typically seeking ways to better exploit the IP system's R&D efforts.

The third tier consists of the lowest-income countries, in which there is neither a strong IP system in place nor a great number of domestic patents applicants. These include countries like Ethiopia, Kenya, Tanzania, and Uganda. In this survey, all of the representatives of the third group are in Sub-Saharan Africa. These countries have little research or technological capacity, generating less than 300, and on average less than 100, science and engineering articles per year. Their national patent offices are not very active, granting less than 50 patents per year. Most significantly, no patents are granted to domestic inventors, only to foreigners.

4.2 *Trends in IP ownership policies*

On the question of ownership over inventions developed from government-funded research, policies appear to be converging on the practice of giving the rights and responsibilities of ownership to research institutions, with some flexibility for exceptions depending on the national context. This convergence typically stems from strengthening IP protections and/or increasing government spending on R&D, but it also grows out of an awareness of global policy trends and a desire on the part of governments to enhance the impact that their spending on R&D will have on economic development.

The mechanisms through which policies on ownership of intellectual property arise are more diverse (Table 2). These include:

- ownership clauses in patent law
- ownership clauses in labor law
- national R&D system laws
- ministerial rulings

In several countries (Jordan, Malaysia, South Africa) new policies are currently under review or exist in draft form. In a number of other countries, no explicit policy addresses IP ownership by universities or research institutes under public funding. In these cases, ownership questions are typically covered by the general ownership clauses of patent law, without specific reference to universities or research institutes, publicly funded R&D, or technology transfer.

4.3 *Trends in institutional IP management*

The more than 80 specific institutions named in this survey have all to some degree developed an IP policy and management infrastructure. They cover many of the leading research universities and institutes in the countries surveyed. Many more IP management programs, in hundreds of other emerging and developing countries, could not be mentioned here. Still, the range of strength and sophistication in this representative sample is vast. Some operations efficiently review hundreds of technology disclosures and file dozens of patent applications a year; in others, IP policy is in draft form and no action has been taken to implement an IP management system.

If anything, strong, sophisticated institutional IP management is most strongly correlated with the underlying determinants of scientific and technological capacity, including, most importantly, the amount spent annually on R&D at universities and in the public sector. Institutional IP management is more weakly correlated with the adoption of national-level policies explicitly encouraging IP ownership by public sector research institutions. In a number of cases, the practice of IP management has preceded policy changes governing IP ownership.

4.4 *Conclusions*

While the call for policy reforms modeled on the U.S. Bayh-Dole Act has been made around the world, the particular policy reforms and

Table 2: Specific Policies on Ownership of Intellectual Property Arising from Research Funded by the Government

	Country	Year	Policy specific to ownership of intellectual property
	United States	**1980**	**Patent law: ownership of inventions made under federal government funding (Bayh-Dole Act)**
TIER 1	Russia	2003	Patent law: ownership of inventions made under government contract
	China	1985 2002	State Council on Technology Transfer regulations Ministry of Education and Ministry of Science & Technology joint ruling: university ownership and transfer of intellectual property
	Poland	-	-
	South Africa	In process	Legislation on national research system: ownership of inventions made under government funding
	Brazil	1996	Patent law: ownership of inventions by employer, with terms of revenue sharing for public-sector employers
	India	2000	Ministry of Science & Technology ruling: ownership under ministry funding
TIER 2	Argentina	1990 1995	Law on national research system: universities and institutes establish TTOs Patent law: ownership of inventions by employer
	Mexico	1998 2002	Labor law: ownership of inventions by employers Law on national research system: ownership of inventions to be determined by policy of the institution
	Chile	1991	Patent law: section on university ownership and transfer of inventions
	Indonesia	2002	Law on national research system: universities and institutes to establish TTOs
	Malaysia	In process	Ministry review of incentive system for scientists, including ownership of intellectual property
	Jordan	In process	High-level commission review of all relevant legislation and regulations for technology transfer
	Vietnam	-	-
	Philippines	-	-
TIER 3	Ethiopia	-	-
	Kenya	-	-
	Tanzania	-	-
	Uganda	-	-

proposals exhibited in developing and emerging economies have varied. In some, the Bayh-Dole model is clearly discernible, but in many others the approaches to reform are more specifically adapted to local legal, political, and economic situations. Some national policies, such as those of China or those emerging in South Africa, clearly attempt to institute stronger IP protections in the economy and to emulate Bayh-Dole in the public sector. But many others merely make perfunctory efforts at conforming to TRIPS and only borrow the basic idea of encouraging institutional ownership of IP. Some national policies set institutional ownership and management of IP as the default option among several possible modes of technology commercialization. Others provide it as one alternative among multiple options, without a clearly defined preference. This survey noted one general trend: that strong IP protections and the institutional capacity to manage them grow in tandem, driven primarily by the amount of R&D being conducted and, secondarily, by the ability of the local economy to absorb new technologies into existing industry or an entrepreneurial sector. These insights may offer lessons for policymakers and practitioners seeking to use IP as part of an integrated strategy to drive economic development through the public financing and commercialization of innovation. ■

AUTHOR'S NOTE: By their nature, the policies and institutions reviewed in this chapter are constantly evolving and changing. The author invites any corrections, updates, and additional information, including policy studies or institutional case studies. New information will be used to update future reviews on this topic and may be added to the online version of the IP *Handbook* at www.IPHandbook.org.

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172 Salazar S. 2005. Capacity Building for Intellectual Property Management in Four BIO-EARN Network Countries. In *Institutional Management of Intellectual Property in Biotechnology Research and Development in East Africa: Country Case Studies* (eds. J Bananuka, C Mugoya and J Komen). BIO-EARN. October 2005: 4–15.

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182 International Monetary Fund. *World Economic Outlook Database*. September 2006.

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Technology Transfer Snapshots from Middle-Income Countries: Creating Socio-Economic Benefits through Innovation

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ABSTRACT

This chapter examines the outcomes of technology transfer policies adopted in the past 20 years by five middle-income countries: Brazil, India, Ireland, Israel, and Jordan. The outcomes in those countries suggest that nations whose governments enable the assimilation of new technologies grow faster, create more jobs, and reduce poverty levels. The outcomes suggest also that a mixture of government and market strengths are needed to efficiently use technology transfer. Without this balance, technology transfer will have limited effects.

1. INTRODUCTION

The founders of the United States understood the importance of innovation and took pains to promote and protect it in the U.S. Constitution:

The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and provide for the common defense and general welfare of the United States; but all duties, imposts and excises shall be uniform throughout the United States; … to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries. (U.S. Const. article I, § 8, cl. 8)

The same principles embodied in this Constitution are used around the world today to encourage research and development. For example, inventors and developers can apply for patent rights that give them exclusive use of their own innovations for a limited period of time. Patent rights are essentially "negative" rights: that is, they allow one party to exclude others from gaining benefit from an inventor's work, but, of course, they cannot ensure that the invention will be profitable. In return for the patent right, the inventor discloses information in the patent that would enable a person who is "skilled in the art" (that is, knowledgeable in the field of the invention) to understand and replicate the invention for him- or herself. Patents thus seek to serve both the inventor's and the community's interests.

We can see this dual effect in the case of a well-known American. George Washington was a mill owner and operator eager to improve his mill's productivity. He was interested in new agricultural technologies, particularly in the Evans Mill System, patented by the prolific inventor Oliver Evans (U.S. Patent No. 3), and now recognized as the first mass production process. As president, Washington reviewed and signed all of the patents issued in 1790; and as the owner of the Mount Vernon Gristmill, Washington was one of the first to license the new technology. This automated mill produced high-quality flour using two men instead of six; the mill operated continuously and turned out greater quantities of flour than the traditional process in a fraction of the time. In addition to Washington, within two

Finston SK. 2007. Technology Transfer Snapshots from Middle-Income Countries: Creating Socio-Economic Benefits through Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

years, over a hundred other U.S. mills were using the new Evans technology. Evans' invention changed U.S. mills forever and boosted U.S. agricultural exports to Europe. It benefited not just Evans but the entire country, including George Washington.[1]

Another example, predating Bayh-Dole, involving the contrasting paths of penicillin and streptomycin underscores the importance of incentives to ensure commercialization of science. Penicillin was first discovered in 1928, and is often cited as a laudable case where the innovator, Dr. Louis Pasteur, did not seek a patent or licensing for the drug. As a result, however, there was no commercial development of penicillin, for more than a decade, until World War II necessitated scale-up and mass manufacture of the drug.[2] In contrast, streptomycin, developed by Dr. Salman Waksman at Rutgers University in the 1930s, was on a faster track, enabled by an early exclusive licensing agreement with Merck.[3]

Then as now, a climate that encourages the adoption of new technologies will also encourage increased rates of job creation, lower poverty levels, and create greater opportunities for economic growth. We live in an unprecedented era, however, when the investment assets of companies are increasingly intangible, and particularly suited to forms of IP protection.[4] Microsoft® founder Bill Gates concludes that the nature of the global economy increases the need for incentives to innovation given "*the economic competition between nations going forward, particularly with regard to the rapid innovation and development in emerging countries … We need incentive systems that drive that innovation in an appropriate manner, because we can no longer compete exclusively on the basis of cost of labor.*"[5] This chapter looks at how technology transfer policies have affected countries from three different regions (the Middle East, Asia, and Europe) in the past 20 years.

2. WHAT IS TECHNOLOGY TRANSFER?

T*echnology transfer* is the process of developing practical applications from the results of scientific research. Defined more broadly, technology transfer is anything that increases the capacity of people to benefit economically and/or socially from innovation.

Technology transfer is a complicated process, and the journey from exploratory research to successful product can be a long one. R&D falls into three categories or phases:

- The primary objective of *basic research* is the advancement of knowledge for its own sake. This type of research is exploratory or investigative and is often driven by the researcher's curiosity, interest, and hunches.
- The primary objective of *applied research* is to answer specific questions that have practical ramifications. These questions may or may not arise out of basic research. Applied research can be exploratory, but is usually more focused.
- In *commercial development*, ideas arising from basic and/or applied research are used to create a product intended for commercial sale.

An example of an R&D process that includes all three phases is the discovery and development of pharmacogenetic drugs: decoding the human genome (basic research) led to the identification and isolation of particular enzymes (applied research), which in turn led to the development and testing of drugs (commercial development). This example suggests that governments have a significant role to play in identifying which areas of innovative research can and should be promoted (the initial research on the human genome was a public effort). Governments also have a role in moving inventions from the theoretical level to the applied level (government-funded research drives a good deal of this movement) and in providing incentives to encourage the development of new products and processes arising out of applied research (for example, forms of intellectual property). But as research moves further from basic research toward product development, the government's role in directing this process diminishes. For the most part, the market distributes investment resources much more efficiently than the government.

3. WHAT FACTORS PROMOTE TECHNOLOGY TRANSFER?

The core elements of a robust technology transfer system are:

1. *a durable government commitment to science education, research, and related infrastructure.* Governments create an enabling environment for science and technology by investing in education and training (both at home and abroad, at secondary and university levels), funding basic and early applied research, and improving technology-related physical infrastructure.
2. *broad rule-of-law protections, including strong IP protections.* Rule-of-law protections give individuals the ability to enter into enforceable agreements or contracts with others; they promise predictable and timely judicial remedies in case these agreements or contracts are breached.
3. *reliance on market forces as the engine for technology transfer.* Market-oriented policies encourage risk taking and increased private sector investment.

These three pillars of technology transfer are like the three legs of a stool: all are necessary, and none of them is sufficient by itself. However, it can be difficult to provide all three simultaneously. In the mid-20th century, the U.S. government thought it strongly supported science, rule-of-law protections, and market incentives, but it did not grant private rights to publicly funded inventions. The effect of this was to greatly weaken market incentives for investing in new technologies. Such rights only became part of the U.S. technology transfer regime with the passage of the Bayh-Dole Act of 1980.[6] Once government-funded scientists were allowed to engage with those who had the skills needed to bring products to market, an explosion of innovation ensued, bringing remarkable new products in health, agriculture, and other fields.

4. TECHNOLOGY TRANSFER PROFILES

The power of technology transfer is available to people everywhere, and it is a power that can facilitate not just a nation's research abilities but its overall economy. Drawing on his experience in Bangladesh, David Sack, observed that:

> *[W]ell-qualified local scientists generally prefer to remain in their home country if they can find meaningful employment in institutions where they can be productive. Well-functioning institutions contribute to "brain-gain," thus increasing the scientific and economic resources of a country as a whole*.[7]

No matter what stage of development a country is in, its government can train scientists and encourage them to remain at home by promoting a sensible, well-functioning technology transfer system. The remainder of this chapter provides brief profiles of five middle-income countries whose governments, over the past two decades, have supported science and education, created effective IP protections within a broader framework of strong rule-of-law protections, and used the market to efficiently distribute investments in commercialization. These countries have developed successful innovation-intensive sectors like biotechnology and information technology that have, in turn, produced widespread social and economic benefits. The experiences of these countries can provide all of us with valuable lessons and insight into how to harness effectively—and fairly—the power of technology transfer.

4.1 *Brazil*

The strength and durability of the Brazilian government's commitment to science education and infrastructure are impressive. The State of São Paulo Research Foundation (*Fundação de Amparo à Pesquisa do Estado de São Paulo*, also known as FAPESP) has supported basic scientific research and graduate education at several universities in São Paulo for the last half-century. The federal Ministry of Health has funded two major public research institutes: the Instituto Butantan and the Oswaldo Cruz Foundation. In recent years, the Instituto Bhutantan has been recognized for its role in the development of a hepatitis B vaccine.[8] The Oswaldo Cruz Foundation has a long and distinguished history, including historic health and sanitation campaigns against bubonic plague, yellow fever, and small pox,[9] and the

foundation most recently announced advances in development of an algae-based microbiocide for use against HIV/AIDS.[10]

However, Brazil lacks market-based incentives to drive private capital into commercial development. As Michael Ryan observes, "*The Brazilian public sector has made substantial investment into university and public laboratory research, thereby establishing the potential for biomedical technology innovations, but the lack of private sector R&D capabilities and lack of public-private linkages has traditionally prevented technology from being commercialized into the marketplace.*"[11] Partly due to these weaknesses in its technology innovation system, the country's economic growth in the 1970s and 1980s faltered.[12] Currently, two-thirds of R&D spending in Brazil is funded directly by the government (for comparison, only one-third of R&D spending in the United States is funded directly by the government), and only 18% of scientists and technicians work in the private sector.[13] The dynamism and flexibility of market forces were stymied by the government's decisive intervention in the innovation process, and the resulting inefficiencies contributed to slow economic growth.

Currently, a number of reforms are underway in Brazil to encourage private sector investment in R&D activities. As a result, there are more international patent applications being filed by Brazilian companies through the World Intellectual Property Organization (WIPO) Patent Cooperation Treaty,[14] and new products are beginning to enter the market.[15] This trend should strengthen the economy and provide Brazil's people with more and better products in every economic sector.

According to Ryan, Brazil was not alone in giving a dominant role to government in the pursuit of scientific and technological development. He cites a number of large developing countries that had also followed a policy of state-led economic development. Many of these have since revamped policies to promote greater private sector investment in the commercialization of new technologies. These include China, Mexico, Egypt, India, and Turkey. The lesson here is not that government should not provide funding to develop new technologies but that such funding should be focused on basic research (which functions as a kind of "seeding" for innovations). Applied research and research focused on commercializing an innovation should rely more on investments from the private sector to ensure maximum efficiency and economic growth.

4.2 *Israel*

Israel is another state with a commitment to long-term investment in science and infrastructure. Recent investment data show that at least 50% of science funding in Israel comes from the State of Israel and international public sector sources.[16] Each of Israel's ministries includes a chief scientist,[17] and Israel's primary and secondary schools have a strong basic science curriculum.[18]

Israel is a world leader in areas related to information and communications technology. These technological areas do not require capital investments to the same high degree as biotechnology and are characterized by short lead-times and low regulatory barriers to market entry. In fields such as biotechnology, however, Israel is not as innovative. As Avi Molcho observes, "*Israel is among the world leaders in many fields of technology. It is a hub for innovative technologies in communications, semiconductors, information technology, and medical devices—innovation that has been translated into commercial success. While the same, if not greater, degree of innovation is found in Israeli life sciences research, this has yet to be transformed into a more mature biotechnology start-up industry.*"[19] In fact, Israel's patent prowess appears formidable: "*Israel ranks first worldwide in the proportion of life-science patents to the total number of patents written by Israeli inventors. The country ranks fourth in total number of biopharma patents granted, in terms of patents per capita, and 12th in the absolute number of biopharma patents.*"[20] Alla Katsnelson suggests that this is because patents are underutilized: "*Israeli life-sciences patents comprise almost a third of the country's total patents. What seems to be lacking is the ability to turn all this life-sciences-focused intellectual property into biotech products.*"[21]

The Milken report cites the lack of sufficient market incentives for commercialization of science,[22] while others point to relatively weak levels

of patent protection and data exclusivity.[23] Some identify the market dominance of the generic pharmaceutical manufacturer Teva,[24] as one reason why Israel has not strengthened market and/or IP incentives for international biotechnology companies to enter or remain in the market.

Interestingly, Israel has maintained weaker levels of IP protection at the same time many of its neighbors, including Bahrain, Jordan, Morocco, Saudi Arabia and the United Arab Emirates (UAE), have strengthened their IP systems through WTO accession, bilateral free trade agreements and/or unilateral reforms.[25]

Whatever the reason or combination of reasons, Israel continues to suffer from a dearth of private clinical biotechnology research. David Haselkorn succinctly notes, "*Not one single [multinational pharma] company has developed an R&D center here.*"[26] The Milken Institute goes farther, stating that the Israeli biotechnology sector is in decline, "*as measured by the amount of venture capital funding.*"[27]

4.3 *Jordan*

Until the early 1990s, the Hashemite Kingdom of Jordan was best characterized as an aid- and remittance-based economy, with an estimated per capita gross domestic product (GDP) of about US$800. Over the past 15 years, however, the Jordanian government has increased its commitment to science education and infrastructure, improved its IP laws and the enforcement of those laws, and adopted a model of economic planning that relies on the private sector for job and wealth creation. The impact of these changes has been profound: the country has become more integrated into the world economy and enjoyed a more than five-fold increase in per capita GDP since the mid-1980s, reaching US$4,700 in 2006.[28]

The growth of Jordan's export-led pharmaceutical industry is particularly remarkable. In 2001, production in the pharmaceutical sector totaled US$180 million; in 2002, it was US$210 million; and in 2003, it reached US$275 million.[29] This was achieved both through higher levels of domestic IP protections and through trade benefits provided by the World Trade Organization (WTO) and the United States–Jordan Free Trade Agreement.[30] Jordanian pharmaceutical companies are beginning to invest more in research and product development. For example, local Jordanian companies Triumpharma and Advanced Pharmaceuticals are both investing in research to produce and patent drug delivery mechanisms. In addition, two new clinical research organizations have been established in the last three years.[31] Today, Jordan exports its pharmaceutical products to over 60 markets worldwide.

In addition, Jordan has adopted market-friendly policies that are attractive to international pharmaceutical companies. Major international pharmaceutical companies, such as Organon, Novartis, and Aventis, have worked with new Jordanian clinical research organizations and Jordanian hospitals to conduct clinical trials. Since 2000, Jordanian companies have established licensing relationships with pharmaceutical companies from Italy, Japan, Korea, Italy, Switzerland, the United Kingdom, and the United States. These foreign companies often rely on their Jordanian partners to provide marketing and distribution expertise in the Middle East. In return, Jordanian companies benefit from foreign investment by gaining a broader product base for sale, both at home and into export markets, and for the in flow of know-how and technology.[32]

The government of Jordan continues to invest in science and technology. Areas of investment include: natural products development; early diagnostics using monoclonal antibodies; applied microbiology in food; production of biogas, biofertilizers, pesticides, and yeast; and the development of new biotech equipment. Moreover, Jordan has recently established the King Hussein Cancer Center and Biotechnology Institute with support from the U.S. National Institutes of Health through the Cancer Biomedical Informatics Grid program.

4.4 *India*

When it comes to adopting technology-friendly policies, few countries have faced as many challenges as India. R. A. Mashelkar, recently retired as the Director General (1995-2006) of the Council of Science and Industrial Research (CSIR), an early and persistent advocate for India's adoption

of technology transfer policies, calls India's history with such policies "*a series of missed busses,*" in terms of lost opportunities for leveraging India's intellectual assets in the global knowledge economy.[33]

Many have cited India's confidence in biotechnology as rooted in its earlier success in the information technology (IT) sector. It is less well known, though, that patent protection also fueled India's original IT success, in the form of Dr. Sam Pitroda's software patents.[34] In 1980, prominent nonresident Indian and software guru Pitroda sold his first U.S. company and brought the profits to India to support his dream of installing telephones throughout rural India.[35] Telecommunications has been widely recognized in India as foundational to the entire industry sector known as "Information and Communications Technology (ICT)," as well as the related sub-sectors known as "Business Process Outsourcing (BPO)" (which include back-office operations for multinational corporations, and call centers, among others) , and BioInformatics (the analytic processing of data generated as part of clinical research in the life sciences and provided India's initiation into biotechnology).[36] Pitroda's software patents helped him to made his first fortune and provided the resources he needed to bring telephony to rural India, laying the foundation for India's IT revolution.

Now the government of India is preparing to introduce comprehensive technology transfer legislation in 2007. Under the bill, academic inventors and their institutions would share royalties, and academic entrepreneurs will be encouraged to file patents to gain both increased research funding for their institutions and individual benefits for themselves, in the form of royalties.[37] The law would also include key mechanisms to benchmark patentable research undertaken by Indian academic and research institutions with support from the government of India.[38] In the past year, product patent protection has been adopted and implemented in several fields, including pharmaceuticals. Patent processing reform has improved efficiency and reduced patent review times, and, increasingly, domestic companies are recommending that India adopt protection for commercially valuable clinical research dossiers (a protection known as *data exclusivity*).[39]

India is engaged in a cooperative internal dialogue about how to implement these IP reforms. The Indian government continues to promote India as a global biotechnology R&D hub, and the country has become a primary global location for preclinical and clinical R&D. Most recently, the 2006 Ernst and Young European Attractiveness Survey placed India among the top five countries as a pharmaceutical and biopharmaceutical R&D destination. Commercial biotechnology, which crossed the billion-dollar mark in 2005, has now reached nearly US$1.5 billion, with 36% annual growth.

4.5 *Ireland*

Over the past 20 years, Ireland has gone from "net brain-drain" to "net brain-gain" by systematically adopting pro-technology transfer policies and becoming a major importer of foreign direct investment in the area of life science. Ireland offers strong patents and data exclusivity for terms of up to 11 years. There is substantial government support for science education and technology-related infrastructure, and the government's corporate regulatory policies ensure greater market orientation in terms of increased moderation in labor policies,[40] reduced corporate taxation,[41] and other reforms:

Foreign direct investment in Ireland has been attracted by low rates of corporate tax. Today, Ireland has one of the world's lowest rates of corporation tax, with the maximum rate for trading profits being 12 percent. Other factors that help attract biopharmaceutical companies to Ireland include the ready availability of the required specialist skills. Output from the third-level institutions is being continually refined to meet the sector's needs. Further, the considerable growth in the Irish economy over the past ten years has seen very significant repatriation of skilled people. In addition, Ireland is seen as a desirable expatriate location with a minimum of bureaucratic obstacles and an excellent educational system that facilitates family relocation. The free movement of labor within the enlarged European Union has facilitated the swift acquisition of a further pool of skilled people.[42]

As a result, Ireland has become more attractive to foreign investors for biotechnology and other high technology sectors[43] and is also winning the global competition to attract and retain well-educated, creative workers.[44] More than 170 companies employ 35,000 people in Ireland's chemical, pharmaceutical, biopharmaceutical, medical device, and diagnostics industries.[45] Together, these sectors generated more than US$52 billion in exports in 2005. Ireland's per capita income has grown from about US$5,000 in 1986[46] to US$43,600 in 2006,[47] a level of per capita income that is comparable to that of the United States and the United Arab Emirates.

5. CONCLUSION

Technology transfer can improve lives by introducing innovations that directly contribute to improved public health, nutrition, and communications. Less obviously, but more importantly, the policies that promote technology transfer—such as an emphasis on personal rights and education—also promote economic development. Ideally, any positive changes in political and economic climate will create a self-perpetuating cycle: an improved economic environment and a general increase in education levels will lead to improved public health, which will in turn strengthen the economy.

The above overview strongly suggests that such technology transfer works best when there is strong, consistent government support of basic research—including science education and technology-related infrastructure—and robust IP protection. Government policies should also strive to encourage market guidance and private sector investment in applied research and commercialization efforts. In this way, the strengths of the government and of the market can be synergistically applied to improve the lives of all of us. ■

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1 For more background on Oliver Evans, the mechanized flour mill and other inventions, see www.greenbankmill.org/oliverevans.html. For more about Washington's gristmill, see www.mountvernon.org/visit/plan/index.cfm/pid/806/.

2 Public Broadcasting Service. A Science Odyssey: People and Discoveries. www.pbs.org/wgbh/aso/databank/entries/bmflem.html.

3 "*An agreement was drawn up with Merck whereby the company provided chemical assistance, experimental animals for pharmacological evaluation of antibiotics, and large-scale equipment for producing any promising discoveries. In return, Waksman assigned Merck any patents resulting from research in his laboratory. Should any of the patents prove commercially successful, Merck was to pay the Rutgers Foundation a small royalty.*" acswebcontent.acs.org/landmarks/antibiotics/trials.html. Streptomycin is broadly recognized as one of the important early antibiotics. In addition to being the first effective chemotherapeutic treatment for tuberculosis, it also showed effectiveness against typhoid fever, cholera, bubonic plague, tularemia, urinary tract infections, and others. As Dr. Waksman recognized the importance of the new drug, he became uncomfortable with the agreement giving Merck exclusive rights, and Merck agreed to a renegotiated non-exclusive license and was granted a rebate on royalties to compensate the company for the cost of development of streptomycin. "*Merck was praised for its generosity and Rutgers made licensing agreements with other drug companies*."

4 See Brief of *Amicus Curiae* BayhDole25, Inc., supporting respondent in *Microsoft vs. AT&T*, pp. 14–16.

5 26 January 2004 Keynote address by Bill Gates, Chairman and Chief Software Architect, Microsoft Corporation, at the Enterprising Britain Conference, London, UK. www.hm-treasury.gov.uk/documents/enterprise_and_productivity/enter_conf/ent_entconf_gates.cfm.

6 For and extensive discussion of the debate over the issue of allowing exclusive rights to private actors to commercialize publicly funded research outcome, see *BayhDole at 25: A Survey of the Origins, Effects, and Prospects of the Bayh Dole Act*. www.bayhdole25.org/resources. The author of this chapter is a founding board member of BayhDole25, a not-for-profit organization that promotes technology transfer in developing and developed countries through education and outreach activities. For more background and information on this organization, see www.bayhdole25.org.

7 Sack DA. 2005. Letters: International Gaps in Science Publications. *Science* 309 (5739): 1325–1326.

8 Ferrer M et al. The Scientific Muscle of Brazil's Health Biotechnology. *Nature: Biotechnology 22(Suppl.)*:DC9, DC10. www.nature.com/naturebiotechnology; see also www.swissbiotechassociation.ch/files/countryprofile/Ferrer%20u.a.%20Scientific%20Muscle%20of%20Brazils%20.

9 See *supra* note 9. Historic background on the first hundred years of Oswaldo Cruz Foundation (originally

founded as the Federal Serum Therapy Institute). World Health Organization (WHO) at www.who.int/tdr/publications/tdrnews/news65/oswaldo-cruz.htm.

10 Algae Gel to Combat HIV Infection. BBC News, 29 January 2007. news.bbc.co.uk/go/pr/fr/-/2/hi/health/6266527.stm.

11 Ryan M. 2006. *Brazil's Quiet Biomedical Innovation Revolution: Drugs, Patents, and the "10/90 Health Research Gap."* Creative and Innovative Economy Center, George Washington University Law School: Washington, DC.

12 See *supra* note 5, p. 3

13 See *supra* note 5, p. 5 (citing a 2005 FAPESP report).

14 Brazil leads Latin America in terms of resident patent applications filed in the Patent Cooperation Treaty. Though it still lags behind China and India, Brazil is in the top 20 patent offices for global PCT filings. WIPO Patent Report: *Statistics on Worldwide Patent Activities, 2006*, p. 7. www.wipo.int/ipstats/en/statistics/patents/. In 2004, Brazilians filed 280 PCT International Applications. Ibid. p. 37.

15 See *supra* note 5, pp. 5–10.

16 www.ilsi.org.il/industry_financing_history.asp.

17 www.science.co.il/ChiefSci.asp.

18 www.science.co.il/SciencePolicy.asp.

19 Molcho A. 2005. Meeting the Challenges of Israeli Biotechnology. *Israel Venture Capital Journal*. 8 March 2005. www.altassets.com/casefor/countries/2005/nz7289.php.

20 DeVol R, et al. 2006. *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization*, The Milken Institute, September 2006, p. 188. www.milkeninstitute.org/pdf/mind2mrkt_2006.pdf.

21 Katsnelson A. 2005. When will Israeli Biotech Grow Up? *Bioentrepreneur*. www.nature.com/bioent/bioenews/092005/full/bioent882.html.

22 Ibid at p. 186–88.

23 See USTR 2006 *"Special 301" Priority Watch List*. www.ustr.gov/Document_Library/Reports_Publications/2006/2006_Special_301_Review/Section_Index.html?ht. (Retaining Israel on the IP blacklist for implementing weak protection for commercially valuable clinical dossiers and curtailing patent term restoration for time lost due to bureaucratic delay in patent review, USTR "*continues to urge Israel to strengthen its data protection regime in order to promote increased bilateral trade and investment in the field of pharmaceuticals and other knowledge-based sectors.*")

24 The dominant market position of Teva is illustrated by its outsized presence on the Tel Aviv Stock Exchange (TASE), on which the market value of the company is the largest of any company in Israel and stands at five times that of the next largest company, Bank HaPoalim. See Israeli Ministry of Finance. 2005. *Capital Market Annual Review*. www.mof.gov.il/beinle/capitalmarketsreport2005final.pdf. Teva remains among the largest generic pharmaceutical producers in the world, employing 25,000 people worldwide, with a total of $5.3 billion in global sales in 2005. See *supra* note 21, p. 185.

25 See www.ustr.gov/Trade_Agreements/Section_Index.html for bilateral free trade agreements in the Middle East/North Africa region and related IP provisions. In addition, two governments, Jordan and Saudi Arabia, adopted enhanced protection for intellectual property protection as part of their WTO TRIPS accession, including strong patent protection, data exclusivity, and linkage between patent offices and regulatory bodies to prevent marketing of infringing products. For Jordan see http://www.wto.org/English/thewto_e/countries_e/jordan_e.htm; for Saudi Arabia see http://www.wto.org/English/thewto_e/acc_e/a1_arabie_saoudite_e.htm. The UAE unilaterally ratcheted up its levels of patent and data protection starting in the 2000–2002 period. See Haider L. United Arab Emirates: Agreement Set to Boost Research. *Managing IP*. www.managingip.com/Page=10&PUBID=34&ISS=20608&SID=588197&TYPE=20.

26 See *supra* note 12.

27 Citing the 19th annual Ernst & Young biotechnology report, which concludes that the medical devices sector received more investment in 2004 than did biotechnology. See *supra* note 21, p. 185.

28 For 1980s data see: Sullivan P. 1999. Globalization: Trade and Investment in Egypt, Jordan and Syria Since 1980. *Arab Studies Quarterly* (*ASQ*), 21: p. 35-72.

For 2006 data see CIA. The World Factbook: Jordan. www.cia.gov/cia/publications/factbook/geos/jo.html.

29 Ryan M. 2004. *Establishing Globally Competitive Pharmaceutical and Bio-Medical Technology Industries in Jordan: Assessment of Business Strategies and The Enabling Environment*. International Intellectual Property Institute, Georgetown University McDonough School of Business: Washington, DC.

30 The growth in bilateral U.S./Jordan trade flows provides a general example of the benefits of greater integration into the world economy through the WTO and the U.S./Jordan Free Trade Agreement. When the FTA was signed in 2000, the bilateral trade flow was not much more than a trickle: total bilateral trade between the United States and Jordan was roughly US$385 million, where U.S. exports to Jordan accounted for approximately 80% (US$310 million) of the total. *U.S. Trade Balance, by Partner, 2000*, United States International Trade Commission. swpat.ffii.org/gasnu/us/usjdfta.txt. In contrast, the bilateral trade flow exceeded US$1.7 billion for the first nine months of 2006, 2006 *Jordan Economic and Trade Bulletin*, cited in 16 *Washington Trade Daily*, 20. 26 January 2007. Jordanian exports to the United States have increased 91% since 2001. Ibid. A second general area of benefit is the increased level of foreign direct investment in Jordan since WTO accession, which grew from US$627 million in 2000 to US$2.4

billion in 2002. Haider L. 2007. United Arab Emirates: Agreement Set to Boost Research. *Managing IP*. www.managingip.com/Page=10&PUBID=34&ISS=20608&SID=588197&TYPE=20.

31 See *supra* note 15.

32 See *supra* note 15.

33 "Dr. Mashelkar has often been called a 'dangerous optimist'; so it was no surprise when he suggested that instead of being rueful of the 'missed bus' we should work on the opportunities offered by the waiting buses of the knowledge economy." *Information Pasteboard,* #IP 428/20–26 Nov 2000. www.nal.res.in/oldhome/pages/ipnov00.htm.

34 "*In fact, I spent my childhood without knowing how to use a telephone set. And I never used a telephone till I went to the U.S. to pursue my education in electrical engineering. The reason: I came from a poor background, and those were the days when telephones were locked in wooden boxes and considered an elite possession, so I never got a chance to use one. I left for [the] USA in 1964 with less than $400 in my pocket. I cherished a dream and returned to India in 1984 to realize it as a multi-millionaire with over 50 patents*." The Thursday Interview/ Sam Pitroda. 30 January, 2003, 09:01. sify.com/news/internet/fullstory.php?id=12568313.

35 Pitroda viewed telephones as just as critical to India's modernization efforts as clean water, and his Public Call Offices created a million jobs and began to change the status of the girl child. Ibid.

36 Bhattacharya M. 2003. Background paper submitted to the Committee on India: Vision 2020 . *Telecom Sector in India, Vision 2020*, p. 11. www.ictregulationtoolkit.org/en/Document.1613.html.

37 Remarks of Minister Kapil Sibal, 28 October 2006, at Hi-Tech Pune (also cited by Joshi R. 2006. Patent Rewards. *Business India* [December 31], page 30). Where IT Meets BT, Pune, Maharashtra India, www.hitechpunemaharashtra.com. See also "Patent Rewards," Business India, December 31, 2006, p. 50 ("A new law is being written to ensure that scientists in government-run laboratories will get a share in royalty when their innovation brings commercial dividends.)

38 Ibid. (Business India) (Quoting Montek Singh Ahluwalla, Deputy Chairman of India's Planning Commission: "We need to restructure our universities to make them incubation centers for research.")

39 Jyotha Datta PT. 2006. Domestic Producers of Herbal Products Seek Data-Exclusivity, *Hindu Business Line*, 12 September 2006. www.thehindubusinessline.com/2006/09/13/stories/2006091302850300.htm. See also Finston S. 2006. Data Exclusivity Brooks No Delay. *Hindu Business Line*, 18 July 2006. www.thehindubusinessline.com/2006/07/18/stories/2006071800221100.htm.

40 Glyn A. 2005. Labor Market Success and Labor Market Reform: Lessons from Ireland and New Zealand Fighting. *Unemployment*. February, 2005. www.ingentaconnect.com/content/oso/1050685/2005/00000001/00000001/art00006.

41 Ireland's low corporate tax rates include 12.5% on trading profits and an exemption for patent income, "*U.S. Multinationals Overseas Profits: Ireland's patent income tax-exemption may fund over 5% of Irish Government annual spending in 2006," FinFacts Ireland*, 21 November 2005. www.finfacts.com/irelandbusinessnews/publish/article_10003995.shtml.

42 McCarthy S. 2004. Ireland's Biotech Boom. *BIO-IT World*, citing Ireland's top ranking by the 2004 *Harvard Business Online* Global Creative-Class Index, as well as the Kearney AT. 2004. Offshore Location Attractiveness Index, which ranked Ireland fourth in the world for people and skills, and third for business environment. www.bio-itworld.com/issues/2006/april/si-ireland/.

43 See *supra* note 42.

44 See Florida R and I Tinagli. 2004. *Europe in the Creative Age*, February 2004, p.5 (noting that Ireland is outpacing all other European states in attracting creative, well-educated and productive workers in the 21st century.) www.creativeclass.org/acrobat/Europe_in_the_Creative_Age_2004.pdf.

45 See *supra* note 42. ("*Together these sectors generated more than $52 billion in exports in 2005. Nine of the world's top 10 pharmaceutical companies have major operations in Ireland.*")

46 Ireland's per capita GNP was US $4,970 in 1984 dollars, World Bank *World Development Report* 1986, p. 181.

47 CIA. 2007. The World Factbook: Field Listing; GDP per capita (PPP), 2007. www.cia.gov/cia/publications/factbook/fields/2004.html.

48 See *supra* note 47. For 2006 per capita GDP of the U.S. was U $43,500 and the U.A.E was US $49,700.

Benchmarking of Technology Transfer Offices and What It Means for Developing Countries

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ABSTRACT

At universities in both developed and developing countries, increasing emphasis has been placed on promoting technology transfer. Unfortunately, technology transfer is sometimes undertaken for the wrong reasons, especially in the mistaken belief that technology transfer will lead to substantial additional income for the institution. While it is important to protect intellectual property arising from research and to actively promote the transfer of research results, generating income should not be the primary objective in the transfer of technology. This is particularly important for health science, where there is a risk that research results, if not properly protected, will be inaccessible to private or public entities seeking to use the research for public benefit.

International technology transfer benchmark data can be used to understand the implications of promoting technology transfer and the likely outcomes of a technology transfer initiative. The benchmarks indicate that average income to an institution, after eight to ten years of activity, is likely to be a modest 1%–2% of annual research expenditure. The income is, moreover, highly uncertain and variable. Institutional and public sector managers must understand the nature of this income and the dynamics of the technology transfer process in order to manage this emerging discipline effectively, because unrealistic expectations can lead to dysfunctional policy decisions. The data and dynamic model presented in this paper are intended to promote better decisions.

1. INTRODUCTION

The successful technology transfer programs of universities in Canada and the United States have prompted other countries to emulate them, and major technology transfer and commercialization support programs have been launched in Australia, Japan, the United Kingdom, and many other countries. The high-profile successes of relatively few institutions have, however, generated unrealistic expectations. Additionally, it is not always clear that the success, measured in terms of income earned from commercialization, is proportional to the magnitude of the investment in research. Without a well-funded, high-quality research system, it is highly unlikely that a technology transfer program will contribute significantly to economic or social development. Moreover, it is doubtful whether other countries can easily emulate the performance of the United States, due to differing social and economic conditions.

The income-earning potential of technology transfer activities can, in fact, be a hindrance to effective programs. Technology transfer needs to be undertaken for good reasons, apart from the possibility of earning income. In health sciences and agriculture, in particular, appropriate IP (intellectual property) protection may be essential to effectively exploit research results and ensure that the benefits are widely available to society. Whether exploitation of research is for commercial or humanitarian uses, effective and appropriate transfer of knowledge is still required, in addition to the normal academic requirements to publish.

Heher AD. 2007. Benchmarking of Technology Transfer Offices and What It Means for Developing Countries. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

However, even with comparable investments in research, the performance of individual institutions is highly variable and unpredictable. This is true even for institutions that are comparable in size and maturity. A large portfolio of patents and licenses is required to give a reasonable probability of a net positive income. A large portfolio may be possible at a national level but is problematic in smaller countries, and even more so for smaller institutions. Because the benefits of the innovation system are captured largely at the national level, institutions need public sector support to reduce the institutional risk necessary to develop profitable investments.

Technology transfer is, of course, only one element of the overall research and innovation value-chain. All elements must function effectively for an institution to derive economic and social benefits from its research. In addition to a strong research system, a university must offer academics adequate incentives to encourage their participation, particularly with regard to the crucial initial step of invention disclosure. Universities must possess adequate institutional capacity to take an idea, evaluate it, appropriately protect intellectual property, and then seek a path to commercialization through licensing or a spinout.

It is widely recognized that monetary returns are not, and should not be, the primary motivation for engaging in technology transfer. Increasingly, it is a public research organization's social responsibility to ensure that research results are effectively transferred in a timely manner into the public domain for the good of society. The production of graduates and publication of research results remain the most important ways of affecting knowledge transfer; the more direct transfer of knowledge through technology transfer is, however, an essential adjunct. Far from undermining conventional approaches, effective technology transfer can support and enhance traditional knowledge transfer.

Technology transfer affects a society's economic well being directly and indirectly. In this chapter, both the conditions necessary for deriving economic benefit and the factors that influence the performance of a technology transfer office (TTO) are outlined. The data and models highlight the need for skilled technology transfer professionals. If a country is to profit from its investment in research, then training and capacity building at the institutional and national levels are key requirements.

2. RESEARCH AND INNOVATION VALUE- CHAIN BENCHMARK DATA

Universities and research institutions in North America have been benchmarking the research and innovation value-chain for a number of years.[1] This data covers each step in the value chain, including expenditure on research; numbers of invention disclosures, patents, licenses, and spinout companies; income from licensing; and expenditure on IP protection. A few other countries are following a similar approach, facilitating cross-country comparisons. (A selection of the data is shown in Table 1.)

To assist with comparisons across countries, benchmarks are generally converted to normalized values. The most commonly used approach is to normalize in terms of total research expenditure, converted to equivalent U.S. dollars. This approach is called the adjusted total research expenditure (ATRE). The most commonly used reporting basis is per US$1billion ATRE or US$100 million ATRE. Table 2 presents normalized values of the raw data in Table 1 based on US$100 million ATRE. For simplicity, only selected variables are shown. This normalized data can be considered typical data for a small- to mid-sized U.S. university or a large university in a developing country.

The normalized data shows a remarkably consistent pattern across different countries (summarized in Table 3). While there are variations from year to year and from country to country, they are relatively small and statistically insignificant compared to the variations between institutions in one country.

The data presented in Tables 1, 2, and 3 is for all research disciplines, as no desegregation to field of research was undertaken by any of the countries that conducted the survey. Although such results would be interesting, there is a lack of clear definition of the different fields, even

within one country, let alone across countries, making classification difficult. However, it is well recorded that medical and health-related research constitutes around 50% of all research expenditure. An analysis of individual results of commercialization efforts also shows that health-related products make up around 50% of technology transfer outputs, so the available evidence indicates it is likely that the data for all fields is broadly representative for health sciences. Given that a relatively small proportion of total research is devoted to agricultural research, it is not possible to make similar conclusions about technology transfer in the agricultural sciences. Indications are, however, that it is likely to follow a similar pattern; there is little evidence that one field of research has significantly different results from another in terms of average performance, as indicated in Table 3.

A widely used proxy for the overall performance of the technology transfer system is the total license income earned per year as a percentage of the total research expenditure. This measure is used in this chapter, and elsewhere, but it must be remembered that the measure is a proxy for a complex system and does not, by itself, tell the whole story. License income as a percentage of research expenditure is often referred to, for simplicity, as the "return" from an investment in technology transfer. The concept represents one form of return, with returns to the economy through direct and indirect benefits being equally, if not more, important. The benefits to society, particularly in health and agriculture, are often far more important than any financial return the institution may earn. The difficulty, however, is that the institution bears the costs of undertaking technology transfer, particularly, in terms of IP protection costs. The benefits, in contrast, may be enjoyed by the wider society, or even by another country.

Over the years that data has been collected, the trend in total license income is instructive (the graph is shown in Figure 1). In the United States, the value has increased from 1.5% in the first year of surveys by the Association of University Technology Managers (AUTM) in 1991 to around 3.5% in recent years, ignoring the anomalous peak during the dot-com boom in 2000. Excluding medical research institutes and considering only universities, the figure is slightly lower, at around 3%. The available figures for the United Kingdom, Australia, and Canada are also plotted in Figure 1. Again ignoring anomalous figures in 2000/2001, averages are in the vicinity of 1% to 1.5%. Interestingly, no evidence yet exists of other countries having the same rising trend that was observed in the United States in the early years. Whether a similar trend will occur in the years ahead, or whether there is a systematic difference between the United States and other countries, is still unclear.

The average data set is misleading, however, and the full data set, showing individual institutions, needs to be scrutinized. The AUTM data is excellent in this respect, as is the Australian survey. It is unfortunate that cultural norms in Europe tend to hide individual performance, as this impedes an understanding of the data.

The characteristic distribution of this data is illustrated in Figure 2, which shows the returns of all reporting U.S. universities in rank order. The data is more easily understood when plotted on a logarithmic scale, as shown in Figure 3. The dotted line in Figure 3 shows the approximate trend line for U.S. data. Figure 4 shows the same data for Canadian universities and Figure 5 shows the date for Australian universities, both with the U.S. trend line superimposed. The distribution of returns is remarkably consistent in these three reporting countries. The data for the United Kingdom shows a similar trend, but cannot be displayed in the same way because individual institutional performance is not reported.

Table 4 summarizes the returns for the United States, Canada, Australia, and the United Kingdom in three bands. The first is for all reporting universities, the second for the lower 95%, excluding the upper 5%, while the last row shows the performance of the lower 50%. Excluding the upper 5% removes eight universities in the United States, two in Canada, one in Australia, and five in the United Kingdom.

The affect of the skewness of the returns is evident: 95% of universities have returns of less than half the averages, while 50% earn only very small amounts from technology transfer. This

has important implications whether TTOs earn enough to cover operating costs or if they need to be subsidized. (This is discussed in more detail below.)

An important reason for undertaking benchmarking is the understanding and insight that the process fosters. This is what Lundvall[2] calls a learning-by-comparing approach, and it is especially important when using benchmarks in a different environment. Inherently, long-time delays make innovation-system benchmark data particularly difficult to collect and interpret. A good understanding of the origins and structure is necessary to avoid misuse of the data. The model that has been developed here assists with the interpretation of the raw benchmark data and the underlying processes it reflects.

Analysis of the data is complicated by the existence of a few exceptional cases. In Australia, for example, the omission of a single equity transaction in 2000 changed the income earned by over 50%; while in 2001 and 2002, one university accounted for 66% of all income earned. In Canada, omission of two universities had a similar impact, while in Europe omitting two universities reduced the income by 70%. The affect of a few large transactions makes measuring and interpreting the benchmark data more difficult, particularly for projections and comparisons.

Some observations, with respect to the country average data, are relevant:

- The invention disclosure rate of 40 to 50 disclosures per US$100 million ATRE (or US$2 million to US$2.5 million of research expenditure per invention disclosure) is remarkably consistent across countries and over time. The most recent U.K. data set is an exception and would seem to indicate a difference in policy approach, with the invention disclosure rate increasing by nearly 50% from 2001 to 2002. Not all disclosures are equal, however, and in some instances a higher disclosure rate would appear to indicate a lower "quality" of disclosure, as indicated by the fact that a smaller percentage of the disclosures are converted to license or spinout opportunities, as shown in Table 2.
- The rate at which disclosures are converted into a patent or license varies from 30% to 50%. This is a relatively close correspondence with differences explainable by different national policies and support measures.
- The spinout-company rate shows a similar range, explainable by the greater emphasis on company formation in Europe and in the United Kingdom, in contrast with the emphasis in the United States on licensing. The United Kingdom and Europe generated four to six times more spinout companies in 2000/2001, but the number had dropped in 2002, reflecting a much more difficult venture-capital environment after the dot-com bust.
- A recent report in the United Kingdom, however, has asserted that the reported rate of spinout-company formation is 50% more than the real rate. If true, this would make the United Kingdom data more comparable to other countries and illustrates the importance of clear definitions when collecting benchmark data.
- It is noteworthy that the total percentage of invention disclosures that result in either a license or a spinout is roughly similar in all countries examined, at around 30% to 40%.
- The staffing of TTOs shows interesting variations. The United States averages four staff (per US$100 million ATRE), whereas Australia and Canada have eight to ten staff (per US$100 million ATRE). This reflects economies of scale in the United States, as the average number of staff per institution is similar. Staffing levels in the United Kingdom, however, are six times higher than the United States per ATRE. This reflects the emphasis on spinout-company formation (known to be much more people-intensive than licensing) in the United Kingdom and the strong national support schemes that are in place.
- The cost of operating a TTO can be estimated from the reported staffing levels and salary survey results, formal or informal. As shown in Table 5, these budgets fall into two categories and three groupings. For the

United States, Canada, and Australia, the budget for a small university is about 1% to 2% of total research expenditure and 0.2% to 0.5% at the larger institutions. U.K. universities typically have budgets approximately double these figures.

- The average returns shown in Table 4, coupled with the typical budgets shown in Table 5, enable an estimate of the profitability of the various classes of offices. These results are shown in Table 6. In the United States and Canada, the bottom 50% of all universities operate at a loss, and only the 50% to 95% group are operating at a break-even or slightly profitable level. Only the top 5% are very profitable. It is this skewness that contributes to the all-too-common expectations of unrealistic performance. In the United Kingdom and Australia, only a few universities are profitable, with over 95% operating at a loss.

The similarity in performance among countries with different innovation systems and cultures indicates that the creative innovation process is inherently similar regardless of the environment. The single biggest factor that dwarfs all others is the expenditure on research, and it appears that no innovation system is significantly different with respect to the effectiveness with which ideas are generated and transformed.

This is not to imply that active innovation support systems are not required. All the countries examined and reported in the benchmarks in Table 2 have strong systems of support and are actively involved in training and developing capacity to manage the research and innovation process. Without such capacity, it is highly unlikely that the performance of any institution, region, or country will come even close to matching the average benchmarks.[3]

3. PHASING OF THE INNOVATION-VALUE-CHAIN

The benchmark data is masked by the long delays inherent in the technology transfer process. Each step in the value chain takes a few years; typically six to ten years elapses from the moment of invention disclosure to the time when significant income can be generated from a license. These delays are depicted in Figure 6, and the impact of these delays is illustrated in Table 7 and Figure 7.

This phasing makes interpretation of the benchmark data difficult, because data for a particular year depends on activities that happened many years earlier. The total license income in any one year, for example, depends on the accumulated sum of invention disclosure and patenting activities from prior years and is independent of the disclosure rate in that particular year. For ease of analysis and reporting, ratios are used to measure the relationship between variables that may in fact be years apart. In a steady-state environment, these ratios are correct, but the dynamic relationship must be understood.

The data presented in Table 2 is therefore primarily useful as a steady-state approximation, particularly when used to make projections for a new institution or a country just establishing an innovation system. Misunderstanding these dynamics can contribute to false expectations of returns that are more properly based on observations of essentially steady-state data from mature systems.

The dynamic model combines knowledge of the phasing of the value chain and the time duration of the various steps with the steady-state benchmark data in Table 2. The primary purpose of the model is to provide estimates of the likely rate of return and cash-flow forecasts (institutional and national) of alternative innovation-system scenarios. As the parameters of any particular innovation system are not known in advance (and are difficult to measure even in retrospect), the main use of the model is as a "what-if tool" to explore alternative approaches and understand the impact of policy decisions.

Table 7 illustrates one possible model based on a hypothetical institution expending US$100 million in research expenditure per year for 20 years. (The model is currency independent and whether this is US$ or any other currency makes no difference to the rate of return.) The model has also been used for actual institutions, where

past and future research expenditure is known or can be forecast. Any available data on past invention disclosures, patents, or licenses can be used as initial conditions; the model can incorporate as much past data as is available to generate forecasts.

Figure 7 shows the results of using a range of parameters to represent the three main TTO operating models, called the income, service, or economic models. The choice of office operating model depends on institutional and national policy, and upon capabilities and resources. In practice, a mix of models is normal. Each model can be defined by a set of innovation value-chain operating parameters. These parameters enable the future performance of an office (or country) to be calculated, including investment outlay required, patent prosecution costs, time to break even, and potential internal rate of return (IRR). The IRR is the estimated return to the institution from investing in establishing a TTO, including staff costs and IP protection expenses.

The importance of the model is not the accuracy of its predictions, which will, of course, be no better than the underlying parameters and assumptions underpinning their use. The primary benefit is in understanding the dynamics and relatively long timescales involved in technology transfer. The model can thus help avoid unrealistic expectations and can also provide the basis for a series of intermediate benchmarks that can help ensure that the innovation system is moving in the right direction. Invention disclosure, for example, is clearly an important early indicator to measure both the health and the vibrancy of the research system.

4. ECONOMIC-IMPACT ESTIMATION

The ability to calculate, or even estimate, the economic impact of technology transfer activities has been actively debated for a number of years. The statement below from the AUTM licensing survey for fiscal year 1999 has been disputed, and in subsequent years AUTM has refrained from making claims in the survey, suggesting instead on the need for ongoing research.

"The economic impact of the licensing of technologies developed at academic institutions is remarkable. The responses from member institutions estimate that the licensing of innovations made at academic institutions contributed over [US]$40 billion in economic activity and supported more than 270,000 jobs in Fiscal Year 1999. In addition, business activity associated with sales of products is estimated to generate [US]$5 billion in United States tax revenues at the federal, state, and local levels."[4]

Despite contention over specific claims of economic impact, it is widely accepted that the process is of economic benefit in all countries that have active innovation systems and promote university technology transfer. The many countries that are investing resources in technology transfer development confirm that there is widespread confidence that the investment is worthwhile and generates a positive return.

With considerable justification, developed countries use the overriding argument that, when a research program is already in place, technology transfer can result in significant additional benefits for a small additional cost (as shown in Table 4). But in developing countries with smaller economies, less-developed innovation systems, and many competing demands for resources, the situation is less clear. The benchmark data shows that the volume of innovation activities arising from research is directly proportional to the amount of research funding. If additional investment in research is proposed on the grounds that it supports economic growth, some justification for this needs to be shown (for example, that there will be a positive return from that investment).

While there is some financial benefit to the institution performing the research, the benefit is, at best, around 1% to 2% of research expenditure, as shown in Tables 2 and 3, and is generally between 0.5% and 1.5%. Income generation from technology transfer is therefore clearly not an adequate reason for an institution to invest in research. The financial benefits of technology transfer activities are captured primarily at the national economic level through business creation, with national returns arising from direct and indirect economic

effects. The data makes a compelling case for public funding, not only of research itself, but also of technology transfer activities.

Even when the public sector invests funds in research (whether for economic development reasons or otherwise), a research institution must invest in technology transfer activities over an extended period (eight to ten years) before a positive return can be expected. The highly uncertain and variable nature of the returns compounds these difficulties. Indeed, measuring the national economic impact of technology transfer is difficult and has been the subject of intense discussion and debate. A simplistic model has been developed to illustrate the concepts and motivate the development of more comprehensive models (the approach used here follows that described by Pressman[5]).

Universities report that the typical average royalty rate, from which license revenues are derived, is within the range of 2% to 4%. Direct business activity generated by technology transfer activities is therefore of the order of 25 to 50 times the revenue received by the licensing institution. Using an appropriate multiplier (typically 1.5 to 2.0), the overall direct economic impact can be estimated. This is not strictly an economic model. It is an estimate of the multiplier effects that are required to obtain a positive return. More work is needed to determine the actual multiplier effects that occur or are achievable. In addition to these benefits, the pre-production benefits associated with technology transfer activities have been shown to be significant.[6]

This economic return is the direct return from the activities measured and managed by the institutions' TTOs. There is strong evidence that the entrepreneurial culture resulting from the focus on technology transfer results in many other benefits that are neither captured nor measured by the institution, but which have an impact on the local economy.[7] These are the indirect multiplier effects. Whether similar benefits will accrue in developing countries is difficult to say and requires more research. Certainly, the factors noted by Tornatzky generate cause for concern. He noted that states with strong entrepreneurial support (such as Massachusetts and California) tend to draw entrepreneurial talent and opportunities from states with less support, resulting in a loss of economic benefits accruing to the states where the research was undertaken. This migration constitutes a leakage of benefits from states with less-well-developed entrepreneurial environments to those with a more nurturing environment. If leakages from poorer to richer states in the United States (in terms of entrepreneurial support) have an impact in the United States, the effect in developing countries is likely to be even more pronounced.

Figure 8 illustrates these concepts in an example projecting the returns arising from the technology to an investment in research illustrated in Figure 7. These projections are, of course, sensitive to the assumptions made. The model shows, for example, that a positive national IRR can only be achieved if the indirect multiplier effects are at least three to four times more than the direct effects. This reinforces the need for a more in-depth understanding of innovation system dynamics so that these effects can be understood and measured.

What is clear from the model is that the direct returns resulting from technology transfer are far from adequate to justify additional expenditure on research. In developing countries, the debate on whether higher expenditure on research is justified is intense and the model illustrates the need for more in-depth analysis and better economic data.

5. VARIABILITY OF BENCHMARKS AND RETURNS

The benchmark data from individual institutions (from all countries and over hundreds of institutions) shows a very high variability from year to year and from institution to institution. This variability is observed on all measures in the value chain: invention disclosures, patents, licenses, spinout companies, and income. The variations are up to two orders of magnitude, even for institutions that in other respects are similar. Some of these trends were illustrated in Figures 2, 3, 4, and 5. Analysis of the data by income, size of the institution, maturity, or size of the TTO indicates that none of these variables is strongly correlated with efficiency or performance measures. The only significant

correlation is that innovation output measures are proportional to the volume of research, as measured by expenditure on research. Even this figure is proportional only in aggregate over a large portfolio, with strong institutional variations.

Figure 9, for example, shows the variation in invention disclosure rate in terms of millions of dollars of research expenditure per invention disclosure, as a function of both the age of the office and the magnitude of research expenditure. Although in aggregate over time and across countries the figure is relatively constant, at the institutional level very strong variations occur, irrespective of the size or maturity of the institution. The European, United Kingdom, and Australian surveys show a similar distribution, so this is not unique to the United States.

Figure 10 shows the variation in license income (as a percentage of research expenditure) for U.S. and Canadian institutions. The graphs confirm the theoretical model presented above and demonstrate the ten-year lag before significant revenue is generated. But even after this portfolio-establishing period, returns to offices of similar size and experience vary greatly.

This high variability in returns has been noted and studied.[8,9,10] The variability in innovation returns appears to be inherent to the nature of innovation, but the variation in returns in early intermediate benchmarks (for example, invention disclosure rates) is not affected by the same factors. While still variable, this variability is less inherent and more manageable. Economic returns are determined by an unpredictable set of market factors, while the intermediate benchmarks are more controllable by the institution and TTOs. Institutional commitment, coupled with skilled, experienced staff, can significantly contribute by identifying opportunities and motivating invention disclosure, and, of course, by managing all the subsequent steps in the value chain.

The impact that skilled staff could have on the overall innovation process and benchmark figures is a topic for further research. If best practices could be identified and disseminated, they could potentially increase innovation returns substantially. This is particularly relevant to smaller, more-isolated offices, and offices in developing countries where peer learning is absent. Strong professional networks are critical, and these need to be promoted and developed.

Sherer and Harhoff[11] performed an in-depth study on innovation returns. Based on their analysis of eight large patent portfolios in both the United States and Germany, the researchers concluded:

"Our empirical research reveals, at a high level of confidence, that the size distribution of private value returns from individual technological innovations is quite skew—most likely adhering to a log normal law. A small minority of innovations yield the lion's share of all innovations' total economic value. This implies difficulty in averting risk through portfolio strategies and in assessing individual organizations' innovative track records. Assuming similar degrees of skewness in the returns from projects undertaken under government sponsorship, public sector programs seeking to support major technological advances must strive to let many flowers bloom. The skewness of innovative returns almost surely persists to add instability to the profit returns of whole industries and may extend even up to the macroeconomic level. Although much remains to be learned, some important lessons for technology policy have begun to emerge."

The AUTM data confirms that this skewness is even more apparent in university portfolios, with an average of only one in 200 licenses generating more than US$1 million in revenue.[12] This concurs with Sherer's data: of the eight portfolios he analyzed, the three from universities all had higher levels of skewness than the industry portfolios. This skewness is of particular relevance to smaller institutions and countries.

This disparity in outcome, which can occur even between institutions of similar size, capability, and investment, can lead to problems. Without an in-depth understanding, the benchmarks can result in dysfunctional policy decisions at both national and institutional levels.

6. IMPLICATIONS FOR DEVELOPING COUNTRIES

Data on the actual performance of developing countries is not available, or at least none has

been discovered in the course of conducting this research and making presentations in a number of countries.[13] A limited set of data, which has been obtained by personal contact with a number of institutions, is available for South Africa. This data is shown in Table 8, together with projections of the possible outcome if South Africa was operating within the international ranges summarized in Table 3.

If South Africa was to attain an innovation performance similar to comparable institutions elsewhere, the entire South African higher-education research system could be expected to generate 200 to 300 invention disclosures per year. After seven to ten years, such a disclosure rate should lead to a portfolio of around 500 active licenses, two of which would be likely to be generating revenue of greater than US$1 million per year, with total revenue of US$5 million to US$10 million per year.

Furthermore, the distribution of returns would almost certainly be skewed, even among the five or six major research universities, let alone the 15 smaller institutions. A few institutions are likely to perform relatively well, while the majority are likely to operate at a net loss, even after ten or 15 years. Furthermore, the skewness and variability of returns means that it is not possible to predict who is likely to succeed and who will be considered to have "failed." Given the financial constraints that exist in higher education institutions, continued institutional support for technology transfer is likely to be a risk, unless external support or stimulus is provided.

In the United States, the Bayh-Dole act of 1980 provided a major stimulus for technology transfer, but the difficulty of using a similar measure in South Africa is illustrated by the funding differences. In the United States, the proportion of research from federal funding is 61%, while industry contributes only 9% of total research funding.[14] In South Africa, industry funding is 58% and government funding makes up 28% of total research funding.[15] This funding pattern has implications for IP generation and ownership, as well, and is an example of the differences that need to be considered when making projections based on international benchmarks.

One argument that carries some weight is that the high levels of industry-sponsored research in South Africa and other countries with a similar pattern of funding, represent considerable informal technology transfer embedded in research contracts. The true performance of these institutions, therefore, may be much higher than is indicated by the simple "AUTM-like" technology transfer indicators.

Whether the benchmarks from countries with large, well-developed research and innovation systems will scale to smaller countries is at present unknown. More detailed analysis and measurement are required to determine appropriate benchmarks and to construct a more robust and accurate economic impact model.

7. CONCLUSIONS

The similar relative performance of higher-education technology transfer systems in developed countries indicates that the creative innovation process is inherently similar and that no one country is significantly better in terms of the efficiency with which ideas are generated and transferred. The impact of a technology transfer program is determined primarily by the magnitude of the expenditure on research and the length of time the program has been in operation, provided active innovation programs exist and well-trained technology transfer professionals are in place. These are essential requirements if institutions and countries aspire to attain international norms of performance.

To avoid unrealistic expectations of the benefits of technology transfer in smaller countries and institutions, this data set must be understood. Effective models of the innovation system, preferably based on local data, can help predict budget requirements, the possible return on investment, and the timescales to attain these goals. Measurement of the local innovation system should commence at the earliest possible stage, because early indicators (such as the invention disclosure rate) can provide insight into how the remainder of the value chain is likely to develop.

The long time-period required for individual institutions to derive benefits, and the fact that

the benefits are largely to the national economy, indicate that appropriate national support measures are needed to encourage innovation development and to overcome institutional resistance in resource-constrained environments. Using an innovation-system model (where appropriate) to evaluate and quantify alternatives, further research is needed to determine the most effective support measures.

Institutions and innovation systems need to take into account the skewness and inherent variability of innovation returns. In the early stages, more emphasis needs to be placed on intermediate benchmark measures and less on such traditional measures as license revenues and spinout-company formation. ■

ACKNOWLEDGMENTS

This research has drawn heavily on work done by many colleagues. The sterling, unglamorous work of hundreds of AUTM members in performing the licensing survey each and every year for the past 12 years is noted with particular thanks. Without that data, many of us who are new to the profession would be fumbling in the dark. The surveys sent to me by colleagues in United Kingdom, Canada, Europe, and Australia have filled out an interesting story. If I have misrepresented the data in any way in making comparisons, I apologize.

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This chapter is based on a paper published in the *Journal for Technology Transfer*. It draws on the data presented in that paper but presents a number of new results.

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1 See *AUTM Licensing* Survey™. Association of University Technology Managers. Northbrook, Ill. www.autm.net.

2 Lundvall BÅ and M Tomlinson. 2001. Learning-by-Comparing—Reflections on the Use and Abuse of International Benchmarking. In *Innovation, Economic Progress and the Quality of Life* (G Sweeney, ed.), chap. 8. Elgar Publishers: Denmark.

3 Comprehensive descriptions of the necessary support functions are given in:

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4 *AUTM Licensing* Survey™: Fiscal Year 1999. Association of University Technology Managers. Northbrook, Ill. www.autm.net.

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6 Geist D. 1995. Pre-Production Investment and Jobs Induced by Technology Licensing: The M.I.T. Method. Technology Licensing Office. Massachusetts Institute of Technology: Cambridge.

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9 Sherer, FM and D Harhoff. 2000. Technology Policy for a World of Skew-Distributed Outcomes. *Research Policy* 29: 559.

10 Marsili O and A Salter. 2003. Is Innovation 'Democratic'? Skewed Distributions and the Returns to Innovation in Dutch Manufacturing, Holland. ECIS-Eindhoven Centre for Innovation Studies. Eindhoven University of Technology: Eindhoven.

11 See *supra* note 9.

12 AUTM. 2002. AUTM Licensing Survey™: Fiscal Year 2001. Association of University Technology Managers: Northbrook, Ill. www.autm.net.

13 If any reader knows of benchmark data from countries other than those presented, the author would be pleased to be notified. The research on which this chapter is based is ongoing and the opportunity to extend the work to include data from other countries is welcome.

14 See *supra* note 12.

15 CENIS. 2002. South African S&T Indicators (2002). Centre for Interdisciplinary Studies. University of Stellenbosch: South Africa.

Table 1: Technology Transfer Benchmarks from Selected Countries; Summary of Key Data

	USA[a]			Canada[a]			U.K.[b]		Australia[c]	
	2001	2002	2003	2001	2002	2003	2001	2002	2001	2002
					CAD (billions)				AUD (billions)	
Research expenditure		-	-	-	3.2	3.6	-	-	2.60	2.80.
- in US$b (ATRE)[d]	$27.6	$31.7	$34.8	$2.1	$2.5	$2.5	$2.6	$3.1	$1.90	$2.10
Invention disclosures	11,259	12,638	13,718	933	1,175	1,282	1,402	2,238	541	521
Patents, filed	5784	6,509	7,203	415	422	425	743	1098	401	459
Patents, issued	3,179	3,109	3,450	162	172	179	276	347	112	121
Licenses, executed	3,300	3,739	3,846	333	362	448	383	648	176	223
Licenses, active	22,937	-	-	1,412	1,715	-	-	1,616	-	-
Licenses, yielding income	7,715	8,490	8,976	-	738	891	403	635	270	235
License income ($m)	$827	$959	$963	$54.6	$32.8	$39.7	$26	$33	$33.6	$30.1
Net legal fees ($m)	$79	$96	$176	$3.2	$4.3	$7.5	$13	$16	$3.0	$3.5
Start-ups, total	494	364	348	68	49	58	175	158	46	45
Start-ups, still operating	2,514	-	-	-	493	-	-	-	98	110
Staff, professional	524	613	654	89	113	139	461	752	111	101
Staff, support	546	624	665	95	122	137	-	-	54	53

Note: Data is for all responding institutions for each year indicated, so year-on-year absolute numbers are not comparable.

a Association of University Technology Managers (AUTM) FY 2001, 2002 and 2003 surveys. Data is for universities only in U.S. and only in Canada.

b UNICO-NUBS Survey on University Commercialisation 2001 and UNICO/AURIL-NUBS Survey 2002 (Performed for UNICO by Nottingham University Business School).

c Australian Research Council, National Survey of Research Commercialisation, Years 2001 and 2002 (universities only).

d ATRE stands for Adjusted Total Research Expenditure equivalence in U.S. dollars.

Table 2: Adjusted Total Research Expenditure (All Per $100m)

	U.S.A.			Canada			U.K.		Australia	
	2001	2002	2003	2001	2002	2003	2001	2002	2001	2002
Research expenditure ($b ATRE)	$27.6	$31.7	$34.8	$2.1	$2.5	$2.5	$2.6	$3.1	$1.9	$2.1
Invention disclosures	41	40	39	44	48	50	54	72	28	25
Patents, filed	21	21	21	20	17	17	29	35	21	22
Patents, issued	12	10	10	8	7	7	11	11	6	6
Licenses, executed	12	12	11	16	15	18	15	21	9	11
Licenses, active	83	-	-	67	70	-	-	52	-	-
Licenses, yielding income	28	27	26	-	30	35	16	20	-	-
Start-up companies, total	**1.8**	**1.1**	**1.0**	**3.2**	**2.0**	**2.3**	**6.7**	**5.1**	**2.4**	**2.1**
Start-up companies, still operating	9.1	-	-	-	20.0	-	-	-	5.2	5.2
Staff, professional	1.9	1.9	1.9	4.2	4.6	5.5	17.7	24.3	5.8	4.8
Staff, support	2.0	2.0	1.9	4.5	5.0	5.4			2.8	2.5
Disclosures to:										
licenses	29%	30%	28%	36%	31%	35%	27%	29%	33%	43%
start-ups	4%	3%	3%	7%	4%	5%	12%	7%	9%	9%
licenses + start-ups	34%	32%	31%	43%	35%	39%	40%	36%	41%	51%
License income	**3.0%**	**3.0%**	**2.8%**	**2.6%**	**1.3%**	**1.6%**	**1.0%**	**1.1%**	**1.8%**	**1.4%**
Legal expenses as % total res exp[a]	0.3%	0.3%	0.5%	0.2%	0.2%	0.3%	0.5%	0.5%	0.2%	0.2%
Legal expenses as % of licence income[b]	10%	10%	18%	6%	13%	19%	51%	48%	9%	12%

a Net expenses (spent-reimbursed) as % of total research expenditure.
b Net expenses (spent-reimbursed) as % of license income.

Note: Data are normalized and all curencies expressed in equivalent U.S. dollars.

Table 3: Research and Innovation Value Chain

	Typical Ranges per $100m ATRE
Invention disclosures	40 – 50
Patents	20 – 30
Licenses	10 – 15
Spinout companies	1 – 5
Income	$1m – $3m
	(1% – 3% of research expenditure)

Table 4: Average Returns in 2002 (License Income as % of Total Research Income)

Group	U.S.	Canada	Australia	U.K.
All universities	3%	1.60%	1.50%	1.10%
Lower 95%	1.60%	0.80%	0.60%	0.55%
No. of universities excluded from average	8	2	1	5
Bottom 50%	0.28%	0.23%	0.08%	0.02%

Note: "Group" refers to university rankings by percentage of license income, as indicated in Figures 2–5.

Table 5: Typical Technology Transfer Office Budgets (As % of Total Research Expenditure)

University size	Budget (U.S./Australia model)	Budget (U.K. model)
Small	1%–2%	2%–3%
Medium	0.5%–1%	1%–2%
Large	0.2%–0.5%	0.5%–1%

Table 6: Likely Outcomes (Estimated Budget vs. Likely Income)

Group	U.S. & Canada	U.K. & Australia
Bottom 50% (of all universities)	Loss	Large loss
50%–95%	Break even–profitable	Loss
Top 5% (of all universities)	Very profitable	Profitable

Note: "Group" refers to university rankings by percentage of license income, as indicated in Figures 2–5.

Table 7: Institutional and National Effects on Technology Transfer

Institutional parameters	Parameter	Years lag	Year 1	2	3	4	5	6	7	8	9	10	11	12	.....	20
Research ($m)			100	100	100	100	100	100	100	100	100	100	100	100	-	100
Disclosures ($m)	8.0		13	13	13	13	13	13	13	13	13	13	13	13	-	13
Patents	40%	1	0	5	5	5	5	5	5	5	5	5	5	5	-	5
Average patent cost ($m)	0.2	0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	-	1.0
Licenses, total	20%	2	0	0	3	3	3	3	3	3	3	3	3	3	-	3
Licenses, active period	-	7				0	0	0	0	0	0	3	3	3	-	0
Licenses, cumulative	#	0	1	1	4	6	9	11	14	16	19	19	19	19	-	19
Royalties ($m)	0.2	3	R 0.0	R 0.0	R 0.0	0.2	0.2	0.7	1.2	1.7	2.2	2.7	3.2	3.7	-	3.2
Spinouts, total	10%	3	0	0	0	1	1.3	1.3	1.3	1.3	1.3	R 1.3	R 1.3	R 1.3	-	R 1.3
Income from sale of spinout ($m)	3.0	6	R 0.0	R 0.0	R 0.0	R 0.0	R 0.0	R 0.0	R 0.0	R 0.0	R 0.0	R 3.8	R 3.8	R 3.8	-	R 3.8
Total income ($m)			R 0.0	R 0.0	R 0.0	0.2	0.2	0.7	1.2	1.7	2.2	6.5	7.0	7.5	-	7.0
Office costs, salaries, and overheads	0.3	15%	0.3	0.3	0.3	0.3	0.3	0.4	0.5	0.6	0.6	1.3	1.3	1.4	-	1.3
IP costs ($m)	-	-		1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	-	1.0
Net income	-	-	0.0	-1.3	-1.3	-1.1	-1.1	-0.7	-0.3	0.1	0.6	4.2	4.6	5.0	-	4.6
Cumulative income	-	-	0.0	-1.3	-2.6	-3.7	-4.9	-5.6	-5.8	-5.7	-5.1	-0.9	3.7	8.7	-	42.8

(Continued on Next Page)

Table 7 (continued)

Institutional parameters	Parameter	Years lag	Year 1	2	3	4	5	6	7	8	9	10	11	12	.....	20
IRR to institution	-	-					0%	0%	0%	0%	0%	**-3%**	**8%**	**14%**	-	24%
Income (% of research)	-	-			-1.3%	-1.1%	-1.1%	-0.7%	-0.3%	0.1%	0.6%	4.2%	4.6%	5.0%	-	4.6%
Economic impact estimates		-	-	-	-											
Turnover at average royalty rate	3%	-	0.0	0.0	0.0	6.7	6.7	23.3	40.0	56.7	73.3	215.0	231.7	248.3	-	231.7
GDP Multiplier	1.5		0.0	0.0	0.0	10.0	10.0	35.0	60.0	85.0	110.0	322.5	347.5	372.5	-	347.5
Tax revenue direct	30%		0.0	0.0	0.0	3.0	3.0	10.5	18.0	25.5	33.0	96.8	104.3	111.8	-	104.3
Indirect mulitplier	4		0.0	0.0	0.0	40.0	40.0	140.0	240.0	340.0	440.0	1290.0	1390.0	1490.0	-	1390.0
Tax revenue indirect	25%		0.0	0.0	0.0	10.0	10.0	35.0	60.0	85.0	110.0	322.5	347.5	372.5	-	347.5
Net income			-100.0	-100.0	-100.0	-90.0	-90.0	-65.0	-40.0	-15.0	10.0	222.5	247.5	272.5	-	247.5
IRR - national									-	-	-	-	**-3%**	**3%**	-	**14%**

Table 8: Projections of TTO Activity for South Africa

	International ranges (from Table 3)	Current (2004) (based on five universities)	Projections if at international norms
		US$194m	ZAR2b
Research expenditure (ATRE)	per US$100m	per US$100m	US$500m
Invention disclosures (total)	40–60	23	200–300
Patents filed	20–30	6	100–150
Licenses	10–15	4	60–100
Start-ups	1–5	3	5–20
Patent budget (as % income)	0.2%–0.5%	0.30%	
License income	1%–2% of total	0.1% of total	US$5m–US$10m
Size of staff	4–20	9	20–100

Note: Projections are based on likely ranges from international benchmarks.

Figure 1: License Income (1991–2004 for U.S., 2000-2003 for Other Countries)

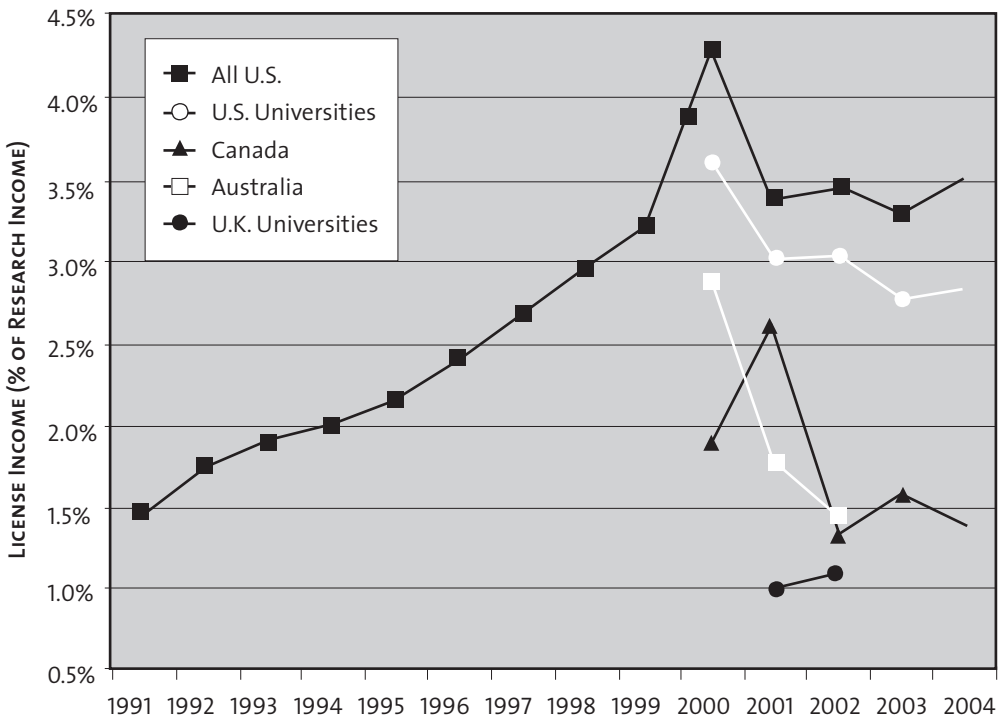


Figure 2: License Income for U.S. Universities for FY 2002

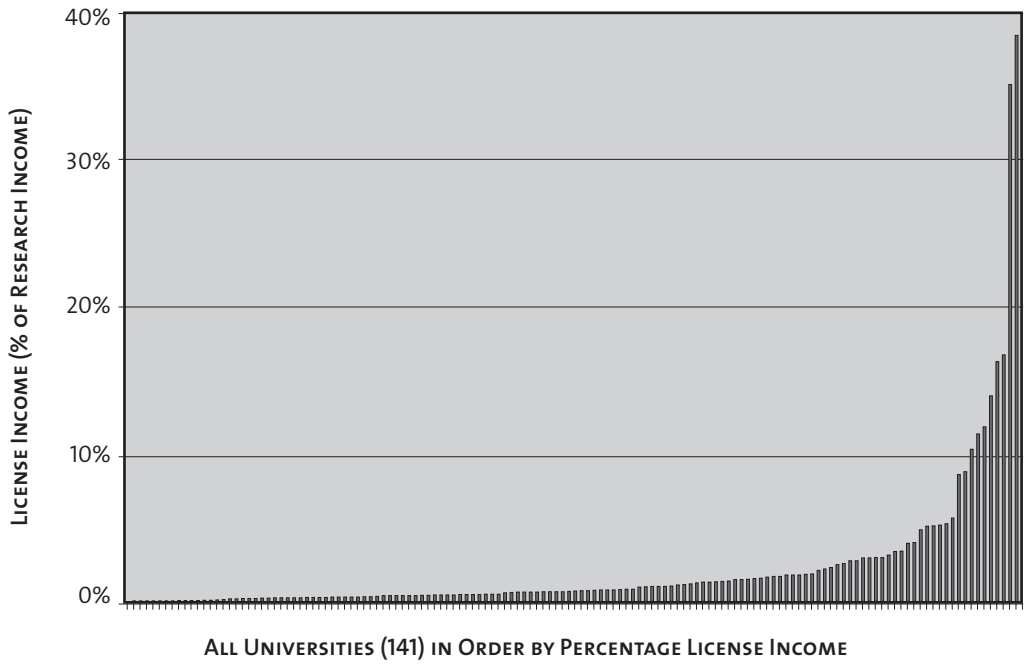


Figure 3: License Income for U.S. Universities for FY 2002 (Logorithmic plot)

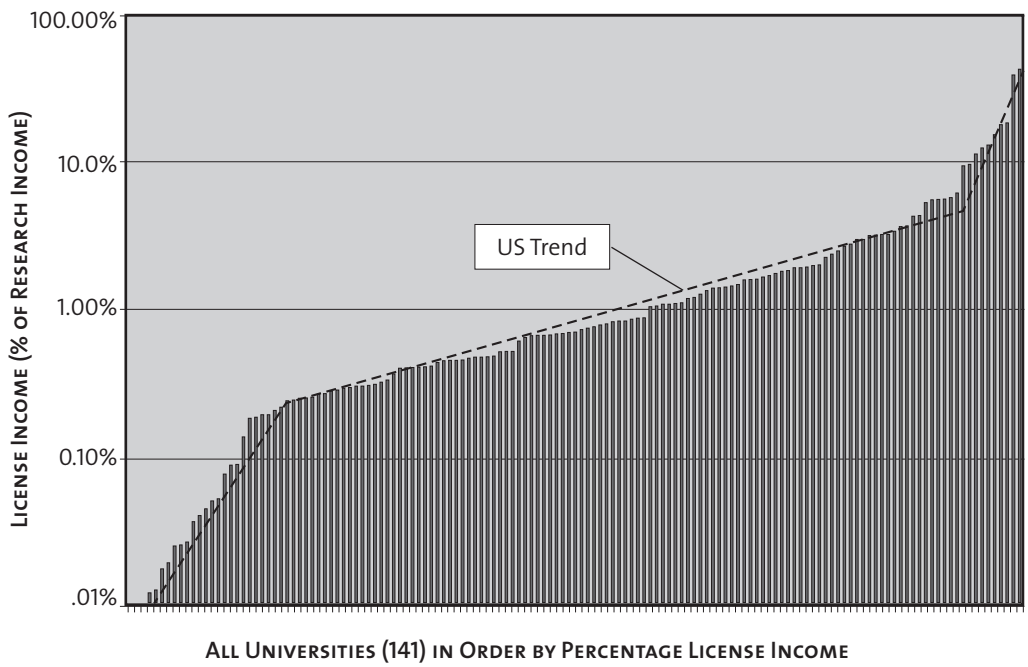


Figure 4: License Income for Canadian Universities for FY 2002 (Logorithmic plot)

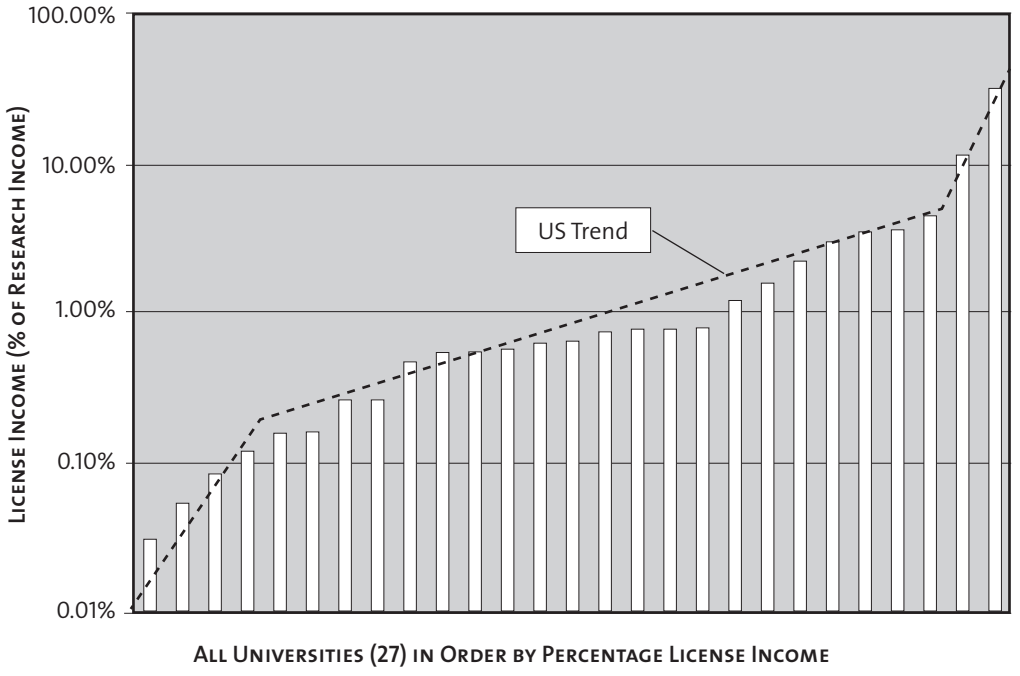


Figure 5: License Income for Australian Universities for FY 2002 (Logorithmic plot)

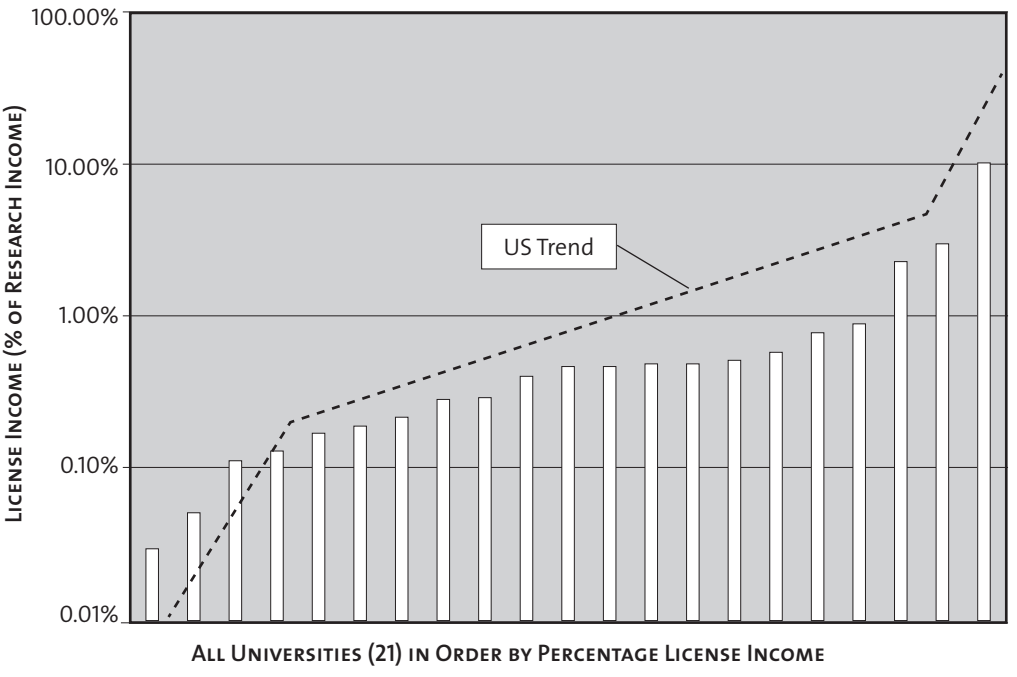


Figure 6: Typical Phasing of the Value Chain

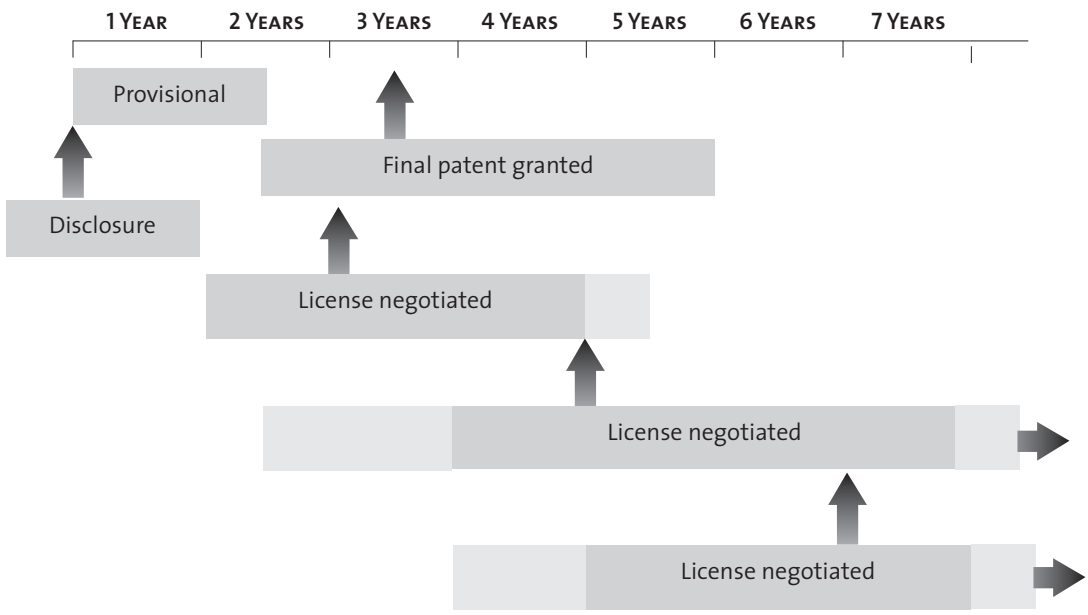


Figure 7: Impact of Policy Choices on Performance

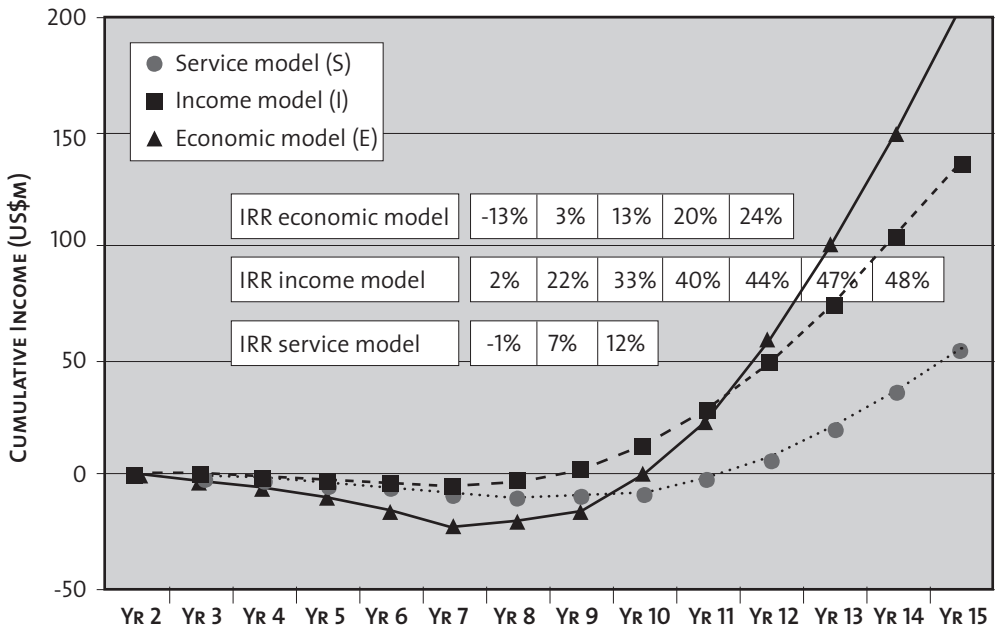


Figure 8: Estimation of National Internal Rate of Return (IRR)

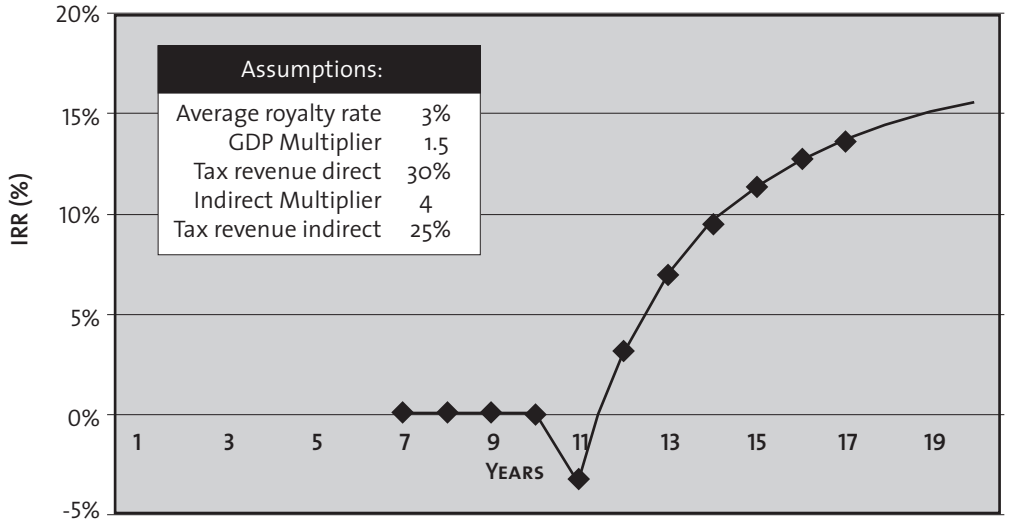


Figure 9A: Disclosure Rate vs. Age of Office

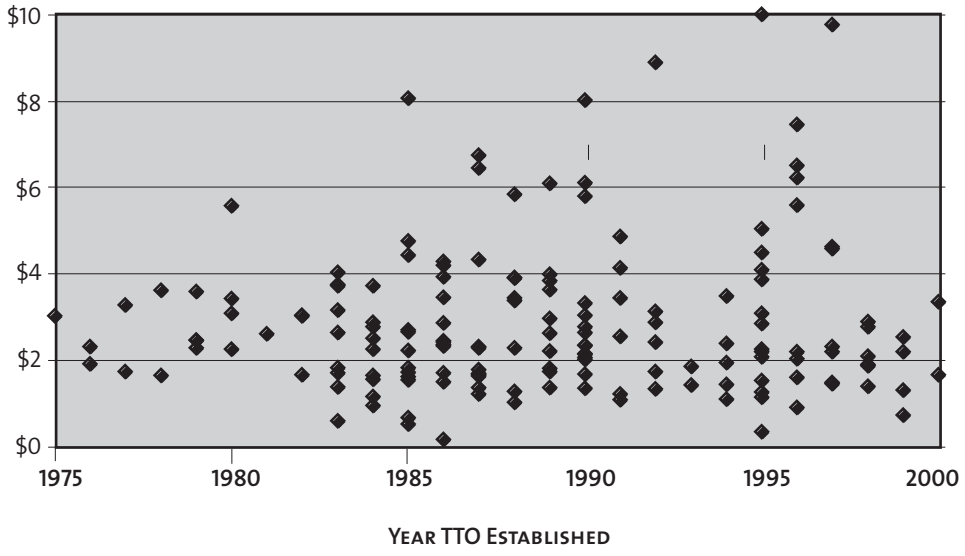


Figure 9B: Disclosure Rate vs. Research Expenditure

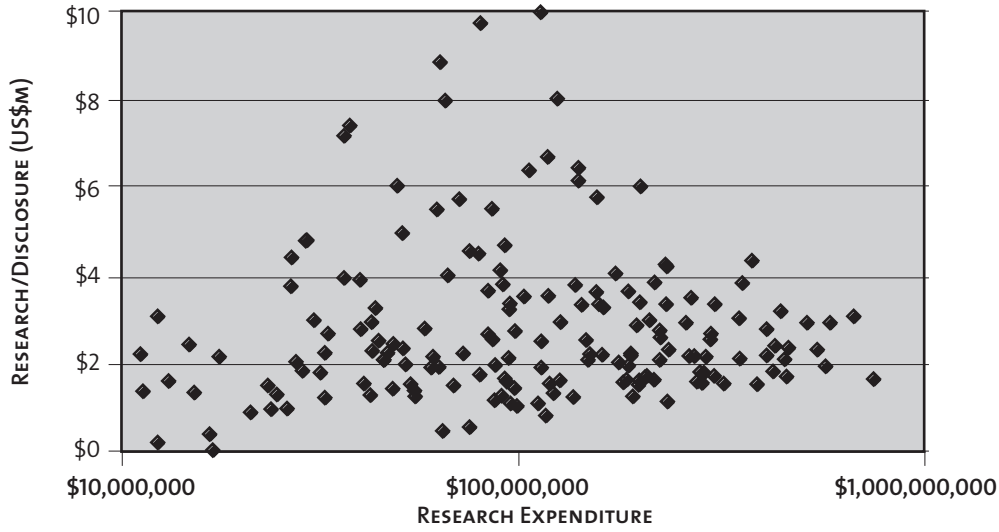
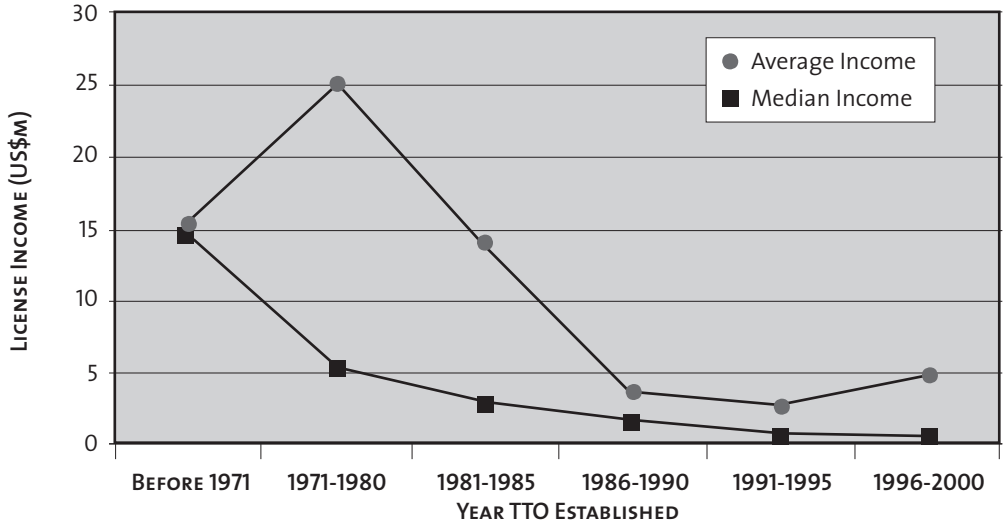
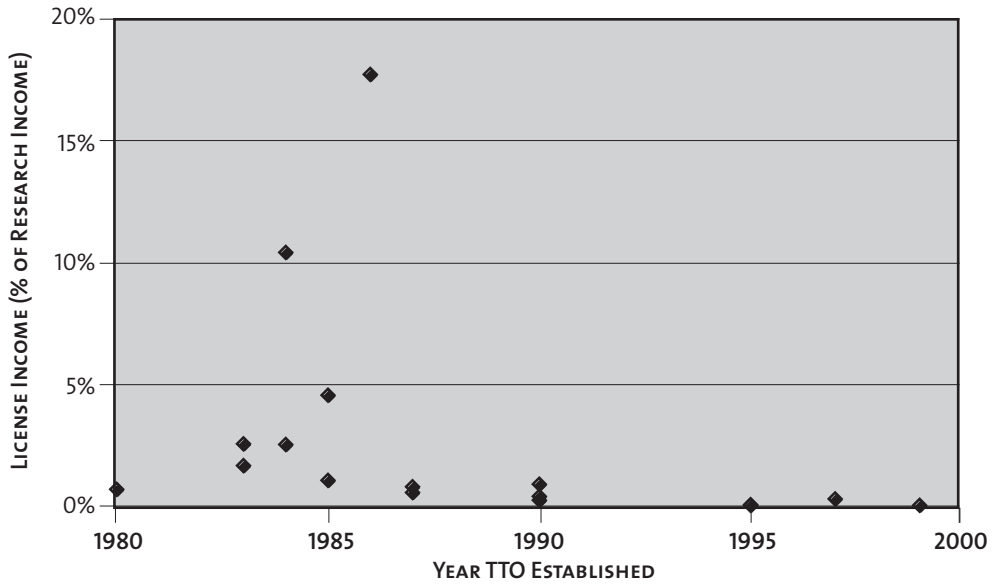


Figure 10A: TTO Age as a Determinate of Licensing Income (U.S.)



Source: IIPI Report on South African University Technology Transfer: A Comparative Analysis, Jan 2004.

Figure 10B:TTO Age as a Determinate of Licensing Income (Canada)



Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy—Perspectives from WIPO

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ABSTRACT

This chapter reviews the options for effective public sector management of intellectual property (IP) in the life sciences, focusing on the need for a judicious, pragmatic choice of options along two axes: (1) deployment of exclusive rights over technology and (2) use of market mechanisms to bring a new technology to the public. The essence of public sector IP management is finding the right settings along these two axes that will deliver tangible outcomes in line with defined public-interest objectives. Experience shows that ex ante assumptions about how to gain optimal leverage from exclusive rights, and the appropriate degree of reliance on market mechanisms, are unlikely to serve a public sector IP manager well. In clarifying objectives and the practical means of achieving them, pragmatic coordination between the practical and policy levels is essential. Public sector IP managers are more likely to be assessed against public interest expectations than their private sector colleagues. In IP management in the life sciences, policy and practice are ultimately two sides of the same coin; practitioners cannot hope, expect, or plan to operate outside the broader policy perspective. Policy-makers therefore need to consider the actual practice of IP management when assessing a policy framework for innovation in the life sciences. IP managers should be open to using legal mechanisms flexibly for inclusion, or exclusion, as required to achieve their goals. Finally, managers should seek mechanisms to pragmatically structure and promote partnerships with those who have the resources necessary to bring life-sciences innovation to the public. Such partnerships may be centered in the public, philanthropic, or private sectors, but more likely fall into a hybrid mix of these categories.

1. OVERVIEW AND CONTEXT

1.1 *Toward policy-rich practice and practice-informed policy*

Researchers, technology managers, and intellectual property (IP) advisors who work in the life sciences and who use the IP system are not operating in a policy-neutral, strictly technical environment. An overarching public interest in life-sciences innovation means that the accumulated impact of many seemingly independent, individual choices will in fact have implications for how the IP system is perceived by policy-makers and will therefore help to determine policy directions. The practical choices made when managing IP rights therefore ultimately influence public policy debate. Indeed, given public expectations for life-sciences innovation, choices over when and how to exercise IP rights are inevitably assessed from a policy point of view.

Practitioners need to be sensitive to the policy environment and alert to the debates that swirl around two related aspects of public concerns: (1) the impact of life-sciences developments in themselves and (2) the impact when intellectual property is applied to life-sciences innovation. While this may frustrate legally trained practitioners, how the IP system is used, and the perceived equities of access to the benefits of a life-sciences

Taubman A and R Ghafele. 2007. Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy—Perspectives from WIPO. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

technology, can affect public perceptions of the legitimacy of that technology. Juma and Konde write:

Resistance to new technologies is likely to be reduced by changing perceptions of access to the new technologies as well as to their markets. This has not been the case with agricultural biotechnology, which involves worldwide exports with the potential for product displacement, while leaving wide margins of uncertainty for technology followers.[1]

Moreover, the policy debate cannot operate in isolation from the practical realm. Policymakers need a robust, practical understanding of the technologies concerned, of the nature of life-sciences innovation, of the overall trends in the IP landscape, and of the real-world impact of the actual exercise of IP rights. Only then can policymakers effectively balance concerns about equity of access with the proper exercise of exclusive rights. Optimal policy choices require the widest range of distilled, neutral empirical information about the use of intellectual property in relation to key life-sciences technologies. Indeed, the experience of practitioners contributes valuable insights needed to guide and buttress policy debate over the future of life-sciences innovation.

1.2 *Resolving the paradox: public interest through private rights*

Reconciling the public policy role of the IP system with the management and exercise of private IP rights addresses the central paradox of IP policy: what legal exclusions from the public domain are required to promote the public interest? And how can those exclusive rights, once granted, be best deployed for IP law to function as a public policy tool? Life sciences concern the basic human needs of food, health, and a safe environment. How then can IP rights be best managed to promote public welfare by making available the fruits of life-sciences innovation and spurring economic development? These benefits arise not from the mere presence of a formal system of assessing, granting, and enforcing IP rights, but from the judicious, skillful application of these legal mechanisms in practice. Positive welfare gains from IP mechanisms emerge from an accumulation of individual choices, not just from the abstract process of shaping a legislative framework This is most directly illustrated by the experience of managing rights held by public sector institutions, which can be held more immediately responsible than their private sector counterparts for securing tangible benefit gains directly from public investment in research and development. Thus, we see the emergence of public sector IP management as a distinct subset within the broader discipline of IP management. For instance, pharmaceutical public-private partnerships "*must be as aggressive in the way they use IP as any commercial unit, but for a different purpose—namely to pursue their social objective of getting quality, affordable products to developing country patients.*"[2]

The optimal implementation of IP rights requires a practical understanding of the full range of options for exercising exclusive rights and a capacity to assess and implement those options as part of a broader strategy. IP rights are exclusive in their formal legal character, but the modes of exercising such rights are highly diverse and will correspond to an institution's broader objectives. A predetermined license template, for example, will not lead to best practice in IP management in the life sciences, because its use may effectively foreclose the full range of choices available and preempt the objective assessment of the implications of each option. A good manager will instead judiciously use IP mechanisms to leverage the resources needed and obtain the freedom to operate, while prudently assessing the likely impact of various forms of IP rights exploitation.

Workable public sector–management models do not normally entail an exclusive reliance on release into the public domain nor on wholly exclusive licensing. While it is rare to see a life-sciences product delivered without some engagement of private sector actors responding to market signals, it is usually misleading to set the full product development pipeline wholly in the public or private sectors. Given especially the necessarily stringent regulatory environment confronting the life sciences and the need to garner resources for the full product development process, investments will likely draw on both public and private resources. Therefore, rather than employing simple public/

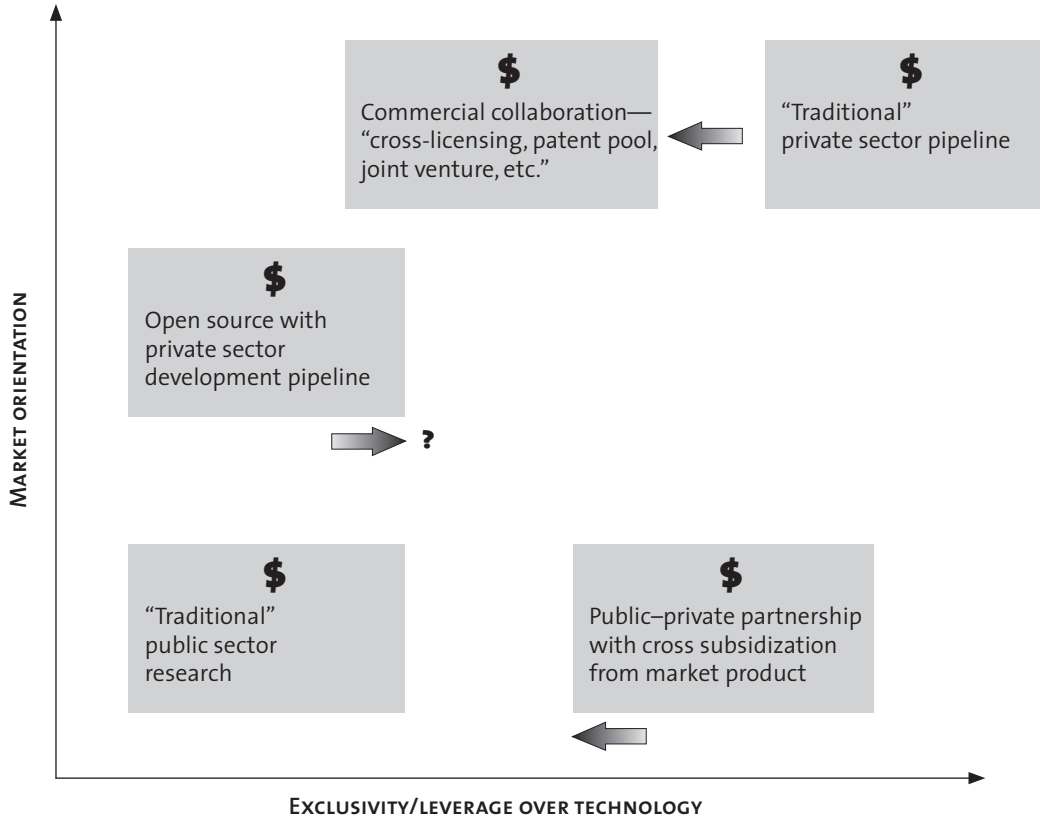
private or open/exclusive labels, the full range of options available to public sector IP managers can be more usefully analyzed along two continuums: (1) degree of exclusivity, ranging from defensive publishing in the public domain through open source or commons-based constructs, and nonexclusive and exclusive licensing, to direct exploitation of exclusive rights; and (2) degree of market engagement, from pure research, through making some use of private resources in the development pipeline, to various modes of outsourcing product development and the dissemination of a proven life-sciences technology, including spinoffs and transfer of rights to private firms. *Even if* a public sector IP manager's core responsibility is to deliver welfare gains to the public in the form of accessible new life-sciences technologies, she or he is likely to have to assess the full range of options across these two spectra when formulating a practical strategy. These options are presented schematically in Figure 1 (which is also further discussed in section 4.2 below).

1.3 *The meaning of global intellectual property*

Participation in the international patent system continues to grow and diversify in three overlapping ways, each with direct ramifications for the field of public sector IP management:

1. Greater geographical and cultural diversity. Membership in the Patent Cooperation Treaty (PCT) has shifted from an early

Figure 1: Public Interest IP Management Goes Beyond Licensing Arrangements



Source: A Taubman[3]

preponderance of developed and transitional economies to a clear majority of developing countries. In terms of the actual use of the system, patent applicants from the developed world continue to predominate, but current trends reveal double-digit growth, sustained over five years or more, on the part of certain key developing countries. This trend, if sustained in the medium term, would significantly shift the center of international patent activity. PCT international applications received from developing countries in 2005 rose 24.8% compared to 2004, and constituted 6.9% of all filings. China, Mexico, and the Republic of Korea are among those countries registering double-digit percentage increases in use of the PCT.[3] (Figure 2)

2. Greater use of the system by public sector and not-for-profit entities. In the life-sciences domain, these are as diverse as India's Council of Scientific and Industrial Research, Empresa Brasileria de Pesquisa Agropecuaria (Embrapa), the Korea Research Institute of Bioscience and Biotechnology, the International Aids Vaccine Initiative, the Medicines for Malaria Venture, and CAMBIA.
3. Growth in use of the system in life-sciences technologies stronger than the general trend. For instance, PCT publications in the technical field represented by IPC Class A61K (Preparations for Medical, Dental, or Toilet Purposes) rose 5.1% in 2005. In the next highest field (G06F—Electric Digital Data Processing) the growth rate was 4.6%.[4]

Public sector users of the patent system who are working in the life sciences face practical questions about how to manage a patent estate to advance their institutional objectives. While this has been the subject of a longstanding debate in the developed world, it is increasingly a practical issue for developing countries as well. The rate of public sector patenting in life-sciences research in developing countries is growing exponentially. These countries are, of course, starting from a small base, so the actual impact will be felt over time as international activity translates into distinct national rights. It is certain, however, that government agencies and other public sector institutions in developing countries will be increasingly responsible for managing a growing stock of life-sciences intellectual property resulting from investment of public resources, or from combined private and public sector inputs. These governments will assume the task in light of their overarching responsibility to promote the public interest through the management of this intellectual property. Doing so entails working on a broader canvas than the mainstream management of intellectual property the essential focus of which is to promote commercial outcomes.

Such social or institutional responsibilities require that public sector IP managers develop and apply practical skills to manage intellectual property effectively. They may need to look beyond conventional, private sector methodologies to find appropriate ways of managing intellectual property to ensure the desired public interest outcomes. These might include ensuring the development and effective dissemination of new technologies to the public (for example, new pharmaceuticals), promoting economic and social development, creating skilled jobs, or enhancing urgent research funding.

Effectively managing public interest IP is a task that requires judgment and acute sensitivity, acutely so in life-sciences domains. It requires advanced skills. There is a wide spectrum of possible approaches, and there are many distinct objectives that may be pursued. IP management to produce public health outcomes is particularly demanding, yet vitally important for the public interest.

1.4 *Choices for public sector IP management*

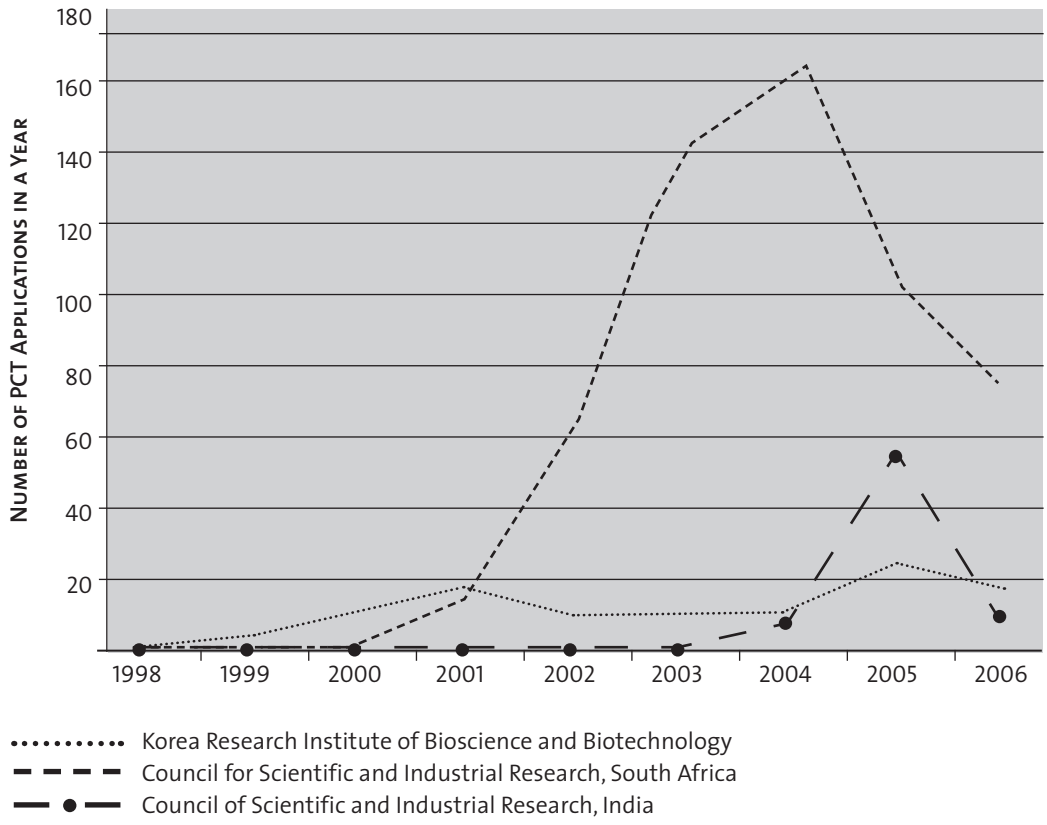
While often debated in abstract terms, the impact of IP laws and IP rights is ultimately determined by a series of practical, yet critical, choices. For the public sector, these choices are increasingly guided by IP management policies. Tom Ogada has categorized these choices in terms of:

- Who owns the intellectual property generated by government-funded research activities?

- How will revenues/benefits from the commercialization of intellectual property be shared between the researcher/inventors, the department, the institution, and government funding providers?
- Which, if any, government rights/stipulations are attached to the commercialization of intellectual property generated under government-funded research?
- In the case of privately funded research, who will own any resulting intellectual property?
- Will spinout companies or licensing contracts be used to transfer technology to the private sector for commercialization?
- Who will manage IP assets, including the negotiation of licenses and royalty sharing?
- To what extent will the institution encourage research commercialization through entrepreneurial activity?
- How will the costs of IP protection and maintenance be paid?
- How should any invention disclosure procedure be managed?
- How will conflicts of interest between teaching/research duties and commercially driven projects be handled?

To assist public sector IP managers and policy-makers in making these decisions, Ogada has authored *Guidelines on Developing Intellectual Property Policy for Universities and R&D Institutions in African Countries*.[5] Other relevant

Figure 2: PCT Applications of Select Research Centers in India, the Republic of Korea and South Africa



Source: PCT Patent Statistics, 2006.

World Intellectual Property Organization (WIPO) resources include:

- *Successful Technology Licensing*. This booklet, written for use by business managers, technology managers, and scientists who deal with licensing questions, aims to help its readers negotiate win-win licensing agreements, in which all parties receive and exchange approximately equal benefits and value.
- *Exchanging Value—Negotiating Technology Licensing Agreements: A Training Manual*. This text focuses on the practical business needs and concerns of nonspecialists who have to deal with licensing in or licensing out of technology. The manual includes an outline for a program schedule and practical guidelines for creating and managing teams/groups for conducting mock negotiations. (These are from a five-day practical workshop on negotiating technology licenses, including a case study on tuberculosis vaccines.)
- *Advanced Distance Learning Course on Biotechnology and Intellectual Property*. This addresses aspects of patenting biotechnological inventions and the plant breeder's rights systems, as well as IP in research and development, and the management and practical use of IP rights.

2. BIOMEDICAL INNOVATION AND DEVELOPMENT

2.1 *Capturing the benefits of indigenous innovation*

Concentrating on technology transfer as a key innovation strategy, mainstream discourse on innovation and development tends to cast developing countries as recipients of technology produced elsewhere. While access to foreign technology is clearly integral to development, it is increasingly important to focus directly on capturing the indigenous innovation potential of developing countries.[6] Given that developing countries hold significant traditional knowledge and genetic resources, this arguably applies in the life sciences more than in any other field. At least one of the lessons of the biopiracy debate is the need to ensure that custodian countries derive social and economic benefits from these vital feedstocks for life-science research. Accordingly, delivering on the promise of life-sciences innovation requires outcomes tailored to the circumstances of individual countries. This means democratizing innovation to address neglected diseases that disproportionately afflict the developing world, or to respond to the agronomic, environmental, and nutritional context of developing country agriculture.

Many developing countries possess the human capital necessary for life-sciences innovation, and they seek the practical pathways to realize this potential, not only from the point of view of economic development, but also from the broader perspective of public welfare. For instance, local health practitioners have extensive practical experience in traditional knowledge systems, as heirs of generations of "clinical trials." In dealing with endemic diseases, the knowledge reserves of the health practitioners need to be drawn on more systematically as part of a sustainable, bottom-up approach to development. The recent launch of the South African Indigenous Knowledge Systems (Box 1) places traditional knowledge policy squarely in the context of innovation policy and the equitable sharing of benefits.

2.2 *Innovation and intellectual property—the practical context*

Debate continues over the overall role and impact of IP protection in relation to meeting the twin goals of fostering innovation and promoting the effective dissemination of the fruits of innovation.[8] Adopting the approach of this *Handbook*, this chapter does not enter into the debate beyond pointing out that the policy context is a highly dynamic one, greatly influenced by feedback from the actual and perceived impact of the accumulated choices of IP managers. It is clear that the effectiveness of the patent system for attaining these objectives depends on its practical context, which can be addressed on three levels:

1. the regulatory and administrative level (discussed in more detail below)
2. the level of skills and capacity (As a complex policy mechanism, the patent system requires skilled operators.)

3. the level of individual users of the system: applicants, opponents, licensees, advisors, and advocates, with a special focus here on public interest users

At the regulatory and administrative level, the key elements of a practically effective system include:

- patent quality, construed here as the greatest possible convergence between actual patenting outcomes and the public interest as delineated in the principles of patent law, especially the conventional criteria for patentability
- the transparency, clarity, and predictability that effective administration provides in terms of the practical accessibility of timely patent information, the clarity of scope and title, and functional patent quality
- practical equity of access to the system, so that the skew of accessibility that favors already dominant private sector players can be reduced
- persuasive deterrents and remedies against the misuse of patent rights once granted

2.3 *System functionality and the capacity to make the system function*

In sum, much of the public welfare impact of the system and actual delivery of equity depend on system functionality—not merely on the formal legal settings that form the focus of international debate. Effective functionality depends on deploying three special skill sets:

1. The legal and policy skills required to draft and implement suitable legislation and policy mechanisms within the framework of international standards but also tailored to national needs and priorities
2. The technological know-how and legal skills required to draft patent documentation and to objectively assess the validity and legitimate scope of patents in patent examination and judicial processes
3. Technological management skills, including valuation of disclosed innovations in light of institutional goals (not just in terms of commercial value), assessment of potential technology development and dissemination pathways, and the formulation of patenting and licensing strategies

As a rough generalization, capacity-building processes in developing countries have tended to focus on each of these skill sets in turn, beginning with a top-down legislative perspective. This has been most conspicuous in the decade of the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This sequence of shifting priorities for capacity building reflects a natural evolution from a legalistic view of implementation and a reactive, or defensive, posture followed by a greater concentration on building administrative and institutional capacity,

Box 1: Traditional Knowledge and Innovation in South Africa

South Africa's Indigenous Knowledge Systems (IKS) Policy aims at "*positive synergy between South African IKS and the South African National System of Innovation*" through:

- the creation of a legal benefit-sharing framework
- the establishment of a formal recording system for IK
- legislation to ensure minimum standards in information and material transfer agreements with respect to IK research
- the promotion of IK links with the science base by means of targeted funding instruments
- amendments to patent legislation to enforce IK prior art declaration

Source: WIPO.[7]

to the current growing emphasis on strategies that practically and proactively capture direct benefits from indigenous research capacity and comparative advantage in knowledge resources. This *Handbook* is emblematic of the culmination of this last trend. But capacity building must continue on these three tracks in parallel, mutually informing and reinforcing one another, especially in the life sciences. In particular, the practical view from the bottom up should inform the view from the top down in a respectful dialogue between policy-conscious practitioner and practically informed policy-maker.

2.4 *The policy impact of effective users*

Clearly, it is the central role and responsibility of administrators to promote the effective and efficient functioning of the system as a system. But users are not just customers of the system; they function as active agents engaged in safeguarding patent quality: "users" have responsibilities as patent applicants, as patent opponents, as litigants, and as licensors or licensees. Adversarial legal processes have shaped much of the important detail of patent law. The costs and limitations of the existing administrative and legal systems have led to calls to more systematically include a user perspective on patenting outcomes.[9] The growth in life-sciences patent filings by government agencies and public sector institutions may lead to further blurring of the boundaries between administration and knowledge management within public sector agencies and to the implementation of a broader, more holistic array of innovation policy settings. Ideally, the responsibility to efficiently manage IP portfolios will be understood in relation to the broader responsibility to contribute to public policy outcomes. This extra layer of operational and ethical complexity creates a distinct challenge for the public sector IP manager. Managers of private sector IP portfolios in the life sciences may need to consider ethical and social constraints, such as professional ethics and corporate social responsibility programs, but this chapter concentrates on the public sector manager.

2.5 *The public sector IP manager as a system user*

Since the informed, judicious management of life-sciences IP is the most realistic way of boosting actual availability of vital life-sciences technologies, the public sector IP manager has fundamentally important responsibilities. IP management is a practical craft, not a rigid legal discipline, difficult to capture in terms of checklists and licensing templates. This section reviews best practice for public sector IP managers in life-sciences technologies. The discussion focuses on two broad categories of responsibility: policy-oriented, or systemic, and outcome-oriented, or practical. Experience has shown that early assumptions about the right mix of exclusivity or openness of access, and the right proportion of a reliance on public resources and an engagement of private interests, are unlikely to be effective or even defensibly fair. Public sector research programs that routinely consign publicly funded research to the public domain can attract just as much criticism as those programs that seek excessive exclusivity in the management of public-funded intellectual property. Inattentively letting research outcomes fall into the public domain can allow richer and more nimble private interests to benefit disproportionately from access to this publicly funded knowledge. Public sector IP management must therefore be viewed with a strong pragmatic, empirical perspective. Accordingly, an outcome-oriented approach to public interest IP management includes:

- promoting an in-house invention disclosure under effective confidentiality rules
- analysis of disclosures in the light of institutional objectives
- assessment of technologies against priorities, categorizing them for public domain release or defensive publication, for open licensing, for nonexclusive licensing, or for a strategic in-house focus
- review of the obstacles to the effective use and dissemination of the new technology, including resource limitations, regulatory obstacles, and constraints on freedom to operate in target markets, noting that developing countries generally have greater freedom to operate due to the relatively low levels of patenting
- formulation of strategies, and identification of potential partnerships, that aim to

bring a life-sciences innovation to targeted groups, which entails considering commercial, technological, and regulatory issues, as well as an assessment of external requirements that include background intellectual property, project management capacity, technological and manufacturing capacity, regulatory process capacity, and investment capital

- leveraging intellectual property holdings to:
  - promote the dissemination of technological knowledge
  - ensure the availability of improvements, further applications, and derivatives of licensed technology
  - secure access to regulatory data and background/platform technology
  - reserve rights for third-party use in humanitarian applications
  - reserve exclusively licensed rights in the event that licensees fail to meet public interest performance criteria (such as low-cost or cross-subsidized distribution to target markets)
  - safeguard grant-back of background intellectual property, project intellectual property, or regulatory dossiers in the event that licensees fail to meet public interest performance criteria
  - bolster institutional research capacity, through licensing fees, partnerships, access to research tools and other platform technologies

In the hands of the public sector IP manager, an IP portfolio is not necessarily viewed purely as a commercial asset, although commercial valuation and product development and dissemination will normally be essential. An IP portfolio also functions as:

- a transactional asset, used to promote, expedite, and clarify the formation of technology partnerships, and to define and structure specific contributions and expectations in partnerships
- an institutional asset, used to leverage access to necessary resources to achieve institutional goals, ranging from specific R&D expertise to research financing
- a policy asset, used to influence choices of technology partners, including private sector partners in public–private partnerships, and to promote humanitarian or cross-subsidized access to life-science technologies in developing countries or in other beneficiary groups

The public sector IP manager in the life sciences may also need to consider the public-policy expectations placed upon her or him, explicitly, implicitly, or even retrospectively. She or he should, in particular, consider the following policy-oriented or systemic responsibilities:

- influencing positive innovation patterns, promoting the effective collaboration and open dissemination of upstream research findings, both for the inherent value of the knowledge as a public good and as a means of promoting the widest possible application of upstream biotechnologies, such as research tools, diagnostic tools, and genetic modification technologies
- promoting analysis, adaptation, and uptake of practical-innovation structures that make effective use of diverse resources, such as strategic partnerships with other public institutions, public–private partnerships, and open collaborative mechanisms
- good-faith participation in the patenting process, focusing on strategic and systemic outcomes, rather than on the tactical use of the system, and actively promoting patent quality
- fostering an interdisciplinary approach to public policy formulation in the life sciences and a comprehensive view of the innovation process within the broader policy context
- promoting open licensing models for research or for humanitarian uses in public health and agricultural development programs for the benefit of developing countries

Exemplifying the crossover between policy and practice is the humanitarian licensing of

medical and agricultural research generated by universities or other public research institutions. "Humanitarian licensing" describes a range of public policy licensing strategies. These might include providing an open license to developing country technology users to sell derivative products back to commercial markets, as in the case of agricultural biotechnology. Humanitarian licensing might also mean establishing reach-through rights reserving access to derivative innovations (for example, for use in licensing early-stage pharmaceutical research). These practices may be seen as a movement to promote certain technology licensing norms, even to create de facto exceptions to patent rights in the life sciences. They might also be imagined as a suite of practical options for public sector technology managers to deploy in pursuit of institutional objectives. But the movement towards humanitarian licensing or reserving rights for humanitarian use still begs important questions at the core of public sector IP management:

- How does the deployment of exclusive rights over life-science technologies promote the public welfare, and when is deployment of exclusivity contrary to humanitarian goals (the exclusivity axis)?
- To what extent, and how, should public sector IP managers engage private interest and private sector resources to draw technologies through a demanding product development process, and when will humanitarian interest be enough to impel a product through the product pipeline (the market axis)?

See Box 2 for a recent exchange that highlights the broader range of options open to public interest IP managers who have objectives that extend beyond the simple commercialization of research.

3. PUBLIC POLICY IP MANAGEMENT IN THE LIFE SCIENCES

IP management is not an end in itself, but an essential part of a wider array of policy tools that need coordinated implementation to achieve desired outcomes. The efficiency and effectiveness of IP management needs to be measured against broader objectives, including its ability to complement innovation policy and public investment in R&D infrastructure. Optimal use of intellectual property in the life sciences requires a well-managed IP system, clear policies about the ownership of intellectual property generated by the public sector or from public sector inputs, adequate R&D resources and infrastructure, technology transfer centers at universities and other research institutes, and mechanisms to bring research outcomes to the market. We focus on three elements in particular:

1. Setting the regulatory and policy framework
2. Building functioning public institutions
3. Managing public–private partnerships

3.1 *The examples of Jordan and Indonesia*

3.1.1 *Overview*

This section reviews information gathered in field interviews with practitioners in biomedical innovation in two disparate developing countries: Jordan and Indonesia. Despite fundamental differences in size, structure, resources, and geopolitical context, Indonesia and Jordan have both set up IP strategies to promote the social benefits of domestic biomedical innovation. The countries have sought the right institutional framework to link IP policy and IP management for the advance of public welfare. Indonesia is the fourth most populous country in the world and, after Brazil, is host to the greatest range of biodiversity worldwide. Jordan, with four million inhabitants, is a relatively small country with little biodiversity, few natural resources, and no oil reserves. Both countries have strong potential for biomedical innovation. Indonesia's opportunities are linked to the natural medicines market. Jordan's pharmaceutical industry is the country's second largest export earner, after textiles.

Jordan's pharmaceutical industry is making a structural shift from focusing solely on generic manufacturing to promoting biomedical innovation. Six out of 12 Jordanian pharmaceutical

Box 2: Alternatives to Commercialization in Public Sector IP Management: Four Points of View

According to Tom Ogada, who is responsible for putting in place a formal policy for dealing with IP issues at Moi University, "*an institutional IP policy serves to promote the generation, protection, and commercialization of IP rights. Universities and R&D institutions are key generators of IP assets, but there are many stakeholders involved in the process—researchers, students, private sponsors, technology transfer units, national patent offices, the public, and so on. An IP policy is needed to harmonize the conflicting interests of the various stakeholders.*" Thus, a university's IP policy should aim to "*create an environment that encourages and expedites the dissemination of new knowledge for the greatest public benefit, while protecting the traditional rights of scholars to control the products of their scholarly work. It should ensure that the financial or other benefits of commercialization are distributed in a fair and equitable manner that recognizes the contributions of the inventors and the institution as well as other stakeholders. It should promote, preserve, encourage, and aid scientific investigation and research. It should sensitize students to IP and tap the creativity of the young. It should create incentives for researchers to conduct research and provide rewards for intellectual capital. In developing country universities, it should also stimulate research efforts to find solutions for pressing problems, such as medicines, clean water, and energy.*"

Dana Bostrom, Industry Alliances Office, University of California, Berkeley, adds that "*most university technology transfer offices do not have a primary goal of revenue generation. Professor Ogada captures the goals of technology transfer well, including: promoting the dissemination of knowledge, and assuring stakeholders that risks, benefits and credit are distributed equitably. The Association of University Technology Managers (AUTM) does not tend to use revenue generation as an indicator of benefit. Rather, [AUTM] uses information about how the university distributes revenue received under licenses to benefit the university community; how products which are brought to market benefit everyone; and how innovative, university-led licensing programs can push an industry or technology forward (among other measures). A blanket give-it-away approach, on the other hand, usually benefits large companies, who are able to create and patent improvements to the "free" intellectual property more rapidly than other organizations or individuals. For developing economies, or early-stage technology of all kinds, "free" can come with a heavy cost. Although free intellectual property can still achieve the best outcomes for everyone, this strategy is best determined on a case-by-case basis. Without resources to sustain a free commons, often only those with resources can benefit from what was released. More than* 500 *new products became available last year as a result of licenses from U.S. and Canadian academic technology transfer efforts. More intangibly, universities benefit from the interaction with companies, to see how academic thinking and solutions can be applied to commercial problems. Ironically, universities also benefit from our academic community's greater awareness of intellectual property; we live in a world where intellectual property plays a greater role, and companies, in their interactions with universities, demand greater accountability. Ultimately, universities are increasingly being asked to demonstrate to their community the benefit they provide in the knowledge economy.*"

Gavin Moodie, Principal Policy Advisor at Griffith University, Australia, notes that "*the fundamental question for a public university's IP policy should not be: 'How can the commercial potential of the property be maximized?' but 'How can the transfer of new ideas be maximized?' Commercializing intellectual property is only one way—and often the worst way—to transfer new ideas. Concentrating on commercializing intellectual property encourages universities to overvalue their property, leading to protracted negotiations using lawyers and other intermediaries, which frustrates rather than facilitates the free flow of ideas necessary for research and innovation to flourish. Revenue from licensing intellectual property in fields other than biotechnology is a trivial*

(Continued on Next Page)

Box 2 (continued)

proportion of university revenue. And, of course, licensing revenue isn't all surplus or "profit"—with their business development managers, IP lawyers, and accountants, commercialization units are very expensive. They also impose heavy indirect costs on researchers who must explain their research and its implications to intermediaries. Joshua B. Powers reported in The Chronicle of Higher Education (September 22, 2006) that more than half of U.S. universities consistently lose money on technology transfer. And as the Australian policy and management consultant John Howard observes, researchers and research organizations will, except in very rare situations, earn more from being paid for their work input in contracts and consultancies than from licenses and royalties flowing from intellectual property or from income earned in spinout companies. I therefore suggest that—with the exception of biotechnology—public universities simply give away most intellectual property as a contribution to the general good. This could be subject to universities including in their IP licensing agreements a standard "blockbuster" or "jackpot" clause that provides that should their intellectual property contribute to blockbuster revenues of, say, $50 million over 10 years, there would be a sharing of revenue determined by a nominated commercial arbitrator."

Bernardo Marcos Diez, Secretariat for Technology Transfer (New Technologies Research Group), Faculty of Law, Universidad Nacional de Mar del Plata, Argentina, advised that the Governing Council of the University had "*recently approved a regulation which defines the scope, players, and procedures regarding the protection of any intellectual creation resulting from scientific or cultural research carried out within the university and/or with third parties. We have adopted an active IP awareness policy to reach those involved in this process, from the researchers, teaching staff, and students, to members of the decision-making bodies. We are running conferences in the different academic units in order to explain the objectives, implications, and advantages of IP protection, as well as of technology transfer between the university and external social/commercial milieu. We have also applied to join the WIPO University Initiative in order to appoint a coordinator and benefit from relevant IP reference materials. So we are in the early phase of what will be a lengthy process, but one which, it is already clear, will bring economic, scientific and developmental benefits, not only to our university, but also to our broader society.*"

Source: WIPO Magazine.[10]

companies have now developed patent portfolios, several of which are potential blockbusters (remarkably, until recently most of these companies made no use at all of the patent system). Indonesia is taking several measures to bolster its overall innovation strategy. It is, for instance, promoting awareness among public research institutions and the private sector of the opportunities in the natural medicines market. This market offers annual growth rates as high as 20%.

These countries are steadily increasing their IP holdings on indigenous research activities, particularly in the critical areas of the life sciences: medical and agricultural research. As they do, broad public interest issues arise. How can or should private firms be encouraged to manage their IP holdings to contribute optimally to national social and economic development? Additionally, how can public sector or public-funded IP estates be best managed to safeguard the public interest by capturing and equitably distributing the benefits of innovation? Finally, what broader institutional settings are needed to bolster public welfare outcomes from research? A public interest IP management perspective can help technology transfer centers at public research institutions find answers to these questions. Additionally, effective IP management encourages public–private partnerships that address humanitarian goals, in particular, the creation of affordable new medicines.

The experiences of both Indonesia and Jordan illustrate the broader need for appropriate domestic institutional settings in order for the countries to be able to reap the benefits of biomedical innovation. Their experiences of Indonesia and Jordan also reveal the importance of the interplay between investment in institutional infrastructure and the more diverse and tailored approaches to managing intellectual property within a public interest paradigm. The discipline of IP management has focused on the needs of firms. However, the high level of public concern with capturing public benefits from life-sciences research underscores that countries, and public sector institutions, also need to make strategic decisions about the deployment of intellectual property on a broader base than the traditional focus of private firms.

3.1.2 *Setting the regulatory framework*

IP law and practice cannot be viewed in isolation from the broader regulatory context. This is especially true in the field of life sciences, which is concerned with needs as basic as health, food, and the environment. Public interest IP management in biomedical innovation therefore needs to reconcile public health needs with commercial goals, ideally helping to harness private sector resources to achieve public welfare outcomes.

Indonesia and Jordan have effective IP legislation in place, and both have undertaken extensive legislative programs to bring their laws into compliance with the TRIPS Agreement. Indonesia also adhered to the PCT in 1997, and Jordan has entered a bilateral trade agreement with the United States, which has implications for Jordan's IP laws. In both countries, IP policy has been developed in an interdisciplinary way, as part of a broader public policy mix, rather than as a narrow, specialized discipline. Jordan's Ministry of Planning is responsible for coordinating public policies regarding innovation, and for measuring Jordan's global competitiveness in achieving this goal. Jordan's main innovation policy, King Abdullah II's Vision 2020, proposes the strategic use of IP mechanisms to achieve society's goals. Likewise, Indonesia coordinates intellectual property across policy portfolios, in cooperation with the Ministry of Research and the Directorate General of Intellectual Property, which screens research grants given to public research institutions and conducts patent searches, supplementing the conventional literature review. Indonesia also provides funding to patent applicants to make patent protection more affordable to local companies and public research institutions, which is one way to address the issue of practical equity in access to the IP system.

Jordan is reviewing possible legislative initiatives regarding the management of intellectual property generated in public institutions. Indonesia has passed laws that give ownership over intellectual property generated within public research institutions to the institutions

themselves. This regulatory measure has been accompanied by the establishment of technology transfer offices (TTOs). Ten TTOs were created throughout the country with modest start-up capital. The offices have confounded some expectations by establishing successful business operations in recent years. The Technology Institute of Bandung, for example, has struck international licensing agreements and research collaborations with local companies that are actively seeking to meet local needs. One public-private partnership resulted in the development of a new machine for harvesting local agricultural crops.

3.1.3 *Building accountable and effective public institutions*

The benefits of the regulatory framework will depend on establishing public institutions that are both accountable to the public and effective in serving it. These obligations go beyond the traditional institutional objectives of IP offices concerning administration of the patent system. Their responsibilities broaden into a wider policy role in the knowledge economy. IP mechanisms are actively harnessed to promote the overarching public interest. In both Indonesia and Jordan, the IP office reports to the ministries responsible for commerce and industry. This helps align IP policy with the countries' overall economic and trade policy objectives. As in all countries, there are important choices to be made between the value of administrative independence, self-sufficiency and direct accountability to political masters, and the benefits of linkages to a major policy ministry that can encourage high-level political attention to IP policy-making. In both Jordan and Indonesia, the IP offices focus on the operational challenges of using limited resources to serve diverse stakeholders. The two offices differ in size: Indonesia currently deals with a higher patent filing rate (4,303 applications in 2005); it was reported that Jordan had 200. But Indonesia confronts a problem experienced in many developing countries–that of finding and retaining suitably qualified technical staff to deal with the increasingly complex field of life sciences, effective examination capacity being one important safeguard of patent quality.

3.2 *Managing public–private partnerships*

Life sciences R&D is often characterized by upstream, or basic, research conducted by public sector or academic researchers. Public sector institutions then depend on the private sector to take life-sciences innovations through the development pipeline to yield finished products. Thus, life-sciences innovation pathways are increasingly characterized by an array of public–private partnerships. Those conducting early research and those investing in the product development phase will naturally have different approaches to the relationship. But because life-sciences research has such a strong public interest element, close attention has been paid to how to manage intellectual property for specific public interest outcomes. Public sector research institutions are learning to pursue the option of leveraging their IP holdings to ensure adequate returns from public investment in research, whether those returns are conceived in terms of narrow financial benefits or broader social ones. And public sector IP managers are trying to ensure that promising innovations are not left on the shelf for want of practical mechanisms to garner the necessary resources—finance, expertise, regulatory approval capacity, product development, and manufacturing know-how. TTOs, situated within universities, have also discovered the dual goal of helping to meet humanitarian needs and to mediating between academics and the market, which ultimately may determine a society's capacity to nurture innovation based growth.

The interaction between the public and the private sector in health innovation can result in philanthropic achievements that also satisfy business interests. Successful examples of this in the field of public health include the Medicines for Malaria Initiative, the Drugs for Neglected Disease Initiative, PATH, One World Health, and the Bill and Melinda Gates Foundation.

Publicly funded innovation provides an additional mission and incentive system for businesses. A tension is usually perceived to arise between research and development. Research is often guided by the search for new insights; market interests are generally of secondary relevance. In development, however, the market is

the defining element, since the substantial costs and risks associated with the development of new products and services can often only be justified by expected earnings.[11] Currently, research tends to be concentrated in the public sector, whereas development is most often left to business. The relationship between research and development is usually mediated by the protection and subsequent exchange of intellectual property between the public and private sectors. This means that it is crucial to establish equity and negotiating symmetry between these sectors, bridging between distinct sets of goals and cultural settings. By using the IP system, public research institutions avoid giving away valuable knowledge without maintaining some leverage over how it is developed and disseminated, and without securing an adequate return, whether that return is in the form of money or social return. In this way, intellectual property provides a mechanism to achieve equity with the private sector.

Motivating researchers to patent innovation judiciously is an essential part of participating in the IP system, and institutions need to raise awareness about the necessity and advantages of an active but selective patenting strategy. Incentive structures for academics often help to pave the way from the research lab to the TTO. One way to achieve this is to allow academics to generate additional revenues from consulting agreements, royalties, and licensing agreements. Clearly, this should not provide businesses the opportunity to dictate the research agenda of public research institutions, nor should it compromise the fundamental freedom of research. Institutional policies need to protect these values. Nevertheless, relaxing the institutional restrictions on the interaction between the public sector and business in health-related innovation might allow public research to generate new questions and find alternative approaches to a subject. Engagement in product development in health-related innovation has proven to be a valuable experience that enhances the quality of basic research. Faculty, for example, might develop innovative insights while resolving problems encountered in industrial consulting. Mansfield found that coauthorship by industry and academics increased the overall research productivity in health-related innovation, concluding that such activity can bring a new sense of urgency and reality to the public sector.[12] In Sweden, for example, 10% of articles on health-related innovation are coauthored by scientists working in the private sector.[13] Government funding for such exchanges can provide a useful push to such initiatives. Austria illustrates how such a program can operate. In Austria, academics have the opportunity to spend a year or two in a company and then return to their university. They are guaranteed their post and granted funding for the exchange.

To obtain the best outcomes for public health, researchers and institutions must understand the value of intellectual property, communicate the worth of their intellectual property to potential trading partners, negotiate attractive licensing agreements, and enter agreements that will generate appropriate returns. IP management comprises several components, including the prioritization and identification of research targets, decisions as to whether and which form of IP protection to seek, and methods to gain the attention of prospective investors/buyers of the product.

Technology transfer centers within public research institutions fill an important role in securing IP rights. They help researchers understand the need for intellectual property, give support in the application for IP protection, and help to transfer research results to the market. As in many other developing countries, the staff at these centers needs IP management training. In fact, a train-the-trainers program is often needed to enhance IP management competencies. An exchange with IP management centers in the developed world may, in this context, be beneficial.

To accomplish all of this, researchers and public institutions need to identify potential licensees, facilitate research collaboration, pool patents, and avoid unnecessary duplication. Other ways of encouraging public–private partnerships include commissioning research projects, operating joint research studies, financing doctoral studies with industrial laboratory funds (with due regard to the needs of the doctoral student to publish results), encouraging faculty consulting work,

and creating spinout companies. Establishing research clusters, in which public and private sector researchers and institutions work on common research projects, provides opportunities to exchange both tacit knowledge (know-how) and formal knowledge (such as publications and patents). Through the provision of a clear, transparent regulatory framework and publication of basic research, anticompetitive problems can be avoided.

From a health-equity point of view, the effectiveness of licensing agreements will depend on the conditions negotiated in these agreements and the overall innovation market. Licensing can lessen competition and raise anticompetition issues, even when there is no cumulative aspect. Exclusive licensing arrangements may hamper public health if the cost reduction of one market participant forces competitors to exit the market, or if the licensing agreement facilitates collusion.[14]

Indonesia and Jordan both report positive experiences with public–private partnerships in biomedical innovation. Indonesia has developed an excellent framework for public–private partnerships. The Indonesian Science Foundation (LIPI) may be taken as a best practice example of public interest IP management. LIPI provides IP courses for its researchers, has developed its own in-house IP policy, and manages an active technology transfer center that has already issued several licenses. LIPI has also entered into alliances with research institutions abroad, such as the Max Planck Institute, with whom jointly generated intellectual property is jointly owned.

Technology transfer centers in Indonesia are attached to research institutions, such as public universities or research organizations. These technology transfer centers use different names, such as Gugus HaKI (IP Units), Sentra HKI (IPR Centers), Klinik HKI (IPR Clinics), IPR Management Office, or IPR, and Licensing Office. With the exception of the Eijkman Institute, all major public research institutions dealing with biomedical innovation have their own technology transfer center. The extent of the activities carried out by these centers varies from the most advanced, which provide assistance on IP licensing agreements, to those that assist primarily with applying for IP protection or helping raise awareness about intellectual property among researchers. The statutes of Indonesia's technology transfer offices suggest very clearly that intellectual property held by public institutions should be licensed under a public interest paradigm.

In Jordan, there are several examples of faculty–private sector biomedical R&D collaborative projects, but the emphasis so far has been on research led by the private sector. Discussions reportedly continue regarding a suitable framework for the ownership of innovation created in the public domain. The Royal Scientific Society of Jordan has an applied, rather than a research, orientation.

Jordanian universities do not have TTOs to administer patent applications or negotiate licensing agreements. However, companies increasingly refer to universities as subcontractors for specific biomedical tests. So far, the universities provide skilled labor and conduct some basic research. These activities appear to promise more institutionalized partnerships and the beginning of a relationship between academia and the private sector.

4. CONCLUSIONS: RECONCILING POLICY AND PRACTICE

4.1 *Exclusivity or inclusion: public or private interest?*

The long history of patent law and patent policy has been a dynamic record of attempts to reconcile two complementary goals:

1. The promotion of innovation by directing resources toward beneficial research and development
2. The practical and equitable availability of the fruits of innovation

Public interest IP management in the life sciences is itself a search for practical means of achieving these twin goals. It seeks first to garner necessary resources and then to focus them on finding technological solutions to neglected needs in the public health and agricultural domains. The tangible and intangible resources required for IP development include know-how, research, and product

development capacity, clinical or field trial expertise, regulatory infrastructure, background/platform technologies, and the investment of public and private capital. IP management strategies will be effective if they help to apply these resources toward unmet needs. This requires finding these resources via new private resources (such as incentives and market interventions) and via new public resources (additional funding and infrastructure development). IP managers must also work to better apply existing resources by leveraging access to technologies and by drawing on private sector development skills and R&D infrastructure, indigenous research and innovation capacity, and traditional medical knowledge.

It is tempting to argue that the traditional conception of two distinct public and private spheres in the life sciences is breaking down. But it is more accurate to characterize it as a form of evolution, a broadening of the scope of interaction, and the creation of a far-broader policy canvas that can accommodate more geographical, cultural, and economic diversity in the use of the patent system. Figure 1 (see section 1.2 above), as discussed earlier, illustrates the options for IP management in pharmaceutical product development. The figure illustrates how workable mechanisms for bringing new biomedical innovations to the public may require (1) a range of strategic choices to engage or eschew market mechanisms to various degrees in order to secure the necessary resources and freedom to operate, rather than electing a wholly "public" or "private" technology development and dissemination model, and (2) deployment of exclusive rights afforded by IP protection to greater or lesser degrees of exclusivity and openness, ranging from direct exclusive exploitation or exclusive licensing, through a range of options of decreasing exclusivity, to simple public-domain disclosure.

Though it may seem counterintuitive, some public sector technology-development strategies may require exceptional degrees of exclusivity. This may be useful, for example, when seeking access to a private sector compound library or when negotiating access to an existing regulatory dossier. In contrast, as the SNP consortium (single-nucleotide polymorphism) and the human genome project have demonstrated, private sector players may see commercial advantage in deploying nonexclusive IP management structures, particularly for technologies that are considered precompetitive. No single template is likely to be anything but an indicative guide or catalog of options. Ultimately, good practice is good policy: the same exclusive right may be viewed very differently if it is held by a private firm, by a public sector agency, or by a private charity. Equally, the exclusive right will be viewed very differently depending on how it is deployed in practice.[16]

4.2 *Fostering interdisciplinary IP policies*

Indonesia and Jordan provide complementary and contrasting examples of the role of judicious institutional settings in promoting investment in life-sciences research, tailored to the social and economic needs of developing countries. A country's capacity to set up an effective institutional framework for public-interest-minded intellectual property is the decisive factor. Used in an effective, informed and judicious manner, it creates a positive link between the exercise of exclusive commercial rights and a fairer distribution of the benefits of technological advancement, with strategies carefully tailored to a country's level of wealth or economic development. ■

DISCLAIMER

This chapter does not represent the views of WIPO, its Secretariat or its Member States, and is intended to provide only technical-level contributions to assist in the review of options for public sector IP management in the life sciences.

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Developing Countries and TRIPS: What Next?

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ABSTRACT

This chapter provides an overview of the current and potential impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on low- and middle-income countries. The chapter also summarizes the findings of a meeting in New Delhi, India and explores the legitimacy of concerns about TRIPS. Access to health products relies on many factors, including the successful innovation of new technologies. Innovation, in turn, is a complex process, involving many factors (intellectual property [IP] is just one) that influences product availability and price.

Pointing to the growth of global and national public–private product-development partnerships (PDPs), the chapter highlights one way these countries are seizing opportunities—and reveals how important effective IP management has become for them. Focused on high-priority diseases such as AIDS, malaria, and TB, PDPs require the development and implementation of sophisticated IP management policies and practices in both developed and developing countries in which PDPs operate. Finally, the chapter discusses the possible role of compulsory licensing and parallel trade. The value of these flexible options, provided by TRIPS, is yet undocumented and successfully implementing them represents a significant challenge. Crucially, countries have considerable freedom to control the effects of TRIPS on the availability of new health technologies. The countries can do this most effectively by building capacity for IP management and by formulating policies and practices, for courts, patent offices, and other institutions, that favor the poor.

1. BACKGROUND

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under WTO (World Trade Organization), mandates a minimum set of IP (intellectual property) protection for patented pharmaceutical products. TRIPS raises questions about how new global standards for patent protection will affect innovation, R&D investment, and product availability, especially for developing economies with significant innovative capacities in health R&D (such as Brazil, China, India, and South Africa). To explore these issues, the Indian Council of Medical Research (ICMR), in India, and the Centre for Management of Intellectual Property in Health Research and Development (MIHR), based in the United Kingdom, convened an international meeting in New Delhi in December 2005, titled "Living with TRIPS: Innovation of New Health Technologies for the Poor." This chapter summarizes the findings of that meeting. A full report has been published elsewhere.[1]

Attention has focused on India because of its established strengths in generic-drug production, large prospective market for low-cost medicines, and potential cost advantages as an R&D base for multinational firms. These factors make India a bellwether for gauging the impact of TRIPS on health-product innovation and access. Vigorous debates in India and elsewhere

Eiss R, RT Mahoney and K Satyanarayana. 2007. Developing Countries and TRIPS: What Next? In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

preceded the implementation of TRIPS, and it is timely to follow up on some of the questions raised in that debate. Will TRIPS lead to monopolies on new drugs where, previously, imitation was possible? Will TRIPS encourage foreign investment for the health industry or create external constraints? Will TRIPS lessen interest, by developing country firms, in diseases of the poor where markets are uncertain, or will it motivate the development of innovative drugs against priority diseases in these countries? And will international product-development partnerships (PDPs) that are now generating a pipeline of drugs for poverty-related diseases find it easier to form partnerships with institutions and emerging suppliers in developing countries?

2. PUTTING TRIPS IN CONTEXT

Conclusively documenting the benefits or costs of TRIPS for developing countries may be impossible. Innovation is a dynamic process influenced by many external variables. These include the level of government support for science and technology, government programs to promote trade, the capabilities of national drug-regulatory agencies, and government efforts to enhance competencies in these and other areas. Despite the difficulties of measuring the effects of TRIPS, we can at least point to historical precedent, which suggests that strengthening intellectual property will increase foreign direct investment and flows of technology transfer, as long as essential preconditions exist (namely, supportive R&D environments, effective judicial systems to enforce patent law, and viable domestic and export markets). And while definitive measurements cannot be obtained at this time, it is possible to determine the most important trends to measure.

Perhaps the most controversial issue surrounding TRIPS is its impact on the price and availability of new medicines. If patents are obtained and enforced in developing countries, TRIPS could reduce the availability of copies of patented medicines, thus adversely affecting a de facto price control on medicines in these countries. The manufacture of products that were unprotected by patents led to competition that played a key role in determining prices for HIV antiretrovirals in Brazil, India, South Africa, and other countries.

Accordingly, the price effects of implementing TRIPS should be monitored closely, both in countries with strong generic industries and in countries relying on imports of generic substitutes. But there are other underlying structural impediments to *access* besides price. These include the equity and efficiency of health-care financing and drug/vaccine distribution systems, the availability of evidence-based analysis to improve current practice, and local community involvement. An instructive and often-cited example of delivery failure is the uneven access to medicines on the World Health Organization's (WHO's) list of essential drugs, of which less than 5% are on-patent. To accurately measure access requires carefully considering the historical and social contexts of drug delivery.

Apart from the potential effects of patents on post-TRIPS pricing and availability, the comparative therapeutic benefits of new chemical entities over available generics will have health implications. So, in assessing TRIPS over time, the rate of pharmaceutical innovation will be a key variable in measuring the health impact of strengthened patent regimes.

IP management skills will need to be developed so that TRIPS can be adapted to a nation's advantage. Developing countries that choose to invest in science and technology must, of necessity, address IP issues to participate in the international marketplace. IP competencies will enable these countries to gain access to emerging tools, technologies, and resources. Indeed, an acute need exists to establish policies and procedures and to train staff in effectively managing intellectual property. Priorities include training in contract negotiation, statutory protection, patent searching and filing, technology valuation and business strategy development, as well as the development and implementation of IP policies and strategies at the institutional level, especially within public research institutions and universities. To provide the most useful and most accurate information, evaluations of the costs and benefits of TRIPS should consider investments in capacity building as an important variable.

3. EMERGING STRATEGIES TO REACH THE POOR

Assessing the implications of TRIPS for the development of new products to treat diseases of poverty is difficult. Technology transfer and innovation, in general, are strongly viewed as ways to strengthen an economy; clearly, however, emerging pharmaceutical industries can do more than generate new knowledge, skilled labor, and markets. These industries can address social objectives by developing health-related products to meet local needs. But will the emerging pharmaceutical industries in Brazil, China, India, and elsewhere become sources of new medicines for diseases that disproportionately affect low- and middle-income nations? Early evidence suggests the answer is no. Pharmaceutical firms in India are focusing globally, exploiting their strengths to develop or improve therapeutic drugs for well-characterized medical conditions that exist in robust global markets. For example, based on projected sales growth, Ranbaxy Laboratories aspires to increase its percentage of revenue from sales to member countries of the Organisation for Economic Co-operation and Development (OECD) from 20% in 2000 to 70% in 2007 (presentation at investors conference in Mumbai, September 2004).

The public sector predominantly remains responsible for promoting the development of new technologies to meet local needs. For example, the government of India is addressing this task by promoting investment in drug development through several innovative schemes, such as increased R&D tax benefits and subsidies to support industry–university partnerships. The New Millennium Indian Technology Leadership Initiative, for example, supports local technology partnerships between publicly supported R&D institutes and industrial companies. Among health-related activities, the program supports the development of new targets, drug delivery systems, bioenhancers, and therapeutics for latent mycobacterium tuberculosis to better manage India's high disease-burden of tuberculosis. Researchers are also working to identify gene-based drug targets for prevalent cancers in India. The program may serve as a model for supporting local public–private partnerships in other regions, especially as firms seek academic ties to enhance their R&D base in drug discovery. Importantly, when the public sector invests in product development, it can control the intellectual property to help benefit the poor (for example, by setting conditions for how the covered technology is to be distributed or marketed).

Equally important, the new global IP standards have emerged just as public–private product-development partnerships (PDPs) are pioneering creative forms of IP management. PDPs use intellectual property as a negotiating tool for developing high-quality, affordable therapeutics and vaccines for diseases of the poor. For example, the Medicines for Malaria Venture (MMV) has formed technology partnerships to develop an artemisinin-derived lead compound for malaria. In explaining the success of the partnership, MMV points to its pragmatic approach to collaboration with the private sector, an approach made possible by the effective identification and management of intellectual property. Indeed, each PDP must adapt its IP strategies to the contributions of its public sector and industrial partners. Nonetheless, PDPs share the common goal of constructing deals that both provide incentives to the private sector and meet the social objectives of the public sector. These deals are achieved through negotiated agreements on territorial markets, pricing structures for public and private markets, or field of use, among other areas. The synergistic relationships of PDPs are represented in Figure 1.

4. TRIPS AND PUBLIC-HEALTH SAFEGUARDS

TRIPS also raises issues related to compulsory licensing and parallel trade.[2] These public-health safeguards are provided under the TRIPS agreement and were reinforced by the Doha Ministerial Conference. In December 2005, the WTO Council permanently adopted a key policy on compulsory licenses that had existed as a waiver since 2003. The waiver has significantly improved the ability of developing countries without manufacturing capabilities to import patented drugs from sources other than the originator company.

The waiver will become a formal part of the agreement after WTO members ratify it.

Production under compulsory licenses, however, presents some operational challenges. First, companies need to secure adequate know-how from the original manufacturer, or from elsewhere, to recreate products. Second, the products must reach markets that are large enough to enable compulsory licensees to recoup development and production costs. While compulsory licenses are potentially beneficial tools, developing countries can use other ways to help ensure that intellectual property does not create barriers to access. These include both conventional licensing arrangements and, notably, the enactment of laws to permit and regulate the government's use of patented inventions. Other options include the actions of patent courts to protect the public interest, the thoughtful management of genetic resources and traditional knowledge, and the judicious framing of competition law and policy.

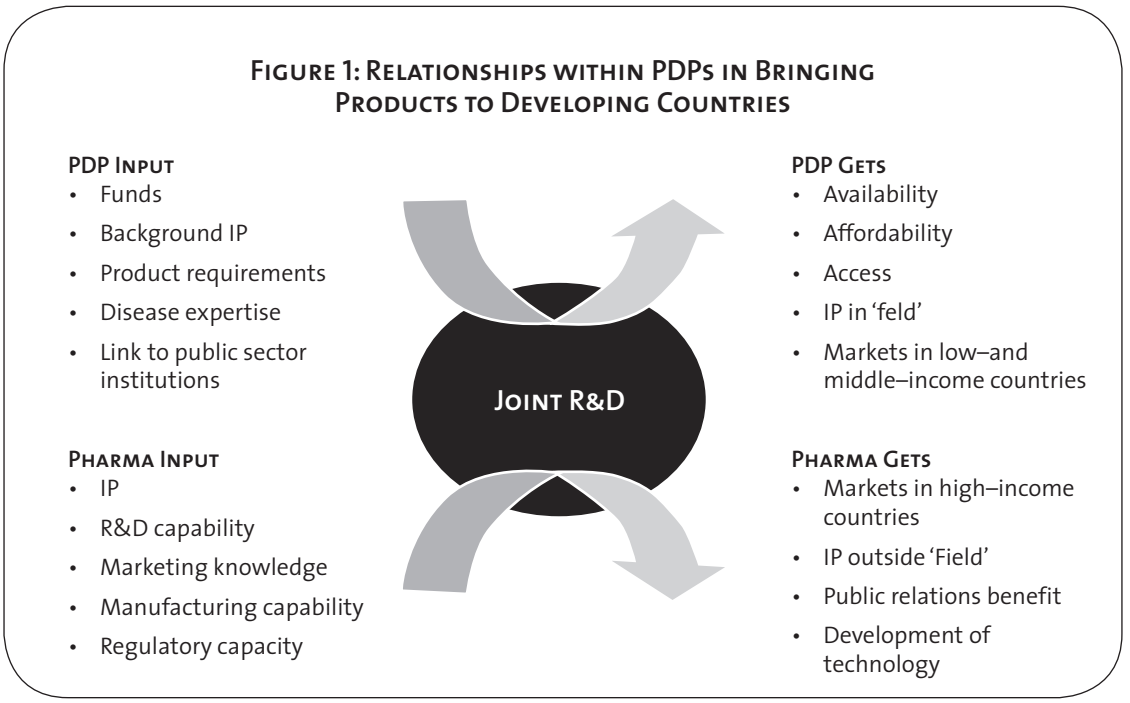
In sum, the international IP standards mandated by TRIPS allow member nations considerable discretion to enact laws and provisions that both meet treaty obligations and support national innovation policies and development priorities.

5. CONCLUSIONS

Issues discussed at the New Delhi conference and the analysis of those issues, presented in this chapter, have raised important considerations for countries adapting to the TRIPS Agreement:

- Intellectual property is one of several innovation determinants in health R&D; when assessing impact, intellectual property must be considered in the context of other competencies.
- Creatively managed, a global IP regime can be used in the public interest to improve the access of poor populations to new medicines and public health interventions.
- Countries aspiring to use TRIPS to national advantage must build institutional IP capabilities and policies in order to participate in the global marketplace and benefit from emerging technologies.
- TRIPS enables countries to establish national patent policies and practices that both meet treaty obligations and address national economic needs and social values. ■

Figure 1: Relationships within PDPs in Bringing Products to Developing Countries



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The TRIPS Agreement and Intellectual Property in Health and Agriculture

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ABSTRACT

This chapter sets out the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as related to intellectual property in health and agriculture and the policy work done in the World Trade Organization (WTO). The first part focuses on matters related to public health, including the protection of patents and undisclosed information. An overview is given of the three key instruments addressing the flexibilities available to Members of the WTO: the Doha Declaration on the TRIPS Agreement and Public Health, the Decision on the Implementation of Paragraph 6 of this Declaration, and the Protocol amending the TRIPS Agreement. The second part looks into TRIPS provisions relevant to agriculture and sets out the issues reviewed in the Council for TRIPS with respect to optional exclusions to patentability and the protection to be given to plant varieties. The second part also addresses work related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), including the suggested introduction of a disclosure requirement into the patent system, as well as the protection of traditional knowledge. In addition, two issues relating to geographical indications are taken up, namely, the ongoing negotiations on the establishment of a multilateral register of geographical indications for wines and spirits, and the extension of the higher level of protection currently available for wines and spirits to other products. To complete the picture, the third part discusses WTO programs aimed at enhancing capacities in the developing world with respect to the TRIPS Agreement.

1. INTRODUCTION

This chapter describes provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the policy work done by the World Trade Organization (WTO) with respect to intellectual property (IP) in health and agriculture, as of July 2006. The chapter discusses WTO programs aimed at enhancing capacities in the developing world with respect to the TRIPS Agreement.

The WTO came into existence in January 1995. Its 149 current Members account for over 97% of world trade, and around 30 other countries are negotiating membership. Decisions are made through the consensus of the entire WTO membership, and the TRIPS Agreement applies to all Members.

The TRIPS Agreement establishes minimum levels of protection that each government has to provide to the IP of fellow WTO Members. By establishing these minimum levels, the WTO seeks to strike a balance between the long-term benefits and possible short-term costs to society. Society benefits in the long term when IP protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain. The Agreement contains provisions enabling governments to reduce short-term costs (for example, through various exceptions to the rights conferred). The WTO's dispute settlement system is available to resolve disputes between WTO Members about compliance with TRIPS rules.

Watal J and R Kampf. 2007. The TRIPS Agreement and Intellectual Property in Health and Agriculture. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

The Agreement covers five broad issues[1]:

- how basic principles of the trading system and other international IP agreements should be applied
- how to give adequate protection to IP rights
- how countries should provide for those rights to be adequately enforced in their own territories
- how to settle IP disputes between Members of the WTO
- how to accommodate transitional arrangements during the new system's introduction

2. RELEVANT PROVISIONS OF THE TRIPS AGREEMENT

The TRIPS Agreement requires Member countries to make patents available for all inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness, and industrial applicability. The Agreement also requires that patents be available and patent rights enjoyable without discrimination as to the place of invention or whether products are imported or locally produced (Article 27.1). Although many aspects of the TRIPS Agreement could potentially bear on health or agriculture, the sections on patents, test data protection, and geographical indications are perhaps the most relevant.

There are three permissible exclusions from patent grant. One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions that are dangerous to human, animal, and plant life or health or that are seriously prejudicial to the environment. The use of this exclusion is subject to the conditions that the commercial exploitation of the invention must also be prevented and that this prevention must be necessary for the protection of *ordre public* or morality (Article 27.2).

The second exclusion is for inventions that are diagnostic, therapeutic, and surgical methods for the treatment of humans or animals (Article 27.3(a)). The final exclusion is for inventions that are plants and animals (other than microorganisms) and essentially biological processes (other than nonbiological and microbiological processes) for the production of plants or animals. However, any country excluding plant varieties from patent protection must provide an effective sui generis system of protection. Moreover, the whole Provision is subject to review four years after the Agreement comes into force (Article 27.3(b)).

A product patent must confer the following exclusive rights on the right holder: making, using, offering for sale, selling, and importing the patented product. Process patent protection must give exclusive rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28). Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties, as well (Article 30). Finally, the term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (Article 33).

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1). If the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood that the protected process was used are met (Article 34).

Compulsory licensing and government use without the authorization of the right holder are allowed, but they are subject to conditions

aimed at protecting the legitimate interests of the right holder. Mainly contained in Article 31, these conditions include the obligation not to, as a general rule, grant such licenses unless an unsuccessful attempt has been made to acquire a voluntary license on reasonable terms and conditions within a reasonable period of time. The requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the license, must also be observed, as must a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. Another important condition is that such use must be made predominantly to supply the domestic market. Some of these conditions are relaxed when compulsory licenses are employed to remedy practices that have been established as anticompetitive by a legal process or in cases of emergency or public noncommercial use.

The TRIPS Agreement also contains provisions to protect undisclosed information. The Agreement requires that a person lawfully in control of such information must have the possibility of preventing it from being disclosed to, acquired by, or used by others without his or her consent in a manner contrary to honest commercial practices. "*Manner contrary to honest commercial practices*" includes breach of contract, breach of confidence and inducement to breach, as well as the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition (Article 39.2). In addition, undisclosed test data and other data that governments require to be submitted as a condition of approving the marketing of pharmaceutical or agricultural chemical products that use new chemical entities must be protected against unfair commercial use. Members must also protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use (Article 39.3).

For the purposes of the TRIPS Agreement, geographical indications identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin. The TRIPS Agreement requires a standard level of protection to be available for all geographical indications (Article 22). In essence, interested parties must have the legal means to prevent geographical indications from being used to mislead the public or in a way that constitutes unfair competition. Article 23 provides a higher level of protection for geographical indications for wines and spirits: subject to a number of exceptions, they have to be protected even if use would not cause the public to be misled or constitute unfair competition. Information supplied by Members shows that countries employ a wide variety of legal means to protect geographical indications: ranging from specific geographical indications laws to trademark law, consumer protection law, and common law. The TRIPS Agreement and current work in the WTO's TRIPS Council takes account of that diversity.

In some cases, however, geographical indications do not have to be protected or the protection can be limited. Among the exceptions that Article 24 allows are: continuous use of the geographical indication for at least 10 years preceding 15 April 1994 or in good faith prior to that date; pre-existing trademark rights; and when a name has become a common (or "generic") term for describing that type of product.

3. CLARIFICATIONS AND FLEXIBILITY REGARDING TRIPS AND PUBLIC HEALTH

On the issue of TRIPS and public health (including access to patented medicines), the WTO has adopted three instruments:

- The Doha Declaration on the TRIPS Agreement and Public Health, November 2001
- The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Geneva, August 2003
- A Protocol amending the TRIPS Agreement, December 2005.

3.1 *The Doha Declaration on the TRIPS Agreement and public health*

The Doha Declaration on the TRIPS Agreement and Public Health[2] responded to concerns about the possible implications of the TRIPS Agreement for public health, in particular, access to patented medicines. As mentioned earlier, the TRIPS Agreement allows countries to take various kinds of measures to qualify or limit IP rights, including for public health purposes. However, some doubts had arisen as to whether the flexibility in the TRIPS Agreement was sufficient to ensure that it supported public health. It was unclear whether it promoted affordable access to existing medicines, while supporting research, and development into new ones.

The Declaration responds to these concerns in a number of ways. First, it emphasizes that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. It reaffirms the right of Members to use, to the full, the terms of the TRIPS Agreement that provide flexibility for this purpose. Through these important declarations, all WTO Members have signaled that they will not seek to prevent other members from using the provisions.

Second, the Declaration makes clear that the TRIPS Agreement should be interpreted and implemented in a way that supports the right of Members of the WTO to protect public health and, in particular, to promote access to medicines for all. Further, it highlights the importance of the objectives and principles of the TRIPS Agreement regarding the interpretation of its provisions. These statements thus provide important guidance to both individual Members and, in the event of disputes, WTO dispute settlement bodies.

Third, the Declaration clarifies some of the flexibilities contained in the TRIPS Agreement. It makes clear that each Member is free to determine the grounds upon which compulsory licenses are granted. This is a useful corrective to views often expressed in some quarters that some form of emergency is a precondition for compulsory licensing. The TRIPS Agreement does refer to national emergencies or other circumstances of extreme urgency in connection with compulsory licensing, but this is only to indicate that, in these circumstances, the usual condition that an effort must first be made to seek a voluntary license does not apply. The Declaration makes it clear that each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency. It also declares that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent such circumstances.

With regard to the exhaustion of IP rights and a Member's right to permit parallel imports, the TRIPS Agreement states that a Member's practices in this area cannot be challenged under the WTO dispute settlement system. The Declaration makes clear that the effect on exhaustion of the provisions in the TRIPS Agreement is to leave each Member free to establish its own regime without challenge—subject to the general TRIPS provisions that prohibit discrimination on the basis of the nationality of persons.

For Members of the WTO that are least developed countries, the Declaration agrees to provide them with an extension of their transition period until the beginning of 2016 for protecting and enforcing patents and rights in undisclosed information with respect to pharmaceutical products. This was given legal effect through a Decision of the TRIPS Council that extended the transition period for least developed countries until 1 January 2016[3] and another Decision of the General Council that waived the exclusive marketing rights provisions of Article 70.9[4] for the same period. In 2005, the TRIPS Council extended, to July 2013, the time given for these countries to implement other provisions of the TRIPS Agreement.[5]

While emphasizing the flexibility in the TRIPS Agreement to take measures to promote access to medicines, the Declaration also recognizes the importance of IP protection for developing new medicines and reaffirms the commitments of WTO Members in the TRIPS Agreement.

3.2 *Paragraph 6 of the Doha Declaration*

In paragraph 6, the Doha Declaration recognized the problem of countries with insufficient or no manufacturing capacities in the pharmaceutical

sector in making effective use of compulsory licensing. Such countries could, under normal TRIPS rules, import under a compulsory license as there is no special problem with Members issuing compulsory licenses for importation as well as for domestic production. The problem, however, was whether sources of supply from generic producers in other countries to meet such demand would be available, particularly given Article 31(f) of the TRIPS Agreement, according to which production under a compulsory license in those other countries must be "*predominantly for the supply of the domestic market of the Member.*" The problems facing countries with insufficient capacities in the pharmaceutical sector in accessing sources of supply were expected to increase as some countries with important generic industries were coming under an obligation to provide patent protection for pharmaceutical products as from 2005.

In order to solve this problem, the WTO General Council adopted on 30 August 2003 a Decision[6] that waives in certain circumstances Article 31(f) and (h) of the TRIPS Agreement. This Decision was adopted in the light of a Chairman's statement[7] that set out several key shared understandings of Members on how the Decision would be interpreted and implemented. The Decision covers any patented pharmaceutical products, or pharmaceutical products manufactured through a patented process, needed to address public health problems recognized in paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health, including active ingredients necessary for the manufacture of pharmaceutical products and diagnostic kits needed for their use. The Decision grants three waivers from the obligations set out in subparagraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products, subject to certain conditions. The three waivers are:

1. *A waiver of the obligation of an exporting Member under Article 31(f) of the TRIPS Agreement to the extent necessary for the purposes of production and export of the needed pharmaceutical products to those countries that do not have sufficient capacity to manufacture them. This waiver is subject to certain conditions to ensure transparency in the operation of the system and that only countries with insufficient domestic capacity import under it, and to provide for safeguards against the diversion of products to markets for which they are not intended.*

2. *A waiver of the obligation under Article 31(h) of the TRIPS Agreement on the importing country to provide adequate remuneration to the right holder in situations where remuneration in accordance with Article 31(h) is being paid in the exporting Member for the same products. The purpose of this waiver is to avoid double remuneration of the patent owner for the same product consignment.*

3. *A waiver of the obligation under Article 31(f) of the TRIPS Agreement on any developing or least developed country that is party to a regional trade arrangement at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries. The purpose of this waiver is to enable such countries to better harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.*

The above Chairman's statement was designed to meet the concerns of those who feared that the Decision was too open ended and might be abused to undermine the benefits of the patent system. It recognizes that the paragraph 6 system set out in the Decision should be used in good faith to protect public health and not to pursue industrial or commercial policy objectives. It addresses some concerns relating to the risk of diversion, and it sets out ways in which any differences arising from the implementation of the system can be settled expeditiously and adequately. The Decision also records that the 33 most-advanced countries have agreed to opt out of the system as importers, including since their accession to the European Communities, the 10 acceding countries.[8] In addition, 11 other Members have agreed to use the system only as importers in situations of national emergency or other circumstances of extreme urgency.[9]

The Decision went into effect on 30 August 2003, and since then a number of Members have modified their laws/regulations to enable exports under their legislation. As of July 2006, Canada, Norway, India and the European Communities have notified the WTO of these modifications.[10]

3.3 *A Protocol amending the TRIPS Agreement*

Paragraph 11 of the August 2003 Decision called for the TRIPS Council to prepare an amendment, based, where appropriate, on the Decision that would replace its provisions. Agreement on such an amendment was reached on 6 December 2005, when the General Council adopted a Protocol amending the TRIPS Agreement and submitted it to WTO Members for acceptance. In substance, the amendment closely tracks the August 2003 text. The Decision on the amendment was also taken in the light of a rereading by the General Council Chairman of the statement of August 2003. The Protocol will enter into force upon acceptance by two thirds of the Members. The waiver provisions of the August 2003 Decision remain applicable until the date on which the amendment takes effect for a Member.

4. WORK ON TRIPS PROVISIONS RELATING TO AGRICULTURE

4.1 *Article 27.3(b)*

As mentioned earlier, Article 27 of the TRIPS Agreement defines which inventions governments are obliged to make eligible for patenting and what they can exclude from patenting. Inventions that can be patented include both products and processes, and should generally cover all fields of technology. Part (b) of paragraph 3 allows governments to exclude some kinds of inventions from patenting (for example, plants, animals, and other "*essentially biological*" processes—but microorganisms and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible for protection either through patent protection or a system created specifically for the purpose ("*sui generis*"), or a combination of the two.

A review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement. The topics raised in the TRIPS Council's discussions included:

- how to apply the existing TRIPS provisions on whether or not to patent plants and animals, and whether they need to be modified
- how to handle moral and ethical issues (for example, to what extent invented life forms should be eligible for protection)
- how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications
- how to ensure that the TRIPS Agreement and the Convention on Biological Diversity (CBD) support each other.

With respect to the protection of plant varieties, the meaning of *effective protection* for new plant varieties has been a part of the discussion under this review.[11] The discussion has included consideration of the kind of flexibility that should be available (for example, allowing traditional farmers to continue to save and exchange seeds that they have harvested). It is widely agreed that, while the standards of protection under the UPOV Convention would be considered adequate for TRIPS purposes (with some differences of view about whether the 1978 or 1991 version is the most appropriate point of reference), WTO Members are not bound to apply UPOV standards as long as they can ensure effective protection of plant varieties.[12] The privilege of farmers to replant, on their own holdings, propagating material of protected plant varieties that have been harvested is not in dispute, but no conclusion has yet been reached about how much further the flexibilities might go and be consistent with TRIPS. There is no authoritative guidance in the WTO on these matters. However, the responses of some Members to a questionnaire about domestic implementation of Article 27.3(b) are contained in a TRIPS Council document.[13]

Following the 2001 Doha Ministerial Conference, the review of Article 27.3(b) has

been accompanied by parallel work on the relationship between the TRIPS Agreement and the CBD, as well as on protecting traditional knowledge and folklore.[14]

4.2 *Biodiversity and Traditional Knowledge*

Discussions on the relationship between the TRIPS Agreement and the CBD first began in the WTO in the Committee on Trade and Environment in 1995. They were brought into the TRIPS Council through the built-in review of Article 27.3(b) in 1999. In the Doha Ministerial Declaration under paragraph 19, the ministers instructed the Council for TRIPS "*to examine,* inter alia, *the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.*" The Hong Kong Ministerial Declaration of December 2005[15] calls for the TRIPS Council to continue this work and for the General Council to report on it to the next ministerial meeting.

In paragraph 12, the Doha Ministerial Declaration also addressed the question of outstanding implementation issues (that is, outstanding issues and concerns raised by developing countries about some existing WTO rules, including a number relating to biotechnology, biodiversity, and traditional knowledge). With regard to these issues, the work has focused on the relation between the TRIPS Agreement and the CBD. Some countries want a solution to the their related concerns to be negotiated as part of the ongoing Doha Round of trade negotiations. Other WTO Members contend that there is no negotiating mandate on this matter and that it would not be appropriate to create one. Consultations on this issue have been held under the auspices of the Director General of the WTO since the end of 2002. The Hong Kong Ministerial Declaration of December 2005 provided for the consultative process to be intensified further and for the Director General to report to each regular meeting of the Trade Negotiating Committee (TNC) and the General Council. This issue is one of the two outstanding implementation issues explicitly referred to in the text of the Hong Kong Declaration (alongside that of the extension of the protection of geographical indications). The General Council is to review progress and take any appropriate action no later than 31 July 2006.

In the TRIPS Council sessions and at other discussions relating to the relationship between the TRIPS Agreement and the CBD,[16] Members' positions fall into three broad categories. First, a group of developing countries propose to amend the TRIPS Agreement to make obligatory disclosure in patent applications of (a) the origin of biological resources and/or traditional knowledge used in the claimed invention, (b) evidence of prior informed consent under the relevant national laws/regulations/procedures, and (c) evidence of fair and equitable benefits sharing with those holding such resources or knowledge. Second, the European developed countries are willing to envisage some measure of disclosure of source or origin within the patent system, but not of access or benefit sharing. Those who agree with the disclosure approach differ on several other aspects, such as whether the requirement should be mandatory or voluntary, and under what instrument (the TRIPS Agreement or the Patent Cooperation Treaty of the World Intellectual Property Organization [WIPO]). There is also disagreement about the legal effects of wrongful disclosure or nondisclosure (invalidation of the patent or outside the patent system under civil/criminal law).

Third, other WTO Members are opposed to a disclosure requirement but are willing to engage substantively on the issue of how the shared objectives in these areas, such as the avoidance of erroneously granted patents and compliance with national access and benefit–sharing regimes, can most effectively be realized. They hold the position that a national-based approach using tailored national solutions, including contracts, is sufficient to ensure that the objectives of the CBD in relation to access and benefit sharing are met. They believe that it would be neither helpful nor desirable to involve the patent system.

The TRIPS Agreement has no specific provisions regarding traditional knowledge. Members are obliged to protect traditional knowledge when it falls under covered IP rights, and they are free to introduce a sui generis law to protect

it, as long as that does not conflict with TRIPS. They can similarly implement Article 8(j) of the CBD (to respect, preserve, maintain knowledge, innovations and practices of indigenous and local communities and encourage the equitable sharing of benefits). Quite detailed work is going on in the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore. The question of the appropriate forum for fleshing out the details of the subject comes up repeatedly in the TRIPS Council discussions. Some want to wait for WIPO to develop an appropriate framework so that it can be determined to what extent such protection can be included in TRIPS. Finally, as indicated above, the focus in the TRIPS Council is presently on the relationship between the TRIPS Agreement and the CBD, which covers some aspects of traditional knowledge.

4.3 *Geographical indications*

Two issues relating to geographical indications are debated under the 2001 Doha Work Program: the establishment of a multilateral register of geographical indications for wines and spirits and the extension of the higher Article 23 level of protection beyond wines and spirits.

4.3.1 *Multilateral register*

The agreed aim of the multilateral system of notification and registration that is currently under negotiation is to facilitate the protection of geographical indications for wines and spirits. Work was initiated as early as 1997 and is mandated under TRIPS Article 23.4 and paragraph 18 (the first sentence of the Doha Declaration). The negotiations on this matter are being conducted in a Special Session of the council for TRIPS.

Two main lines of argument have been advanced in the negotiations. The "joint proposal" of Argentina, Australia, Canada, Chile, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Japan, Mexico, New Zealand, Paraguay, Chinese Taipei,[17] and the United States[18] suggests that the Council for TRIPS should decide to set up a voluntary system under which notified geographical indications would be registered in a database. Those governments choosing to participate in the system would have to consult the database when deciding on the protection of geographical indications and trademarks for wines and spirits in their own countries. Non-participating Members would be encouraged, but not obliged, to consult the database. At the other end of the spectrum, the European Communities propose a TRIPS amendment to establish a system under which the registration of a geographical indication should lead to rebuttable presumptions of its protectability, except where a reservation has been lodged within a specified period, for example, 18 months. Permitted grounds for a reservation would include when a term has become generic or when it does not meet the definition of a geographical indication. In the absence of any reservation, a Member could not refuse protection on these grounds after the term has been registered. These proposals, together with a compromise proposal from Hong Kong, China, have been set forth side by side in a WTO Secretariat document.[19]

Important differences remain, particularly on two key issues: (1) the extent to which legal effects at the national level should be consequent on the registration of a geographical indication for a wine or a spirit in the system and (2) the question of participation, including whether any legal effects under the system should apply to all WTO Members or only to those opting to participate in the system. The Special Session has also discussed a range of other points, including questions of costs and administrative burdens for WTO Members, particularly for developing countries.[20]

4.3.2 *Extension*

Article 22 requires protecting geographical indications for all goods. The issue here is whether to expand the higher level of protection under Article 23, currently required only for wines and spirits, to other products, including agricultural products and foodstuffs, handicrafts, and industrial products.

Paragraph 18 of the Doha Declaration notes that the TRIPS Council will handle work on extension under paragraph 12 of the Declaration,

which deals with implementation issues. As indicated earlier, WTO Members interpret paragraph 12 differently. Many developing country and European Members argue that the so-called outstanding implementation issues are already part of the "single undertaking" and therefore are also part of the negotiating agenda of the Doha Round. Others argue that these issues can only become negotiating subjects if the TNC decides to include them in the talks—and so far it has not done so. Presently, the topic is the subject of consultations under the auspices of the WTO Director General. At the Hong Kong Ministerial Conference, ministers requested the Director-General to intensify consultations on all outstanding implementation issues, including the extension of the protection of geographical indications, and 31 July 2006 was set as the deadline for the General Council to review progress and take any appropriate action.[21]

With regard to the substance of the TRIPS Agreement, Members remain divided, but there is a willingness to continue discussing the issue. The proponents consider, among other things, that progress on geographical indications would make it easier for them to agree to a significant deal in agriculture. The proponents see the higher level of protection as a tool to enhance rural development, support quality production, and enable them to improve the marketing of products by differentiating them more effectively from other competing products. Consequently, the latest proposal from the European Union calls for the TRIPS Agreement to be amended so that all products would be eligible for the higher level of protection in Article 23.[22] To meet the concerns of other countries, the exceptions in Article 24 would also apply, adapted as necessary. Opponents argue that the existing level of protection pursuant to Article 22 is adequate. They caution that providing enhanced protection would be burdensome and disruptive to existing, legitimate marketing practices, that the interests of prior trademark right holders and other third parties may be affected, and that considerable costs may result from the need to re-label their products.

The issues raised and the views expressed in this debate have been compiled in a document prepared by the WTO Secretariat.[23] The issues include, among others, those relating to the protectable subject matter (definition and eligibility), potential implications for administrative costs and burdens, and the impact of extension on (1) producers in and outside the area designated by geographical indications, (2) the relationship between trademarks and geographical indications, and (3) consumers.

5. TRANSFER OF TECHNOLOGY

Article 7 of the TRIPS Agreement reflects the objective that the transfer of technology should be promoted by the protection of IP. Some developing countries have expressed the view that more needs to be done to "operationalize" this notion. The TRIPS Agreement calls for more proactive measures to promote technology transfer and dissemination in the case of the least developed countries. Article 66.2 obligates developed countries to provide incentives for the transfer of technology to these countries. The effective monitoring of this obligation through regular reporting and TRIPS Council reviews was the subject of a political agreement at Doha that was turned into the TRIPS Council Decision of February 2003.[24] Reports under this new mechanism, submitted at the end of 2003, 2004, and 2005, are being studied by the Members that are least-developed countries.

6. TECHNICAL COOPERATION AND CAPACITY BUILDING PROGRAMS

Article 67 of the TRIPS Agreement obligates developed country WTO Members to provide, on request and according to mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed-country Members. This cooperation includes assistance in preparing laws and regulations for the protection and enforcement of IP rights, as well as the prevention of their abuse. The cooperation also includes support for the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel. On the basis of annual reports from developed-country Members, each autumn the

TRIPS Council reviews the technical cooperation that is being provided.[25]

Considerable assistance is also provided by other intergovernmental organizations, notably WIPO, UPOV, the World Bank, and the WHO. Such organizations are annually invited to share information on their activities with the TRIPS Council.[26] In addition, the WTO Secretariat's technical cooperation program includes activities related to the TRIPS Agreement.[27] These activities seek to help Members understand their rights and obligations—including the options and flexibilities—under the TRIPS Agreement and relevant decisions of WTO bodies. The cooperation program encourages Members to participate fully in the ongoing work of the WTO on TRIPS matters and emphasizes the importance of ensuring complementarity and cooperation with other intergovernmental organizations, in particular the WIPO and the WHO.

These activities include regional workshops on topical issues under discussion, examination, or negotiation in the TRIPS context, in particular TRIPS and public health, biotechnology, traditional knowledge, biodiversity, and geographical indications. These regional workshops, as well as specialized workshops held in the regions and Geneva, also aim to provide information that will assist developing-country Members in implementing and making effective use of the mechanism set out in the Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Upon request by developing- country Members, the WTO Secretariat regularly organizes national seminars or workshops devoted to IP matters. TRIPS issues also figure prominently in broader WTO training courses, seminars, and workshops held in Geneva and in developing countries. An important new component of the Secretariat's capacity-building activities is the annual joint WIPO/WTO colloquiums for teachers of intellectual property in Geneva, for participants from developing countries. This program seeks to enhance the capacity for teachers to train IP personnel in their own countries, by providing teachers with expertise on international aspects and allowing them to provide informed policy advice to their governments. ■

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1 For more details, see www.wto.org/english/tratop_e/trips_e/trips_e.htm#WhatAre.

2 Document WT/MIN(01)/DEC/2.

3 Document IP/C/25, June 2002.

4 Document WT/L/478, July 2002.

5 Document IP/C/40.

6 Documents WT/L/540 and Corr.1.

7 Contained in paragraph 29 of document WT/GC/M/82.

8 The Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia.

9 Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates.

10 Notifications about the use of the system will be accessible through a dedicated Web page on the WTO Web site: www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

11 See document IP/C/W/369/Rev.1, paragraphs 51–60 available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

12 See document IP/C/W/369/Rev.1, paragraphs 61–66 available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

13 Document IP/C/W/273/Rev.1, available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

14 Secretariat summary notes of the work done on these issues (IP/C/W/368/Rev.1, IP/C/W/369/Rev.1, IP/C/W/370/Rev.1) are available at www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

15 Document WT/MIN(05)/DEC.

16 Summarized in Secretariat paper IP/C/W/368/Rev. 1.

17 In the WTO accession document, Chinese Taipei is referred to as Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu.

18 Document TN/IP/W/10 and Add.1.

19 Document TN/IP/W/12.

20 See Chairman's report on the work done in 2005, document TN/IP/14.

21 Paragraph 39 of document WT/MIN(05)/DEC.

22 Document TN/IP/W/11.

23 Document WT/GC/W/546, document TN/C/W/25.

24 Document IP/C/28.

25 The most recent reports can be found in document IPC/W/445 and addenda.

26 The most recent information documents are in document IPC/W/456 and addenda.

27 The most recent information can be found in document IP/C/W/454.

U.S. Laws Affecting the Transfer of Intellectual Property

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ABSTRACT

This chapter provides an overview of some of the legislative bills that have profoundly affected the evolution of technology transfer and intellectual property (IP) rights in the United States. The chapter references provisions of the specific bills as codified in U.S. law and explains their goals and historical circumstances. While not an exhaustive presentation of all of the bills that have contributed to laws governing IP, the codification references will provide a useful starting point for those researching the applicability of the laws to particular situations.

1. INTRODUCTION

In the United States, the fundamental basis for the transfer of technology as property lies in the U.S. Constitution. In an effort to protect the rights of its more creative citizens, the framers of the Constitution struck a compromise position: creators of intellectual property (IP) would own it and be able to exclude others from using it for a limited period of time. After this time period expired, the right to use the IP was extended to all. By agreeing to accept the "disclosure inducement theory" of advancing science and the arts, the framers also allowed a creator of IP to deny others the use of that property for a limited period of time in exchange for disclosing the nature of the property to all. The conveyed right is expressed in article I, section 8, clause 8 of the U.S. Constitution:

The Congress shall have Power—
to promote the progress
Of Science and useful arts, by securing
for limited Times
To Authors and Inventors the exclusive
Right to their Respective Writings
and Discoveries.

2. U.S. PATENT SYSTEMS

The U.S. patent system finds its origin in the U.S. Constitution (art. I, § 8, cl. 8). The system described therein is the primary vehicle for transferring IP from the university and nonprofit sectors to the private sector or, as is often the case, from the government to the private sector. Within its scope, the clause includes trademarks and copyrights. Indeed, all of these elements—patents, trademarks, and copyrights—are classified as intellectual property and in the United States have the imprimatur of personal property rights. The terms and provisions governing these forms of IP are codified in various statutes: U.S. Code, title 35 for patents (35 U.S.C.); U.S. Code, title 15 (15 U.S.C.), chapter 22 for trademarks; and U.S. Code, title 17 (17 U.S.C.) for copyrights. Detailed regulations governing the application of these statutes are found in title 37 of the Code of Federal Regulations (37 C.F.R.), chapters I and II. These laws and regulations outline

Bremer H. 2007. U.S. Laws Affecting the Transfer of Intellectual Property. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

the obligations for obtaining and maintaining IP protection and for asserting the property rights that the laws convey.

2.1 *Specific legislation*

Two pieces of legislation, both of which were passed in 1980, are of particular interest. The first gave the government authority to engage in the transfer of federally owned or federally originated technology. The second gave the government statutory authority to patent and license federally owned inventions and was instrumental in enhancing the nonprofit sector's technology transfer function—especially for universities.

The first law was the Stevenson-Wydler Act. Its reach expanded by amendments over a period of years, the law is codified in title 15 (15 U.S.C.), chapter 63 of the U.S. Code, under the heading "Technology Innovation." Its fundamental purpose was to promote the utilization of technology owned by the federal government and generated with its help. The act accomplished its purpose by aiding the transfer of that technology to the private sector and to state and local governments. The act initially called for setting aside 0.5% of each federal laboratory's budget to fund technology transfer activities; a later amendment required "sufficient funding to support technology transfer activities."

The second law was the Patent and Trademark Amendment Act of 1980—known as the Bayh-Dole Act. The terms and provisions of this act, as amended by the Trademarks Clarification Act of 1984, are codified in title 35 of the U.S. Code (35 U.S.C. § 200–212). The Bayh-Dole Act changed the presumption of title in and to inventions made, in whole or in part, with federal monies at nonprofit organizations—including universities and small businesses—from the government to those entities. For the first time, the law established a uniform federal patent policy and provided the first statutory authority for the U.S. government to take title to and hold patents through its agencies. The regulations pertaining to the Bayh-Dole Act are found in the Code of Federal Regulations, title 37 (37 C.F.R.), part 401; those regulations pertaining to the licensing of government-owned inventions are set forth in part 404, and those pertaining to inventions made by government employees are set forth in part 501.

The Bayh-Dole Act also embraces any novel variety of plant that is or may be protected under the Plant Variety Protection Act, which is codified in title 7 of the U.S. Code (7 U.S.C.), chapter 57, and includes sections 1545 and 2353 of title 28 (28 U.S.C. §§ 1545 and 2353), amendments to title 27, sections 1551 and 1562 (27 U.S.C. §§ 1551 and 1562) (the Federal Seed Act), and sections 1338 and 1498 of 28 U.S.C (28 U.S.C. §§ 1338, 1498).

Because the Bayh-Dole Act depends upon the U.S. patent system to transfer technology from the nonprofit, university, and small business sectors, it is axiomatic that changes in the patent system and in the regulations governing that system can affect the ability to protect and transfer technology.

2.2 *Patents and antitrust laws*

Many people classify patents as monopolies, a view that brings into sharp focus the issue of antitrust laws and patents, particularly the right of the patent holder to exclude. The passage of antitrust legislation in the United States was driven by the growth and expansion of business and the efforts of competitors to stabilize markets through price and quota arrangements. These activities made it clear that growing industrial combinations and monopolies would have to be controlled.

As a result, in 1890 the Sherman Act was passed (codified at 15 U.S.C. §§ 1–7). The Clayton Act (codified at 15 U.S.C. §§ 12–29 and 29 U.S.C. § 52) followed in 1916. As a supplement to the Sherman and Clayton acts, the Federal Trade Commission Act was passed in 1914, amended in 1980 and1994, and reauthorized in 1996 (codified at 15 U.S.C. §§ 41–58).

The Sherman Act prohibits the restraint of trade and monopolies. Antitrust law and patents oppose each other because according to the act, patents can contribute or be a part of an attempt to restrain trade or to establish a monopoly of "*any part of the trade or commerce between the several States (of the United States) or with foreign*

nations." Specifically, the substantive governing provisions are:

- ***Section 1**. Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.…*
- *Section 2. Every person who shall monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a misdemeanor.*

It should be noted that under section 1, restraint of trade requires action by two or more parties, but monopolization requires action by just one party.

In contrast to the broad language of the Sherman Act, the Clayton Act focuses on more specific trade abuses: price discrimination, the acquisition of one corporation by another, restrictions forbidding a purchaser of goods to deal in the goods of competition, and the use of interlocking directorates among large corporations. The relevant, specific statutory language is:

- ***Section 3.** …[I]t shall be unlawful for any person engaged in [interstate] commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies or other commodities, whether patented or unpatented, for use, consumption or resale within the United States or any Territory thereof or the District of Columbia of any insular possession or other place under the jurisdiction of the United States, or fix a price charged therefore, or discount from, or rebate upon, such prices, on the condition, agreement or understanding that the lessee or purchaser thereof shall not use or deal in the goods, wares, merchandise, machinery, supplies or other commodities of a competitor or competitors of the lessor or seller, where the effect of such lease, sale, or contract for sale on such condition, agreement or understanding may be to substantially lessen competition or tend to create a monopoly in any line of commerce.*
- ***Section 7**. …[N]o corporation engaged in [interstate] commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no corporation subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another corporation engaged also in commerce, where in any line of commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.*

The early historical perception that patents and antitrust principles are antithetical has been ameliorated over the years; today they are recognized as complementary tools that enhance competition. Nevertheless, the inherent right-to-exclude conveyed by a patent forecloses third parties from practicing the invention patented, and patents can be used for various kinds of conveyances. (For example, patents can be the basis for exclusive, partially exclusive, or nonexclusive licenses, bailments, or actual sales.) Attention must be paid to the nature of those conveyances and to the context within which and purpose for which they are generated and will be used. At present, patents, per se, are not viewed as conveyers of market power. But when coupled with other assets, or when patents are acquired in order to build a monopolistic position (other than through internal research and development efforts), patents do contribute to market power. When combined with apparent predatory practices that restrain trade, such a position can invite antitrust scrutiny. For example, a violation of the Clayton Act would occur if a purchaser were forced to purchase certain materials or supplies from a specified supplier to the exclusion of a competitor—this is referred to as a *tying arrangement*. In terms of antitrust issues, this arrangement would be viewed as extending the scope of a patent by restricting the use of the patented invention to goods necessary for its operation but not part of the patented invention. For example, the license (or franchise) under the patent might require the purchase of nonpatented items from the licensor as a condition for the license itself. Without the element of coercion,

however, the parties are free to enter into such a supply agreement.

2.3 *Export Administration Regulations and International Traffic in Arms Regulations*

The Department of Commerce administers the Export Administration Regulations (EAR) to protect trade, while the Department of State administers the International Traffic in Arms Regulations (ITAR) to protect national security. The regulations apply not only to the transfer of physical items to persons and/or entities outside the United States, but also to the transfer of technology—whether or not it is associated with a physical item. The regulations also cover disclosure to foreign persons while in the United States of technical data or information on controlled items, as well as to the training and offering of services involving controlled equipment to foreign persons.

The EAR can be found at title 15, sections 730–74 of the Code of Federal Regulations. EAR regulations apply to and regulate the export of goods and related technology on the Commodity Control List (15 C.F.R. § 774, supplement 1). The ITAR can be found at 22 C.F.R. 120–30. The regulations control the export of articles, services, and related technical data that are inherently military in nature. Regulated items are specified in the Munitions List at 22 C.F.R. 121.

Additionally, the regulations restrict the export of goods and technology that could hamper the economic vitality of the United States or that might contribute to the military capability and potential of its adversaries. Because of global terrorism, the latter has been particularly emphasized in recent years.

IP, as represented by patents, know-how, trade secrets, and copyright can also be affected by EAR and ITAR. The Patent and Trademark Office asserts some control over the export of sensitive technology by issuing export licenses—in most cases, automatically, during the early consideration of a patent application, or upon request from the applicant. In some cases, the office will impose a secrecy order on a patent application that contains sensitive materials. In such cases, an applicant may prosecute the application so ordered in a special group in the examining corps, but the patent will not be issued until the restriction has been lifted. Corresponding applications can be filed and prosecuted in other approved countries to the point of acceptance, but the patent itself will not be issued. With the patented technology embargoed, the technology itself would fall under the EAR or ITAR.

Inasmuch as they embrace transfers of controlled information (including technical data, physical items—inclusive of scientific equipment—and verbal, written, electronic and/or visual disclosures of controlled scientific and technical information), the EAR and ITAR can affect university research and development, as well as university technology-transfer functions, via patent licensing and/or other means. Because of the tradition of academic freedom and the open nature of research and development in U.S. universities, the EAR and ITAR can be more difficult to administer; nevertheless, universities must comply with the regulations. Although EAR and ITAR cover virtually all of the same science and engineering fields that universities research and develop, compliance tends not to be viewed as essential. This is partly because of the open environment of universities. Control is more difficult, and neither the EAR nor the ITAR require an export license to disclose technical information to foreign nationals in the United States inside classes, laboratories, or conferences, or in publications, if the information is in the public domain. Information is considered to be in the public domain if it is, at least in part, published and generally accessible to the public through unlimited and unrestricted distribution. This public-domain exemption, however, may not apply to all information that a university generates. There are circumstances in which a specific export license may be required or, particularly where a secrecy order has been imposed, export of the information and/or technology is illegal.

Ancillary to the EAR and ITAR is the Treasury Department Office of Foreign Assets Control (OFAC). OFAC acts under presidential wartime and national emergency powers and has the

authority of specific legislation to prohibit transactions, including the provision of services, and freeze foreign assets under U.S. jurisdiction of targeted persons and entities. Individuals may not provide technologies or services to countries on OFAC's list of embargoed entities or to specially designated persons without first obtaining licenses from OFAC and the state or commerce department.

2.4 *The Cooperative Research and Technology Enhancement Act of 2004*

In 2004, the U.S. Congress passed the Cooperative Research and Technology Enhancement Act, (CREATE Act). The law is codified at 35 U.S.C. § 103(c) and applies to any patent (including reissued patents) granted on or after December 10, 2004. The law was designed to overrule a judicial decision that held that confidential information derived from another individual (termed *secret prior art*) could render an invention *obvious* and thereby preclude patentability of the invention. Since such an exchange of information tends to occur most frequently where researchers, engaged by different entities, are collaborating on a given research project, the decision was construed to have a "chilling effect" on collaborative research among different entities. The CREATE Act enables two or more entities to obtain and separately own patents containing claims that are not patentably distinct from each other (where one claim in one patent would be "obvious" in view of a claim in the other patent). To involve the provisions of the CREATE Act, the collaborative research must have been conducted under a Joint Research Agreement that was in effect on or before the claimed invention was made, the claimed invention must have been made as a result of activities undertaken within the scope of the agreement, and the application for patent for the claimed invention, initially or by amendment, must have disclosed the names of the parties to the agreement.

2.5 Cooperative Research and Development Agreements

Authority for Cooperative Research and Development Agreements (CRADAs) is found at 35 U.S.C. § 3710(a). The purpose of CRADAs is to promote technology innovation in government-operated federal laboratories and government-owned, contractor-operated laboratories across all federal government agencies. The specific authorization language at 35 U.S.C. § 3710(a) is reproduced below:

> *(a) General authority. Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement or, if permitted by the agency, in an agency-approved annual strategic plan, the director of any of its Government-owned, contractor-operated laboratories—*
>
> *(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and*
>
> *(2) to negotiate licensing agreements under section 207 of title 35, United States Code, or under other authorities (in the case of a Government-owned, contractor-operator laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government.*

Under a CRADA, the involved laboratory may grant, or agree to grant, in advance to a collaborating party patent licenses, or assignment, or options thereto, in any invention made, in whole or in part, by a laboratory employee under the agreement for reasonable compensation (35 U.S.C. § 3710a(b) enumerated authority).

2.6 *Department of Energy/Nuclear Regulatory Commission inventions and atomic weapons*

The laws pertaining to this subject are codified at title 42 U.S. Code, beginning with section 2014 and continuing with section 2181 (42 U.S.C. §§ 2014–181). The law specifically prohibits the granting of any patent for any invention or discovery for the utilization of special nuclear material or atomic energy in an atomic weapon; the law revokes any patent granted for such an invention or discovery. The prohibition extends even further to state that no patent granted shall confer any rights with respect to any invention or discovery insofar as it is used in the utilization of special nuclear material or atomic energy in an atomic weapon.

2.7 *National Aeronautics and Space Administration*

The property rights for inventions made under the aegis of the National Aeronautics and Space Administration (NASA) or in contracts issued by NASA are codified at 42 U.S.C. § 2457. Generally, inventions made in the performance of any work under a contract with NASA shall be the property of the United States. The provisions of 42 U.S.C. § 2457c extend beyond the obligation arising under contract with NASA to all patents that "have significant utility in the conduct of aeronautical and space activities subject to a patent applicant's positive action to dispute ownership by the United States." A right of appeal presents an opportunity to obtain a waiver of rights by NASA (42 U.S.C. § 2457f). Even if the agency waives its right of ownership in a given patent, the government will, nevertheless, retain or receive an irrevocable, nonexclusive, nontransferable, royalty-free license to practice the inventions of such patent on behalf of the United States or any foreign government pursuant to any treaty or agreement with the United States.

2.8 *IP and international trade*

The applicable law under the general heading of IP and international trade can be found at 19 U.S.C. § 1337 under "unfair practices in import trade." Such issues fall under the aegis of the International Trade Commission. The provisions under subsection (a), titled "Unlawful activities; covered industries; definitions," are self-explanatory and are reproduced in Box 1.

Moreover, 19 U.S.C. § 2242 requires the identification of countries that deny adequate protection or market access for IP rights before suitable action can be taken by the U.S. Trade Representative to counter, correct, or suspend the benefits afforded in trade and related activities to such a country. (The authorization for actions available to the Trade Representative can be found at 19 U.S.C. § 1526(c).)

2.9 *Small Business Innovation Development Act of 1982*

Codified at 15 U.S.C. § 631, et sequens, the Small Business Innovation Development Act (SBIR) was intended to strengthen the role of small, innovative firms in federally funded research and development and to utilize federal research and development as a base for technological innovation. An important feature of the SBIR is the directive for federal agencies to set aside a portion of each agency's funding for small business R&D. The Bayh-Dole Act allows small businesses to retain title to inventions made, in whole or in part, with federal funds. SBIR enhances the position of small business.

2.10 *Small Business Technology Transfer Program*

The Small Business Technology Transfer Program (STTR) (15 U.S.C. § 638) supplements the SBIR program. STTR requires a set-aside for applicable agencies to support cooperative research-and -development projects involving small businesses and a nonprofit research institutions. STTR provides the latter with the opportunity to call upon the funding federal agency for technical assistance. IP rights between the United States and the recipient small business are required to be set forth in the funding agreement, along with any right to carry out follow-on research.

Box 1: Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

(A) Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E) into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is—

(i) To destroy or substantially injure an industry in the United States;

(ii) To prevent the establishment of such an industry; or

(iii) To restrain or monopolize trade and commerce in the United States.

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17, United States Code; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

(C) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that infringe a valid and enforceable United States Trademark registered under the Trademark Act of 1946.

(D) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of title 17, United States Code.

(E) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consigner, of an article that constitutes infringement of the exclusive rights in a design protected under chapter 13 of title 17, United States Code.

(2) Subparagraphs (B),(C), and (D) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, Trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, Trademark, mask work, or design concerned—

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

(4) For the purposes of this section, the phrase "owner, importer, or consignee" includes any agent of the owner, importer, or consignee.

3. CONCLUSIONS

This overview of the laws and regulations governing IP in the United States provides a general orientation to the goals and historical concerns of the legislation. As these goals and concerns change, so will the laws addressing IP rights. Moreover, issues surrounding IP rights are addressed in many pieces of legislation, including authorization bills for funding various federal agencies. The effects of the legislation may be temporary or permanent, another reason for understanding not just the statutes, but also the motivation and reasoning behind them. ■

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Compulsory Licensing: How to Gain Access to Patented Technology

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ABSTRACT

Voluntary patent licenses are often difficult for institutions to obtain, particularly those in developing countries. This chapter discusses why, how, and by whom compulsory patent licenses may be obtained and used. The main focus is on patented research tools rather than patented end products.

1. INTRODUCTION

Some scientific discoveries and inventions, particularly in biotechnology, have no obvious practical application; to use the metaphor of a river, we might say that they are patented at a point upstream from practical application. Broad patent claims often hamper the development of downstream applications.[1] For instance, in the United States, DNA sequences (genes) are legally considered to be chemical compounds and can therefore be patented. The gene's functions, even those that are not yet known, can therefore be exploited only by authorization of the patent owner.

One example of the problems that can occur when downstream researchers need to use upstream discoveries is the case of antigen MSP-1, an important candidate for the development of an antimalaria vaccine. The Program for Appropriate Technology in Health (PATH), which is working to develop such a vaccine, found that the antigen was protected by more than 20 partially overlapping patents. Extensive negotiations and a considerable amount of time and money were required to obtain permission to use it. A representative of the program notes:

Why does the IP landscape for MSP-1 not sort itself out through traditional channels such as technology transfer and the courts? Developers who want assurance of the rights to use MSP-1 would have to obtain licenses from no less than eight organizations. Though theoretically possible, a licensing transaction of this type would take years, require significant staff time, and cost hundreds of thousands of dollars in attorney fees. While companies routinely make such efforts on behalf of commercial products, the economics of malaria vaccines make developers more reluctant to invest in such cumbersome technology acquisition.[2]

Several studies in the United States[3] and elsewhere[4] have examined the potential impact of research tool patents. Although the U.S. National Academies of Sciences found that private companies and research institutions in developed countries are generally able to deal with the complexities of patent law, it warned that "*the patent landscape, which already is becoming complicated in areas such as gene expression and protein-protein interactions, could become considerably more complex and burdensome over time*."[5] A Swiss survey on the obstacles to research stemming from patent protection found that a majority of companies and

Correa CM. 2007 Compulsory Licensing: How to Gain Access to Patented Technology. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

institutions favored the creation of either an exception for the clinical use of the patented subject matter or the granting of compulsory licenses.[6]

Small companies and research institutions will likely be more adversely affected by upstream patents than will large companies or institutions. Entities in developing countries that lack the legal, financial, technological and negotiating capacity to engage in complex negotiations, may be significantly constrained. For instance, a survey of 103 Indian pharmaceutical companies revealed that the most common reason firms decided to abandon R&D projects was because of restricted access to patented upstream technologies.[7]

Some initiatives are being considered that would allow low-income countries access to technology under special conditions. The Science and Intellectual Property in the Public Interest project (SIPPI) of the American Association for the Advancement of Science (AAAS)[8] has promoted the idea that technology managers in developed countries should include legally enforceable provisions in licensing agreements to preserve the possibility of sharing protected technologies with third parties for humanitarian reasons in developing countries.[9]

Patented upstream technology can create barriers to agricultural research,[10] unless the use of the protected subject matter is permitted under a research exception or otherwise consented by the patent owner. Golden Rice, which has been genetically modified to contain pro-Vitamin A or beta-carotene, is a tool for combating vitamin A deficiency in developing countries. Syngenta Seeds AG negotiated access to all major technologies necessary for Golden Rice production[11] and then granted the inventors of Golden Rice the right to sublicense breeding institutions in developing countries, free of charge, provided that the rice would be used only for subsistence farming and not for commercial purposes. Subsistence farming has been defined as any farm not generating income more than US$10,000 from the sale of rice. Syngenta is not interested in commercializing Golden Rice in developed countries, where vitamin A deficiency is almost unheard of.[12]

Other examples of removal of patent barriers through "humanitarian IP management" include Cornell University's transfer of papaya-ringspot-virus-resistant papaya to Thailand; several projects brokered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA); and the agreement between Yale University and Bristol-Myers Squibb regarding the patent on stavudine (d4T), a widely used HIV/AIDS antiretroviral drug. Humanitarian IP management could be expanded to involve research and experimentation as well as the transfer of patented technologies.

2. PATENTS AND DOWNSTREAM RESEARCH

A *compulsory license* is an authorization given by a "national authority" to a natural or legal person for the exploitation of the subject matter protected by a patent; the consent of the patent title holder is not necessary. Compulsory licenses may be required to import or produce a given product, or to use a patented technology for research. They are especially important when there are no close substitutes for a product or process and a research exception is not available or is too narrow.[13]

Compulsory licenses are granted in order to attain various public-policy objectives, such as: to address emergencies and public-health needs, to counteract anticompetitive business practices, or to permit the exploitation of a patent in cases of lack of working thereof.

The right to use compulsory licenses was recognized in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994.[14] The Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), adopted by the 4th WTO Ministerial Conference in November 2001,[15] confirmed, inter alia, that each WTO member was free to determine the grounds under which it would grant compulsory licenses.[16]

In the United States, compulsory licenses have been widely used for government use and in settlements for antitrust cases.[17] Countries such as Zambia and Zimbabwe have recently issued compulsory licenses to facilitate access to cheap medicines; others, such as Malaysia and Indonesia, have

issued government-use provisions for the same purpose. A public non-commercial use provision is somewhat different from a compulsory license for commercial production. Public non-commercial use provisions, which exist in many countries, authorize a government department to exploit, by itself or through a contractor, a patented invention, without the consent of the patent right holder, as long as such exploitation is to provide a public service and for noncommercial purposes. Other countries, such as Brazil and South Africa, have threatened to grant compulsory licenses in order to obtain cheaper medicines.[18] A compulsory license is likely to be less advantageous to the patent owner than a voluntary license. It is therefore to the advantage of patent owners to price their products fairly and grant voluntary patent licenses with reasonable terms and conditions.

Compulsory licenses may be needed when patents restrict the freedom to operate (FTO) [19] in a given field of R&D. Such licenses are subject to several conditions, notably that the licensee must remunerate the patent holder. These conditions are examined in section 3 below.

3. COMPULSORY LICENSES FOR RESEARCH

3.1 *Who can apply?*

National laws normally allow companies, nongovernmental organizations, and research institutions to apply for compulsory licenses. In some countries, licensees must first demonstrate that they have the technical or economic capacity to utilize the license properly.

3.2 *When can a compulsory license be applied for?*

Some types of compulsory licenses, such as those granted to remedy abuses, for example, lack of working, cannot be granted until four years after the date of filing of the patent application or three years from the date of the grant of the patent, whichever date comes second.[20] These terms do not apply when the compulsory licenses are granted on other grounds, such as when public health is at stake, in emergency situations, or where necessary to remedy anti-competitive practices.

3.3 *Prior negotiation of a voluntary license*

Except in the case of emergency, anti-competitive practices, and government use, the potential compulsory licensee must first request a voluntary license on reasonable commercial terms from the patent owner.[21] Such "reasonable commercial terms" must be consistent with standard commercial practice and must ultimately be in accordance with the requirements set by national law and by the competent authority. If such a voluntary license is denied, the potential licensee may apply for a compulsory license—though it may be necessary to prove that the patent owner has refused to grant a voluntary license within a reasonable time period.

Many patents for research tools are held by universities—where the initial invention has often been made—that sometimes decline to provide voluntary licenses to certain applicants or are unable to do so. The reasons for this may be multifold. One reason may be that the university has already granted an exclusive license; another reason may be that the university is in licensing negotiations with another party. Determining reasonable commercial terms when the patent owner is a university is also difficult. However, there are many universities with extensive experience in these matters, and their standard practices may serve as models. This is certainly one reason why universities should be encouraged to retain humanitarian-use rights.[22]

3.4 *How should the application be made?*

National laws govern both the substantive requirements and the relevant procedures for obtaining a compulsory license.

3.4.1 *The appropriate authority*

In most countries, compulsory licenses are granted by the government's executive branch. In others, such authority lies with the judiciary branch. The services of legal professionals are not generally required, but may be advisable.

3.4.2 *Grounds for the application*

The appropriate authority should be provided with a reasoned justification for the application. The application should, to the greatest extent

possible, specify the legal provisions and grounds on which it is sought. Requests must abide by the restrictions set by national law.[23]

The application should specify the scope and duration of the requested compulsory license. An application may request access to all of the subject matter covered by a patent, or it may request access to only certain elements of a patent, or certain uses of a patented invention.

To avoid the trouble of having to file future license extensions, it is advisable to request the license for the full remaining term of the patent.

3.4.3 *Identification of the applicant*

The applicant, if not a natural person, will normally have to submit copies of the relevant statutes or bylaws. In addition, any person representing the applicant will have to demonstrate his or her capacity to do so. Depending on national law, the applicant may also have to provide evidence of sufficient economic or technical capacity to utilize the compulsory license (information about personnel, funding, activities, partnerships, publications, and so on).

3.4.4 *Identification of patents*

The identification of the patents involved can be determined by indicating the product or technologies at stake. The compulsory license application may refer to all patents relating to the products or technologies the applicant seeks to exploit. In other words, one application can request the rights to many patents. In the United States, there have been cases in which compulsory licenses were even granted for both current and future patents.[24]

3.4.5 *Conditions of the compulsory license*

Remuneration. Governments have considerable discretion to define the level and kind of remuneration that the patent owner should receive. The general rule is that remuneration should be adequate, taking into account both the particular circumstances of each case and the economic value of the compulsory license.[25] Following are some of the methods that have been used to calculate remuneration:[26]

- The 1998 Japan Patent Office (JPO) Guidelines (for government-owned drug patents) specify royalties that amount to 2%–4% of the generic product price; this amount can be increased or decreased by as much as 2%, for a range of 0%–6%.
- The 2001 United Nations Development Programme (UNDP) Human Development Report proposed a base royalty rate of 4% of the generic drug price. This can be increased or decreased by 2%, for a range of 2%–6%, depending upon various factors (how innovative the medicine is, or the role of governments in paying for research and development).
- In accordance with the WTO Decision of 30 August 2003, the 2005 Canadian government established royalty guidelines for compulsory licensing of patents to countries that lack the capacity to manufacture medicines. The royalty rate (between 0.02% and 4% of the price of a generic drug) is determined by a country's rank in the UN Human Development Index. For most developing countries, the royalty rate is less than 3%. For most countries in Africa, the rate is less than 1%.
- The tiered-royalty method is unusual in that the royalty rate is based upon the price of a brand-name drug, not the generic equivalent, in the high-income country in which the patent is owned. The base royalty (4% of the brand-name price) is adjusted to account for relative income per capita or, for countries with a particularly high burden of disease, relative income per diseased person.

These guidelines are used to determine royalty rates for products, not research tools. For research tools, royalty payments may be lower since no products are yet on the market.

With regard to agricultural technology, a relevant precedent may be the determination of 1,1% of the net sales of products within the Multilateral System in the context of the standard material transfer agreement adopted, in June 2006, by the Governing Body of the FAO

International Treaty on Plant Genetic Resources for Food and Agriculture.[27]

Finally, the act granting a compulsory license should specify time of payment, basis for the calculation of fees or royalties, currency of payment, the bank account where the payment will be deposited, and other relevant details.

Other conditions. In all cases, a compulsory license will be nonexclusive:[28] that is, the patent owner or other voluntary or compulsory licensors may simultaneously exploit the patented invention or research tool. According to some national laws, the license may be revoked if not utilized within a certain term. Moreover, a compulsory licensor can request that a license be terminated, if and when the circumstances that first necessitated the license cease to exist and are unlikely to recur.[29]

3.4.6 *Appeal*

A compulsory license may be delayed if the patent owner appeals the validity of the license or the level of remuneration that it grants.[30] For this reason, in some countries, a license can be put into effect even while appeal procedures are pending.

4. CONCLUSIONS

The problems generated by patent infringement on downstream use of inventions, especially in developing countries, can be minimized through a number of approaches. Countries should adopt and enforce strict criteria of patentability and broad exceptions for research. If patents on research tools limit FTO, the first step should be to negotiate voluntary licenses on reasonable terms and conditions, particularly as this may allow for the licensing of knowledge not disclosed in the patent. If it cannot be achieved, or proves too cumbersome or costly to do so, the next step should be to apply for compulsory licenses. Applicants need to be certain that they have the capacity to exploit the licenses and the financial ability to remunerate the patent holder or patent holders. Nonprofit research institutions may often find this particularly difficult because even with a compulsory license, commercial partners will need to be in place to produce and distribute products that were developed under compulsory licenses. This is one reason for further investments in capacity building and the establishment of strong institutional networks. ■

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1 Steil B, DG Victor and R Nelson. 2002. *Technological Innovation and Economic Performance* (A Council on Foreign Relations Book). Princeton University Press: Princeton and Oxford, p. 21.

2 Intellectual Property Rights and Vaccines in Developing Countries. Meeting report. Geneva, World Health Organization, 2004 (WHO/IVB/04.21). www.who.int/vaccines-documents/DocsPDF05/Dip-789-screen.pdf. Quoted in Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH). 2006. *Public Health, Innovation and Intellectual Property Rights*, World Health Organization. p. 77.

3 In a seminal contribution on this issue, Heller and Eisenberg stated: "*... the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an* anticommons *in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.*" (Heller M and RS Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280: 698–701). See also Tran C. 2006. WARF Stem Cell Patents Challenged: Research Could Get Faster and Cheaper If the Patents Are Narrowed, Some Scientists Say. *The Scientist*. 10 October 2006.

4 See, for example, Cho MK, S Illangaskekare, MA Weaver, DGB Leonard and JF Merz. Effects of Patents and Licences on the Provision of Clinical Genetic Testing Services. *Journal of Molecular Diagnostics* 2003: 3–8.

5 National Research Council. 2006. *Reaping the Benefits of Genomic and Proteomic Research Intellectual Property Rights, Innovation and Public Health*. The National Academies Press: Washington, DC. www.nap.edu/books/0309100674/html/.

6 Thumm N. 2005. Patents for Genetic Inventions: A Tool to Promote Technological Advance or a Limitation for Upstream Inventions? *The International Journal of Technological Innovation and Entrepreneurship* 25: 1410–17.

7 See Sampath G. 2005. Breaking the Fence: Can Patent

Rights Deter Biomedical Innovation in "Technology Followers"? Maastricht, UNU/INTECH, Discussion Paper Series No. 2005-10. www.intech.unu.edu/publications/discussion-papers/2005-10.pdf (CIPIH, p.77).

8 See sippi.aaas.org/.

9 See also, in this *Handbook*, chapter 2.2 by A Brewster, AL Chapman and SA Hansen.

10 The effects of patents, although territorial in nature, may extend beyond the territory of cultivation and reach derivatives of patented plants or genes. Monsanto, for instance, does not have a patent on Roundup Ready® soybean in Argentina, which is exporting processed soybean flour to European countries. In Argentina, the original Monsanto materials have been used in breeding since 1996, and around 160 local varieties containing the gene have been developed and registered by third parties. Although Monsanto, did not oppose the commercialization of those varieties, it has filed requests to the customs authorities of several European countries (where Monsanto does have patent protection for Roundup Ready® soybeans) demanding that the importation of soya flour produced in Argentina be prevented, and has initiated litigation against European importers. See also Correa C. 2006. La disputa sobre soja transgénica. *Monsanto vs. Argentina*, *Le Monde Diplomatique/El Diplό*, Buenos Aires, April 2006.

11 See for example, Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm.

12 www.goldenrice.org/Content2-How/how9_IP.html.

13 In some jurisdictions, research or experimentation exceptions may allow follow-on research *on* an invention, but not *with* it. This distinction is commonly accepted under European law. See, for example, Cornish W. 1998. Experimental Use of Patented Inventions in European Community States. *International Review of Industrial Property and Copyright Law,* 2. no.7; Correa C. 2005. *International Dimension of the Research Exception*, SIPPI Project, AAAS, Washington, D.C. sippi.aaas.org/intlexemptionpaper.shtml. In the United States, research without the authorization of the patent owner is narrowly admitted for scientific purposes only. The Federal Circuit Court of Appeals held in *Madey v. Duke* that regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or nonprofit status of the user is not determinative (64 U.S.P.Q. 2d 1737 (Fed. Cir. 2002).

14 See Article 31 of the TRIPS Agreement available at www.wto.org.

15 WT/MIN(01)/DEC/W/2, 14 November 2001. www.wto.org (full text in Annex I).

16 Paragraph 5 (b): "*Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*"

17 See, for example, Correa C. 1999. *Intellectual property rights and the use of compulsory licences: options for developing countries*. Trade-Related Agenda, Development and Equity, Working Papers. Geneva, South Centre; Reichman J and Hasenzahl C. 2002. Non voluntary licensing of patented inventions: history, TRIPs, and Canadian and United States Practice. Bridges (UNCTAD/ICTSD) Vol. 6, No. 7.

18 See *supra* note 2, CIPIH, p. 135.

19 FTO may be achieved through inventing around, nonassert covenants, opposition to the grant of a patent or invalidation thereof. For a comprehensive discussion on the various options for obtaining FTO, see in this *Handbook*, chapter 14.1 by A Krattiger.

20 See Article 5A of the Paris Convention for the Protection of Industrial Property.

21 See Article 31(b) of the TRIPS Agreement.

22 See, also in this *Handbook,* chapter 2.1 by AB Bennett.

23 If the permitted grounds are too narrow, a request for compulsory license may fail. For instance, the free trade agreement between the United States and Jordan (2000) limited the grounds on which compulsory licenses can be granted as follows: "*Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirement, provided that importation shall constitute working.*" (Article 4.20).

24 Correa C. 1999. Intellectual property rights and the use of compulsory licenses: options for developing countries. Trade-Related Agenda, Development, and Equity, Working Papers, South Centre, Geneva. Available at www.southcentre.org.

25 Article 31(h) of the TRIPS Agreement. The obligation to pay a remuneration is waived in the case of a compulsory license granted under the system established by the WTO Decision of 30 August 2003 (incorporated as Article 31bis of the TRIPS Agreement, but still subject to ratification) to import pharmaceutical products in cases where the importing country has established that it lacks sufficient manufacturing capacity in pharmaceuticals. Payment in these cases will only take place under the compulsory license granted in the exporting country.

26 Love J. 2005. Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies. World Health Organization: Geneva. (WHO/TCM/2005.1), p 83–85.

27 Correa C. 2006. Considerations on the Standard Material Transfer Agreement under the FAO Treaty on Plant Genetic Resources for Food and Agriculture. *The Journal of World Intellectual Property* 9(2): 137–65. See also the text of the adopted standard agreement at ftp://ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf.

28 Article 31(d) of the TRIPS Agreement.

29 Article 31(g) of the TRIPS Agreement.

30 The TRIPS Agreement specifically provides that "*the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member*" (Article 31(i)).

The Role of Clusters in Driving Innovation

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ABSTRACT

The promise of biotechnology relies on new science that is increasingly complex and specialized and depends on sophisticated, global intellectual property rights systems. This complexity requires a more open system of knowledge sharing than previous research and development programs. Studies suggest that successful innovation requires developing clusters of institutions, businesses, and personnel. "Location, location, location," the battle cry for property realtors everywhere, is increasingly becoming the key phrase in studies of innovation dynamics and knowledge-based growth. Offering an overview of recent research on clusters in Canada, this chapter suggests that governments have an important role to play in the process of cluster formation and that ensuring a mix of "local buzz" and "global reach" is part of the recipe for success.

1. INTRODUCTION

Biotechnology has changed the discussion about research and development in agriculture and medicine. In the past, research tended to be distributed widely to meet agronomic and human health needs, but now we are seeing agglomerations forming around the research, development, and commercialization of globally mandated technologies and products. Governments view this change as an opportunity to invest in and create comparative advantages or as a threat to their competitive status and ability to access new technologies.

Theory and evidence suggest that competing, innovative companies and their related industries will tend to concentrate in a few locations. Most innovation involves a lot of learning-by-doing, which creates a barrier for imitators who want to use the innovation: they can do so only after they have gone through their own learning process. Furthermore, the cumulative impact of learning-by-doing creates stronger competition in more-innovative companies and sectors, thus erecting barriers to less-innovative actors. While basic science and inventions (usually codified through scientific journals and patents) can often be transferred at low or no marginal cost, know-how and experience are very difficult to transfer across long distances. Applied science (know-how) does spill over to others in the sector, but estimates suggest that the spillover benefits of tacit knowledge are limited to between ten and 100 miles of the epicenter. This pattern is frequently seen in the innovation corridors of Silicon Valley, Boston's Route 128, and Austin in the United States, Cambridge in England, Bangalore in India, and Saskatoon in Canada.

Grossman and Helpman[1] argue that technological spillovers limited to a specific location (due, for example, to climate or industrial structure) create an opportunity for endogenously generated comparative advantage. According to the authors, countries that engage in technology-related

Phillips PWB and CD Ryan. 2007. The Role of Clusters in Driving Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

competitive activity can produce comparative advantage over time. If technological spillovers are geographically concentrated, then the initial and sequentially established conditions will affect subsequent economic growth. Grossman and Helpman further argue that, as a result, the high-technology share of GDP and exports will be greater in first movers than elsewhere. In the extreme, a country that inherits even a small technological lead could come to dominate world markets for high-technology products. A productivity differential then becomes self-sustaining.

Gilpin[2] argues that the new theories of economic growth create a new role for the state. Governments can generate growth, and numerous countries and regions have sought to do just that. By some counts, all large industrial economies, almost all major cities around the world and many smaller countries, cities, and regions have decided to invest in and nurture some form of a biotechnology cluster. There are literally hundreds of putative biotechnology clusters around the world right now.

2. BIOTECHNOLOGY, HEALTH, AND AGRICULTURE

Some 40% of the world's market economy is based upon biological products and processes—mainly food, protein and fiber production, and human health.[3] The security and the supply of food and fiber are threatened by increasing consumer demand, shrinking cultivable land, limited water, and diminishing returns on existing technologies. Further, while great strides have been made in extending and improving the quality of life, disease remains a constant daily threat in many countries. Food-supply insecurities and unchecked disease go hand in hand in many low-income developing economies, yielding a dismal, Malthusian outlook for a large portion of the world's population.

Biotechnology has potential to transform food production and health. A number of key scientific discoveries since 1970 in the fields of genomics and proteomics (for example, gene selection, gene splicing, and metabolic profiling) have opened up vast novel avenues of research, on new plants, animals, and microbes, that could have applications in medicine, agriculture, extraction, processing, and the environment. Despite some major obstacles, many scientists and policy advisors see great potential in modern, molecular-based biotechnology, especially through the new capacities to genetically modify plants and to detect and treat disease. In 2001, Daar and colleagues[4] undertook a Delphi survey of more than 30 scientists and bioethicists from around the world to identify the top ten technologies that could address a wide range of problems in the developing world. The list included eight biomedical applications: molecular technologies for affordable, simple diagnosis of infectious diseases; recombinant technologies to develop vaccines against infectious diseases; technologies for more-efficient drug and vaccine delivery systems; sequencing pathogen genomes to understand their biology and to identify new antimicrobials; female-controlled protection against sexually transmitted diseases, both with and without contraceptive effect; bioinformatics to identify drug targets and to examine pathogen-host interactions; recombinant technology to make therapeutic products such as insulin and interferon more affordable; and combinatorial chemistry for drug discovery. It also included one agricultural use: genetically modified crops with higher yields and increased nutrients that resist biotic and abiotic stresses, and an environmental application: technologies for sanitation, clean water, and bioremediation. If realized, these technologies would go a long way towards addressing the biggest food and health challenges of many developing countries.

3. LIFE-SCIENCE INNOVATION SYSTEMS

One opportunity or constraint, depending on how one looks at it, in achieving a better future is the relationship of innovation systems to life science research, development, and commercialization. In the classical model of innovation, relatively small groups of researchers (either in public laboratories or in private research groups) engaged in a mostly self-contained, linear process of research and development, a process that ultimately led to commercialization through direct or contracted production and marketing. This type of structure

was exemplified by the research departments at Consolidated Edison, 3M, and Xerox, where fully dedicated research staff were given the freedom to investigate and invent new products for commercialization by the host company.

Much of the early life-science research also conformed to this model, except that it was often carried out in public laboratories (for example, the discovery of insulin by Banting and Best at the University of Toronto in 1922, the discovery of the structure of DNA for which Watson and Crick at Cambridge University received a Nobel Prize, and the creation of low-erucic acid, low glucosinolate rapeseed in Canada). While these individual efforts drew upon knowledge generated by others, most of them operated in relative isolation, with little formal or informal exchange of information during the discovery phase. This "standing on the shoulders of giants" model has generally been the basis for research efforts since the scientific and industrial revolutions of the seventeenth century. While the model may have been appropriate in earlier times, since many innovations were simply the product of inventors' ingenuity, in more recent years, many institutions, companies, and industries have used a different strategy to develop and exploit life science inventions.

Indeed, the global life-science research effort has been significantly transformed. Two specific trends have led to this change. First, this new science has become increasing complex and specialized, which makes it increasingly difficult for isolated or independent scientists to realize breakthroughs or to pursue comprehensive research programs. Instead, teams or networks of researchers pursue investigations. Second, intellectual property (IP) rights have been extended into new subject areas and new jurisdictions. The United States started the process by extending patents through the Chakrabarty case in 1980 to living, single-celled organisms; patents were then extended through a series of subsequent decisions to whole plants, animals, and many human organs (but not the whole human being). Patent granting on living matter was internationalized over the past 20 years as other countries (for example, Australia, Canada, the European Union [E.U.], and Japan) either amended their own patent laws or issued judicial decisions extending rights. This IP rights system has been extended globally through the adoption of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) of the World Trade Organization (WTO), which, in 2006, began to require that all member states (virtually all countries) offer patents, plant breeders rights, or some other sui generis system of protection for IP embodied in living matter. Private (and public) inventors have adapted rapidly to this new regime, patenting almost all of their inventions (including the tools of discovery and the resulting products). By 2005 there were an estimated 58,000 patents relating to biotechnology tools and products in the United States, and a confusing array of rights claimed or allocated in other countries around the world. The increased role of profit seeking and the extensive use of formal IP rights mechanisms such as patents have created barriers to the free exchange of knowledge, which is now heavily scrutinized.

The specialization of science and the fragmentation of IP rights have forced scientists to collaborate and network more extensively to achieve research results (the Human Genome Project represents one type of widespread research network). Networks of institutions and researchers have evolved to handle the transfer, acquisition, and use of various forms of knowledge. Increasingly, research programs are not simply standing on others' shoulders but instead are working side-by-side through formal or informal collaborations or research networks. Sometimes these structures have grown organically; sometimes they have been actively supported and encouraged by government. Typically, they operate above the level of the company or the organization but below the global level; they are inherently regional and supraorganizational.

4. NETWORKED KNOWLEDGE

Networked knowledge exhibits three important attributes. First, it comes from a nonlinear research system, perhaps best illustrated by a chain-link model of innovation.[5] In essence, a chain-link system embeds the traditional linear development

process in a series of feedback loops. At the core, new technology or product development still goes through a relatively linear process, beginning with identification of the potential market, and involving successive efforts to design, adapt and adopt a new technology or product to the market need. But, unlike the linear model, where many of these steps were taken inside a closed R&D system (either inside a single company or involving only a few, formally aligned partners), the chain-link now involves extensive search and discovery functions, with innovators often going out beyond their own system to seek out existing knowledge or to undertake or commission research to solve specific problems in the innovation process. At the root, such a system depends on the efficacy and efficiency of the relationships that link the often disparate actors together.

Second, multiple types of knowledge are involved in such a system. Malecki[6] identifies four distinct types of knowledge: "know-why," "know-what," "know-how," and "know-who." Each type of knowledge has specific features.[7] *Know-why* refers to scientific knowledge of the principles and laws of nature. It is almost always derived from research efforts undertaken in publicly funded universities and nonprofit research institutes and is subsequently codified, published, and made accessible in academic or professional journals. *Know-what* refers to knowledge of techniques; usually it can be codified and transferred through the commercial marketplace. *Know-how* refers to the combination of skills, analytical capacity, and intellectual, educational, and physical dexterity of individuals and systems to effectively combine the know-why and know-what to innovate. This capacity is often learned through education and technical training and perfected by doing. This makes it more difficult to codify and also more difficult to transfer to others. Finally, know-who, which "*involves information about who knows what and who knows how to do what,*"[8] is becoming increasingly important in biotechnology-based industry. The breadth of knowledge that is required to innovate has expanded to such extent that collaboration has become indispensable. In today's context, know-who also requires knowledge of—and access to—private-sector knowledge generators who, at times, may hold back the flow of crucial enabling information, expertise, and knowledge. Know-who knowledge is seldom codified; instead, it often accumulates within an organization or, at times, in communities where a cluster of public and private entities are all engaged in the same type of research and development. These clusters often exchange technologies, biological materials and resources, and pursue common staff training or cross-training opportunities.

Third, each of the above-mentioned types of knowledge is likely to be subject to some form of exchange costs. Different types of knowledge are likely to be delivered by different actors.[9] Depending on the nature of the knowledge (whether it is easily codified as well as the cost of exchanging it), the exchange may be an arms-length market transaction (for example, contracts or spot markets) or may involve nonmarket organization (for example, intracompany transfer, development and use in the public sector or via collective institutions).

The public sector is optimally structured to create know-why scientific knowledge for the public good. Private companies and markets are generally well suited to managing codified knowledge, often in the form of patents. Collective organizations are often best for delivering knowledge, such as know-how and know-who.[10] Different domains, moreover, favor different formal or informal IP mechanisms, according to organizational objectives and abilities. Academics developing pure science emphasize publication and the use of copyright, while actors developing technology look to patents and trade secrets to protect interests. Collective institutions use less formal, open, pooled or networked knowledge, controlling access through a shared language, a common culture, and extensive collective experience.[11]

In sum, to understand networks and networked knowledge, we must consider the nature of the knowledge being developed and used, the transactional forms mediating the exchanges, and the institutional structure of the relationships that manage the development and use of IP. Increasingly, networks or communities of innovators are locating in aggregated clusters.

5. CLUSTER THEORY

"Location, location, location," the battle cry for property realtors everywhere, is increasingly becoming the key phrase in studies of innovation dynamics and knowledge-based growth. Theories about how innovation occurs, and more specifically about how and why companies and other actors co-locate in clusters, are incomplete but continue to evolve. As our understanding of innovation grows, so does our ability to direct its revolutionary power.

Widely used both in the academic literature and among economic development practitioners, the term *cluster* is helpful. The Oxford English Dictionary defines the generic term to mean a "*group of similar things, especially such as grow together*." Although companies and various not-for-profit entities in the same sector or product market have been observed since the beginning of recorded economic history to locate themselves in specific geographic regions (rather than spreading out evenly across the geography or economy), the search for ways to encourage clustering has only recently begun. Economists first began to develop models to explain such agglomerations in the 1700s. By the mid-1800s, economists were beginning to develop new theories and undertake intensive analyses of the phenomena. While that work continued on and off into the 1900s, the rise to dominance of the neoclassical economic paradigm after 1950 pushed these studies (and related policy prescriptions) to the margins.

That all changed in the 1990s. Beginning in the early part of the decade, economists began to refocus their attention on the microeconomic foundations of growth. After a decade of stagflation, new "conservative" governments shifted to a low-inflation macroeconomic stance and began to look for new microeconomic options to accelerate productivity and economic growth. Michael Porter's well-timed release in 1990 of the *Comparative Advantage of Nations*[12] reintroduced the concept of clusters, this time in a paradigm that posited that local competition is the primary dynamic behind cluster development and sustainability. This concept dovetailed with the shift in strategies by governments. Since then, the general concept of "*similar things… growing together*" has been applied widely to economic and industrial policy around the world.

Cluster theory is now a fabric of many threads drawn from economic geography, regional economic innovation systems, national innovation systems, and knowledge transfer and social networks. While there is no consensus on a complete theoretical explanation for clusters, a few threads are becoming common to most explanations of the phenomena. These return to the basic observations by Marshall,[13] who identified three clear and straightforward sources of external economies (Krugman[14] calls them "*centripetal forces*") that explained the location of some industry: knowledge spillovers, related and supporting industry, and specialized labor markets.

Much of the literature on clusters focuses on the potential for external economies to develop from information spillovers. Beyond the basic economies of scale in knowledge-based industry, external factors can significantly influence the industry due to "*mysteries being in the air*."[15] The literature on "*national systems of innovation*" (initiated by Lundvall[16]) posits that such systems involve "*that set of distinct institutions which jointly and individually contribute to the development and diffusion of new technology and which provide the framework within which governments form and implement policies to influence the innovation process. As such it is a system of interconnected institutions to create, store, and transfer the knowledge, skills, and artefacts which define new technologies.*"[17] In other words, innovation now involves and generates significant externalities—innovators increasingly rely on an array of formal and informal collaborators, and the efficacy of those relationships will determine their ability to successfully launch a new innovation. Mowery and Oxley[18] point out that these systems must include more than the research actors. They also require public programs intended to support technology adoption and diffusion, as well as an array of laws and regulations that define IP rights and manage discovery, production, and marketing.

Studies have focused mostly on the role of universities in innovation systems. The traditional role of a university is to generate and diffuse basic or explorative knowledge and to develop a skilled

academic and technical labor force. However, these traditional roles (in terms of knowledge-generation activity and culture) are evolving. As Cooke[19] argues, a strong local science base needs to be complemented by a thick entrepreneurial culture in both the regional business and academic communities. Brown and Duguid[20] suggest calling these connections "*communities of practice*." Not surprisingly, measuring such connections is complex and difficult because such knowledge is often tacit and nebulous.

A similarly large amount of research has concentrated on evaluating extensive local and regional networks of related and supporting industry (often called "backward linkages") and their access to large, sophisticated markets ("forward linkages"). Porter[21] analyzed 2,500 potential clusters around the world based on the strength and value of their arrays of forward and backward linkages. The Innovation Systems Research Network, a consortium of scholars examining 27 clusters in Canada, similarly evaluated the importance of industrial and supply-chain relationships on competitiveness and innovation. While these studies have shown that linkages are important, the evidence is still out on whether the linkages are a causal factor or are a result of effective innovation.

Finally, a number of researchers have attempted to evaluate the role of labor market dynamics for growth. These studies argue that when local labor markets expand and specialize, this creates incentives both for companies to co-locate and for specially skilled employees to migrate to those locations. This reduces the searching and negotiating costs for operating in the region. In addition, these labor force dynamics sustain and support the flow of knowledge among actors. Zucker, Darby, and Brewer,[22] for example, looked at the role of research stars such as high-impact academic researchers that were concentrated geographically, concluding that agglomerations of stars are positively correlated with greater local innovation. Stars appear to provide valuable signaling functions for capital markets to facilitate commercialization of new technologies and products.

Metcalfe[23] notes that Malerba's 1991 study of Italy identified two discrete, independent systems of innovation. One, typified by the computer software industry, is based on flexible networks of small- and medium-size companies, often co-located in distinct industrial districts (such as Silicon Valley). These companies were both very volatile and growing rapidly. The other type of system, which perhaps better reflects current biotechnology systems, is based on universities, public research laboratories, and large firms performing and commercializing R&D—called "*the triple helix*" by Etzkowitz and Leydesdorff.[24] It has been further argued that, regardless of the prevailing model, no institution can be self-contained in its technological activities.[25] All companies, large or small, have to rely on knowledge from other sources. Systems that support a company's ability to access, absorb, and use external knowledge can be critical to the growth of companies, sectors, and regions. This is especially so in the early stages of a technology's development or when a technology has a rapidly changing knowledge base, as is the case with biotechnology.

Critics argue that the term *cluster* is vague and has become mere rhetoric. Markusen[26] argues that the cluster literature involves "*fuzzy concepts*" based on "*scanty evidence*" that produces "*wimpy policy*." According to the OECD, the definition of a cluster "*provides little guidance for narrowing the scope of inquiry in a meaningful way*."[27] Similarly, according to Martin and Sunley,[28] "[Clusters have been] *accepted largely on faith as a valid and meaningful way of thinking about the national economy, as a template or procedure with which to decompose the economy into distinct industrial-geographic groups for the purposes of understanding and promoting competitiveness and innovation*." Finally, some critics argue that clusters can be interpreted to imply rising self-sufficiency, which may work against the economic benefits of specialization and open trade based on comparative advantage.

6. CLUSTER PRACTICE

No matter how vague the term, this has not prevented its rapid adoption. Economic development agencies in developed and developing countries

have applied Porter's generalized approach to clusters, customizing it to their particular geopolitical region. More than 1,100 clusters have been examined in recent years,[29] but few of these have examined the research components of health or agriculture, and only three major studies have focused on clusters in the life-science area.

Ryan and Phillips,[30] for example, identified and categorized 14 life-science clusters in seven countries in 2001, concluding that life-science-based innovation clusters vary in scope and scale across the regions of Australia, Europe, and North America (see Table 1). Some clusters are discrete communities in which development and preservation are driven by clearly defined public policy. The communities often have names signifying their status as an innovation cluster (for example, BioBelt, BioValley, and Innovation Place). Ryan and Phillips discovered that most clusters were based on a core of biomedical research. In those that claimed to have an agri-food focus, the effort was often only a small, relatively insignificant adjunct to the core. There are very few established clusters dedicated to agricultural or agricultural biotechnology other than Canada's Innovation Place in Saskatoon, Saskatchewan; the Agri-Food Quality Cluster in Guelph, Ontario; and perhaps Adelaide Centre in Australia. In each case, a large percentage of the primary and supporting (private and public) actors are directly involved in food quality and agricultural biotechnology.

Table 1: Selected Life Science Clusters

Country	Region	Number of actors	Private sector presence	Ag/ag-biotech component
Canada	Innovation Place, Saskatoon, Saskatchewan	115	73%	29%
	Agri-Food Quality Cluster (AFQC), Guelph, Ontario	41	76%	49%
United States	Connecticut Bioscience Cluster	110+	98%	1%
	The Research Triangle Park (RTP), Raleigh-Durham and Chapel Hill, North Carolina	145	92%	3%
	BioBelt, St. Louis, Missouri and Illinois	1,183	90%+	24%
	Biotech Beach, San Diego, California	700	90%+	3%
Europe	Innovation Triangle, Edinburgh, Dundee and Glasgow, Scotland	428	95%	2%
	BioValley, France, Germany, and Switzerland	459	90%	6%
Australia	Qbio, Brisbane, Queensland	43	42%	5%
	BioHub, Sydney, New South Wales	28	75%	18%
	Bio21, Melbourne, Victoria	24	0%	4%
	Adelaide, South Australia	25+	65%	44%
	Perth, Western Australia	27	80–90%	20%

Source: Adapted from Ryan and Phillips.[31]

Cluster models appear to be very different.[32] The United States focuses on commercial outcomes and investment attraction, placing key multinational companies (some might call them national champions) at the center of their regional clusters. In Europe, the public sector (universities and large research institutes) is the main driver. Canada's key clusters tend to be community led, while Australia appears to use a blend of cluster approaches. Phillips and colleagues[33] examined the seven Canadian biotechnology-based clusters studied through the Innovation Systems Research Network.[34] These seven communities represent a wide range of size, scope, foci and histories (table 2).[35]

Consisting of both large pharmaceutical and small biotechnology companies, the Montreal cluster is the largest biotechnology cluster in Canada. It benefits significantly from provincial-government programs and national research labs. Recent surveys identified 351 actors: 130 in human health, 26 in human nutrition, 12 in agricultural biotechnology; and seven environmental companies; 171 service and supporting enterprises; one government lab; and four related universities. As of 2002, 29 companies in Montreal had patented 234 locally invented technologies, but 89% of the patents were owned by the eight largest companies. Growth in the region since 1999—when only 14 companies had 66 patents in total—has been explosive.

The Toronto cluster is a two-part cluster: one part is dedicated to core biotechnology activities and the other to biomedical devices. Anchored by the Medical and Related Sciences (MaRS) Discovery District, the University of Toronto (U of T), and the Health Network have also been identified as primary knowledge generators. A concentration of companies is situated downtown while some skilled workers are concentrated in peripheral regions. It appears that once firms or organizations move from exploration to exploitation activities, they move to the neighboring cities of Etobicoke or Mississauga to take advantage of lower costs. This contributes to weak network coherence, although Mississauga appears to be more cohesive. While the U of T has a significant number of stars, it has historically been considered unsuccessful in facilitating spinouts. This has been variously cited as the reason for limited local expertise in biotechnology financing.

It is not yet clear whether London, Ontario has a distinct biotechnology cluster or whether the activity there is merely an extension of the Toronto cluster. With an established biomedical-devices competency that started in the 1970s, London would appear to be an early-stage, emerging biotechnology cluster focused on biopharmaceutical applications. Linkages among local actors appear to be weak, with most acknowledging that they are more connected to actors in the Toronto core than they are to one another.

The Vancouver cluster, which focuses largely on biomedical biotechnology, is essentially a research community with the University of British Columbia (UBC) at the core. UBC and, to a much lesser extent, Simon Fraser University, are home to almost 80 research stars who produce a wide array of IP. While there have been some spinouts from UBC, more than two-thirds of which have survived at least five years, the prime focus of the cluster is on developing IP rather than products. Government and industrial support has not fundamentally altered the cluster. Early research suggests that lifestyle may be one of the critical factors that sustains the university and attracts both companies and individuals to the region.

The Saskatoon cluster is almost purely an agricultural-biotechnology cluster, focused predominantly on oilseed crops. While the university is home to the largest number of researchers in the community, many of the stars and much of the IP that is developed and used have come from federal labs. NRC's Plant Biotechnology Institute (NRC/PBI), the focus of considerable research collaboration, appears to share leadership with the local industry association, AgWest Bio. While the cluster is research focused, it has succeeded in commercialising world-first genetically modified plants, vaccines, and inoculants. Recent public investment in the university—including the Canadian Light Source Inc. (CLSI) synchrotron project and various genomics projects—has the potential to change the direction of the cluster over the coming years.

Table 2: Comparison of Canadian Biotechnology-Based Clusters

Cluster	Focus	Core actor(s)	Stars	Preliminary observations
Montreal	Pharmaceutical and biotechnology	A handful of generic and multinational-enterprise patent drug companies	70	• provincial government leads in terms of progressive policies • 15 spinouts University of Montreal
Toronto	Biotechnology and biomedical	Medical and Related Sciences (MaRS) Centre; University of Toronto; and the Health Network	47	• concentrated in Toronto at exploration stage; moved to peripheral regions (Etobicoke) at exploitation stage • limited network coherence
London	Biotechnology / biomedical devices (established in 1970s)	University of Western Ontario; Robart's Research Institute; and Lawson Health Research Institute	5	• early-stage biotechnology cluster • cluster or merely TO 'cohort'? • transportation considered a weakness
Vancouver	Biotechnology	University of British Columbia	80	• producer of IP, not products
Saskatoon	Agricultural biotechnology	National Research Council-Plant Biotechnology Institute; AgWest Bio	45	• research based • new investments in genomics, Canadian Light Source Inc., and University of Saskatoon may change direction
Ottawa	Biomedical and biotechnology	Gamma Dynacare (Ottawa Life Sciences Technology Park)	6	• more than 40 research institutes • 18,000 people employed in life sciences • 15–20 spinouts
Halifax	Pharmaceuticals, health, nutraceuticals, information technology, and biomedical	none	min.	• a variety of companies, with little product focus • not clearly a cluster • weak networks

The evidence available to date suggests that, based on the traditional definition of the concept, neither Ottawa nor Halifax are clusters. While Ottawa appears to have a large number of research institutes, its identifiable biotechnology cluster is quite small. As of 2002, there were only 47 actors: 30 small biotech companies, six government labs, one connected university, and ten service/support organizations. Only two of the Ottawa-based companies had generated patents by 2002, and the University of Ottawa had only a few stars and limited success with patents (11 as of 2002). Meanwhile, Halifax hosts a variety of companies with little or no market focus. Actors are not focused on any specific technology or product application. Instead, some actors are in the heath sector (devices, pharmaceuticals, information technology, and neutraceuticals), while others work on horticulture, environmental applications, and food quality. There is currently no obvious anchor organization, and actors in the region are loosely connected. In contrast to most other clusters, this one has seen little investment in infrastructure in the past few decades. Local surveys suggest that there has been little or no success in facilitating technology transfer, which has led to limited engagement between business and academic scientists.

This review of Canada's clusters offers a number of insights into cluster practice. Although biotechnology-based industries have common, "deeper science" aspects, they appear to differ widely in terms of organization. The significant differences in size (Montreal versus Saskatoon), market focus (core biotech in Vancouver versus medical devices in Toronto), and cohesion (strong in Saskatoon and Montreal but weak in other centers) suggest that the way in which the cluster is organized—its position in a product or technology life cycle and how its actors interact—can vary widely.

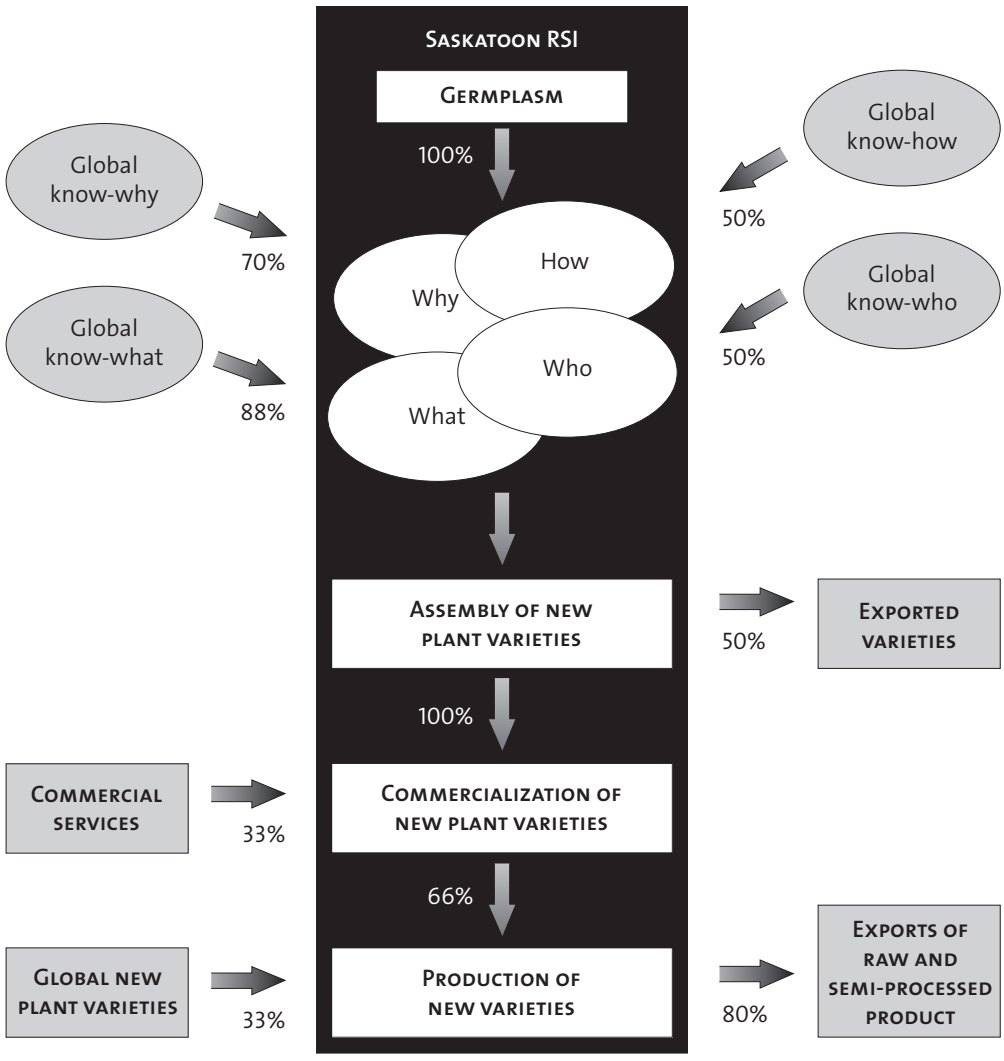
Phillips[36] examined the dynamics of the Saskatoon-based ag-biotechnology cluster by focusing on knowledge flows. Wolfe and Gertler[37] suggest that a more-sophisticated approach to clusters is to consider them as regional systems of innovation that embody local interdependencies (what Wolfe and Gertler call "*local buzz*") and engagement with the broader international economy ("*global reach*"). A local buzz and global reach, or entrepôt, approach would highlight the balance needed between local, regional, national, and global capacities. Phillips[38] analyzed the stocks, flows, and accomplishments of the Saskatoon innovation system through the mechanism of an entrepôt model. It looked at the community's capacity to create knowledge, use knowledge, and commercialize new products. Saskatoon's claim to fame is arguably the development of canola (based on its record as the lead innovator and early adopter of all new traits over the past 40 years). Analysis showed, however, that a significant share of the applied research to develop the processes used in the creation of those varieties has been done in other countries. Moreover, much of the application-based research (for example, uses for new oils) is happening elsewhere. This suggests that Saskatoon has actually operated in a niche of this global, knowledge-based industry—as an entrepôt undertaking and assembling the know-why, know-how, and know-who of varietal breeding and primary production—but that the bulk of the activities up- and downstream of that stage in the production system are now, and may continue to be, carried on elsewhere. Figure 1 illustrates the relationships between the global industry and the Saskatoon entrepôt.[39]

7. CLUSTERS AND IP MANAGEMENT

Research is increasingly generating networked knowledge. This new asset potentially has new economic and commercial value, but it faces a new set of complex relationships and transaction costs. Recent research into cluster structures in the Saskatoon-based agricultural-biotechnology cluster suggests that one driver for agglomeration may be the development of a cost-effective, efficacious system of IP management. This community has been host to a number of highly competitive multinational companies, has patented many critical life-science inventions, and has delivered a number of world-first technologies to the marketplace. Its experiences offer some insights into another possible objective of clusters.

In a perfect world with full information and no transaction costs, complete contracts to finance and undertake common research would be optimal. However, we know that transaction costs (especially with highly fragmented IP rights) are nontrivial, and that the probability of having a commercial success in any given project is relatively low (usually, less than 10% of projects return the costs of investment). Hence, as transaction costs rise, full contracts become less likely. Furthermore, it tends to be difficult to measure the often-tacit inputs to research programs. Attributing respective contributions to success in the discovery process is also tricky. In addition, any resulting outputs often have very specific uses, which makes them hostage to their potential users. These factors can lead to a classic case of "hold up," whereby investors may not be willing to invest because their bargaining power after any research breakthrough would be very

Figure 1: The Saskatoon Biotechnology Entrepôt and Its Global Connections



Source: Phillips 2002 [36]

low.[40] While long-term contracts would be one way to resolve this conundrum, few contracts will be negotiated for one-time projects. An alternate solution is to use social capital (for example, norms and relationships) in a community or cluster. In essence, by using the cluster as the basis for a research relationship, the difficulties of negotiating one-time deals can be overcome: the research community operates as if it is engaged in repeated exchanges. Participants in a cluster thus often will not negotiate each deal as if it were a one-time event. Rather, they would be willing to leave some terms and conditions unspecified, on the (usually justified) assumption that the strength of overall community relationships would reduce the probability that any company or actor would act with guile.

The Saskatoon-based agri-food research cluster gives a sense of how clusters or regional systems of innovation can lower transactional costs.[41] This community is credited with a series of world-market firsts (for example, agrobacterium technologies) and product firsts (for example, herbicide-tolerant canola and flax). It took the lead in the development of the concept for a National Agricultural Genome Centre (which, although unsuccessful in reaching that particular goal, ended up providing a model for Genome Canada) and leads four major genomics agri-food projects. Most of these initiatives were developed without formal *ex ante* contracts; instead, leaders in the community developed the projects under the assumption that any gains and losses would be apportioned equitably, or at least that any short-term losses would be compensated by future joint projects. This apparent altruism is nothing more than an extension of the community's business model, as Phillips and Khachatourians[42] and Phillips[43] show in their examinations of how Saskatoon became a national center for the generation, transmission, and consolidation of noncodified knowledge in the agricultural biotechnology industry. At the core of this community are Agriculture and Agri-food Canada and the National Research Council. Both have extensive arrangements with each other, public universities, and private companies, which allow them to learn from their collaborations, thereby adding further to the local stock of know-how knowledge and providing a visible, efficient point of entry for nonresidents to access know-how and know-who capacity. The public institutes also provide a home base for research stars, which, according to Zucker and colleagues,[44] reduces the search costs for other researchers and subsequent commercialization. The largest single geographic concentration of stars and near-stars in the canola research world is located in Saskatoon, where 11 out of 69, or 16%, of the top scientists live and work.[45] Phillips and Khachatourians[46] report that multinational enterprises (MNEs) and smaller companies in Saskatoon were primarily attracted by the presence of key personnel in collaborating and competing organizations. Although the public and private institutions have changed in recent years, the social capital built up appears to continue to sustain collaborative activities.

8. LESSONS FOR DEVELOPMENT AND IP MANAGEMENT

Knowledge-based development is inherently different from traditional industrial development. While a traditional industrial strategy that promoted infant industry via protection made some sense in the industrial world, it is not clear whether it has any value in a knowledge-based world.

This emerging global pipelines/local buzz cluster model of innovation poses some serious challenges for development policy. Much of the current biotechnology-development effort has a strong mercantilist orientation that focuses on self-sufficiency. Governments at all levels in many countries are actively using their tax and fiscal policy to encourage more local R&D and to attract global companies to relocate their R&D programs so that higher-value exports can be generated and imports replaced. This often involves preferential support for national champions or exclusive deals to encourage MNEs to relocate their activities. Usually governments do this without considering the corresponding relationships and interactions that knowledge-based companies require to succeed. If innovation can be thought of as limited to within a company or within a regional or national community, then

such a narrow approach might have some chance of succeeding. But the increasing complexity and fragmentation of knowledge and IP rights in the biotechnology sector suggests there likely is no single center that can effectively develop new biotechnologies or applications. Networking and partnerships are going to be the order of the day. And, if innovation is truly global, as appears to be the case in many of the life sciences, then narrow, mechanistic, self-sufficiency strategies may either simply fail or prove counterproductive.

One key to success in these circumstances will be to invest in the institutions and mechanisms that encourage the development of and access to the four knowledge factors (know why, know what, know how and know who), which provide the foundation of a research economy. A number of strategic options might be appropriate. First, effective mechanisms to protect and legally transfer IP across international boundaries are the price of admission to collaborations. Second, clusters that are open to new knowledge, IP, and highly qualified personnel and companies will likely be more successful in creating and commercializing new biotechnologies or related products. Third, simply declaring that a region is a cluster is not enough. There must be some regional investment in infrastructure, as well as openness and/or support for the emergence of one or more anchor institutions. While private companies may have the greatest drive for commercial development, governments often have only limited direct influence on their location and operation. Governments can strengthen their hand by considering how their universities or public research labs can be used to anchor the community. Ultimately, the goal should be to create some platform to generate mysteries in the air. Whatever forms this platform takes, it will need to generate both local buzz and tap into global pipelines.

In short, innovation clusters are very attractive economic development and IP management tools, but they must be nurtured with an appreciation for their partial and incomplete nature. Part of a global innovation system, they cannot thrive if cut off from the lifeblood of that system—ideas, skilled labor, and collaborative platforms. ■

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What Does It Take to Build a Local Biotechnology Cluster in a Small Country? The Case of Turku, Finland

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ABSTRACT

There seem to be new biotechnology initiatives springing up in almost every country and every region, no matter how big or small. This is the case for both developed countries and many developing countries. At the same time, many studies seem to suggest that the industrial dynamics of the biotechnology sector strongly favor only a few globally important locations. These are characterized by well-established relations between small R&D companies and the presence of venture capitalists, big multinational corporations, and service providers. The tendency of biotechnology clusters to form in certain locations raises some questions. Can all these new initiatives be successful? Can biotechnology research clusters develop and prosper on a smaller scale? The aim of this chapter is to discuss ideas for building successful biotechnology clusters in less-developed places. Using the example of Turku, Finland, the chapter analyzes how public policy and local activity can "fill the gaps" in the innovation system, thereby facilitating the emergence of a biotechnology industry. Although this case study is from a developed country, many developing countries face similar challenges to those Turku has faced.

1. INTRODUCTION

The economic literature of the past decade has often argued that innovation is the most important source of competitiveness, especially for high-tech industries working within global markets. At the same time, it is widely known that particular industries tend to cluster in certain areas and that the clustering of knowledge is an important reason for this phenomenon.

Biotechnology, one of the most prominent new industrial sectors, is typically a very spatially clustered industry. Biotechnology companies are often located close to major universities, hospitals, and research centers, and are sometimes associated with supportive bigger companies interacting with small- to medium-sized enterprises. Moreover, the biotechnology sector usually makes extensive use of external services in R&D—testing, financing, and marketing—which also tend to be located close by.

Biotechnology activities also tend to concentrate strongly in specific areas of the globe. A few local concentrations (such as Cambridge, Massachusetts, and San Francisco/San Jose, California, both in the U.S.A.) are globally dominant.[1] In the past, biotechnology has been very much dominated by the United States and, to a lesser extent, by the United Kingdom.[2] But the past decade has seen a huge increase in biotechnology-related development in many other places. Countries, regions, and cities all over the world have realized that biotechnology is the next big thing following the success of information and communication technologies (ICT).

Previous studies have shown that the industrial dynamics of the biotechnology sector, especially in biopharmaceuticals, strongly favor only a few globally important clusters characterized by well-established relations between small R&D

Viljamaa K. 2007. What Does It Take to Build a Local Biotechnology Cluster in a Small Country? The Case of Turku, Finland. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

companies, venture capitalists, big multinational corporations, and service providers. It would seem to be at least difficult, and perhaps entirely impossible, to develop an industry when some or most of these factors are missing. Nevertheless, the biotechnology industry is growing in many places that may at first seem unfavorable: in developed countries like Finland, but also in many developing countries such as India, China, Brazil, and South Africa.[3]

This chapter analyzes how public policy and local activity can "fill the gaps" in the innovation system so that it is possible for a biotechnology industry to emerge and grow in seemingly unfavorable places. The basic questions I will answer are: What policies and institutions best support the knowledge generation and dissemination processes of high-tech industries in smaller, more peripheral, or less developed regions? In other words, what are alternative ways of developing a favorable environment for the emergence and development of a local biotechnology concentration? What sorts of relationships between local actors encourage the development process?

My argument is that it is possible, at least to some extent, to compensate for vital resources that may be missing in small economies and clusters. However, there seem to be several basic conditions for success. First, there has to be a substantial local knowledge base (often a university). Second, the national or regional innovation system must compensate for any missing resources (public venture capital, R&D funding, services, and so on). Third, a network of capable local actors (public or private) must develop and strategically direct a local innovation system.

To support the argument that it is possible to compensate for missing vital resources, the chapter analyzes the recent development of the biotechnology industry in Turku, Finland. The development of the biotechnology sector in Finland during the past fifteen years has been largely due to active national innovation policies. In terms of numbers of biotech firms, Finland ranks tenth in Europe.[4] The biotechnology industry in Turku has grown thanks to local activity, and Turku itself is home to the second-largest concentration of biotechnology-related activities in Finland.

The recent rise of biotechnology in Turku is largely due to the fact that it has drawn on decades-old capabilities across a variety of sectors in food processing, pharmaceuticals, and materials sciences. Furthermore, local development activities and a national science and technology innovation program have encouraged development.

It remains to be seen whether or not biotechnology will continue to prosper in Turku. However, this study finds that active policy measures can allow smaller, more peripheral places to attract the interest of biotechnology entrepreneurs.

2. THE BIOTECHNOLOGY INDUSTRY

In this chapter, "biotechnology" refers to a broad range of life sciences (biosciences) and their utilization in medicine, primary production,[5] industry, and services. Biotechnology is a set of powerful tools that employs living organisms (or parts of organisms) to make or modify products, improve plants or animals, or develop microorganisms for specific uses. The Organisation for Economic Co-operation and Development (OECD) defines biotechnology as "*the application of science and technology to living organisms as well as parts, products, and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services.*"

The development of biotechnology can be divided into three phases. Early first-phase biotechnology includes traditional animal and plant breeding techniques, as well as the use of yeast in making bread, beer, wine, and cheese. The second phase started in the 1940s when biotechnology was introduced into modern industry. Modern, or third-phase, biotechnology includes the industrial use of recombinant DNA, cell fusion, novel bioprocessing techniques, and bioremediation. This phase started in the 1970s, when new tools for modifying the genetic structure of living organisms were introduced.[6]

Interestingly, new advances in the biosciences have blurred the boundaries between historically separate disciplines. Biology has begun to overlap with other fields, such as medicine, chemistry, informatics, and physics, thereby increasing the need for interdisciplinary research and bringing

different industries closer to each other. Many new technologies developed for molecular biology research, such as high-throughput DNA sequencing, protein structure determination, and gene expression analysis on "DNA chips," are also used in ecology, agriculture, forestry, and the biotechnology and pharmaceutical industries.[7]

The nature of an industry greatly influences how it develops in any given location. Biotechnology is very demanding in terms of R&D. Bioscientific research is also time-consuming and requires methods and instrumentation that are rapidly evolving and expensive.[8] Because the cost of R&D is so high, funding becomes especially crucial for both universities and industry. Furthermore, many biotechnology innovations are based on basic research, which means that the time from innovation to market is very long.

Cooke[9] has observed that the focus of knowledge creation has changed. In the past, the world of pharmaceutical R&D was dominated by large multinational companies (MNCs). However, there is growing evidence that university or public laboratory research with associated spinouts and dedicated biotechnology firms (DBFs) are now responsible for most knowledge generation and exploitation, while global MNCs are specializing in distribution and marketing. The combination of two factors—spatially highly concentrated R&D and global marketing and distribution strategies—means that the innovation system in biotechnology has become both highly regionalized and highly globalized. The tendency of biotechnology activities to congregate means that local clusters of biotechnology activities are an important unit of analysis.

3. ON INDUSTRY CLUSTERING AND KNOWLEDGE

This chapter focuses on local concentrations of biotechnology-related activities. The first studies on the economics of territorial agglomeration were in the nineteenth and early twentieth centuries: the works of Marshall.[10,11,12] Traditional analysis of spatial clustering tries to analyze the advantages that firms get by locating near to each other (localization economies). According to Malmberg and Maskell[13] there are at least three factors that traditionally encourage spatial clustering:

1. Reduced costs of producing and maintaining a dedicated infrastructure and other collective resources
2. Well-functioning markets for specialized skills
3. Reduced interaction costs for co-located trading partners

In the last few decades, researchers have tried to explain the relationship between the spatial clustering of firms and the innovation process. Several different approaches have been developed, including innovative milieu, new industrial spaces, spatial clusters of innovation, regional innovation systems, and learning regions.[14] The topic has become more relevant in recent years because technological change and globalization have led to intrinsic economic changes.

Globalized markets, increased competition, and the development of information and communications technologies have forced companies to find new ways of increasing their competitiveness. Furthermore, new scientific developments are occurring all the time. This combination of external pressures and opportunities makes for a very turbulent corporate environment.[15] Companies respond to these pressures in two ways: by specializing and by innovating. They outsource in areas where they are weak and try to maximize the profits of their core competencies through innovation. Both of these strategies tend to create local as well as global connections. Many services and external functions have to operate locally. This is typically because of the economics of scale that local clustering of associated actors brings; economies of time and smaller transaction costs are generated by trust and easy face-to-face interaction. Firms can increase their competitiveness by sharing an infrastructure and by sharing supplier and service networks. In order to facilitate knowledge generation and transfer, companies locate themselves near knowledge sources and each other so they

can make better use of local knowledge spillovers[16] and informal types of social interaction that form the basis for innovation and learning.

The fact that knowledge, learning, and innovation are important if an industry is to retain its competitiveness suggests a fourth advantage to spatial clustering:

4. Facilitation of knowledge spillovers, learning, and adaptation

   Local industrial structure with many firms competing in the same industry or collaborating across related industries tends to be dynamic, flexible, and innovative; the existence of a local culture facilitates knowledge transfer. The co-location of firms cuts the expenses of identifying, accessing, and transferring knowledge.[17] There are several reasons why innovation capability is related to spatial clustering:

   - **new knowledge**. Usually difficult to codify and therefore difficult to transfer. New knowledge is best transferred through repeated and frequent face-to-face contacts. Innovation is therefore facilitated by geographical proximity.
   - **knowledge exchange**. Can happen through knowledge spillovers. On the other hand, most actors are unwilling to share crucial information when there is a danger that it could end up in the hands of competitors. Knowledge exchange may happen as a result of long-term cooperation with universities and research institutions.
   - **the availability of a high-level workforce**. A very important requirement for innovation. The mobility of labor, especially in Europe, is lower than the mobility of other resources, and so labor tends to concentrate in certain regions.

All these knowledge-related factors are important because biotechnology typically has a much greater need for basic research and a highly educated workforce than does any other industry. It also tends to collaborate more with universities than do most other industries.[18]

This chapter also investigates the process of cluster formation and the conditions that enable a local biotechnology cluster to emerge and grow. Much of the conventional wisdom regarding successful industry clusters is based on studies of fully functioning innovation systems such as Silicon Valley.[19] However, the conditions under which mature clusters operate are not, in many cases, present at the creation of new clusters. The history of each cluster is unique, suggesting that cluster development is either path-dependent or heavily influenced by chance historical events.[20] The current economic strengths of a particular region are often based on developments and activities that took place over the course of several decades. Examples of this phenomenon are the Research Triangle Park in North Carolina, U.S.A.,[21] Silicon Valley, U.S.A.,[22] and Oulu and Tampere, in Finland.[23]

New clusters often develop thanks to pre-existing local expertise in related fields. Many places with ICT centers were founded in areas that already had expertise in electronics (for example, in Silicon Valley and Oulu). Therefore, it is important to understand both regional assets and the cluster formation process in order to develop policies that will support emerging clusters.

Feldman and Francis[24] have concluded that cluster formation appears to be characterized by three general stages.[25,26] In the initial stage, there are typically few, if any, spinout companies, but there are some needed assets such as large companies and universities. An exogenous shock that lowers the opportunity cost for entrepreneurship (such as a merger and acquisition or a change in the funding environment) tends to encourage active entrepreneurship and the subsequent appearance of new spinout companies.

The second stage is typically characterized by increased interaction between entrepreneurs and their environment.[27] In this stage, the cluster self-organizes in order to better serve its own needs. Various institutions may be created to support the cluster, and these institutions may, in turn, stimulate further innovation and promote localized learning.[28]

In the final stage, the success of the first spinouts and the synergy between them generate new possibilities for other firms in the same field. At the same time, an enhanced innovation

environment develops around the cluster (consisting of universities, technology centers, local policy-makers, service providers, and so on). At this final stage of cluster formation, a critical mass of resources provides locational advantages.

4. INNOVATION AND INDUSTRY STRUCTURE IN BIOTECHNOLOGY

The geographical concentration of biotechnology is also the concentration of *knowledge*. Universities and R&D institutions are local concentrations of knowledge and expertise, and they can potentially provide a workforce for local firms. Many knowledge spillovers are local, either because they are based on tacit knowledge or because people are usually well informed about developments inside their own local knowledge base. For example, Jaffe and colleagues[29] show that most knowledge was used within a 50-mile radius of the university from which it originated. Also, the successful development of biotechnology, especially in the early phases, seems to require a considerable amount of tacit knowledge, which itself often relies on short-distance or face-to-face interaction.[30]

The local existence of high-level knowledge and research seems to have more of an effect on the development of biotechnology clusters than do local knowledge spillovers. According to Cooke and colleagues,[31] the biosciences do not typically make wide use of informal local tacit knowledge and face-to-face exchanges, informal networks, or other indirect region-specific assets that are often referred to as untraded interdependencies.[32] Because biotechnology techniques are so specific and specialized, there is typically not much knowledge transfer through social ties or networking between firms. In the early phases of the creation of biotechnology clusters, localization effects seem to be due to the so-called star scientists who are invaluable to R&D and tend to locate near their home universities.[33]

Another factor in the creation of biotechnology research clusters is the increasingly multidisciplinary nature of biotechnology R&D. In many cases, development work requires a heterogeneous set of cognitive skills and, therefore, a need for transdisciplinary network relationships that are most easily found within a larger concentration of related activities.[34]

What Cooke and colleagues call "exploitation knowledge"—that is, the knowledge of how to use basic research for practical applications—is found in clusters for several reasons. As small DBFs rely on research scientists to translate noncodified knowledge so that it can be further developed into commercial products or services, people with experience in both research and industry tend to be magnets for new companies.

In many cases, special services also play an important role. Business services and specialized expert services tend to locate close to key customers and thereby make these locations more attractive to new companies. I suggest that even if R&D companies trade very little knowledge with each other, they interact quite a bit with companies in fields like business expertise and services.

Biotechnology companies tend to be located close to major universities, hospitals, research centers, and sometimes supportive larger companies that interact with small- to medium-sized enterprises. At least initially, most new ideas and spinouts seem to originate from universities. However, Feldman argues that even though universities seem to be necessary for the development of biotech research clusters, the mere existence of a large knowledge base is not always enough.[35] Orsenigo argues that the existence of a strong scientific base does not guarantee that new companies will start up or that an industry will emerge.[36] There is also no firm correlation between the number of spinouts and either university financing or the number of patents applied for.[37]

As a biotechnology research cluster develops from the "science stage" to commercial application, the cluster may become dependent on a few bigger anchor firms. Larger companies can act as pools of skilled labor and demand special inputs such as specific products and services that may benefit smaller spinouts.[38] Large established companies can also act as sources for new entrepreneurial activity in the form of spinouts or outsourcing.

The mechanisms of co-location and spatial clustering seem to be especially strong in the biotechnology industry. However, the presence of favorable conditions (for example, a

strong science base and a working labor market) is insufficient to explain why an industry develops in a particular region. Favorable conditions in a particular locale may encourage the establishment of an industry, but its growth is determined by other factors: its structure, technological change, economic factors, and changes in the institutional base and local development policies.

4.1 *Typical characteristics of successful biotechnology clusters*

Many studies and strategy papers have analyzed the factors that are needed for the biotechnology sector to prosper, and most of them have come to similar conclusions. They emphasize the role of a strong science base, a skilled workforce, supportive infrastructure, and the availability of services and financing. A British study[39] identified the following factors for successful biotechnology clusters:

- a strong science base
- an entrepreneurial culture
- a growing company base
- the ability to attract key staff
- the availability of financing
- appropriate premises and R&D infrastructure
- the close proximity of business support services and large companies in related industries
- a skilled workforce
- effective networks (for example, associations and cluster councils)
- supportive (national, regional and local) government policies

Although many industries benefit from the factors listed above, they apply especially well to biotechnology. Biotechnology is a science-driven business,[40] which means that clustering often occurs in close proximity to key knowledge centers, usually universities or public research institutes conducting top-level research. Because this knowledge is very often tacit and tied to individual researchers or research groups, effective utilization requires close interaction between actors and multilevel partnerships.

According to Cooke,[41] because research tends to concentrate near the key magnets (that is, universities or public research institutes), it favors the development of a localized "biosciences knowledge value chain." (Agglomerations that are more than mere clusters of commercial firms with some links to local knowledge centers are called "megacenters," which seem to be few and far between.) At the same time, the global "biotech boom" means that many countries and regions are investing in biotechnology. This leaves us with some questions: How successful can these initiatives be? Is it possible for smaller and more peripheral biotechnology clusters to survive?

The development of a smaller biotechnology research cluster in Turku, Finland, offers some answers to these questions. The primary data consist of detailed, interviews and analyses of industry statistics; the policy documents of national, regional, and city governments; and previous studies of the development of industrial activities in Turku, especially those conducted between the mid-1980s and 2004. Over a six-month period in 2002, 36 detailed semistructured interviews were conducted with academics (scientists), policy-makers at various levels, CEOs or R&D heads of companies, city officials, and actors in intermediary organizations, such as economic development agencies and hybrid organizations for sectoral growth.

5. THE CASE OF TURKU: DEVELOPMENT OF A SMALL BIOTECHNOLOGY CLUSTER

Turku is home to the second largest concentration (after Helsinki) of biotechnology activities in Finland.[42] Other regions with dedicated centers for biotechnology development are Oulu, Tampere, and Kuopio. There are also many Finnish universities engaged in biotechnology-related research and education. The period 1996–2000 saw the sharpest rise to date in the number of new biotech firms in Finland. Turku underwent a similar growth spurt, with most new biotechnology companies emerging during the 1990s.[43] Biotechnology companies that were started in the period 1998–2000 can be broadly categorized as biomedicine (37%), diagnostics (31%), biomaterials (13%), and "other" (19%).[44,45] However, during the past few years,

industry growth has almost stopped, and the number of companies has remained relatively constant.

The Turku region is especially strong in biopharmaceuticals, but its firms are also involved in diagnostics, biomaterials, and functional foods. In March 2006, there were approximately 80 biotechnology-related companies in Turku, employing approximately 3,000 people. Two large pharmaceutical companies, Schering and Orion, conduct R&D in Turku, as do a number of smaller drug discovery companies, such as Tie Therapies, Hormos Medical (a subsidiary of QuatRx), and Juvantia Pharma Ltd. These firms, along with the universities and service companies, form a relatively tight drug-development network.

Although the growth of biotechnology in Turku has been very rapid, the roots of the industry are much older. The first drug companies (Leiras [a Nycomed Co.] and Farmos Ltd.) were established in the 1940s, as was Wallac Inc. (now part of the PerkinElmer group). These mid-sized companies cooperated with the universities when such cooperation was not common practice in Finland. A good example of this is the diagnostic company Wallac, which already cooperated with universities in the 1960s. Interactions with university researchers were institutionalized in many ways, and this culture seems to have diffused to other companies.[46] At the time Wallac also needed a steady supply of professional employees, and the university cooperation provided a good opportunity for them to develop this resource.

Older, larger companies have provided local expertise in business and development activities, as well as labor pools for new spinouts. In fact, many key people in the universities and the smaller companies have worked for these larger companies at some point. Many ideas have also been exported by individual workers leaving their jobs and establishing new start-ups or by dedicated spinout strategies of larger companies.

Several studies have noted that in biotech, the performance, strength, and width of the scientific base are perhaps the most important factors affecting industry development.[47] Indeed, Turku's scientific knowledge base did not emerge overnight: it has been developing since the 1960s or 1970s. Moreover, the level of scientific research in biotechnology-related fields has been on par with top research around the world. The establishment of spinouts owes much to strong academic links with the United States. When the molecular biology revolution occurred in the 1970s, many Ph.D.s and M.D.s from Turku did their postdoctoral research work in some of the best American laboratories. During their time abroad, they witnessed the birth of commercialized biotechnology firsthand and saw the many ways that academics can become involved in the business of medical biotechnology. A few leading researchers subsequently returned to Turku and became intimately involved in the establishment of both the Center for Biotechnology and several promising start-ups.

5.1 *Strong national support for biotechnology research and business*

The Finnish model for supporting biotechnology has been described as a "science-led strategy from above."[48] In Finland, the national innovation system has played a significant role in developing the biotechnology sector. Various government agencies support science-based and resource-intensive businesses. The Academy of Finland funds basic research: TEKES (the Finnish Funding Agency for Technology and Innovation) funds applied research, development, and knowledge transfer; VTT Technical Research Center conducts applied and contract research; and Sitra (the Finnish National Fund for Research and Development) used to provide venture capital funding for small high technology firms particularly in the 1990s.[49] Furthermore, public programs, such as the regional Centers of Expertise, coordinate and focus resources in key industries in many cities. Many of the institutions and organizations affiliated with the national biotechnology innovation system are located in the Helsinki region.

In the late 1980s, the Ministry of Education started the first biotechnology research program. Since then, public funding in the form of various research and technology programs (especially those provided to universities by The Center of Excellence) and public venture capital have all increased tremendously. Roughly 40% of the

national R&D budget is spent on the biosciences. TEKES has invested some US$90 million, or 27% of the total amount spent on biotechnology in Finland. The Ministry of Education has also created new centers of excellence in universities. These efforts have paid off: in 2000, nine of the 26 most highly ranked university departments in Finland were in the field of biotechnology.

In Turku, the impact of the national science and technology policy has been remarkable. Partly because local actors have been active in national development programs, the newly dedicated university research units have received a lot of public funding. Public venture capital has also played a big part in the growth of new firms. However, in Turku, national institutions have been used as resources for local activity rather than initiating new activities themselves. Turku was not very visible in the biotechnology industry (compared with, for example, Helsinki) until the late 1980s. In 1987, the Ministry of Education launched a new biotechnology research program that was Helsinki centered, despite the fact that Turku had a biotechnology sector that was not much smaller than Helsinki's. The Turku research community protested this "injustice," and local informal initiatives, designed to increase the visibility of Turku's biotechnology activities, were instrumental in developing a local biotechnology cluster.[50]

5.2 *Local networks and local initiatives facilitate cluster building*

The development of Finnish biotechnology has been aided not only by national policies but also by the local efforts of actors in business, academia, university administration, and city governments. Individuals have promoted change, whether or not they had strategic support from their own institutions; this is important to note because the role of individuals as instigators of change has often been overlooked.[51]

The first changes in Turku's innovation network occurred in the mid 1980s. Particularly important was the first dedicated project for improving biotechnology research, the South-West Finland Biotechnology Project (SWB), started in the mid 1980s. At approximately the same time (1986), the Foundation of New Technology (FNT) was established. This was a very informal organization, composed of approximately 30 people, most of them drawn from industry and academia. The FNT was originally formed to establish Turku's first technology center, DataCity.[52]

The Turku Technology Center Ltd. regional development company is owned by the city of Turku (90%). It consists of two subsidiaries (100% ownership): Turku Bio Valley Ltd. and ICT Turku Ltd. The second stage of the technology center, BioCity, was built in 1989, after DataCity achieved some success. People with different needs joined for a common cause: the real estate business saw a new business opportunity; biotechnology firms saw an opportunity to gain more contacts and influence by cooperating with universities; and universities saw an opportunity to obtain better resources for research and education. Because city governments played a central role in planning five of the seven technology parks existing in Finland in 1989,[53] it is interesting that the city of Turku did not participate in the planning of BioCity.

BioCity has been very important to Turku's biotechnology cluster. It was not merely a physical structure but an ambitious new concept. Its founders wanted to create synergy between industry and academia by gathering a critical mass of researchers in various fields.[54] This critical mass was achieved by establishing new facilities and labs that were jointly administrated by the University of Turku and Åbo Akademi. The universities entered the project not so much because they shared the founders' vision but because they were suffering from a lack of resources. Today, the BioCity Turku research community consists of more than 50 research groups and more than 500 people working in different fields.

A recession in Finland in the early 1990s made local actors and the Turku city government look for new industries to develop. Compared with other mid-sized cities in Finland, like Oulu, Tampere, and Jyväskylä, Turku became active in the local economic development quite late. This was partly because of the local industrial structure—the impacts of economic restructuring in the 1970s and 1980s were not as severe as in many other cities. The Finnish recession and the

collapse of the Russian markets, which were important for many local industries, also made local authorities pay more attention to economic development. Since then, the city of Turku has been very active in promoting new industries, particularly biotechnology, and investing in infrastructure. The government has encouraged life-sciences research and commercialization in Turku, partly because the city did not have pre-existing information-technology-related skills and industry like many other midsize cities in Finland.

Local authorities have supported the national Center of Expertise program, which organizes cooperation within the biotechnology sector in Turku. In general, local actors have taken advantage of opportunities provided by national and regional policies regarding science and technology. The use of biotechnology as a leading theme in city marketing should not be underestimated.

5.3 *Turku as a biotechnology cluster*

Turku has created a successful biotechnology cluster, but substantial efforts have been needed to guarantee its success. Below is an analysis of the aforementioned factors for successful biotechnology clusters, as they apply to Turku:

- **a strong science base**. In recent international evaluations, Turku's science base was highly rated.
- **an entrepreneurial culture**. Although many new companies have been created, there is no strong entrepreneurial culture.
- **a growing company base**. The company base has grown rapidly in many fields in the latter part of the 1990s, but there have not been many new DBFs in the past few years.
- **the ability to attract key staff**. So far, employees have come from within Finland. Many companies have noted that Turku is too small to be attractive.
- **the presence of investors**. Missing are MNCs and international venture capital (VC), though domestic VC (especially public) has made up for a lack of international VC. Recently, VC money has been less available and there have been substantial problems in attracting financing.
- **infrastructure**. Generally, the infrastructure for both research and business is very good. The public sector (especially the City of Turku) has recently supported the building of new infrastructure. This has been crucial, since university funding has been tight.
- **business support services and large companies in related industries**. Larger companies do not use local services very much. Many specialized services are in Helsinki and abroad. There are some good local services but the number is still quite small.
- **a skilled workforce**. The local universities have so far provided an adequate source of new employees. The region's traditional strengths in pharmaceuticals and diagnostics provide some experienced people, though not enough. The city is too small to provide an adequate labor pool. There is also a lack of local business expertise.
- **effective networks**. Local networks work effectively. Many of the networks arose voluntarily from local needs and have therefore been very active as opposed to policy-led network initiatives, which often turn out to be rather artificial. Networks linking Turku with the rest of the globe are quite extensive and important for research and commercialization.
- **a supportive policy environment**. National policy has been very important in providing financing for both research and commercial development. Local policy is increasingly supportive of infrastructure. University policies have neither helped nor hindered.

Turku has been able to overcome the weaknesses mentioned above for two reasons: strong national support and the ability of local actors to exploit both internal and external resources. The factors contributing to Turku's success can be summarized as follows:

(A) A strong science base with local and international networks
- Expertise from older, medium-sized companies provided the cluster with the experience and skills that new university-based start-ups often lack.

- Early on, companies established long-term relationships with university researchers, thereby developing a culture of collaboration.
- Pre-existing scientific networks and cutting-edge research in medicine, biology, and chemistry compensated for the lack of local expertise and local institutions, such as business support services, banks, consultancies, and venture capital funds. Strong research ties to the United States, for example, have been very important.
- The difficulty of recruiting foreign employees has been at least partially compensated for by the expertise of Finnish researchers who have spent time abroad.

(B) National policies
- Extensive research funding and education supports the science base.
- The TEKES technology programs support R&D.
- Public VC partly compensates for a lack of foreign VC.
- Local centers of expertise facilitate networking.

(C) Local initiative
- Local initiative has led to improved infrastructure, as well as improved organization in universities and R&D firms.
- The success of Turku has been crucial in influencing national policy-makers to invest in biotechnology.
- BioTurku has brought various actors together, thereby improving the integrity of the local biotechnology cluster.

Despite its relative success in compensating for the missing success factors, Turku still faces problems. First, its small size makes it difficult to maintain local services. Lack of foreign VC is also a potential problem, because public support for biotechnology is limited. Technology transfer mechanisms are still underdeveloped, even though there are close connections between university researchers and companies. In addition, universities do not have a clear strategy for capitalizing on biotechnology research. The biggest problem, however, is that Turku lacks many parts of the value chain. There are few services, venture capitalists, and big MNCs with expertise in commercialization and marketing. This is a problem because external links are usually more difficult and costly to maintain than internal ones, especially for small companies.

6. DISCUSSION AND CONCLUSIONS

A small, peripheral biotechnology cluster can prosper under the right conditions. First, a strong local science base must already exist. Second, there must be a way to compensate for any missing links in the value chain. Turku has been fairly well able to provide adequate conditions for its biotechnology industry. Although its biotechnology cluster is young, quite small, and in many ways peripheral, its development has been successful because of the region's strong science base and well-established strengths in medicine and diagnostics. Both national innovation policies and strong local initiatives have been important in overcoming obstacles.

Several lessons can be learned from the Finnish experience. First, a good educational system is important. There are many ways to compensate for missing links in the value chain, but it is extremely difficult to build new entrepreneurial activity in biotechnology without a good local knowledge base.

Second, human capital formation (in the form of educated people and research groups) should be drawn mostly from the local pool, though it is often necessary to bring in experienced people to work in R&D. It is difficult for developing countries to compete with major research centers in Europe and the United States. However, biotechnology requires the best available scientific knowledge and expertise. If it is difficult to attract people from abroad, locals should go abroad to study, conduct research, and build international networks. It is easier to attract expatriates than it is to attract foreigners.

Third, the development of clusters is path-dependent and based on previous historical events and existing capabilities. It is extremely difficult to build new clusters from scratch. It is therefore

advisable to match research activities and start-up formations to the existing strengths of the region. In many countries, this may mean concentrating on specific fields, such as agriculture or health care, in which local expertise is strong. A strong health care system is important for the development of biotechnology because it is a consumer of local products, a source of new ideas, and an environment for testing and clinical trials. It is also important to make good use of the R&D capacity and expertise of existing companies and universities. Many successful clusters in emerging technologies have been created around older but related industries. For example, the biotechnology industry was created around pre-existing food and medical industries in Turku, and the semiconductor industry was created around a pre-existing electronics industry in Silicon Valley.

Fourth, local and national policy support of emergent industries is important, especially if there are problems with the innovation support system. This support can take many forms: substituting public services for missing private services, supporting research, building up a working education and research system, creating a favorable legal and economic environment for new start-up companies, and working to prevent "brain drain."

Fifth, the role of individuals, especially in the early stages of cluster formation, should not be underestimated. The Finnish experience demonstrates that local networks of key individuals increase the capabilities of the cluster as a whole and help different actors achieve consensus. Support for key individuals in enterprises, universities, and research institutes is therefore important, and networking should be promoted.

There is indeed hope that smaller and more peripheral biotechnology clusters can prosper. However, it is also clear that strong, well-designed policy support is needed to overcome the various setbacks that these small clusters tend to face. Of course, there still remains the question of how this should be accomplished. So far, the "Finnish way" has worked quite well, but it is always difficult to determine how well policies and practices will work in the future or how well they will work in other institutional environments. There also remain the perennial questions of how much a government should invest, and how much it would be ready to invest, in a new industry sector such as biotechnology. Success in such endeavors is not guaranteed. ■

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The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship

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ABSTRACT

This chapter describes the structure, policies, and operations of the Technology Licensing Office at the Massachusetts Institute of Technology (M.I.T.). The chapter emphasizes the licensing office's role in generating spinout companies and considers the importance of the biotechnology cluster within the state of Massachusetts and it's surrounding regions. Also discussed is M.I.T.'s approach to ensuring that licensing procedures maximize access to medicines and vaccines arising from M.I.T.'s research.

1. INTRODUCTION

The Massachusetts Institute of Technology (M.I.T.) is probably not a direct model for universities and research institutes just beginning their technology-transfer activities, whether in the United States or in developing countries. Instead, the institute is an example of what can be achieved by a mature organization that has built its patent portfolio and technology-transfer skills over the course of half a century. We, at M.I.T., live in an entrepreneurially advanced city, where technology-based companies originating from university research inventions have become an important part of the Massachusetts area's economy. M.I.T. and the other major research institutions in the area, such as the Whitehead Institute for Biomedical Research, Harvard University, Massachusetts General Hospital, Brigham and Women's Hospital, and Boston University, have helped to build this entrepreneurial cluster and have benefited from it.

Nevertheless, other organizations can learn from our experiences, and M.I.T.'s Technology Licensing Office[1] is both honored and pleased to help in the *transfer* of technology-transfer practices.

1.1 *History and mission*

M.I.T.'s Technology Licensing Office is one of the most active university patent and licensing offices in the country. M.I.T. has had more than 1,500 issued U.S. patents in its portfolio, many with foreign counterparts.

M.I.T.'s technology licensing endeavors follow the mandate of the U.S. Congress who, in 1980, gave to universities title to inventions developed with federal funds through the Bayh-Dole Act. Technology licensing from universities was greatly accelerated by Bayh-Dole, which allowed universities to own the patents arising from federally funded research, to grant exclusive licenses, and to charge royalties that could be shared with inventors. Since nearly 90% of the basic research funds in U.S. universities comes from U.S. federal funds, the new law drastically changed the face of university technology transfer.

The theory behind the law's application to university research was based on Congress'

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understanding of the embryonic nature of university discoveries and inventions. Since universities do not develop products, early investment by industry is needed to turn university findings into commercial realities. Typically, such investment involves high risk, since neither the practicality of the inventions nor their market utility has been proven. Patents, and particularly exclusive licenses, can be used as incentives for *first mover* companies to make the investment: if the product were to succeed, the patent would protect the initial investor from competition for a period of time, rewarding the initial risk taking.

Finally, the law provided an economic incentive for both universities and their researchers to patent their inventions and to participate in the technology-transfer process. Although the royalties gained from technology transfer are only a very small contribution to university budgets (averaging about 3% of university research budgets for U.S. universities), there is enough economic return to support the process—and considerable incentive for individual researchers. More importantly for the biotechnology industry, the technology-transfer process is an organized, effective method of transferring university findings via protected IP for the purpose of forming a protected technology dowry for new companies. Investors in most technology companies—and certainly in such high-risk/high-investment fields as biotechnology—must have proof of the exclusive rights to patents and other forms of IP by the company before they will invest.

Consequently, we use licenses to our IP to stimulate the development of our inventions into products that serve the public good. Through our patenting, licensing, and copyright protections, we encourage companies to take the necessary risks to develop our inventions into products and/or services that benefit humanity. Royalties derived from licenses support further research and are shared with inventors. These, in turn, provide incentives for further innovation.

Each year, more than US$1.2 billion in sponsored research is conducted on the campus of M.I.T., at the Lincoln Laboratory, and at the Whitehead Institute for Biomedical Research. This research leads to more than 500 new inventions per year. These inventions and software are marketed through M.I.T.'s Technology Licensing Office. The core of this office is a group of technically trained and business-oriented people. They work with industry, venture capital sources, and entrepreneurs to find the best ways to commercialize new technologies.

The Technology Licensing Office at M.I.T. began its operations many decades ago as the Patent, Copyright, and Licensing Office. It was reorganized in 1986 and became the Technology Licensing Office. It is administered by the Vice President for Research/Associate Provost and is now part of the academic arm of the university. Its mission statement declares that:

The mission of the M.I.T. Technology Licensing Office is to benefit the public by moving results of M.I.T. research into societal use via technology licensing, through a process which is consistent with academic principles, demonstrates a concern for the welfare of students and faculty, and conforms to the highest ethical standards.

This process will benefit the public by creating new products and promoting economic development.

It will help M.I.T.:

- show tangible benefits of taxpayers support for fundamental research
- attract faculty and students
- generate industrial support of research
- generate discretionary income
- generate new job opportunities for graduates

We will continue to be a world-class model of excellence in university technology licensing.

1.2 *Staffing*

The Technology Licensing Office is staffed by:

- Director Lita Nelsen, chemical engineering background (BS, MS, MBA) with 20 years experience in industry in the fields of medical devices, membrane separations, and biotechnology

- Associate Director Jack Turner, electrical engineering background (BS) with 18 years of experience in industry
- seven technology licensing officers, all with degrees in engineering or science, each with one to two decades of industrial experience; each is responsible for one of the seven technology areas: biotechnology, chemistry, medical devices, semiconductors, communications, software, and nanotechnology
- four technology licensing associates, all with BS degrees in science and little or no other experience; associates assist the technology licensing officers
- legal personnel: one corporate attorney, one junior lawyer, and one legal assistant; these staff members provide advice on licensing and particularly on corporate structure, manage outside attorneys for litigation, and manage M.I.T.'s trademark and end-use software licensing; patent prosecution is handled by outside attorneys and patent agents
- financial and computer systems personnel: one financial manager, two accountants, one programmer, and one desktop support administrator
- office management and clerical support: office manager, compliance manager (government reporting), three secretaries, a receptionist, a files manager, and a file clerk

1.3 *Numbers of patents and licenses*

M.I.T. currently holds about 1,500 active U.S. patents and many corresponding foreign patents. About 150 U.S. patents are issued to M.I.T. each year. We have about 600 active licenses and issue around 100 new licenses every year.

The gross annual revenue of the office is about US$40 million. Net revenue is about US$10 million (after patent expenses, personnel expenses, and distribution of a portion of royalties to inventors).

The majority of our licenses are to existing companies—both small and large. But about 25% of the licenses are to new spinout companies, which are specifically formed to develop a licensed technology.

2. THE ROLE OF THE TECHNOLOGY LICENSING OFFICE IN THE BUSINESS COMMUNITY

2.1 *The "virtual incubator" for spinouts*

Twenty to 30 new companies are *spun out* from M.I.T. each year. All of them are based on M.I.T. inventions and are built upon licenses to our patents and software. The companies based on our biomedical inventions form an important part of the biotechnology cluster in the Massachusetts area (see section 3 below).

Our formal role in starting up new companies is confined to filing patents and negotiating license agreements with the companies, and although we will often take equity shares in the company as partial payment of royalties, we do not take board seats on the company or any management role. The purpose of these restrictions is to keep the company clearly separate from the university. We believe this separation is necessary for the university to concentrate on its mission of basic discovery research, dissemination of knowledge, and education. Through these policies, the management of technology transfer essentially becomes a by-product of the academic process and will not distort the long-range mission of the institution.

We can only achieve this mission through clear and transparent conflict-of-interest policies and procedures (see Box 1). The conflict-of-interest rules may seem unusually strict, but this careful approach is necessary because of the very large number of companies spun out (more than 250 since 1987). Management that allows exceptions to the rules would not be possible given this large number. Our task is not to use these rules as deterrents but to efficiently and creatively craft arrangements within the rules. Put differently, our operating motto is "*A firm wall between university and industry—but a wall with many doors.*"

We do not formally incubate these spinouts; we do not invest M.I.T. money in any of these companies; we do not allow the companies to use M.I.T. laboratory facilities; and we do not write their business plans nor do we participate in their management.

Box 1: M.I.T.'s Conflict-of-Interest Rules for Spinout Companies

(Last Revised February 2005)

1. Faculty member may consult but not be a line officer in any company. Consulting activities should not use university resources and should not use students.

2. Faculty member must distinguish direction of research at university from responsibilities at company in which he/she owns equity.

3. The university will not accept sponsored-research grants from the company if the faculty member owns equity.

4. No confidentiality of research results (anytime). All research must be publishable.

5. Only patents, copyrights and tangible property can be licensed for compensation (no *know-how* or *trade secret licensing* can be done since this would preclude open publication).

6. Faculty members may not conduct the license negotiations (nor attend the negotiations).

7. Consulting is *third-party*, between the faculty member and the company. No tie-in with the license.

8. Only very minimum commitment of future inventions (those dominated by previously licensed patents). No pipelining of *improvements*.

9. Faculty member/founder who holds equity signs Conflict Avoidance Statement promising:

   - Not to accept research support from company
   - Not to suppress dissemination of research findings
   - Not to use students on company-related work at M.I.T.

10. Arm's length relationship between the university and the company

    - No M.I.T. monetary investment in the company
    - No board seat
    - Equity managed by Treasurer of M.I.T.—*not* the Technology Licensing Office

11. Technology Licensing Office enforces diligence terms, payment of patent costs, other license obligations *just like any other company*. No special status for M.I.T. spinouts.

12. Yearly departmental overview of faculty outside professional activities.

Common sense: Emphasis on the spirit (not just the letter) of the rules, administered by people with judgment and authority.

Our informal role, however, is much broader. We call it a "virtual incubation" function, which encourages and accelerates the formation and growth of our spinout companies. The initial license agreement itself includes contract terms that help. Our financial terms are quite generous for the first few years of operation, reflecting our understanding that new companies are often cash poor. Similarly, our royalties on products are low, because we know that the company will have to make substantial investments and develop and contribute substantial IP of its own before the product can be successfully commercialized.

An important part of the license agreement—both for us and for the company—is that which defines the *milestones*, or *diligence terms*. These require companies to raise minimum amounts of capital and achieve progress in product development. Milestones related to raising capital assure us that the outside market finds the company worthy of investment and that sufficient capital will be raised to fund product development.

Our virtual incubation incorporates many other functions. We meet with inventors, helping them to define the direction of the company and their own career aspirations. We introduce them to consultants, potential executives, and other advisors who can help them formulate their business strategy and write business plans. And, because of our long relationships with sources of investment capital, we can introduce inventors to venture capitalists and angel investors who may be willing to invest in the new companies.

2.2 *The role of students in entrepreneurship at M.I.T.*

The admission criteria for prospective M.I.T. students, particularly those for undergraduates, contribute to the entrepreneurial spirit at the institute and the ultimate impact of our graduates on the economy. In evaluating candidates for admission as undergraduates, we look not only for academic achievement (such as high grades and strong standardized test scores), but also for a certain quality of potential leadership—an intensity and focus that fosters achievement and also influences others. Young people who are strong potential leaders often possess a self-confidence that allows them to think unconventionally and take risks—including the risk of joining (or forming) an entrepreneurial company.

Our education of these students (and of their "big brothers and big sisters" in graduate school) stresses the fundamentals of science, rather than short-term applications. The students are involved in leading-edge research projects early in the course of their studies. We seek to produce graduates who will have leadership capabilities based on a solid grounding in science and a familiarity with the state of the art.

Role models in business are an important influence on these students during their years at M.I.T.. Many of the professors and many alumni who visit campus—and not a few of the students' friends—have started companies based on M.I.T. technology. These entrepreneurs expose students to entrepreneurial thinking. The presence of strong role models is important for developing an entrepreneurial culture; the plethora of such role models at M.I.T. and in the Boston/Cambridge area leads others to think that "*I can do it too*"—and offers resources for advice and strategy.

Finally, our culture at M.I.T. stresses that risk taking is necessary for achievement. And, importantly, that "*failure is a learning opportunity—not a black mark*." We assume that our students are good enough to take risks and succeed. They have sufficient talent, energy, and self-confidence to recover rapidly from failure and to learn from failure to become more effective in their next endeavor. A willingness to take risks and the ability to learn from failure are critical for entrepreneurship.

2.3 *Interaction with the business community*

A key part of the technology-transfer function at the university is to develop and maintain a wide range of contacts with the surrounding business community and to leverage these resources to help build our spinout companies. Our model for spinning out companies depends on a mature, entrepreneurial community surrounding the university.

The geographic area of M.I.T. is the Cambridge/Boston area, which in many ways provides an infrastructure of support for spinout

companies. High technology companies have been regularly spawned here for more than 40 years. As a result, there are many executives, lawyers, accountants, consultants, real estate managers, and other professionals who are experienced at working with new companies. And the community is well connected. Networking organizations, such as the M.I.T. Enterprise Forum and the Massachusetts Biotechnology Council (MBC), keep people in contact with one another.

Finally, the community has developed "knowledgeable money": investors who contribute to spinout companies not only funds, but wisdom, guidance, and connections to management talent, business development opportunities, and follow-on money. A new breed of high-technology angel investors—former entrepreneurs who founded and cashed out from successful companies—is now bringing wisdom, connections, and experience, along with money.

There are also venture capital funds that specialize in technology-based spinouts. Many even subspecialize in biotechnology and have partners and associates with MD and PhD degrees in biology who are experienced in the biotechnology industry.

3. THE BIOTECHNOLOGY CLUSTER: EXPERIENCES FROM MASSACHUSETTS

It is helpful for those who are involved in technology transfer to be in proximity to others with similar issues and challenges. The Boston/Cambridge area is one of the three main biotechnology clusters in the United States. (Biotechnology clusters are geographical regions where a disproportionately large number of biotechnology companies are located.)[2] The other two biotechnology clusters are:

- the San Francisco Bay Area of northern California
- the San Diego/La Jolla area of southern California

Many factors have led to the formation and growth of the Massachusetts cluster, with research institutions playing a critical role. This cluster of more than 280 companies accounts for almost 20% of the total number of U.S. biotechnology companies. Almost all of these companies started as small, entrepreneurial companies within the last two decades, the majority having been formed within the last 12 to 15 years. According to data from the Massachusetts Biotechnology Council, these companies now employ more than 30,000 people. In addition, there are more than 220 medical device companies in the area that employ an additional 25,000 people.

3.1 *Key elements for a biotechnology cluster*

It all starts with early fundamental support of basic research by the U.S. government. Leading research institutions make the discoveries, develop the IP, and train the scientists that form the biotechnology companies. Where the research institutions cluster, the new companies eventually form. The process continues with alliances developing between biotechnology companies and large pharmaceutical companies, which will often provide necessary testing, manufacturing, and distribution of the drugs discovered by the biotechnology companies.

For a robust cluster to form, the area needs investment capital (and experienced investors), executive talent, trained scientists, and a host of supporting professionals—lawyers, accountants, real estate professionals, and others—who understand biotechnology entrepreneurship and can help fledgling companies establish themselves. Good airports are critical, and local communities that are attractive to highly talented personnel and their families create a competitive advantage.

The Boston/Cambridge area of Massachusetts has an unusually large concentration of world-class research institutions (universities and research hospitals) funded in large part by the U.S. government—particularly the National Institutes of Health (NIH)—to perform basic discovery research in biology and biomedicine. Together, Massachusetts research institutions received more than $2.1 billion in NIH research grants in fiscal year 2003, approximately 10% of the national total.

From this research comes much of the "feedstock" for new biotechnology companies: new discoveries, IP, knowledgeable scientific

advisors for new companies, and, importantly, well-trained scientists to staff the new companies.

3.2 *The self-feeding cluster*

Even with a base of world-class university research and its resulting technology and IP, getting a cluster started is difficult—there is no simple formula for doing so. But once started, a cluster begins to feed itself in a virtual cycle. The biotechnology cluster feeds itself through:

- **role models.** These are people who have founded companies and can offer examples of success and advice to new entrepreneurs.
- **management/founders.** Often new company management is recruited from other companies in the area. People who were employees of early companies in the cluster acquire the skills and interests to become founders of new companies. New companies also can recruit other skilled personnel from the older cluster companies.
- **retention of new graduates.** A cluster of biotechnology companies in an area encourages new graduates from nearby universities to seek employment in the area, consolidating skills.
- **infrastructure support.** The area's patent attorneys, lawyers, accountants, recruiters, real estate managers, consultants, and equipment suppliers develop special skills in biotechnology as they respond to the needs of the cluster.
- **technology transfer.** As the universities and other research institutions become more experienced in dealing with biotechnology companies and biotechnology startups, they become more effective in starting new companies that strengthen the clusters. Successful technology licensing and spinouts lead to revenue, which funds the filing of more patents and more opportunities.
- **angel investors.** Local angel investors bolster the process, since they can offer their skills and experience in addition to their money. As clusters mature, founders of the early companies frequently become investors in new companies.

At some point venture capital moves in. At the start of the Massachusetts biotechnology cluster, there was little indigenous venture capital. Most venture capital money came from investment funds located in New York, California, and other states. With the growth of high-tech clusters in Massachusetts (both biotechnology and telecom), many of these funds opened new offices in Massachusetts, and many new venture funds were formed locally. Currently, the majority of new company financings in Massachusetts are led by venture funds with offices in Massachusetts.

4. CONCLUSIONS

4.1 *The importance of clusters*

Many elements contribute to the success of a biotechnology cluster. Its origin and continued health depend on a continuing source of state-of-the-art science, usually provided by universities and research hospitals funded for basic research. The source of this funding probably needs to be from government: no private institutions can afford to fund sufficient speculative basic research to sustain the flow of discoveries necessary to support a cluster's growth.

Effective technology transfer is also necessary. The legal infrastructure for transferring inventions from universities must be in place (and relatively nonbureaucratic), and sufficient funds must be available for universities to file patents and protect their IP.

The formation of new companies also requires a business infrastructure in the community. A simple legal system for company formation, consulting, accounting, and legal professionals to advise the company—as well as adequate physical space—are all necessary. Good transportation into the area is important, since investors and business partners need to visit the company. And investment capital is, of course, critical.

Most of all, the formation of companies and the subsequent development of clusters requires talented people: world-class researchers to lead the discovery, trained and talented technology-transfer professionals, entrepreneurial company

founders, scientists and managers to staff the companies, and knowledgeable investors who can both fund and guide the company. All will need the support of a variety of professionals in the community. It takes a whole community to build a biotechnology cluster—but once built, the cluster can achieve a self-sustaining life that strengthens itself and the community.

4.2 *The importance of policies for ensuring the availability of products for the poor*

M.I.T. usually files patents only in North America, Europe, and Japan (though occasionally we file in China, Singapore, Republic of China, and Korea for the electronics field). Thus, the biomedicine-related patents we file are not often likely to affect the development and distribution of medicines and vaccines in developing countries.

We are, however, mindful of the issues surrounding the development and distribution of new health-related products for developing countries, and we consider both our patenting procedures and our licensing terms when working with relevant technologies. For example, it may sometimes be advisable for patents to be filed in some developing countries so that local companies in those countries can protect their investments in further developing our technology. In other cases, we may choose not to file patents in those countries and may prohibit our licensees from doing so—or we may refrain from granting exclusive licenses in developing countries unless we feel exclusivity will enhance development and access. Other agreements could require preferential pricing for the public sector of developing countries.

There are no rigid written policies guiding the way we handle technologies; instead, we leave our options open, creatively crafting agreements to maximize access. However, the number of technologies arising from our research that are relevant to neglected diseases is relatively small, since we do not have a medical school nor a school of public health. Our experience with such technologies is relatively scant, as is our experience in crafting such agreements. We discuss our approach to those technologies in greater detail in another chapter. ■

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1 web.MIT.edu/tlo/www.

2 See also in this *Handbook*, chapter 3.12 by K Viljamaa and 3.11 by PWB Phillips.

3 See, in this *Handbook*, chapter 1.3 by L Nelsen and A Krattiger.

Building Research Clusters: Exploring Public Policy Options for Supporting Regional Innovation

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ABSTRACT

Governments at all levels are showing great interest—and some are spending lots of money—in developing research clusters that they hope will benefit their local and national economies. Clusters are complex, however, and this chapter aims to help policy-makers maximize their benefits. The chapter offers a taxonomy of countries and their potential for cluster development and explains a five-stage process for realistic cluster building. Stage one assesses capacities, resources, and opportunities. Stage two involves choosing an anchor strategy. In stage three, organizational and institutional leaders are identified to take the lead in developing the cluster. In stage four, proactive tactics are chosen. Stage five identifies the cluster's lifecycle and the strategies needed to sustain it. Cluster building is knowledge-based development, which is inherently different from traditional industrial development. For one thing, cluster building requires global links. Companies and skilled employees are less interested in fiscal incentives, public infrastructure, or other government support than in the innovation community and its networks.

1. INTRODUCTION

Theory suggests that competing companies and their related industries often concentrate in a few locations and generate higher value, more jobs, and more innovation than companies that do not locate near clusters with companies in related businesses. Ultimately, those that do are benefiting from some traded or untraded interdependencies: economies of scale in related or supporting industries, economies of scope in labor and capital markets, or knowledge spillovers from competitors and collaborators.[1]

Some analysts estimate that the benefits of scale, scope, and—perhaps most importantly—tacit knowledge spillovers are usually limited to between 10 and 100 miles of the epicenter of a community. Given that the cities, regions, and countries that host these clusters would likely benefit, all levels of government are greatly interested in doing whatever is appropriate to spur local development of these clusters.

While analysts do not agree about much, they generally accept that clusters are complex. Subject to industrial evolution, changes in global markets, the knowledge bases that drive them, and the geopolitical forces that influence their development and success, clusters are diverse and their characterizations are open to interpretation. Additionally, clusters go through cycles. There are periods when they require high reinvestments (public, private, or both) of money, time, and resources. At other times they provide high payouts. No one cookie-cutter approach or measure can be employed to develop and manage a cluster.

Assuming that the cluster is a dynamic phenomenon and subject to a lifecycle, a number of important factors come into play when assessing and supporting innovative capacity. This chapter first examines a taxonomy of countries and their potential for cluster development. It then looks

Phillips PWB and CD Ryan. 2007. Building Research Clusters: Exploring Public Policy Options for Supporting Regional Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

at a five-stage process for cluster building. Stage one involves using an array of common analytical tools to assess a candidate for a cluster: these tools include an overview of discrete measures along with some more general analytical tools, such as social network analysis and emerging markets analysis. Stage two involves choosing one of the strategic options. Stage three identifies and mobilizes actors or organizations within the region (public, private, and others) to take a lead in the cluster. Stage four involves choosing from a set of proactive tactics for encouraging companies to cluster. Stage five identifies the lifecycle of the chosen cluster and the strategies needed to sustain the initiative.

2. THE CONTEXT

According to Mashelkar,[2] building indigenous technological capacity, in any context, requires a number of conditions: a conducive policy environment, entrepreneurship, promotion of a culture of innovation, access to technology (where necessary, through international technology transfer), an educated and skilled workforce, and a "learning by doing" mentality. Although Mashelkar explores indigenous technological capacity exclusively from a developing country perspective, his approach can be applied to examine, not only the disparities between developed and developing countries, but also disparities within and between developed countries as well.

Morel and colleagues[3] present a taxonomy to assess economic strength and innovation capacity in health and health-related organizations. Six dimensions (manufacturing capacity, domestic market, export market, R&D, IP system, and drug regulatory system) are explored across three stages of development that, in combination, are used to measure the capacity for developing countries to progress in terms of innovation. We have adapted this taxonomy to assess the capacities of different groups of nations for supporting cluster development and growth (see Table 1).

Most countries can be relatively cleanly assigned to one of Mashelkar's four quadrants. Quadrant I countries consist of leading industrial nations, such as the United States, Canada, Australia, Japan, and E.U. countries. Quadrant II countries, which have relatively low per capita incomes but high innovative capacity, include Korea, China, Brazil, India, and some eastern European countries. Quadrant III includes resource-rich and resource-dependent countries such as those in the Middle East. Finally, Quadrant IV consists of developing nations, such as those in southeast

Table 1: Taxonomy for Determining Nation/State Cluster Capacity

	Quadrant I countries	Quadrant II countries	Quadrant III countries	Quadrant IV countries
Economic strength	high	low	high	low
Innovative capacity	high	high	low	low
Comprehensive cluster policies	advanced	emerging	n/a	n/a
Incidence of formalized clusters	high	moderate	low/none	low/none
Degree of specialization	high	moderate to high	moderate to low	low

Source: Adapted from Mashelkar[4] and Morel[5] and colleagues.

Asia countries, Sub-Saharan Africa, and south and central America.

Quadrant I countries rank highly in terms of economic strength and science and technology capacity: by most measures they have the lion's share of the clusters and are the most aggressive supporters of cluster development. A closer look at the United States shows that there are more than 160 clusters identified across 25 states, with cluster activity ranging from narrowly defined categories such as oil and gas (for example, Louisiana) or gun manufacturing (for example, South Dakota) to more broadly based categories such as biotechnology[6] or life sciences.[7] Moreover, nine state legislatures in the United States have either written into law, or at the very least recommended, that the State apply a cluster approach to economic development,[8] while seven other states[9] have nonlegislated, cluster-based economic development strategies in place. In contrast, while Canada has no formalized national cluster policy,[10] most of the provinces have examined and attempted to support clusters in their jurisdictions; there would appear to be at least 25 clusters or emerging clusters in nine sectors across Canada.[11] In Australia, a national cluster policy has been proposed that advocates for strategic, proactive polices rather than the current laissez-faire approach, but the program has yet to be formally implemented.[12]

On the opposite end of the continuum, Quadrant IV nations rank low in terms of economic strength and innovative capacity. This is due to a range of limitations, including weak infrastructure and incomplete IP regimes. However, some cluster activity is emerging. Several small artisan or trade-type clusters (for example, the garment industry in Kenya) have emerged in Sub-Saharan African regions,[13] but these clusters are characterized as low in terms of specialization and are often composed of networks of "petty commodity producers."[14] Another approach has been to create export-processing zones. Mauritius was the first African country to establish an export-processing zone (EPZ) in the early 1970s.[15] Meanwhile, in Asia, despite the financial crisis of the 1990s, countries such as Indonesia, Malaysia, and Thailand have encouraged significant economic development by emphasizing industrial exports.

The middle quadrants (II and III) include countries that have low to medium capacities in terms of economic strength and innovation. Clusters, if present, often exhibit low technological or industrial application. The exception is Korea. Although categorized as a Quadrant II country, it has developed significant cluster capacity in such specialized areas as movies and animation, information technology, and digital media.[16] Similarly, China and India are growing in terms of economic strength and innovative capacity. In India, the United Nations Industrial Development Organization (UNIDO) and the national government support over 350 small-scale industry (SSI), rural and artisan-based clusters. India has also had some acknowledged success in creating world-class clusters in Bangalore in biomedical research and software engineering.[17] Some Middle Eastern countries, although ranked high in terms of economic strength, are often solely dependent upon the extraction and processing of natural resources such as oil and petrochemicals; scientific and technological capacity is limited in these countries.[18]

In short, while clusters are both stronger and more prevalent in Quadrant I countries, all countries have the potential to benefit from clusters. Every region needs to evaluate its capacities and opportunities, make strategic choices about which areas to nurture, choose specific tactics, and identify and support indigenous leadership. Such choices, moreover, will need to be tailored to the capacities and opportunities of the individual countries and regions.

2.1 *Step 1: Evaluation*

The first and most important step in developing clusters is to assess capacities, resources, and opportunities. Given the importance of planning, the tools are surprisingly weak. No one tried-and-true acid test for cluster capacity or potential exists. A number of methods have been used—ranging from ad hoc to formalized consulting and opinion formation, to valuing or analyzing cluster capacity through descriptive or institutional analysis, to empirical, statistical analyses of detailed

industrial data—but to truly understand or evaluate the potential efficacy of a cluster likely requires a blend of quantitative and qualitative approaches.

Given that clusters are to some extent self-defining, one approach often used is to convene an industrial, expert, or community forum to identify common interests and opportunities. While useful for identifying actors, or at least companies that would willingly participate, these processes are simply a starting point. In the first instance, they will likely determine whether the necessary number of interested/engaged actors can foster effort to develop a cluster. The processes can also be valuable for identifying the scale and scope of current traded or untraded interdependencies, as well as for planning future development that may either require or generate greater connections in a community. They often run the risk, however, of becoming either subject to groupthink (where everyone goes along with the most important or loudest participant) or unfocused debates about what is, is not, could be, or should be happening locally. Every process needs to move beyond rhetoric. Depending on local capacities, two main approaches have been tried.

One common analytical approach is to look at the institutional composition and leadership of the industry, supply chain, technology, or market. Generally speaking, clusters always represent a high concentration of people and activity within a particular region. Thus, a quantitative analysis of clusters would use measures that reflect those concentrations relative to benchmarks or other regions. A foundational theory that underlies any number of quantitative approaches is central place theory, a geographical theory that seeks to explain the size and spacing of human populations. The theory relies on the notion that centralization is a natural principle of human order and that nested hierarchies of people and institutions will follow this principle.[19] In the context of that theory, many communities will seek to identify the community's array of industry (for example, leading companies and suppliers), supply chain (the linked suppliers ranging from input industries through production to transportation, wholesale, and retail trade), and functional actors (finance, marketing, research, and labor services).

Both of the above approaches can be used by all countries in all quadrants. As data becomes available (often only as a country becomes more developed), a number of other approaches can be used, including location quotient measures, shift/share analyses, and emerging-industry cluster analyses.

The location quotient (LQ) measures competitiveness by comparing a region's relative share of a particular activity to the share of that activity in some reference economy. This identifies specializations in a given regional economy. A commonly utilized economic-analysis method, it was developed in part to offer a slightly more complex model to input/output analysis.[20] A location quotient of less than one indicates that there is lower share of activity or nominal competitiveness within that region—in other words, the area has less than its share of activity or is less competitive than the larger region or country. A location quotient equal to one indicates the area has a share of activity in accordance with its share of the base. Finally, a location quotient greater than one indicates that the area is more competitive relative to other regions or the nation-state as whole. The location quotient can be applied similarly to regional wage levels relative to national or state levels. Additionally, the measure may be used to highlight policy impacts (for example, federal funding initiatives or support of science and technology) within a cluster or region. If a location quotient for support activities is significantly less than one, but the LQ for the cluster is greater than one, then there may be a case for reallocating effort more in line with natural competitiveness. The Boston Consulting Group adapted this methodology and examined year-to-year changes in location quotients to test the specialization of regions in particular industrial sectors. It arranged the results into four categories of clusters: stars (specialized with increasing specialization), mature (specialized with decreasing specialization), emerging (unspecialized with increasing specialization) and transforming (unspecialized with decreasing specialization). This methodology was then used to analyze Indiana's cluster data: of the 15 Indiana-based clusters identified, most were categorized as stars or "transforming."[21]

Shift/share analysis is another technique used to determine how much of an area's employment change is due to the nature of the national economy, the industrial mix, and local competitiveness. This approach makes it possible to separate growth into three components: national growth, industrial structure, and regional competition.[22] The shift/share analysis tool is composed of three components or equations. First, the national growth component measures the effect of national growth on a given local economy. Second, the industrial mix component identifies the relative growth or decline of local industries as compared to overall economic performance. Third, the differential shift component measures the change in the local economy that is attributed to local economic advantages, such as natural resources, or disadvantages, such as low wages. Shift/share analysis was used to analyze the composition of the growth of the southern United States in the 1980s.[23] More recently, shift/share analysis has been used to assess the competitiveness level of Singapore's exports.[24]

Emerging cluster analysis is a broader tool. It begins by using employment levels to identify a dominant industry or a fast-growing, emerging industry. The measure compares employment and wage changes in an area's cluster over a defined period of time with the larger region, state, province, or even the nation. Overall, if the net change in employment and/or wages is greater than or equal to 100%, the cluster is considered to be emerging. However, if the change is between zero and 99%, the cluster is considered to be relatively stable. A cluster is considered mature when the percent change is less than zero.[25]

Social networks analysis (SNA) is yet another diagnostic tool for cluster analysis. It is primarily used to collect and analyze data about relationship patterns among individuals, though it does not simply examine the economic consequences of those relationships. According to Wellman, it is a powerful method for "*explaining variances in resources, social behavior and socio-economic outcomes.*"[26] SNA is guided by a focus on the dialectical relationships between agents, nodes, and actors. It makes the invisible work visible.[27] When applied to knowledge management, it can identify patterns of interaction and knowledge-exchange flows within a network. It shows how knowledge-intensive work is done and can illustrate complex communication channels within a network. As a tool for analysis, SNA views "*actors and actions … as interdependent*" units and acknowledges that the "*relational ties*" between actors are "*channels for transfer or flow of resources.*" It can also provide "*opportunities for or constraints on individual action,*" which is antithetical to more traditional economic approaches.[28] SNA helps to identify boundary spanners, gatekeepers, and knowledge bottlenecks, as well as under- and overutilized individuals or organizations. So many things are coordinated in networks (for example, workplace environments, clubs, and memberships) that SNA appears to have almost universal application. Indeed, multiple levels of analysis can be employed: the dyad, the node itself, or even the entire network. The entire incidence matrix (agent by agent or agent by event) can become the target of analysis, or it can merely become one variable in an adjacency matrix to explore correlations between variables.

A number of measures inherent in SNA help to illustrate realities that cannot otherwise be observed in the social setting. *Density* measures how many potential linkages within a social setting (that is, pairings of different actors) are actually operational. Theory suggests that some nontrivial amount of density is required, but that too dense a community can stifle innovation and change. The concept of *centrality* refers to the importance of particular actors and the hierarchical nature of an entire network. In general, centrality measures are used to "*… describe and measure properties of 'actor location' in a social network.*"[29] Centrality (applied to the node level) is a family of three measures, each answering a different theoretical question. *High degree centrality* refers to a high number of ties and the level of power or informal leadership capacity of an actor, agent or node. *High closeness centrality* builds upon high-degree centrality but also looks to the nature of the distance between nodes. *Betweenness centrality* identifies the critical route for flows in the network and the dominant node or agent that has more close relationships to other dyads. In terms of centrality, it is not just

how many connections an agent or node has, but how central its connected actors or agents are.[30] The power of a node or actor can be measured as a function of its position within a given network.[31] The eigenvector measure is useful for this analysis. An actor or agent who is high on eigenvector centrality is connected to many actors who are themselves connected to many actors, thus multiplying their risk and/or opportunity: this is their power indicator.[32] While the data requirements for SNA can be large, there are a number of generally available proxies. Co-publications (bibliometrics) and co-patents (technometrics) are often used as proxies for social interactions among agents.[33]

These discrete measures and analytical approaches have been employed to varying degrees in a number of regions or countries around the world. Table 2 provides a provisional assessment of analytical approaches and measures used to analyze regional competencies across a select number of regions worldwide. Upon closer examination, it appears that when multiple clusters are analyzed within a region, more analytical approaches are required or undertaken. Also, specialized or knowledge-based clusters often demand a more complex blend of analytical methods. For example, Minnesota's (low technology) industrial clusters were analyzed using location quotients and input/output analysis alone, while Iowa's

Table 2: Cluster Analysis Methods across Select Countries and Regions

Cluster(s) or region(s) of interest	Knowledge intensiveness	Shift/Share analysis	Location quotient	Emerging industry analysis	SNA	I/O or descriptive analysis
Indiana (1) (multiple)	med to high	√	√			√
Iowa (2) (multiple)	high	√	√	√		√
Pennsylvania (3) (multiple)	low to high	√	√			√
Minnesota (4) (multiple)	low		√			√
Canadian communities (50+ cmas) (5)	low to high		√			
Calgary wireless cluster (6)	high		√			√
Mississauga's ICT cluster (7)	high		√			√
Quebec photonics cluster (8)	high				√	√
Saskatoon's canola research cluster (9)	high				√	√
Singapore's export industry (10)	low to high	√				

Sources: See endnotes for full list of sources.[34]

more-advanced technological clusters were analyzed using a combination of approaches. SNA appears to be less commonly used as a cluster analysis approach, at least partly because the process can be resource and time intensive and frequently requires gathering primary data, which is often not pragmatic from a practitioner's point of view. Past practice suggests that input/output and institutional or descriptive-based analyses are the most commonly used approaches for exploring clusters. Additionally, the location quotient appears to be the quantitative tool most commonly used in this selection of regions or clusters.

No matter what approach or tool is used to analyze a given cluster, the efficacy of such measures depends upon the quality of the data. Knowledge-based industries in particular, such as biotechnology, often are not adequately reflected in data collected through North American Industry Classification System (NAICS) codes. Furthermore, there is no consensus on where to draw lines or pull together multiple codes to best represent a cluster. Cluster boundaries, particularly in advanced technology sectors, cannot be defined by conventional product-based industrial or sectoral boundaries. This limitation is particularly important with respect to biotechnology.

2.2 *Step 2: Choosing a cluster strategy*

Table 3 outlines a chronological typology of cluster definitions, beginning with Porter's industrial approach. Different cluster approaches will have a different set of requirements, a different mix of leaders and tactics, and will fit better with some categories of countries than others. Economic development agencies in developed and developing countries have usually applied Porter's generalized approach to clusters, customizing it to the particular geopolitical region (see chapter 3.12 for examples). Indeed, despite the lack of consensus about what a cluster does and how it operates, Porter's version of a cluster has been rapidly adopted by practitioners from all over the world.

Porter's industrial managerial characterization focuses heavily on the local and regional relationships between competing and collaborating companies, often without any specific industrial, product, or technological core. These types of clusters appear to emerge and succeed where there are a number of highly competitive companies or competing supply chains that rely on the economies of scope and scale delivered by related and supporting industries. Porter emphasizes that the most successful clusters of this type have either a direct local or a strong link to demanding, leading-edge consumers. Few centers in the world (especially in Quadrants II–IV but even in some of the more-advanced Quadrant I countries, such as Australia, Canada, and New Zealand) can meet this criterion. In this sense, these types of clusters have a greater chance of success in Quadrant I nations, such as the United States, European Union, and Japan, all of which have large, wealthy, and demanding (that is, trend-setting) indigenous local markets.

The product/market, flagship company, and value chain models are all variations on clustering focused around a technology, product supply chain, or product market. As companies in these types of clusters seek greater efficiencies, they begin to formally and informally acknowledge their local and regional interdependencies with other competing and completive companies. Over time, various types of nontrade interdependencies arise, which strengthen the collective. This model has perhaps more applicability to a wider range of countries because all economies, regardless of their local capacity, are fundamentally linked to a technology, product, or market through some form of supply chain or industrial structure. The difference in the three approaches is who takes the lead. In the product/market cluster there often is no single formal leader; instead, varying combinations of companies and civic leaders will work to build the needed infrastructure, scale, and scope to realize the cluster's potential. A number of clusters actually have sole leadership vested in a flagship company or national champion. The value chain model usually vests leadership in some "integrator." This can vary widely depending on the nature of the supply chain: it can be the largest enterprise in the chain; a logistics, wholesale, or retail actor; the owner of some key technology, infrastructure, or product in the chain; or it can be a leader of some industrial, technical, research, educational, or financial organization. This type

Table 3: Chronological Typology of Cluster Definitions and Examples

Cluster type	Definition/description	Example(s)
Industrial/managerial characterization	a geographic concentration of competing and cooperating companies, suppliers, service providers, and associated institutions based on industrial interdependence (supply and demand linkages)	Italian textile districts, Third Italy[36]
Product/market focus	characterized as networks of production of strongly interdependent companies, knowledge producing agents, and customers linked to each other in a value-adding production chain	Italian footwear cluster Australian wine cluster
Flagship/company	Multinational-enterprise-ledclusters/anchor; act as flagships	Monsanto-led St. Louis, Missouri, BioBelt Cluster
Value chain (horizontal and/or vertical)	includes final market producers, and first-, second-, and third-tier suppliers that directly and indirectly engage in trade (A value chain cluster is an industry cluster identified as an extended input/output or buyer/supplier chain. The cluster comprises multiple sectors or industries.) system of market and nonmarket links between geographically concentrated companies and institutions (The links enable cooperation among suppliers and competitors on business processes, purchases, investments, strategies, and technical research.)	Silicon Valley Boston Life Sciences Cluster
Networks	most salient in a domain between the flexibility of markets and the visible hand of organizational or political authority	Biovalley (borders France, Switzerland, and Germany)
Innovative entrepôt	geographic specialization in a few linked stages in the innovation supply chain (for example, research, development, gestation, and adaptation)	Saskatoon canola research cluster (Canada)

Source: Adapted from Phillips[37]

of model would appear to be scalable to all of the categories.

Finally, some clusters are defined by their role in developing useful knowledge. The networked model is increasingly common in large centers in Europe and the United States. Examples include world-scale universities (for example, Stanford/UC Berkeley in San Francisco), critical research infrastructure (CERN in Switzerland), and often the head offices and research centers for large multinationals. Malerba[38] identified two discrete, independent systems of innovation that would fit the networked model. Typified by the computer software industry, one system is based on flexible networks of small- and medium-sized companies, often co-located in distinct industrial districts (for example, Silicon Valley), and coordinated by a range of commercial venture-capital corporations and angel investors. Companies in these communities tend to be significantly volatile and rapidly growing. The other type of system, which perhaps better reflects the biotechnology world, is based on the universities, public research laboratories, and large companies that perform and commercialize R&D. While clearly attractive, this model has limited scope to expand beyond the largest agglomerations. These are currently in the United States, the European Union, and Japan (and perhaps in the larger research centers at Melbourne, Australia, and Toronto, Canada). In time, however, it could be attractive, especially to Quadrant II countries with large populations (such as China, India, and Brazil), which are increasingly focused on adopting, adapting, and increasingly developing new technology.

An alternate "innovative entrepôt" model being adopted by some smaller, research-intensive communities concentrates on a narrower range of inventive areas and seeks to fashion some comparative advantages by being an expert in something in a particular location. While this model[39] requires most of the elements of the larger networked clusters, it relies on small, nimble, highly specialized networks to create a comparative advantage for the region. This has particular appeal to many communities because it does not require the scale of the networked model, and it can be adapted and adopted realistically in most countries. Scale is less important than focus and strong networking. The challenge of this model, however, is that it requires the capacity for a high degree of trade in people, knowledge, technologies, and products, making it less attractive to Quadrant III and IV countries where there remain significant economic, legal, social, cultural, and physical barriers to the flows necessary for such a model to work.

2.3 *Step 3: Finding institutional and organizational leaders*

Actors provide varying levels of leadership based on the dominant activity of different stages of the industrial life cycle. Key actors in most clusters are often the university, public sector research laboratories and institutions, and the private sector. The first two categories of clusters—Porter's industrial managerial model and the product, market, value chain approach—tend to be led by private companies, while more innovative networks or entrepôts will have varying arrays of leaders, depending on the rate of innovation. Zilberman and colleagues[40] undertook a conceptual analysis of agricultural biotechnology, proposing a five-stage linear development process (including discovery, development, gestation, production, and marketing), with different actors (universities, public labs, and corporations), taking the lead at different stages. In early stages, public labs and universities tend to lead, with corporations doing little beyond marketing any resulting products. The model suggests that as the technology matures, corporations contribute more and increasingly take the lead.

Almost all scholars and practitioners agree that competitive, profit-seeking companies are at the core of any cluster. While some clusters seem to be able to operate without a clear dominant player, many scholars have noted that some of the strongest clusters are formed around multinational enterprises (MNEs).[41] Rugman and D'Cruz[42] argue that MNEs frequently act as flagships to lead, direct, coordinate, and manage strategic, value-added activities of collaborative companies in combined business and social networks. According to their research, 14 of the world's 20 largest international MNEs (defined by revenues

and global presence) were largely home-based organizations with strong regional strategies and networks. Gassman and Gaso[43] argue that regardless of whether the MNE is home-based or not, it can act as a broker of knowledge in a cluster. Some MNEs contribute information in disembodied forms: they set up "listening posts" in many regions around the world and distribute information. Other MNEs transfer knowledge embodied in new technologies, new processes, and new products. Regardless of the method, companies are a necessary condition for a cluster.

The regional university can also directly or indirectly drive the evolution and success of a technology cluster. According to Niosi and Bas,[44] innovation in emerging technologies and industrial clusters can be spurred indirectly through decentralized, horizontal policies that include the creation of both government laboratories and research universities. A source for skilled labor, the university acts as a magnet (directly and indirectly) for "stars" and business. Moreover, its publications can be a conduit for local and nonlocal knowledge exchanges. The traditional role of a university is to generate and diffuse basic or explorative (know-why) knowledge and generate a skilled academic and technical labor force. However, these traditional roles are evolving. As Cooke[45] argues, a strong local science base needs to be complemented by a rich entrepreneurial culture not only within the regional business community but also within the academic community. He further suggests that "*… the science base is a magnet, even if only indirectly … for biotechnology business.*" This is supported in previous research, which found that the existence of a diversified, mainly academic, knowledge base is a prerequisite for successful, localized innovative activity in knowledge-based sectors like biotechnology.[46] Niosi suggests also that universities are a foundational element of the "*virtuous cycle*" embedded within the cluster phenomenon—star scientists become entrepreneurs and spinout commercial ventures.[47]

Regional leadership is not limited to just organizations and companies. Key individuals can be ambassadors or civic entrepreneurs for regions and/or act as catalysts for change. For example, Robert Mondavi altered the face of the wine industry when he founded the wine cluster in the Napa Valley in California. Wine producers were already in the region, but most guarded their operations with secrecy. Mondavi opened the doors of his winery to tourists, customers, and competitors alike, effectively transforming the regional wine industry into an open platform of pooled knowledge and diverse products that eventually spelled success for the region.[48]

Finally, collaborative leadership has been another powerful tool in some regions. For example, the BioValley network (located in the Rhine valley where France, Germany, and Switzerland meet) was initiated in 1996 following the merger of Ciba-Geigy AG and Sandoz AG, both of Basel, Switzerland, to form Novartis AG. The region had lost jobs from the merger, so advocates, both key individuals and existing organizations, led revitalization efforts. The original BioValley concept, developed by Georg Endress and Hans Briner, was to re-create the region as a "Silicon Valley" dedicated to biotechnology and chemical technologies.

Cooperation or collaboration among public/private actors and individuals is important for the innovation process. Cross-fertilization through partnerships, either in projects or in efforts to build innovative regions, alerts the public sector to market demands and provides companies with access to basic research.

2.4 *Step 4: Choosing tactics*

While many purposive, directed strategies can help, perhaps a cluster's most important requirement is that the economic and business climate support market efforts. Because clusters involve both traded and untraded interdependences that can thrive only with strong underpinnings for market and social activity, centrally planned markets are unlikely to develop a true cluster. Minimally, a country needs to have the legal and social structures that create certainty for what would otherwise be risky transactions: the rule of law; effective and efficient mechanisms to protect and adjudicate property; the lowest possible barriers for entering or exiting any of the key input and output markets; the ability to trade

domestically and internationally; and effective tax, regulatory, and trade rules. Moreover, clusters tend to thrive best when at least a base investment has been made in education, training, and general community infrastructure. Clusters do not go in search of the lowest cost site; rather, they locate where things can get done. Unfortunately, such basic conditions are absent in many regions of the world, but especially in Quadrant IV countries. Any proactive measures to create a cluster without most if not all of these basic preconditions would likely be useless. In some instances, one or more of these foundational conditions may be missing (or weak) and a cluster might emerge, but generally proactive efforts will only succeed if markets can function.

Beyond ensuring an appropriate climate, an almost limitless array of proactive investments can nurture one or more cluster types. Some are more appropriate for some types of cluster than others. (Of course, there is no guarantee that the efforts will create the benefits envisaged.) A favorite tactic is to start with a cluster's core actors. All successful clusters appear to have a hub or anchor. Depending on whether the cluster is industrial/managerial or product, technology, or supply-chain-focused, this could be a set of competing companies, a leading company, a university, a public laboratory, or an industry association. If an anchor does not already exist, most regional planners and politicians will instinctively think of an investment-attraction program; virtually every jurisdiction in the world has someone marketing their location as a place to do business. But while expectations are often high, prospects are poor. Few companies are truly mobile. Most that are mobile would need inducements: large subsidies that could have a higher impact in other areas and that, in the end, would add little to job creation and wealth generation in the long term. In the absence of an obvious anchor, it usually makes more sense to build on potential local candidates than to try to lure others with subsidies. In lieu of a dominant companies, regions have sometimes been able to nurture Porterian or supply-chain type models, as long as they have been able to tap into distribution systems that provide access to global markets.

A second common model is to build potentially attractive infrastructure on the assumption that "*if we build it they will come.*" Unfortunately for many of these ventures, infrastructure is only a minor attraction: "*You will build it and they will not come.*" Increasingly, infrastructure needs to be tailored to the specific needs of a user, so if it is built on speculation, it often can be far more costly than if it is built to suit. Having said that, industrial actors often cite infrastructure, in the form of labs, incubators, and sophisticated machinery that benefits a wide range of users, as a key reason for their presence in a community. The physical plans for any infrastructure may be less important in the long run than the business model. An operator of infrastructure—be it a research park, special laboratory, or experimental facility—will need to tailor the terms of access and use to ensure that highly volatile and competitive research and development programs are able to access the facilities at the right time and under the right terms (for example, clearly defined IP rules). In research today, timing and terms are often more important than cost. Nevertheless, there is no single infrastructure set that is necessary or sufficient to make any cluster work.

Some think money is the key to the problem: If only more programs were created and more money made available, a cluster would emerge. It is true that money drives activity, but not all activity is desired. While in theory money is fungible—it shouldn't matter where it comes from—in practice money comes with strings attached. Who provides it and under what conditions can influence what others are able to accomplish with it. MNEs and other for-profit companies provide the lion's share of capital in almost all markets, so engaging profitable operating enterprises is almost a prerequisite for creating a sustainable cluster. During growth phases, however, public and private venture capital can be a critical contributor to the success of new technologies, products, and ventures. In the early stages of research, public funding tends to dominate, with private capital taking over as technologies, products, and processes mature and get closer to the market. In fact, public funds at later stages can be both good and bad. Government decision-making processes

(designed to ensure accountability and transparency) are generally inimical to effective and efficient financing: many companies ultimately supported by government grants or subsidies find the benefits are dissipated by slow decisions and inflexible terms. Furthermore, governments often have difficultly exerting the same influence as private investors. For example, it is hard for most governments to change management in a venture they have invested in or to divest or write down their equity. Public funds tend to be most effective when they are partnered and leveraged with private funds or private management skills (for example, microcredit systems and public/private venture pools with private management).

Locations lacking an anchor, an irresistible piece of infrastructure, and unlimited financial resources often look to their public research institutes or universities, especially in the early stages of developing a new technology area. Particularly with knowledge-intensive industries such as biotechnology, universities' public investment in R&D facilities is arguably a crucial precondition for a knowledge-based innovation system. Their capacity to create social capital, nurture and support stars, and provide a basis for collaboration and innovation—while harder but not impossible to measure—is ultimately the real value of such investments. As previously mentioned, the regional university can drive (directly and indirectly) the evolution and success of a technology cluster. Niosi and Bas[49] assert that universities do four main things: they generate know-why knowledge; they provide skilled, educated labor; they draw (directly and indirectly) stars and business; and they facilitate local and nonlocal knowledge exchanges (for example, publications and joint research). Many argue that a university's most important output is the base that it provides for the "absorptive capacity" of an economy. While the university is vital, it will only be able to perform this function in conjunction with a number of other essential elements. First, there must be an effective mechanism to both practically and legally transfer knowledge. At a minimum, this requires a domestic research community with international collaborations, companies with proprietary technologies, and an appropriate national system to legally protect IP. Second, there must be open and accessible labor markets for skilled and educated workers. Third, an institutional platform, such as a major national laboratory, a university, or a big research institute/program, is needed for community-based interaction and synergies to develop. These provide the foundation for absorbing global knowledge. Other elements, such as preferential financing and specialty commercial services, may be important but appear to be second-order requirements.

Ultimately, many theorists and practitioners are looking to "people policies" to nurture clusters. People are at the heart of generating new ideas and technologies, people lead and work in companies and institutions, and people are the core of networks. Some clusters seek to build up their local talent by creating new educational and skills training programs focused on the market needs of their local companies and clusters. Others work on building bridges to attach graduating students to the local labor market. These programs range in focus from technical training, entrepreneurial training, and mentoring to specialized advanced research techniques. Some clusters seek to attract highly skilled, educated, motivated, and experienced stars from elsewhere to populate their community and provide new ideas and leadership. Florida and Gates50 have suggested that the most vital and vibrant communities in the United States and Canada are those that value and support tolerance and talent. They suggest that creative, entrepreneurial people will tend to vote with their feet and move to communities with the most accommodating lifestyle. Other researchers suggest that good climate, culture, civic amenities, tax levels, and other quality-of-life measures are vital to creating a cluster. There is, however, some contradictory evidence: attraction to clusters may be less about quality of life and more about the depth of local labor markets (for example, the potential of there being more than one employer for one's specialized skills in the area) and the nature of the job (for example, one that is on the cutting edge of a technology or market).[51]

A closely related people-policy strategy is to target local stars in a community. Zucker

and colleagues[52] have noted that in the U.S. biotechnology field, academic and professional research stars (that is, those with a significant number of patents or publications) appeared to be instrumental in attracting major peer-reviewed grants, were key players in translating knowledge between academic and applied research, and were major contributors to the spinout of many new biotechnology companies. These stars assisted other researchers and industry. When the stars became affiliated with new spinouts, this signaled the presence of an opportunity to the marketplace. Some regions have attempted to collect more clusters of stars by collecting research expertise in national centers of excellence in public labs or universities. These regions and stars have also provided added incentives for the scholars and scientists to engage in more external activities, on public and private boards and commissions, or through consulting work. Similarly, many communities promote or nurture civic entrepreneurs. Often in university, industry, or industry associations, these individuals undertake efforts to defend, explain, or inform the entire cluster to its members and others outside. These civic entrepreneurs are highly valued—they will often personify and coalesce a cluster's spirit and aspirations. The regional entrepreneurial culture is also considered important, but it is not clear whether it is an independent variable or is simply determined by local economic development.

2.5 *Step 5: Sustaining a cluster through its life cycle*

Clusters appear to have life cycles. Sometimes strong centripetal forces pull activity to the community (for example, through knowledge spillovers and economies of scale and scope); at other times, centrifugal forces will dominate (for example, diseconomies and congestion costs).[53] Lundvall[54] offered a neo-Schumpeterian model of industrial development that explains localization patterns based on the degree of technological development: innovative clusters have the highest incentive to agglomerate, but markets become concentrated and profits stagnate as benefits decline, costs rise, and products are standardized. Sustaining a cluster, therefore, is not ensured. Successful clusters continue to focus on innovation (rather than on production efficiencies), which requires sustained investment in R&D.

The cycle of investment and return in clusters has been explored also by Davis and Schaefer,[55] who outline a five-stage evolutionary process. In the first stage, assets are accumulated, with investments often coming from the public sector (for example, the recent worldwide infusion in genomics research). In the following stage, assets are converted into business resources through entrepreneurial effort. Next, the cluster is established and companies grow by exploiting new resources and capabilities in external markets. Then as production and markets mature, collective efficiencies are realized. Finally, various market and non-market selection processes lead to local specialization. Crone offers a more formally delineated and stylized five-stage cluster-development model: precluster, protocluster, emerging cluster, established cluster, and restructuring or renewal states.[56] According to Crone, these stages are not intended to constitute a deterministic life cycle model but to serve as an analytical tool. Rosenfeld[57] alludes to yet another life cycle model in his exploration of clusters and cluster policy in less favored regions of the European Union. According to Rosenfeld, clusters progress from an embryonic stage through growth and maturity until they finally decay. The embryonic stage is stimulated through innovations, inventions, or inward investment. During the growth stage, markets develop sufficiently to spinout and attract imitators and competitors; entrepreneurship is also cultivated. In the maturity stage, the activities of the cluster have become more routine. More imitators enter the market, and lower costs become the key competitive advantage. The decay stage is when products or processes become expendable and are easily substituted in the marketplace by more cost-effective alternatives.

Just as in the industrial life cycle, clusters differentiate according to scale, scope, character, and activities. Regardless of how a cluster is characterized, it is still likely to be subject to the evolutionary dynamics of markets. At any given point in the developmental cycle—cluster or industrial—activities must shift. Different actors take

on differentiated roles. At some points, activities may be concentrated or centralized within one institution. At other times, activities may be carried out collectively by a number of actors working in collaboration. Such responses to global market signals and industry developments must be orchestrated to avoid the declining stage of industrial development or the decay of a cluster.

3. CONCLUSIONS

Cluster strategies would appear to be high-risk, high-return economic policies. While not all types of clusters are appropriate for all countries, most countries could attempt at least one or more options. If thoughtfully and prudently undertaken, the investments in analysis, strategizing, building local leadership, and pursuing various tactics would generate positive social returns even if a sustainable cluster did not develop. Indeed, most of the options appropriate for clusters are also just good economic policy. One point that anyone interested in economic development should keep in mind is that most sectors are becoming more knowledge intensive. Even in low specialized areas, such as garment industries in developing nations, technologies are being adopted to increase productivity and flexibility. In short, while clusters are attractive economic development tools, they must be nurtured with an appreciation for their partial and incomplete nature. Fundamentally, they are part of a global innovation system, and cannot thrive if cut off from the lifeblood of the system—ideas, skilled labor, capital, and competing and collaborating companies and organizations.

Knowledge-based development is inherently different from traditional industrial development. While infant industry protection made some sense in the industrial context, it is not clear whether it has any value in a knowledge-based world. The imperatives of innovation pose some serious challenges for development policy. Many current development efforts have a strong mercantilist orientation, with a focus on self-sufficiency. In an effort to generate higher-value exports or to replace imports, governments at all levels in many countries are using their tax and fiscal policy to encourage greater local R&D or to attract global companies to relocate their R&D programs into their jurisdiction. This often involves preferential support for national champions or exclusive deals to encourage MNEs to relocate their activities. Usually governments do this without considering the corresponding relationships and interactions that knowledge-based companies require to succeed. If innovation can happen within a company, companies, or a regional or national community, then such a narrow approach might have some chance of success. But if innovation is truly global, as appears to be the case in many of the life sciences, then narrow, mechanistic self-sufficiency strategies may either simply fail or be counterproductive. This is why both companies and skilled employees are more interested in the innovation community than in fiscal incentives, public infrastructure, or other government support. By extension, a mercantilist policy that discourages global links could not only fail to attract global companies but could also drive out local companies or researchers as they seek access to the global community. ■

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1 For an in-depth discussion of the theory of clusters and how they work, see, also in this *Handbook*, chapter 3.11 by PWB Phillips and CD Ryan.

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5 See *supra* note 3.

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7 Louisiana, Michigan, and Pennsylvania. See also Akundi KM. 2003. Cluster-based Economic Development, Part 1: A Survey of State Initiatives. *Research Corner* no. 4; July. Business and Industry Data Center: Austin, Texas. www.bidc.state.tx.us/researchcorner/Archives/Issue4/PART1_BandwagonEffect.pdf.

8 Connecticut, Kentucky, Louisiana, Maine, Oregon, Pennsylvania, Rhode Island, Texas, and Washington.

9 Arizona, California, Delaware, Indiana, Iowa, Massachusetts, and Tennessee

10 Canada has prioritized the identification and facilitation of 10 key clusters by 2010 in its Innovation Strategy.

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19 The concept was originally founded by Christaller (see Christaller W. 1972. How I Discovered the Theory of Central Places: A Report about the Origin of Central Places. In *Man Space and Environment* (eds. PW English and RC Mayfield) Oxford Univ. Press. pp. 601–610; Lösch A. 1954. *The Economics of Location: A Pioneer Book in the Relations Between Economic Goods and Geography*. Translated from the Second Revised (1944) Ed. by WH Woglom with the assistance of WF Stolper. Yale University Press: New Haven, Conn.

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27 Mead SP. 2001. Using Social Network Analysis to Visualize Project Teams. *Project Management Journal*. 32 (4): 32-38.

28 Wasserman S and K Faust. 1994. *Social Network Analysis*. Cambridge University Press: Cambridge.

29 Ibid., at 169.

30 According to Bonacich, power is a function of centrality plus the centrality of others, weighted by the distance and number of walks between the central node and other agents. See Bonacich P. 1972. Factoring And Weighting Approaches to Status Scores and Clique Identification. *Journal of Mathematical Sociology* 2: 113–120.

31 It is important to qualify the term *power*. Power can be endowed or it can be "referential" in nature, built up over time based upon a sound track record of good performance.

32 The attenuation level, or beta coefficient, reflects the nature of power levels. Centrality and being connected to central actors is not always positive. For instance, an agent that wishes to maintain a monopoly position would choose to be connected to multiple, nonconnected actors in order to maintain a power position.

33 Coenen and colleagues use both to analyze regional differences between the Scanian and Saskatoon regions (see Coenen L, J Moodysson, CD Ryan, B Asheim and PWB Phillips. 2006. Knowledge Bases and Spatial Patterns of Collaboration: Comparing the Pharma and Agro-Food Bioregions Scania and Saskatoon. *Industry and Innovation*: in press). Similarly, bibliometric analysis has been used to contrast and compare agricultural

biotechnology clusters. Other proxies can be used as well. For instance, Ryan and Phillips employ an activity-based analytical approach, qualifying linkages between Saskatoon-based actors as research-based, financial, or exchange of high-quality personnel, just to name a few (see Ryan CD and PWB Phillips. 2004. Knowledge Management in Advanced Technology Industries: An Examination of International Agricultural Biotechnology Clusters. *Environment and Planning, Government, and Policy* 22(2): 217–32.)

34 Sources for Table 2:

(1) see *supra* note 21;

(2) see *supra* note 20;

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(10) see supra note 24.

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36 The interest in SME clusters has been fueled particularly by the experience of what has come to be called the "Third Italy." The concept started to be used in the late 1970s when it became apparent that while little economic progress was in sight in the poor South (Second Italy), the traditionally rich Northwest (First Italy) was facing a deep crisis. In contrast, the Northeast and centre of Italy showed fast growth, which attracted the attention of social scientists. In a number of sectors where small companies predominated, groups of companies clustered together in specific regions seemed to be able to grow rapidly, develop niches in export markets, and offer new employment opportunities.

37 Adapted from Phillips and colleagues (see (9) of *supra* note 34).

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39 Phillips P. 2002. Regional Systems of Innovation as a Modern R&D Entrepôt: The Case of the Saskatoon Biotechnology Cluster. In *Innovation, Entrepreneurship, Family Business, and Economic Development: A Western Canadian Perspective* (ed. J. Chrisman, et al.) University of Calgary Press. pp. 31–58.

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SECTION 4

The IP Toolbox

The Statutory Toolbox: An Introduction

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ABSTRACT

This chapter presents the main forms of statutory intellectual property (IP) protection with emphasis on utility patents, trademarks, geographical indications, copyright, and trade secrets. Basic questions with regard to who can get protection, the subject matter of each form of protection, statutory requirements, and certain exceptions. The chapter concludes with short sections on institutional aspects including employee agreements, how to mark the protected intellectual property, how to integrate the various rights, and how to identify infringement. The authors conclude that the form of protection chosen for a given invention should be guided by the mission of the institution (whether public or private), the purpose of the work it conducts, and the nature of the invention, or other IP, that will be subject to IP rights protections.

1. INTRODUCTION: WHAT IS INTELLECTUAL PROPERTY?

Intellectual property (IP), sometimes called intangible property is any product of the human mind or intellect. Intellectual property can therefore be almost anything: a technical invention or an improvement of an earlier invention; it can be a unique name or logo, design, method, software, database, domain name, a chapter in a book (like this chapter), or an entire book (like this *Handbook*). The broad area of intellectual property is subdivided into different types, each clearly defined and protected through statutes or laws, which then can be protected by different means. In the United States, for example, IP rights protection is even enshrined in the Constitution of the United States of America:

> The Congress shall have power … to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries … .[1]

By this clause the Constitution grants the rights to patent and copyright protection. Even though trademarks are not expressly protected by the Constitution, trademarks have a long history of use and protection in the United States and globally. Likewise, trade secret protection has long been accepted as a means for protecting IP rights. Other forms of IP protection include plant breeders' rights.

What makes these forms of IP protection particularly useful is that they have been able to adapt to the changing times. Even if the present technologies are different from the technology that was protected in Thomas Jefferson's day, the means to protect are similar. But the essential nature of patents was "invented" well before the Constitution was written. They emerged in medieval Europe where first rights were granted to individuals for what they owned, using a remuneration or an award as a means to encourage individuals to generate "property desired by themselves." A more formal system of patents was born in the Venetian Republic where the first patent

Dodds J and A Krattiger. 2007. The Statutory Toolbox: An Introduction. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

was granted in 1443 to a manufacturer of conveyors for loading and unloading ships.[2] Two centuries later, in 1623, the British Crown passed a patent law, then called the Statute of Monopolies. This law defined basic concepts that continue to influence to this day the interpretation of patents around the world.

In the United States, the first patent law was adopted in 1790, shortly after the Constitution was ratified. The first U.S. patent was signed by President George Washington on July 31, 1790 and was issued to Samuel Hopkins (of Pennsylvania) for his improvement of the potash manufacturing process. The invention saved what was then the country's leading export industry.

In the following chapters we will look briefly at issues related to the protection of intellectual property; Table 1 provides an overview of the main tools of IP protection. We especially focus on the law in the U.S., though in general terms, similarity exists throughout many parts of the world. Where international agreements regulate IP protection, that is noted. In national laws there are differences: some countries give broader protection to intellectual property, others, narrower, but basically the forms of protection are similar, especially in member countries of the World Trade Organization (WTO), which adhere to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

2. PATENTS

2.1 *What is a patent?*

A patent, which usually refers to a *utility patent,* can be granted to anyone who invents a new and useful process, machine, article, manufacture, composition of matter, or any new and useful improvement thereof. A utility patent is usually granted for a period ending 20 years after the filing date. A patent gives the inventor a right to exclude others from making, using, offering for sale, or selling the invention in the country where the patent is issued or importing the invention to the country where the patent is issued. In exchange for being granted a patent, the inventor agrees to disclose in the patent application, the invention in detail as well as the best mode of practicing the invention. The disclosure is published normally 18 months after the filing but, at the latest, when the patent issues. Disclosing the invention to the public will help others to invent further, thus pushing technology forward for the benefit of the society.

In the United States, there are three different kinds of patents: utility patents, design patents, and plant patents. Plant patents are essentially specific to the United States. In addition to these types of patents, several counties provide additionally *utility model protection*. Utility models are also called *petty patents*. Basically they allow the right holder to prevent others from commercially using the protected invention during a limited time period. Therefore, a utility model is basically similar to a patent. The main difference is that the requirement of nonobviousness, or innovative step, is not as stringent for utility models as it is for patents. Moreover, the duration of the protection given by utility models is shorter than that given by patents. The duration depends on the country; usually the protection is between seven and ten years. In Estonia and Finland, for example, an invention can be protected by utility model for ten years, at most.

In the United States, a utility patent can be filed as a provisional or a nonprovisional application. A provisional patent application is a lower-cost first patent application, which does not have to contain any claims. A provisional patent application has a pendency of 12 months from the date of its filing. A provisional patent application cannot mature to an issued patent but it gives the inventor an early filing date, and the term *patent pending* is applicable. In order to benefit from the early filing date of the provisional application, a nonprovisional patent application has to be filed before the end of the 12 months pendency of the provisional application. It is possible to extend the period of patent life up to 21 years by first filing a provisional application and then later a nonprovisional one.[4]

A *design patent* can be granted to anyone who invents a new, original and ornamental design for an article of manufacture. A design patent is

Table 1: What is the intellectual property of your business?

Means of protection	What can be protected	How to protect	Term of protection	The rights of the owner
Patents	Any useful, novel, and nonobvious invention; design patents can be filed on new, original, or ornamental design	Submit a patent application	20 years from filing of the priority application; for design patent, 14 years from the date of issuance.	Right to exclude others from making, using, manufacturing, selling, and offering to sell
Trademarks	Words, phrases, and logos that can distinguish the goods and services from those of others	Use or have a bona fide intent to use and apply for a federal registration	Unlimited duration as long as the mark is in use; the mark has to be renewed every tenth year	Right to exclude others from using the mark and other marks so similar they cause confusion
Copyright	Literary works, software, dramatic works, music, pictures, sound recordings, architectural works, movies	Apply for federal registration	Life of the author plus 70 years	Right to prevent unauthorized copying or public performance
Trade Secrets	Any technical or business information that is secret and that gives the holder an advantage over a competitor who does not have the information	Keep secret; no registration available	Unlimited duration as long as the subject matter is secret	Right to prevent unlawful use

Note: An overview and introduction of protections available for plants are treated elsewhere in this *Handbook*.[1]

granted for a period of 14 years from the date of issuance.

Certain countries provide protection called registered or industrial designs, which is similar to the U.S. design patent. In some countries, industrial design provides protection of up to 25 years. Since April 2003, one can also get a Community Design in the European Union, which protects the design in all the member countries of the European Union for up to 25 years.

Plant patents are a form specific to the United States. A plant patent can be granted to anyone who invents or discovers and asexually reproduces any distinct and new plant variety. Tuber-propagated plants are excluded from plant-patent protection. For sexually reproduced (by seeds) or tuber-propagated plants, one can get protection via the Plant Variety Protection Office administered by the U.S. Department of Agriculture. Several countries provide protection to sexually reproduced plant breeds through plant breeders' rights.[5] It is important to note the distinction between plant patents and utility patents on plants.[6]

2.2 *Who can get a patent?*

According to the law in perhaps any country with patent law, only the inventor can apply for a U.S. patent. However, if the inventor is dead, a legal representative can make the application. Similarly, if an inventor assigned the right to his or her employer or any third party, that entity may file for the patent. In any case, it is important that the true inventors are named in the patent application. If there is more than one inventor, the inventors apply for the patent jointly. A person who contributed to the invention only financially cannot be a joint inventor. None of the inventors needs to be a U.S. citizen or live in the United States in order to be entitled to a U.S. patent.

2.3 *U.S. and "international" (PCT) patent applications*

A patent is territorial. This means that there is no such a thing as a world patent. A U.S. patent is valid only in the United States and the owner of a U.S. patent therefore can, based on the U.S. patent, only claim rights in the United States.

The Patent Cooperation Treaty (PCT) is an international treaty harmonizing patent application procedures in its member countries. Through a PCT patent application, the inventor can get a filing date with one application in all the member countries. Thirty months after the filing, the applicant has to decide in which member countries he or she actually wants and needs a national patent. The benefit of PCT application is that there is no need to file separately in all the countries; the procedure can be done by one application. Moreover, the PCT system gives the inventor approximately 30 months to shop around before deciding in which countries a national patent would be relevant.

All the PCT applications will be published 18 months from the filing if not abandoned before that. Usually, a U.S. patent application is published 18 months after the filing, if nonpublication is not specifically requested. The applicant is entitled to request nonpublication if the application is not and will not be a subject of filing in any country publishing the patent application 18 months after filing. Nor may the invention be subject to a PCT application. When the patent has issued it will be published. Due to the publishing policy of PCT, some inventors prefer to file a U.S. patent and request no publishing, thereby keeping the invention secret until the patent issues.[7]

2.4 *First to file versus first to invent*

The United States is the only country in the world not applying the first-to-file concept. In the United States a patent is granted to the party that first invented. Because of this concept the U.S. patent system is known for its interference practices. Interference is a proceeding conducted before the Board of Patent Appeals and Interferences to determine priority on invention between a pending application and another pending application or unexpired patent. The key elements of determining priority are the date of conception, the date of reduction to practice, and diligence or lack of it.

2.5 *Subject matter of patents*

In the United States, statutory subject matter of a patent is defined as "*any new and useful process,*

machine, manufacture, or composition of matter or any new and useful improvement thereto."[8]

The Supreme Court acknowledged through legislative history that Congress intended that statutory subject matter includes "*anything under the sun that is made by man*."[9]

The Supreme Court has specifically identified three categories that are not patentable. Laws of nature, natural phenomena, and abstract ideas do not fall into any statutory class and they are, therefore, unpatentable. Furthermore, items from these categories are not patentable according to the national legislations of many other countries. Some national laws give further provisions for nonpatentable subject matter. For example, India does not allow patents on agricultural methods. The European Union and many other countries do not allow patents on methods to treat a human condition or surgical methods.

Mathematical algorithms as such are abstract ideas when they stand alone and are not reduced to a practical application. However, when an abstract idea is reduced to a practical application, the practical application of the abstract idea can be a useful, concrete, and tangible result and therefore patentable.[10] In the United States, such applications of mathematical algorithms are increasingly patented as business-method patents. Business-method patents are, however, not allowable in several countries; for example, the European Patent Office does not currently examine applications disclosing a business methods.

2.6 *Statutory requirements for patentability*

2.6.1 *Novelty*

Because patents are granted to promote the progress of the useful arts, a product or process is not patentable unless it is new. A product or process is not new if all the claimed elements are present expressly or inherently in a single piece of relevant prior art. If a single piece of relevant prior art contains all the claimed elements, it is said to anticipate the product or process. An invention is not new and therefore not patentable, if "*it was known or used by others in this country or patented or described in a printed publication in this or a foreign country …*"[11] *Known* has been interpreted to mean that the knowledge is accessible to the public. An oral presentation may be enough to make the knowledge accessible to the public. *Used* in this clause means publicly accessible use. A machine that is operated in an open field is publicly accessible use even if no one sees the machine,[12] but a machine in a windowless building where no one can enter without swearing to secrecy has been ruled not to be public use.[13] *Printed publication* has been very broadly interpreted to mean all material accessible to the public in tangible form.[14] Oral communication is excluded, but if copies of a paper were distributed at a conference, they would be publications. However, if those receiving the copies were asked to keep the content of the communication secret, the paper would not be a publication.

An invention is not patentable "*if the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for the patent in the United States.*"[15] This section creates the one-year grace period, during which the inventor may develop the invention further, market it, and prepare a patent application.

It is noteworthy that the U.S. patent system is different from systems of the most other countries because of this grace period. In most other countries the inventor would lose the rights to patent if the invention were published before filing the patent. In European countries, for example, a public disclosure is an absolute bar to patentability. Japan gives a six-month grace period for filing a patent if the public disclosure was a presentation at a scientific meeting.

2.6.2 *Utility*

The purpose of granting patents is to promote the progress of the useful arts. Therefore, in order to be patentable an invention has to be useful. For a product or process to be useful it must, at least, work, although it does not have to work perfectly or even better than any competing products or processes. However, products or processes that are working but can be used, for example, only for immoral or illegal purposes are not considered useful. Also, products and processes that

are regarded as useless are not considered useful. A process for producing a steroid that had no known use, for instance, was found to be not useful and therefore not patentable.[16]

2.6.3 *Nonobviousness*

A new and useful product or process is not patentable unless it was nonobvious when it was made. The nonobviousness requirement is included in Section 103 of the Patent Act. Different from the novelty determination, the nonobviousness determination does not include a strict identity requirement. Therefore, prior art that does not disclose all the elements of the claim at issue might be relevant when determining obviousness. When making a decision of obviousness, the examiner has to determine the level of ordinary skill in the art at the time the invention was made.

2.7 *Experimental-use exemption*

U.S. patent law does not have a written research-exemption clause, but current practices are based on case law, that is, on court decisions. The basic rule says the patentee shall not be allowed to prevent experimentation using a patented product or process for bona fide research activities designed to further scientific knowledge.

However, the experimental-use exception is very narrow, such that any research aimed at commercialization (with even the slightest commercial implication) will not fall under the exemption and will hence be subject to infringement liability.

3. TRADEMARKS AND RELATED RIGHTS

A *trademark* is a word, phrase, symbol, design or a combination of those items, that distinguishes the source of one's goods or services from the goods or services of others. A trademark can be valid only when it is used in, or in connection with, goods or services in the course of commerce.

There are various types of marks that can be registered with the Patent and Trademark Office. In addition to trademarks[17] and service marks (marks that indicate a specific service, such as a rental or leasing service), the Trademark Act provides for registration of collective marks, membership marks, and certification marks. *Collective marks* are trademarks or service marks that are used by a member of cooperation, an association, or other collective group or organization. One type of collective mark is a membership mark. These are not trademarks in the ordinary sense. *Membership marks* do not indicate the origin of the good or service. The purpose of a membership mark is, rather, to indicate that the user of the mark is a member of a particular organization.

There are generally three types of *certification marks*. First, there are marks that certify that the good or product is from a certain geographic region; for example *Cognac* for the distilled brandy from a certain region in France. Second, there are marks that certify that the goods or services meet certain standards, for example, quality standards or safety standards. Third, there are marks that certify that a member of a union or other organization performed the work or labor on the goods or services and that the performer meets certain standards.

In addition, one can register a *trade dress* of a good or service. Trade dress can, for example, be product design, packaging, or color. Trade dress of a service can be, for example, the overall look of restaurant.

The most effective way to get trademark registration is to choose a mark that is fanciful or arbitrary. An example of a fanciful mark is *EXXON*—a made-up word—something that does not mean anything in itself. An example of an arbitrary mark is *Apple* used by Apple Computer—an existing English word that itself has no connection to computers.

A mark that resembles another mark already in use in the United States cannot be registered because of the likelihood of customer confusion. Therefore, before filing a trademark registration it is important to perform a trademark search to discover whether the mark or a similar one is already in use.

An important element of trademark law is the *naked licensing* doctrine. Quality assurance and protection of the public is a central purpose of the trademark law. Therefore, an indispensable condition of a valid trademark license is that the licensor controls the nature and quality of the good or service sold by the licensee under the

mark. Naked licensing results when the licensor does not adequately supervise the quality of the licensee's products or services. Naked licensing can be regarded as abandonment of a mark and therefore leads to cancellation of registration.

4. GEOGRAPHICAL INDICATIONS

A geographical indication is a sign used on goods that have a specific geographic origin and possess qualities or a reputation that are derived from that place of origin. Geographical indications are defined in the TRIPS agreement as a type of intellectual property. WTO members provide legal means for interested parties to prevent the use of a geographical indication that indicates or suggests that a good originates in a geographical area other than the true place or origin in a manner that is misleading to the public or constitutes an act of unfair competition.

Most commonly, a geographical indication consists of the name of the place of origin of the goods. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Examples of geographical indications are Idaho (potatoes) and Roquefort (cheese).

Whether a sign functions as a geographical indication is a matter of national law and consumer perception. The TRIPS Agreement does not require that a WTO member extend protection to a geographical indication if that geographical indication is the generic name for the goods in that member country. Therefore, the word *champagne* is not registrable as a geographical indication in the United States, because *champagne* is a generic term, in the United States, meaning a light-colored wine with bubbles.

The United States offers robust protection for geographical indications, generally through registration as a certification mark.

5. COPYRIGHT

A copyright is a type of intellectual property protection for authors of original works. Generally the categories of works that are protected are:

- literary works
- musical works, including words accompanying music
- dramatic works
- pantomimes and choreographic works
- pictorial graphic and sculptural works
- motion pictures and other audiovisual works
- sound recordings
- architectural works

A copyright protects an original work and allows the author an exclusive right to:

- reproduce the work exclusively
- prepare derivative works
- distribute copies or phonorecords by sale, transfer of ownership, lease, rent or lend
- perform the work publicly
- display

An original work of authorship is immediately protected by copyright after it is fixed in a tangible medium. The duration of a copyright protection on or after 1978 is that of the author's lifetime plus 70 years. If there are two or more authors, the term is 70 years after the death of the last surviving author. If the creation is a work for hire, and the works are created anonymously, the duration is 95 years from publication or 120 years from creation, whichever is shorter.

Only the author, or those deriving rights from the author, can claim the copyright. A copyright requires no registration or publication to be protected, but a copyrightable work is protected automatically when the creation is fixed in a tangible form.

Importantly, federal copyright registration is a legal formality intended to make a public record of the basic facts of a particular copyright. Copyright registration may be filed at any time during the life of a work. Even if registration is not a requirement for protection, registration brings several advantages. For example, before an infringement suit may be filed in the court, registration is required for a work of U.S. origin. Moreover, if registration is filed within five years of publication of the work, the registration will establish prima facie evidence, in court, of

validity and of the facts stated in the copyright certificate. Registration makes available to the copyright owner statutory damages and attorney fees, in case of an infringement suit, if the registration was made three months after publication of the work or prior to an infringement of the work. Registration also enables the U.S. Customs Service to protect the copyright owner against importation of infringing copies.

To be copyrightable, a work has to be original and in a fixed medium. This means that a work has to be the independent creation of an author and that it has required a modest quantum of creativity. Being in a "fixed medium" means that the creation is in a tangible form: a short story is written down, a song is recorded, and so on. A pure idea or concept cannot be copyrighted without description or illustration.

An important question is whether software and databases can be protected. The last decades have seen a revolution in knowledge management, library services, and information-resource database configurations. The use of integrated computer networks and the ability to produce and distribute information have had far-reaching implications for IP (intellectual property) protection. In order to demonstrate IP laws and their application, another chapter discusses these aspects together with respect to geographic information systems and remote sensing.[18]

As mentioned earlier, the author of a work owns the copyright. In a case of work for hire the employer is regarded as the author and, therefore, the employee does not own the copyright. A work for hire is defined in copyright law as a work prepared by an employee, within the scope of his or her employment, or a work specially ordered or commissioned for use as a contribution to a collective work, a part of a motion picture or other audiovisual work, a translation, a supplementary work, a compilation, an instructional text, a test, answer material for a test, or an atlas, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.

Copyright protection subsists from the time the work is created in fixed form. The owner of a copyright can assign all his or her rights unconditionally to another. Alternatively, the owner can license the rights exclusively or nonexclusively. If, at the time of creation, the authors intend to combine their contributions into inseparable or interdependent parts, the work is considered joint work and the authors are considered joint copyright owners. Each copyright owner has an equal right to exploit her or his rights. In such a case, a company can license or get an assignment for the copyright of the whole work from only one of the authors. If at the time of creation the authors did not intend their works to be part of an inseparable whole, the fact that their works are later put together implicates the work as a collective work. In such a case, each author owns a copyright in only the material she or he added to the final product. In this case, the company needs to have an agreement with each of the authors to convey the copyrights.

It should be noted that in countries of the European Union, greater protection of databases is provided than in the United States. The European Union Database Directive adopted by the European Parliament in 1996 sets out two rights for the makers of databases:

- the right to prevent unauthorized acts of extraction from a database
- the right to prevent unauthorized acts of reutilization of the contents of a database

The first right is similar to that provided under the U.S. Copyright Act. With this right the directive provides protection to a database but not to the underlying data, and the right is limited to databases containing a sufficient degree of creativity in the selection or arrangement of the data. The second right, however, provides for a sui generis right that prohibits the extraction or reutilization of any database in which there has been a substantial investment in obtaining, verification, or presentation of the data contents. Under this second right, there is no requirement for creativity or originality. The protection is available for 15 years from creation of the database. If substantial changes are made to the content of the database, the modified database will be protected a new term of 15 years. Protection under the directive is available only to nationals of member countries

of European Union. Other countries will obtain such protection only if they offer comparable protection to databases of a European national and if a bilateral agreement is reached.

In the U.S. Copyright Act, there is a *fair use exception* that states that use of an author's original creation is authorized for the purposes of criticism, comment, news reporting, teaching, scholarship, or research. Fair use takes into consideration the purpose and character of the use, the nature of the copyrighted work, the amount and substantiality of the portion used in relation to copyrighted work as a whole, and the effect of the use on the potential market. There are four aspects to the fair-use exception:

1. **Classroom use**. Certain educational establishments are allowed to publicly display and perform others' works in the course of face-to-face teaching activities. But this exemption applies only to the use of legally acquired works.
2. **Copying in a library**. In academic and research institutions, copying limited portions of certain copyrighted works[19] is not an infringement, provided that libraries (or their users) make single copies of the works, provided that all of the following apply:
   - only individual articles (for example, of a book) or small portions of a larger work be copied
   - the copies become the property of the person making the copies
   - the copies are used for private study, scholarship, or research
   - the copying is not done for commercial advantage
   - the library displays prominently a notice warning of copyright restrictions in accord with requirements published by the U.S. Copyright Office[20]

Finally, it should be noted that no "international copyright" exists. But since most countries offer protection to foreign works under simplified international copyright treaties and conventions, a rule of thumb is that if a work could be protected as a U.S. domestic work, it is protected as a foreign work. There are cases, however, where foreign copyright law is less restrictive than the U.S. code, so the work may still be protected even though in the United States the work would be in the public domain.

6. TRADE SECRETS

6.1 *What can be a trade secret?*

Trade secrets are an important and widely used business asset in the United States. Both small and large businesses rely on trade secret protection, often without even realizing it. It has been estimated that 90 percent of inventions are protected by trade secrets.

There are various kinds of trade secrets. The most popular example of a trade secret is the formula for Coca Cola, which has been kept successfully in secrecy now for more than 100 years. In addition to chemical formulas or processing methods, trade secrets can involve software, accounting records, customer lists, plant designs, and so on. Although trade secrets may overlap with patentable subject matter, they go well beyond that.

A generally accepted definition of a trade secret appears in the 1939 Restatement of Torts. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by anyone as a secret, nor can matters that are completely disclosed by the goods one markets be trade secrets. Therefore, a trade secret is known only in the particular business in which it is used.

6.2 *How are trade secrets protected?*

Intentional theft of trade secrets can constitute a crime under both federal and state law. The most significant federal law dealing with trade secret theft is the Economic Espionage Act (EEA) of 1996.[21] The EEA applies not only to thefts that occur within the United States, but also to conduct outside the United States, if the thief is a U.S. citizen or corporation, or if any act in furtherance of the offense occurred in the United States. All of the 50 U.S. states have enacted trade secret laws, most of which are some version of the Uniform Trade Secret Act (UTSA).

6.3 *To file a patent or to keep a trade secret?*

Before filing a patent one should always consider the possibility of keeping the invention in secrecy, because there are situations when one of these two protection methods is more useful than the other.

There is no limitation in the time that a trade secret can protect the invention. On the contrary, a patent is normally enforceable for a period of 20 years after the filing. If the subject matter is easy to keep in secret, if there will be no products being marketed that could be used to reverse engineer the trade secret, then keeping trade secret might be worth considering.

Sometimes it is very difficult to prove that someone has infringed a patent. For example, infringement of a patent on a laboratory method might be difficult to prove, and, therefore, keeping the method as a trade secret might be a better means of protection.

In order to be patentable an invention has to be useful, novel, and nonobvious. There are no such requirements for trade secrets. The only "usefulness" requirement for a trade secret according to the Restatement of Torts § 757, is that "*it confers the owner an opportunity to obtain an advantage over competitors who do not know or use it.*" Therefore, an improvement or a variation of a method, for example, can be a trade secret, but it might not be patentable. The field of trade secrets is much wider than that of patents.

6.4 *Misappropriation of trade secrets*

Based on the definition given in the 1939 Restatement of Torts, one who discovers a trade secret properly, for example, by analyzing a commercial product embodying the secret, reverse engineering the secret, or by independent invention, is free to disclose it or to use it in his or her own business without liability to the owner. The cases rising from trade secret misappropriation are basically of three types:

1. Cases in which a trade secret is learned by improper means, as through industrial espionage
2. Cases in which an employee knowing a trade secret is hired by a competitor to whom the employee discloses the trade secret, or the employee knowing the trade secret begins his or her own business basing it on the trade secret
3. Cases in which a trade secret is disclosed during licensing negotiations, and the licensee later refuses to pay royalties but continues to use the trade secret[22]

7. OWNERSHIP OF RIGHTS

Ownership of rights is an important question with regard to licensing and transfer of the rights to another party. It may be that there are some rights belonging, for example, to an employee of an organization, that might interfere with the interest of the organization to license the rights further. In order to prevent misunderstandings related to such situations, it is worthwhile to think how the technology was created: Did the organization hire a consultant? What were the conditions of the agreements? Who sponsored the research? Where are the inventors now?

7.1 *Ownership of patent rights*

Employed to invent. As a general rule, the inventor owns the patent rights to the subject matter of his or her invention, even if the inventor conceived it or reduced it to practice during his or her employment. The main exception to this rule is the *employed-to-invent-exception*. An employer owns the invention of the employee if the employee was employed to invent something or to solve a problem.

Shop right. When an employee makes an invention or discovery that is outside her or his employment, but she or he uses the employer's resources, the invention may be owned and patented by the employee, but the employer has a shop right to the invention. A shop right is a royalty-free, nonexclusive, nontransferable, implied-in-law license granted to an employer to use the employees patented invention.

A shop right exists for the life of a patent, regardless of whether the employment continues or not. The employer having a shop right can make, use, and sell articles embodying the patented invention. The employer may, however, not sell articles outside his or her normal range of business.

Joint inventors. In the Code of Federal Regulations, the term *joint inventor* is defined as one who "*must have made a contribution, individually or jointly, to the subject matter of at least one claim of the application.*" To be legally named as an inventor, a person must have contributed to the discovery of the way of obtaining the wished-for results. Creating the idea of the general wished-for result desired is not, by itself, sufficient to constitute joint invention.

It is important to remember that any patent with a named inventor who cannot meet the legal test for the minimal requirement of inventorship will lead to that patent becoming invalidated. Similarly, if all joint inventors are not named, the patent is invalid.

In absence of an assignment of the patent, the joint inventors are co-owners of the patent. Each of the co-owners has all the rights of a patent owner. This means that each of them may make, use, or sell the patented invention without the permission of or the need to account to the other joint owners.

7.2 *Ownership of copyright*

As a general rule, a person who creates a work is the author and therefore owns the rights to the work. However, a work made for hire is an exception to this rule. If an employee within the scope of his or her employment prepares a work, the employer and not the employee is considered to be the author.

8. PROTECTING THE ORGANIZATION'S IP

8.1 *Notebook keeping*

Under U.S. law, a patent is granted to the first to conceive the idea for an invention, not to the person who first files a patent application. Because of the first-to-invent concept, a notebook must be able to serve as essential evidence of the date of conception. In a case of interference, the notebook might also be essential for proving diligence in developing the invention after the conception. For these purposes proper notebook keeping is important.[23] All notebook entries should be made with permanent ink. The pages of the notebook should be numbered and filled consecutively, with no intervening pages left blank. Someone able to understand the work, but not participating in it, should witness all of the entries.

8.2 *Employee agreements*

Employees make the majority of inventions patented in the United States. Therefore, it is important for an organization to establish practices related to inventions made by its employees. Employee agreements often contain clauses that require protection of trade secrets and confidential information, require the employee to assign inventions to the employer, require the employee to cooperate in disclosing inventive activity, and require the employee to cooperate in patent-prosecution activities. Employee agreements can also include trailer clauses requiring the employee to assign inventions made for a certain period after leaving employment.

Some states have recently enacted state statutes attempting to prevent an employer from abusing his or her unequal bargaining power. The statutes are limiting the type of inventions that an employer can contractually require an inventor to assign.

8.3 *Marking the protected intellectual property*

Patent marking. Patent law gives a patent owner an option to mark the patented product. Marking the product is not required, but owner failure to mark a patented product may raise a risk that the owner would not be able to collect damages from infringers during the time the product was not marked. An appropriate way to make the marking is: *U.S. Patent No 5,555,555* or *U.S. Pat. No. 5,555,555*. After obtaining a filing date one can also use the marking: *Patent Pending* or *Pat. Pending*.

Trademark marking. The designation *TM* indicates that a particular word, symbol, or logo is considered by its user to function as a trademark. Similarly, the designation *SM* indicates a service mark.

When a mark becomes registered with the U.S. Patent Office, the designation should change from *TM* or *SM* to the registered-mark symbol,

®. Instead of this symbol, the mark owner can use the designation *Registered in the U.S. Patent and Trademark Office* or *Reg. U.S. Pat & TM off.* A marking *Registered trademark* is not appropriate because it could be misleading by not indicating *where* the mark is registered. It is important to indicate that the mark is registered with the U.S. Patent and Trademark Office, because the law provides that the owner of the mark is precluded from recovering profits and damages unless it can be established that the defendant had actual notice of the registration.

Copyright marking. The copyright symbol, ©, or the designations *Copr.* and *Copyright* are the proper legal notices for copyright protection. The copyright notice is usually included directly on the product or product label and typically takes this form:

© ABC Corporation 2007.
or
© MIHR and PIPRA. All Rights Reserved.

Failure to include the notice of copyright once was, but is no longer, fatal to the owner's rights. Before the United States acceded to the Berne Convention, the author lost his or her rights if failing to include notice of copyright. It is still good practice, however, to include the traditional copyright notice where applicable. Very often a copyrighted work carries the notice *All Rights Reserved,* in addition to the copyright symbol. This is because the *All Rights Reserved* designation is required under the Buenos Aires Copyright Convention, which is important in several South American countries.

9. INTEGRATION OF IP RIGHTS

A question that often comes up is whether a party can one have a patent and a trade secret simultaneously? At first sight it might seem that patents and trade secrets would exclude each other: patent application will become public, at the latest, when the patent is issued, and trade secret has to be kept in secrecy. Furthermore, the patent law requires the patent applicant to disclose the best mode of the invention in the patent application. It seems as if there would be no room for trade secret if one has filed a patent.

This, however, is not the case. One can have a patent and also keep trade secret. One very common situation is that after filing a patent, the invention has been developed further and after filing, the development is kept secret. The patent law requires the inventor to disclose the best mode known when the patent is filed, but there is no requirement to disclose any improvements made later. In addition, sometimes trade secrets can be "negative know-how." For example, information learned during research and development that shows some formula or process does not work can be kept as a trade secret. It has been estimated that 80 percent of all license and technology transfer agreements cover proprietary know-how or trade secrets.

Importantly, trademarks can prolong the protection of a patented good. The life of a patent is usually 20 years, while there is no limit to the life of a trademark as long as it is used. Many companies use trademarks to prolong the protection of a patented good. During the lifetime of the patent, the product is well protected, but if the company has also trademarked the product, the public will recognize the patented product also after expiration of the patent. When filing a trademark for a patented product, the applicant should, however, remember that one cannot get trademark protection for any functional features.

10. IP INFRINGEMENT

Patent infringement can be either direct or indirect. *Direct infringement* is either literal or it takes place under the Doctrine of Equivalents. Direct infringement occurs when a party makes, uses, offers to sell, or sells any patented invention, within the United States, or imports the patented invention in the United States during the patent term without the patentee's authorization during the term of patent.

An infringement is literal when every limitation recited in any claim in the patent appear in the alleged infringing product or process. If the alleged infringing product or process is missing on one of the claim limitations, there is no literal infringement.

In a case where the accused product or process is missing a component or step of the claims, there can still be direct infringement, if the accused product or process has a component or step that is insubstantially different from the missing one. Such a case is known as infringement under the Doctrine of Equivalents. In such a case, the alleged infringing device (or method) substantially performs the same function, in the same way, with the same result as the patented invention.

In addition to direct infringement, the patent law describes *indirect infringement*. Indirect infringement can be either induced infringement (knowingly aiding another in an act of infringement; aiding and abetting infringement) or a contributory infringement (knowingly selling an article that has no other use than as part of a patented invention).[24]

A copyright is infringed if the defendant copied from the plaintiff's copyrighted work. A plaintiff can prove copying through direct evidence of copying, or through circumstantial evidence that the defendant had access to the plaintiff's work and the work is substantially similar to the work of the plaintiff.

11. SO I HAVE INTELLECTUAL PROPERTY. NOW WHAT?

Evidently, intellectual property is really only useful if indeed the invention is used, applied, and incorporated into a productive process. This can be done either by those who own it or by authorized third parties, called licensees. Inventing something new is important. Protecting such an invention might also be important. But bringing an invention from "bench to bedside" is undisputedly the most important. For this, IP protection might not always be the most efficient way as other chapters in this *Handbook* suggest.[25] Equally important are the complex decisions regarding when, to whom, and how to license intellectual property in order to optimize both economic and humanitarian value.[26] Suffice it to say that the form of protection chosen for a given invention should be guided by the mission of the institution and the purpose of the work conducted, as well as by the specific subject of the invention. ■

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1 Article I, Section 8, Clause 8.

2 Some 30 years later, in 1474, the first patent law was enacted, called the "Inventor Bylaws," also in Venice.

3 See, also in this *Handbook*, chapter 4.4 by JP Kesan, and chapter 4.6 by J Dodds, A Krattiger and SP Kowalski.

4 See, also in this *Handbook*, chapter 10.2 by RL Cruz.

5 See, also in this *Handbook*, chapter 4.7 by M Blakeney.

6 See Dodds et al., *supra* note 3.

7 See, also in this *Handbook*, chapter 10.7 by AM Schneiderman; chapter 10.8 by R Yin and S Cunningham; and chapter 10.6 by AS Viksnins and AM McCrackin.

8 35 U.S.C. 101.

9 *Diamond v. Chakrabarty.* 447 U.S. 303 (1980).

10 *State Street Bank v. Signature Financial Group.* 47 U.S.P.Q. 2d 1596. This case was the most important case to establish the concept of business-method patents. As a result, during fiscal year 2001, the U.S. Patent Office was expecting to receive about 10,000 business-method patent applications. This was in a year the U.S. Patent Office issued only 433 business-method patents.

11 35 U.S.C. § 102(a).

12 *Rosaire v. Baroid Sales.* Div. 218 F 2d 72.

13 *Kimball Int'l Inc. v. Allen Organ.* Co. 212 U.S.P.Q. 584.

14 *Ritter v. Rohm & Haas Co.* 271 F. Supp. 313.

15 35 U.S.C. 102(b).

16 *Brenner v. Manson,* 383 U.S. 519 (1966).

17 See, also in this *Handbook,* chapter 4.3 by W Needle.

18 See, also in this *Handbook,* chapter 4.8 by J Dodds, S Somersalo, SP Kowalski and A Krattiger.

19 Musical works, graphic, pictorial or sculptural works, motion pictures, or other audiovisual works are not included in this exception.

20 Note that libraries may make copies of entire works if the work cannot be obtained after a reasonable search and at a reasonable price. This exemption is also the basis of the fair-use doctrine that libraries may copy and place materials on course reserve.

21 18 U.S.C. §§ 1831–1839.

22 For further information on trade secrets, especially the licensing of trade secrets, see, in this *Handbook*, chapter 11.4 by KF Jorda.

23 See, also in this *Handbook*, chapter 8.2 by JA Thomson.

24 See, also in this *Handbook*, chapter 17.26 by M Goldman.

25 For example, see, in the *Handbook*, chapter 10.1 by S Boettiger and C Chi-Ham.

26 See Sections 2 and 10 in this *Handbook*.

How to Read a Biotech Patent

CAROL NOTTENBURG, *Principal/Patent Lawyer, Cougar Patent Law, U.S.A.*

ABSTRACT

This chapter provides an annotated description of a sample U.S. patent. The U.S. patent is a convenient model because its format is well laid out and is similar to the required formats of patents granted in other major jurisdictions, including Europe.

INTRODUCTION

A patent is an exclusionary grant of intellectual property (IP) rights, typically awarded by a government through a patent office, and effective for a limited period of time. Article 28 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), binding for member countries of the World Trade Organization (WTO), states that a patent owner has the right "*to prevent third parties … from the acts of: making, using, offering for sale, selling or importing*" the protected product. If the protected invention is a process, the owner can prevent third parties not only from using the process, but also from using, offering for sale, selling, or importing "*at least the product obtained directly by that process.*" It is important to note that under TRIPS the patent owner does not have the right to practice her or his invention, only the right to prevent others from practicing it.

The TRIPS Agreement requires the time limit of the patent (*patent term*) to be at least 20 years. Most countries allow a 20-year term, starting from the date on which the application for the patent was first filed. Extensions of the patent term may be available in cases of regulatory or patent office delays that were imposed before a product is commercialized. Significantly, a patent grant is only legally binding in the country in which it was awarded.

2. PATENT PUBLICATION

Box 1 (at the end of this chapter) contains the front page of U.S. Patent No. 6,551,586,[1] and Box 2 contains extracts of U.S. Patent No. 5,723,765 (hereafter referred to as "the '765 patent").[2] A cursory review of the '765 patent reveals that it has three main sections:

- a front page, which presents bibliographic information (Box 2a, also at the end of this chapter),
- text, which describes the invention (Box 2b), and
- claims, starting in column 35 (Box 2c), which define the limit of the protected invention.[3]

2.1 *Cover Page*

The cover page primarily contains bibliographic information, historical facts about prior patent applications, and identifying elements, none of which has any legal import for interpreting the

Nottenburg C. 2007. How to Read a Biotech Patent. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

patent. The bracketed number adjacent to each data subsection is used by the patent office for internal identification purposes.

At the top of the cover page is the vital identification of Patent No. 6,551,586 (Box 1):

[12] **nature of the publication.** In this case, United States Patent and, below, the first inventor's name, Davidson et al.[4]

[10] **patent number.** In the United States, the patent number is sequentially assigned by the patent office. Prior to early 2000, the patent number was the only publication number.[5]

[45] **date the patent was issued.** This date (in this case, Apr. 22, 2003) is important for two reasons: (1) if the patent was not published as a patent application, then this is the date it became public knowledge and thus prior art for non-U.S. jurisdictions;[6] and (2) in the case of applications filed in the United States prior to the General Agreement on Tariffs and Trade (GATT) treaty (8 June 1995), as in this example, it is the date that initiates the patent term.[7]

The remainder of the front page presents the main bibliographic data:

[54] **title of the patent.** Should be representative of the content, is written by the inventors or their attorney and has no impact on the interpretation of the patent. In many cases, the title is wishful thinking.

[75] **inventor(s)' name(s) and place(s) of residence**. For patent purposes, the order of the names is not important; the applicant determines the order, not the patent office. In the United States, the inventors and their assignees (see below) can independently practice or license all of the patent rights without the permission of the other inventors. It is important to note that Australia and Europe, among other countries, have the opposite rule: an inventor cannot practice or license patent rights without the permission of the other inventors.

[73] **assignee(s) and his/her/their place(s) of business.**[8] An assignee is an owner of the patent because an inventor or inventors have signed over the rights to the invention. Typically, an inventor who is also an employee in a company or university is obligated to formally assign invention rights to the employer. In the United States, such assignment documents are recorded by the patent office and are publicly accessible, once the patent application is published. The identity of the owner of a patent is public knowledge, but the identity of those who have licensed a patent is not necessarily available to the public.

[21] **application number.** Assigned by the patent office

[22] **filing date of the subject patent application.** If there are no related U.S. application data (see below), this date is used to determine the beginning of the 20-year patent term.

[63] **related applications.** It is from these related applications that the patent claims priority. The United States is unusual in allowing applications to be refiled, either with or without new disclosure. A refiled application is called a *continuation*, or, if it contains new disclosure, a *continuation-in-part.* U.S. Patent 6,551,586 was filed on 27 November 1998 (field 21); however, an earlier application filed on Jan. 29, 1996 (serial number 08/593,006) contained at least some of the disclosure of the subject patent; in other words, this patent is a continuation-in-part of the earlier application.[9] As the patent term begins from the filing date of the earlier application, this patent expires on 29 January 2016.

[60] **provisional applications.** The filing date of a provisional application does not affect the patent term, but it is critical for considering prior art that might affect patentability.

[51] **International Patent Classification (IPC) code.** A combination of letters and numbers.[10] A patent application's IPC code is assigned by the national or regional patent office that publishes it. The IPC is an indispensable tool for patent-issuing authorities, potential inventors, attorneys, and others

concerned with the application or development of technology.

[52] **U. S. Classification Code.** Assigned by the U.S. Patent Office.

[58] **field of search.** Contains the U.S. classification codes that the examiner used to perform searches for prior art.

[56] **references.** Subdivided into U.S. patent documents, foreign patent documents, and other publications that the examiner considered when evaluating the patentability of the claimed invention.[11]

[no number] **examiners.** The names of the primary examiner at the patent office and the assistant examiner (if any).

[74] **attorney, agent, or firm.** Representatives of the inventor or assignee.

[57] **abstract.** A short description of the invention written by the applicant(s). The abstract enables the patent office and the public to quickly determine the content of the patent. Although the "abstract shall not be used for interpreting the scope of the claims," courts have taken it under consideration on one or two occasions.[12]

[no number] **number of claims and drawings**. In this patent, there are eight claims and 13 drawings.

2.2 *Text of the patent*

The text of the patent is also called the *disclosure* (In the United States, it may also be called the *specification*). According to the TRIPS Agreement, the invention must be disclosed "*in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art*" (Article 29.1). Each country specifies its own requirements; the U.S. Patent Office requires a written description of the invention, a so-called *enablement*, and a so-called *best mode*.[13]

The layout of the patent varies somewhat from country to country. The United States and Europe have a similar required layout, except that (b) and (c) below are unique to the United States:

a. title of the invention
b. cross-reference to related applications
c. statement regarding federally sponsored research, if applicable
d. background of the invention
e. summary of the invention
f. description of the drawings
g. detailed description of the invention
h. listing of relevant nucleotide and peptide sequences
i. claims defining the scope of the invention

2.3 *Background of the invention*

The *background* is typically drafted for the patent examiner and a jury audience, in case the patent is ever litigated. It compares selected art in the field with the current invention and explains why the current invention is necessary. As one can see from downloading the full patent (and the extract on Box 2b), a large part of the background of the '765 patent explains the technologies of several relevant references.

2.4 *Summary of the invention*

The *summary of the invention* is distinct from the abstract and summarizes the scope of the invention (the claims). It often discusses the advantages of the invention or explains how it solves problems existing in the art.

The summary of the '765 patent discusses the invention as embodied in the claims. It also describes the specific advantages of the invention (see, for example, col. 1, lines 61–64; col. 2, lines 1–6; and col. 2, lines 51–54; not shown here). The inventors believe that the advantages of their invention include: positive control of gene expression by an external stimulus without the need for continued application of the stimulus, the ability to grow plants under various conditions with expression of different phenotypes, and the ability to develop seed where a trait is desirable only in the first or in subsequent generations.

2.5 *Detailed description of the invention*

The *detailed description* of the invention is the most substantial section of the patent. It is made up of two sections: the first section (col. 2, line 58–col. 8, line 40) explains the invention and how to practice it; the second section (col. 8, line 43 to col. 20, line 33) provides specific examples of the invention. Many new readers mistakenly assume that examples are intended to delineate how

the invention must be practiced or used, but this is not the case. The examples are merely meant *"to illustrate, but in no way to limit, the claimed invention."* While examples are not required by the patentability statutes, in practice the enablement requirement is difficult, if not impossible, to satisfy for biotechnology inventions without examples.

Paragraphs 1 and 2 describe the *broadest concept* of the invention, explaining how DNA constructs are used to create transgenic plants and then describing how the invention works to control gene expression.

Paragraphs 3–11 (col. 4, lines–1-39) set forth some *definitions* of key terms. Definitions are extremely important in interpreting the scope of the claims. For example, this patent defines the term *"plant-active promoter"* as *"any promoter that is active in cells of a plant of interest."* The promoter can be derived not only from plants, but also from viruses, bacteria, fungi, and so on. This list only provides examples of sources from which promoters can be derived and the inventors do not intend it to be exhaustive.

The next three paragraphs (col. 4, line 10–col. 5, line 47) describe *preferred embodiments* of the invention. These are usually more limited versions of the broadest concept. They provide a "safety net" for the inventors in case the broader concept is not patentable.

In paragraph 12 (col. 4, line 10), the preferred embodiment is a "*transiently-active promoter*" (active only in late embryogenesis) and a "*gene linked to this promoter"* that is a "*lethal gene."* The next two paragraphs describe an embodiment in which a pair of transgenic plants is crossed to produce progeny that display an altered phenotype, and an embodiment in which the recombinase is linked to an inducible promoter. In addition, the paragraph provides a few examples of inducible promoters.

The next several paragraphs (col. 5, line 48–col. 7, line 48) define and give examples of some of the important elements of the **claim** (transiently active promoters, genes whose expression results in a detectable phenotype, lethal genes, blocking sequences, repressor and repressible promoters, and recombinase/excision sequences). These paragraphs support the scope of the inventors' claim. In col. 6, lines 47-60, the inventors define "lethal gene," then provide a single example (saporin-6, which acts by cleaving the large ribosomal RNA molecule and thus inhibiting protein synthesis). Overall, the disclosure in this patent is relatively thin.

The next four paragraphs (col. 7, line 49–col. 8, line 29) discuss the techniques that can be used to transform the target plant (col. 7, lines 62-65). This is a classic style of patent drafting and clearly indicates that the actual method used for transformation is not critical. Other methods of introducing the DNA constructs are described in paragraphs 21–23.

Finally, paragraph 24 (col. 8, lines 30–40) discusses suitable plant species. The inventors do not believe that the process they describe need be limited to particular species.

The next section presents the **examples**. Typically, the examples show how one or more specific embodiments of the invention could be put into practice. The examples may or may not be based on successful experiments performed by the inventors. If the experiments have been performed, the examples are called "*working"* examples; if not, the examples are called "*prophetic*" examples and are always written in the present or future tense. In the '765 patent, examples 1–6 (Box 2c) describe the cloning of three DNA sequences: (1) a lethal gene, saporin-6, under control of a late embryogenesis promoter, and separated by a blocking sequence, LOX; (2) a tet repressor gene under the control of a CaMV 35S promoter; and (3) a CRE (recombinase) gene under the control of a tetracycline-derepressible 35S promoter. Examples 7–10, which describe the introduction of the constructs into plants and activation of the system are written in a future tense because the relevant experiments were not performed as of the filing date of the application.

2.6 *Sequence listing*

The sequence listing includes all nucleic acid molecules mentioned in the patent application that are comprised of at least 10 nucleotides and all peptide sequences comprised of at least four amino acids.

2.7 *Claims*

The claims must "particularly point out and distinctly claim the subject matter which the applicant regards as his invention."[14] The claims define the boundaries of the patent owner's right against possible infringement.

Each claim must be written as a single sentence. A claim is presented in two parts, the **preamble** and the **body**, with a transition word or phrase between them.

- The **preamble** is an introductory statement that names the subject of the claim. For example, the preamble of claim 1. is: "*A method for making a genetically modified plant."*
- The **body** of the claim describes the elements or steps that compose the claimed subject. In claim one, the body of the claim consists of the steps of "*stably transforming …*" and "*regenerating …*"

The transition words or phrases between the preamble and the body of the claim indicate whether the claim encompasses *at least* the listed elements or steps or whether the claim encompasses *only* the listed elements or steps. The transition word *comprising* means "*including the following elements but not excluding others.*"[15] In claim one of the '765 patent, *comprising* is used in two places: (1) in the preamble ("*A method... comprising …*") and (2) in the body ("*a … DNA sequence comprising …*"). If someone were to use the patented method with small changes—additional steps or a DNA sequence with additional elements, for example—he or she would still be infringing on the claim.

In contrast, the transition "consisting of" limits the claim scope to the recited elements or steps. If the claim were "a DNA sequence consisting of ACGTGC," a person would be able to make the DNA sequence "ACGTGCTA" without infringing on the claim.

The meaning of the transition phrase *consisting essentially of* falls somewhere between the other two. It indicates that the patent does not regulate the use of variables that do not affect the basic and novel characteristics of the method or product. It is not often used in biotechnology patents.

Furthermore, there are two kinds of claims: independent and dependent. An *independent claim* (for example, claims 1, 10, 19, 28, 37, 46, and 55) includes all necessary limitations and does not depend on nor include limitations from any other claim. Curiously, although *dependent claim* is defined in the patent rules of the United States, *independent claim* is not. U.S. patent rules state that a dependent claim must "*refer[s] back to and further limit[s] another claim or claims.*"[16] Moreover, a dependent claim "*shall be construed to include all the limitations of the claim incorporated by reference.*"[17]

Claim 4. of the '765 patent is an instructive dependent claim. Since claim 4. depends upon claim 1., the transiently active promoter is limited to the LEA promoter. All other elements of claim 1. remain intact and are not limited any further.

Dependent claims serve several very important purposes. In the first place, they help with so-called claim differentiation: in patent law, no two claims can have the same scope. Therefore, the transiently active promoter in claim 1. must encompass more than the LEA promoter mentioned in claim 1.; otherwise, claims 1. and 4. would have the same scope. Dependent claims are also written to protect specific embodiments of an invention. Should the main claim fail in a court case, a dependent claim may still stand. In addition, it is easier for a jury to have the alleged infringing activity clearly spelled out.

3. CONCLUSION

Patent documents contain substantial information that has value to researchers, even if infringement isn't an issue. While many patent documents are readily available on the Internet for free—generally from patent offices—they may not always be capable of being understood or appreciated. One reason for inaccessibility is that patent applications are written in a special style that does not follow the conventions of scientific or technical literature. To understand a patent document, a roadmap helps until the route is familiar.

This chapter provides a roadmap for reading a patent document. The various sections of a

document are explained in view of their purposes. The purposes especially delineate the amount and type of reliance that can be made of each of the sections. Each section contains its own set of useful information. The importance of the claims is paramount for knowing the boundaries of the patent right, however, interpreting claims requires more of a roadmap than this chapter provides. Even without a full appreciation of claim boundaries, much information may still be obtained from patent documents. ■

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1 patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=6,551,586.PN.&OS=PN/6,551,586&RS=PN/6,551,586.

2 patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,723,765.PN.&OS=PN/5,723,765&RS=PN/5,723,765.

3 More typically, patents contain four sections with drawings comprising the last section.

4 In the United States, a patent application must be filed for in the name of the inventors. In most of the rest of the world, patent applications can be filed for in the name of the inventors or in the name of the assignee(s).

5 Patent applications are generally published 18 months after the earliest priority application date. Depending on the country, the publication number may or may not differ from the patent number. If the numbers are the same, a suffix is usually used to denote the status of the application. For example, in Europe, the publication and patent numbers are the same, but the suffix *A* is used to indicate an application and *B* is used to indicate an issued patent.

6 In the United States, inventions that are disclosed but not claimed are prior art against other U.S. applications and patents, as of their filing date. 35 U.S.C. § 102(e).

7 Before the GATT treaty implementation, the patent term in the United States was 17 years from the date of issuance. Under GATT, the patent term is 20 years from the earliest claimed priority date.

8 An assignee in the United States is called an applicant in the rest of the world.

9 Priority applications determine both patent term and which prior art can be applied in a patent examination. A particular claim has a priority date as of the earliest application that contains the patentable subject matter. Art available after the priority date cannot be cited against the claim. In practice, U.S. examiners rarely determine the priority date of a claim, whereas European examiners frequently review priority applications to determine priority dates of claims.

10 The IPC system is a hierarchical classification system administered by the World Intellectual Property Organization. For more information on international classifications and IPC, see WIPO's Web site at www.wipo.org.

11 In the United States, each individual associated with the filing and prosecution of a patent application (for example, inventor, patent attorney, assignee) has a duty to disclose all material information to the patent office.

12 37 C.F.R. 1.72(b).

13 The written description shows that the inventor has the invention in mind. The enablement describes the invention clearly enough that one skilled in the art can understand it, make it, and use it without undue experimentation. In the best mode, an inventor discloses the most effective method of practicing or using the claimed invention. The patent office does not ask applicants whether or not they have disclosed the best mode, a question which usually only arises during litigation.

14 35 U.S.C. § 112.

15 Equivalent words are *having* and *including*, but most practitioners use *comprising* because it has become a standard term of art.

16 37 C.F.R. 1.75(c).

17 See *supra* note 16.

Box 1: Sample Front Page of Issued U.S. Patent

US006551586B1

(12) **United States Patent**
Davidson et al.

(10) **Patent No.: US 6,551,586 B1**
(45) **Date of Patent: Apr. 22, 2003**

(54) **MALARIA VACCINE BASED UPON THE ADDITION OF A MSA1 PEPTIDE**

(75) Inventors: **Eugene A. Davidson**, Washington, DC (US); **Shutong Yang**, Washington, DC (US)

(73) Assignee: **Georgetown University**, Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/117,415**

(22) Filed: **Nov. 27, 1998**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/593,006, filed on Jan. 29, 1996, now abandoned.
(60) Provisional application No. PCT/US97/01395, filed on Jan. 29, 1996.

(51) **Int. Cl.**[7] **A01N 63/00**
(52) **U.S. Cl.** **424/93.2**; 514/44; 435/320.1; 435/69.1; 435/325; 435/455
(58) **Field of Search** 514/44; 536/23.1, 536/23.4, 24.1; 435/69.1, 320.1, 325, 455; 424/93.1, 93.2, 184.1

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Primary Examiner—Dave Trong Nguyen
(74) *Attorney, Agent, or Firm*—Henry D. Coleman; Coleman Sudol Sapone P.C.

(57) **ABSTRACT**

The present invention relates to an expression vector which expresses a malaria MSA1 peptide in combination with a signal peptide and anchor peptide in a host animal. The MSA1 peptide is combined with a signal peptide and anchor peptide for expression. Chimeric peptides being expressed with both signal peptides and anchor peptides were the most effective in eliciting an immunogenic response from a vaccinated host.

8 Claims, 13 Drawing Sheets

BOX 2A: FRONT PAGE OF PATENT NO. 5,723,765

US005723765A

United States Patent [19]

Oliver et al.

[11] **Patent Number: 5,723,765**

[45] **Date of Patent: Mar. 3, 1998**

[54] **CONTROL OF PLANT GENE EXPRESSION**

[75] Inventors: **Melvin John Oliver**, Lubbock; **Jerry Edwin Quisenberry**, Idalou; **Norma Lee Glover Trolinder**, Quanah, all of Tex.; **Don Lee Keim**, Leland, Miss.

[73] Assignees: **Delta and Pine Land Co.**, Scott, Miss.; **The United States of America as represented by the Secretary of Agriculture**, Washington, D.C.

[21] Appl. No.: **477,559**

[22] Filed: **Jun. 7, 1995**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 283,604, Aug. 1, 1994, abandoned.

[51] **Int. Cl.**[6] **C12N 15/29**; C12N 15/82; A01H 4/00; A01H 5/00

[52] **U.S. Cl.** **800/205**; 800/250; 536/24.1; 536/23.6; 536/24.5; 435/320.1; 435/240.4; 435/172.3

[58] **Field of Search** 536/24.1, 23.6, 536/24.5; 435/320.1, 240.4, 172.3; 800/205, 250

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[57] **ABSTRACT**

A method for making a genetically modified plant comprising regenerating a whole plant from a plant cell that has been transfected with DNA sequences comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter, the gene and promoter being separated by a blocking sequence flanked on either side by specific excision sequences, a second gene that encodes a recombinase specific for the specific excision sequences linked to a repressible promoter, and a third gene that encodes the repressor specific for the repressible promoter. Also a method for making a genetically modified hybrid plant by hybridizing a first plant regenerated from a plant cell that has been transfected with DNA sequences comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter, the gene and promoter being separated by a blocking sequence flanked on either side by specific excision sequences to a second plant regenerated from a second plant cell that has been transfected with DNA sequences comprising a second gene that encodes a recombinase specific for the specific excision sequences linked to a promoter that is active during seed germination, and growing a hybrid plant from the hybrid seed. Plant cells, plant tissues, plant seed and whole plants containing the above DNA sequences are also claimed.

55 Claims, No Drawings

Box 2b: Extract of Patent No. 5,723,765 Describing the Invention

CONTROL OF PLANT GENE EXPRESSION

This is a continuation-in-part application of application Ser. No. 08/283,604, filed on Aug. 1, 1994, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to certain transgenic plants and involves a method of creating transgenic plants with controllable genes. More particularly, the invention relates to transgenic plants that have been modified such that expression of a desired introduced gene can be limited to a particular stage of plant development, a particular plant tissue, particular environmental conditions, or a particular time or location, or a combination of these situations.

Various gene expression control elements that are operable in one or more species of organisms are known. For example, PCT Application WO 90/08826 (Bridges, et al.) discloses an inducible gene promoter that is responsive to an exogenous chemical inducer, called a "gene switch." This promoter can be linked to a gene and introduced into a plant. The gene can be selectively expressed by application of the chemical inducer to activate the promoter directly.

PCT application WO 94/03619 (Bright, et al. discloses a gene cascade consisting of a gene switch linked to a repressor gene and a repressible operator linked to a disrupter protein capable of disrupting plant development. Growth of the plant can be controlled by the application or withholding of a chemical inducer. While the inducer is present, the repressor is expressed, the promoter attached to the disrupter gene is repressed, the disrupter protein is not expressed, thereby allowing the plant to grow normally. If the chemical inducer is withheld, the gene switch is turned off, the repressible promoter is not repressed, so the disrupter protein is expressed and plant development is disrupted. This system is said to be useful for controlling the escape of plants into the wild by making their continued growth and development dependent on the continued application of a chemical inducer, and to mitigate the problem of preharvest sprouting of grains by withholding the chemical inducer at the last stages of seed development.

Gatz and Quail (1988) and Gatz, et al. (1992), (Hoppe-Seyler), 372:659-660 (1991), disclose a plant-active repressor-operator system that is controlled by the application of tetracycline. The system consists of the Tn10 tet repressor gene, and a cauliflower mosaic virus (CaMV) 35S promoter, modified to contain two tet operons and linked to the chloramphenicol acetyltransferase (cat) gene (Gatz and Quail, 1988), or modified to contain three tet operons and linked to the beta-glucuronidase (gus) gene (Gatz, et al., 1992). So long as the Tn10 tet repressor gene is active, the modified promoter is repressed by the interaction of the repressor with the tet operons, and the cat or gus gene is not expressed. The presence of tetracycline inhibits repressor binding, enabling expression of the cat or gus gene.

SUMMARY OF THE INVENTION

The present invention involves, in one embodiment, the creation of a transgenic plant that contains a gene whose expression can be controlled by application of an external stimulus. This system achieves a positive control of gene expression by an external stimulus, without the need for continued application of the external stimulus to maintain gene expression. The present invention also involves, in a second embodiment, the creation of transgenic parental plants that are hybridized to produce a progeny plant expressing a gene not expressed in either parent. By controlling the expression of genes that affect the plant phenotype, it is possible to grow plants under one set of conditions or in one environment where one phenotype is advantageous, then either move the plant or plant its seed under another set of conditions or in another environment where a different phenotype is advantageous. This technique has particular utility in agricultural and horticultural applications.

In accordance with one embodiment of the invention, a series of sequences is introduced into a plant that includes a transiently-active promoter linked to a structural gene, the promoter and structural gene being separated by a blocking sequence that is in turn bounded on either side by specific excision sequences, a repressible promoter operably linked to a gene encoding a site-specific recombinase capable of recognizing the specific excision sequences, and a gene encoding a repressor specific for the repressible promoter whose function is sensitive to an external stimulus. Without application of the external stimulus, the structural gene is not expressed. Upon application of the stimulus, repressor function is inhibited, the recombinase is expressed and effects the removal of the blocking sequence at the specific excision sequences, thereby directly linking the structural gene and the transiently-active promoter.

In a modification of this embodiment, the sequences encoding the recombinase can be introduced separately into the plant via a viral vector.

In an alternative embodiment, no repressor gene or repressible promotor is used. Instead, the recombinase gene is linked to a germination-specific promotor and introduced into a separate plant from the other sequences. The plant containing the transiently-active promotor, blocking sequence, and structural gene is then hybridized with the plant containing the recombinase gene, producing progeny that contain all of the sequences. When the second transiently-active promotor becomes active, the recombinase removes the blocking sequence in the progeny, allowing expression of the structural gene in the progeny, whereas it was not expressed in either parent.

In still another embodiment, the recombinase gene is simply linked to an inducible promoter. Exposure of the plant to the induce specific for the inducible promoter leads to the expression of the recombinase gene and the excision of the blocking sequence.

In all of these embodiments, the structural gene is expressed when the transiently-active promoter becomes active in the normal course of growth and development, and will continue to be expressed so long as the transiently-active promoter is active, without the necessity of continuous external stimulation. This system is particularly useful for developing seed, where a particular trait is only desired during the first generation of plants grown from that seed, or a trait is desired only in subsequent generations.

DETAILED DESCRIPTION OF THE INVENTION

This invention relates to a method of creating transgenic plants wherein the expression of certain plant traits is ultimately under external control. In one embodiment the control is achieved through application of an external stimulus; in another embodiment it is achieved through hybridization, in still another embodiment it is achieved by direct introduction of a recombinase or recombinase gene into a plant. The transgenic plants of the present invention are prepared by introducing into their genome a series of functionally interrelated DNA sequences, containing the

Box 2c: Extract of Patent No. 5,723,765 Containing the Claims

-continued

(i i i) HYPOTHETICAL: NO

(i v) ANTI-SENSE: NO

(x i) SEQUENCE DESCRIPTION: SEQ ID NO:26:

GATCCATAAC TTCGTTATAA TGTATGCTAT ACGAAGTTAT 40

We claim:

1. A method for making a genetically modified plant comprising

stably transforming a plant cell with a first DNA sequence comprising a first gene whose expression results in an altered plant phenotype, and a transiently-active promotor, the first gene and the transiently-active promotor being operably linked to one another, but separated by a blocking sequence that is flanked by specific excision sequences, such that the presence of the blocking sequence prevents the expression of the first gene, a second DNA sequence comprising a second gene that encodes a recombinase specific for the specific excision sequences flanking the blocking sequence of the first DNA sequence, and a repressible promotor operably linked in functional relation to the second gene, and a third DNA sequence comprising a third gene that encodes a repressor specific for the repressible promotor of the second DNA sequence, the third sequence being linked to a plant-active promoter;

regenerating a whole plant from the plant cell.

2. A method according to claim **1**, wherein the blocking sequence comprises the third DNA sequence.

3. A method according to claim **1** or claim **2**, wherein

the transiently-active promotor is selected from the group comprising a promotor active in late embryogenesis, in seed development, in flower development, in leaf development, in root development, in vascular tissue development, in pollen development, after wounding, during heat or cold stress, during water stress, or during or after exposure to heavy metals,

the first gene is selected from the group comprising a lethal gene, an insecticidal gene, a fungistatic gene, a fungicidal gene, a bacteriocidal gene, a drought resistance gene, a protein product gene or a gene that alters secondary metabolism,

the specific signal sequences are selected from the group comprising LOX sequences and se quences recognizable by either flippase, resolvase, FLP, SSV1-encoded integrase, or transposase,

the second gene encodes a specific recombinase selected from the group comprising CRE, flippase, resolvase, FLP, SSV1-encoded integrase, and transposase,

the third gene encodes a repressor selected from the group comprising the Tn10 tet repressor, and the lac operator-repressor system,

the repressible promotor is selected from the group comprising a 35S promotor modified to contain one or more tet operons, a modified ubiquitin promotor, a modified MAS promotor and a modified NOS promotor.

4. A method according to claim **3**, wherein the transiently active promotor is the LEA promotor.

5. A method according to claim **3**, wherein the first gene encodes ribosomal inhibitor protein (RIP).

6. A method according to claim **3**, wherein the specific excision signal sequences are LOX sequences and the second gene encodes CRE.

7. A method according the claim **3**, wherein the third gene encodes the Tn10 tet repressor.

8. A method according to claim **3**, wherein the repressible promotor is a 35S promotor modified to contain three tet operons.

9. A method according to claim **2** wherein the plant is cotton, the transiently active promotor is a LEA promotor, the specific excision signal sequences are LOX sequences, the first gene encodes ribosomal inhibitor protein (RIP), the repressible promotor is a 35S promotor modified to contain three tet operons, the second gene encodes CRE, and the third DNA sequence is the Tn10 tet repressor gene.

10. A method for producing seed that is incapable of germination, comprising

stably transforming a plant cell with a first DNA sequence comprising a lethal gene and a promotor that is active in late embryogenesis, the lethal gene and the late embryogenesis promotor being in functional relation to one another, but separated by a blocking sequence that is flanked by specific excision sequences, such that the presence of the blocking sequence prevents the expression of the lethal gene, a second DNA sequence comprising a gene that encodes a recombinase specific for the specific excision sequences flanking the blocking sequence of the first DNA sequence, and a repressible promotor linked in functional relation to the specific recombinase gene, and a third DNA sequence comprising a gene that encodes a repressor specific for the repressible promotor of the second DNA sequence, third sequence being linked to a plant-active promoter;

regenerating a whole plant from the plant cell;

allowing the regenerated whole plant to produce a first generation seed;

exposing the first generation seed to a stimulus that blocks the function of the repressor, such that the repressor element no longer inhibits expression of the specific recombinase gene, thereby allowing expression of the specific recombinase and excision of the blocking sequence of the first DNA sequence at the specific excision sequences, resulting in the direct functional linkage of the late embryogenesis promotor with the lethal gene;

germinating the first generation seed to produce a first generation plant expressing the late embryogenesis promotor/lethal gene sequence;

allowing the plant to produce second generation seed, whereby in the course of embryogenesis, the late embryogenesis promotor becomes active, permitting expression of the lethal gene in the second generation seed, thereby rendering the second generation seed incapable of germination.

11. A method according to claim **10**, wherein the blocking sequence comprises the third DNA sequence.

12. A method according to claim **10** or claim **11**, wherein the seed is cotton seed;

the late embryogenesis promotor is selected from the group comprising a LEA promotor and a promoter other than LEA that is active in late embryogenesis,

Trademark Primer

WILLIAM NEEDLE, *President and Founder, Needle and Rosenberg PC, U.S.A.*

ABSTRACT

Trademarks, in the broadest sense, encompass a range of indicators for goods and/or services, including service marks, collective marks, certification marks, trade names and trade dress. A trademark, which may be a name, symbol, feature, or design, functions as an indicator of source and identifies and distinguishes a good or service, enabling customers to ascertain the quality of the good (or service) based on the trademark. Unlike other forms of intellectual property rights (for example, copyrights and patents), the rights extended by trademarks are not generated from the creative activity of an author or inventor, but rather via their use in commerce, and it is the customer's association of the trademark with a specific product (or service) that is the key factor in establishing rights. The relative effectiveness of a trademark depends on its degree of distinctiveness. By way of classifying trademarks, a hierarchy based on strength of protection, from fanciful to merely descriptive, has been established. Whereas fanciful trademarks are inherently distinctive because they are terms invented solely for a specific purpose (for example, *Kotex*), descriptive marks (for example, *Chap-Stick*) must acquire secondary meaning to become protectable. In the United States, trademarks are protected by both state and federal laws. Although federal trademark registration is not necessary to assert trademark rights, it affords many advantages and benefits to the owner, and hence is by far the preferred means of protection. It is important to remember, however, that trademarks must always be maintained, protected, and correctly used. Their strength, and therefore value, is directly linked to public perception.

1. INTRODUCTION

This trademark primer is intended both to provide a general understanding for technology transfer practitioners and to introduce a protection tool for those who might, in the future, need to license trademarks for their own inventions or those of others. As trademarks are a distinct, legal form of intellectual property (IP), a working knowledge of trademarks will be useful for individuals who are active in the field of technology licensing.

While trademarks, patents, and copyrights all are referred to as IP, they do, of course, serve different functions: patents protect inventions, trademarks protect unique product or service identifiers, and copyrights protect original artistic or literary works. While the meaning of invention is generally known, the distinction between a trademark and a copyright is often confused. As an example, the contents (for example, format, photos, text) of a periodical are protected under copyright law, but the title of a publication (such as *Newsweek*) is protected under trademark law. More information about these topics can be found on the World Wide Web.[1]

Unlike patents and copyrights, trademarks (often called brands or marks) are regulated under federal and state laws. A mark may be registrable

Needle W. 2007. Trademark Primer. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Third Edition, Part IV: Chapter 2.4).

in the United States under the federal trademark legislation known as the Lanham Act (Title 15 of the U.S. Code of Federal Regulations). Federal registration provides protection throughout the United States. A mark may also be registrable in individual states; registration in a particular state is enforceable only inside that state. Registration is not required to establish rights in a mark; actual use in commerce is all that is necessary. A federal application can be filed in the U.S. Patent and Trademark Office (PTO) based only upon a good-faith intent that the mark will be used in interstate commerce, but a registration will not issue until actual use of the mark occurs in interstate commerce. Unregistered marks are protectable under common law but only in the market area in which they are actually used.

2. TERMINOLOGY

2.1 *Trademark*

A *trademark*, or *brand name*, is any word, name, symbol, device, or any combination of these elements that is adopted for use in commerce by a manufacturer or businessperson to (1) identify the company or person's goods or products, (2) distinguish those goods from goods manufactured or sold by another person or company, and (3) indicate the source of the goods carrying the trademark.

Examples of what may function as a trademark include the following:

- a word or group of words, such as a slogan (Tide®, Cabbage Patch Kids®, Don't Leave Home Without It®)
- a logo, symbol, pictorial representation, or design (Nike's Swoosh symbol, McDonald's golden arches, the five interlocking Olympic rings)
- a combination of a word or words plus a symbol, pictorial representation, or design (the word *Nestea* plus its design, the phrase *Cabbage Patch Kids* plus its design [see Figure 1])
- numerals, letters, or combinations thereof (Levi® 501® Original Jeans, IBM®, V8® [juice made by Campbell Soup Co.])
- the shape of a container or other packaging (Coke's bottle shape, the conical shape of the top of a Cross pen, the shape of Toblerone chocolate packaging)
- color (The Home Depot's orange, Owens Corning pink insulation)
- sound (MGM's lion roar, NBC's chimes)
- scent ("the high impact, fresh flower fragrance reminiscent of Plumeria blossoms" owned by Celia Clarke, doing business as Clarke's OSEWEZ)

2.2 *Service mark*

A *service mark* is similar to a trademark; however, the service mark is used in the sale or advertising of services, rather than goods. A service mark is used to identify the services of one person and to distinguish them from the services of others, (McDonald's® and Office Depot®). Service marks are afforded the same legal protection as trademarks and are registrable in the same manner and have the same effect.

2.3 *Trade name*

Normally, the name of a business entity is not registrable unless it is also used as a trademark or service mark, that is, in conjunction with the

Figure 1: Sample Trademark

goods and/or services of the business entity. A *trade name* is usually identified by its ending in the term Company/Co., Corporation/Corp., Incorporated/Inc., or Limited/Ltd. (for example, McDonald's Corp. [trade name] versus McDonald's® restaurants [service mark]). Trade name infringement is actionable under federal and state laws.

2.4 *Trade dress*

Trademark protection has been expanded by courts beyond words, slogans, symbols, and other devices to protect distinguishing, albeit unregistered, features of products. While *trade dress* originally referred exclusively to a product's packaging or dressing that was not protectable by registration, the concept has grown to include product designs, for example, the decor of a chain of Mexican restaurants ("a festive eating atmosphere having interior dining and patio areas decorated with artifacts, bright colors, paintings, and murals") and even sales techniques, such as Original Appalachian Artworks' simulation of adoption procedures and provision of birth certificates for the Cabbage Patch Kids® dolls.

To recover damages for trade dress infringement, a plaintiff must prove by a preponderance of evidence that (1) the trade dress has obtained secondary meaning in the marketplace (that is, that the primary significance of the trade dress, in the minds of the public, is to identify the product's source rather than the product itself); (2) the trade dress of the two competing products is confusingly similar; and (3) the appropriated features of the trade dress are primarily nonfunctional.

2.5 *Domain names*

A *domain name* is a name that identifies one or more Internet addresses and is part of the URL for a Web site (examples are *.com*, *.org*, and *.net*). Domain names do not act as marks in identifying the source of goods or services, however, where a domain name is used as something other than merely an address, it becomes a trademark or a service mark. For example, in *Amazon.com*, the domain name (*.com*) is functioning as a service mark because *.com* is part of the identity of the service of the Amazon.com Web site. For example, when the term *Google*® is used on the home page of Google or is used in advertising or promoting the Web site, it is being used to identify the source of specific services and, therefore, is acting as a service mark. Similarly, the domain name *Amazon.com* also functions as a service mark because it, along with the service mark *Amazon*®, is used in advertising to designate the source of the services.[2]

2.6 *Certification marks*

Certification marks certify that products or services manufactured or provided by others have certain qualities. Vidalia® of Vidalia onions provide an example. According to Georgia's Department of Agriculture, "*The certification mark is intended to be used by persons authorized by the certifier and will certify that the goods in connection with which it is used are yellow Granex type onions and are grown by authorized growers within the Vidalia onion production area in Georgia as defined in the Georgia Vidalia Onion Act of 1986.*"[3]

2.7 *Collective marks*

Collective marks are used by members of a group or organization to identify the goods it produces or services it provides. An example of a collective mark is *ILGU*® (International Ladies Garment Union).

3. SELECTION AND ADOPTION OF A MARK

3.1 *Types of marks*

A hierarchy of marks exists within this protection system, with the more distinctive marks being afforded a wider scope of protection than the less distinctive ones. The order of marks from most distinctive to least distinctive is: fanciful mark, arbitrary mark, suggestive mark, and descriptive mark (see Figure 1). It is best to select a mark that is fanciful, arbitrary, or suggestive. As one might expect, the more distinctive the mark, the better the chance of protecting and registering it.

A *fanciful mark* is one that is created solely for the purpose of functioning as a mark and has no other meaning. Examples are *Xerox*®, *Pentium*®, *Kodak*®, *Exxon*®, *Clorox*®, *Kotex*®, and *Polaroid*®.

An *arbitrary mark* is one that comprises a common word or symbol that is arbitrarily applied to the goods or services in question such that the word or symbol does not describe

or suggest the product. Nor would the words normally be associated with the product. Examples are Command® (hair-care products), Shell® (gasoline), Apple® (computers), Ice Cream® (chewing gum), Guess?® (jeans), and Die-Hard® (batteries).

A *suggestive mark* is one that suggests, but does not describe qualities or functions of a particular product or service. If the qualities are not instantly apparent from the mark, but with an exercise of imagination could convey the characteristics or qualities of the product or service, the mark is "suggestive." Examples are Crosstalk® (software), Stronghold® (nails), 7-Eleven® (retail store services), Coppertone® (tanning products), Rapid Shave® (shaving cream), Gleem® (toothpaste), Roach Motel® (roach bait), Woolite® (wool cleaner), and Honey Maid® (graham crackers).

Arbitrary, fanciful, and suggestive marks are inherently distinctive and are given a high degree of protection.

A *merely descriptive mark* generally affords the narrowest scope of protection. The descriptive mark immediately identifies or brings to mind the characteristics, qualities, ingredients, functions, composition, purpose, attribute, use, or other features of a product or service. A merely descriptive mark is not protectable because the word or words comprising the merely descriptive mark should be available for all competitors to use. It is sometimes difficult to distinguish a suggestive mark from a merely descriptive mark. A merely descriptive term is protectable only when it holds a secondary meaning or distinctiveness, that is, the consumer accepts and recognizes it as denoting only one source (product or service) and the term is synonymous with that product or service (and, thus, functions as a mark), rather than merely being a descriptor of the goods or services. Courts will often look to the following when deciding whether a term is merely descriptive:

- the amount and manner of use of the term in advertising
- the volume of sales of products/services bearing the mark
- the length and manner of the term's use
- the results of consumer surveys

Marks that have been found to be merely descriptive include: Chap-Stick® (chapped lip treatment), Shear Pleasure® (beauty salon), Hair Color So Natural Only Her Hairdresser Knows for Sure® (hair coloring), Beef and Brew® (restaurants), Hour after Hour® (deodorant), and Raisin-Bran® (cereal). To illustrate, the term *brilliant* would be merely descriptive for diamonds, suggestive for furniture polish, and arbitrary for applesauce.

Finally, *generic terms* are the common name of a class of things and are, by definition, incapable of indicating source and can never function as a trademark or service mark (examples of generic terms are *blended whiskey, computer software, mouse, disk,* or *keyboard*).

In some cases, generic terms are those that, at one time, functioned as trademarks but that, as a result of widespread use, lost their ability to function as a source identifier and came to mean, to the general public, the product itself (specifically) rather than merely one

Figure 2: Types of Marks

manufacturer's brand or version of the product. Such loss of distinctiveness in a trademark, so-called genericide, happens when a mark, via misuse, becomes a generic term (for example, Frigidaire® becomes equivalent with refrigerator) and thus, ceases to indicate the source and falls into the public domain where it is thereafter owned by no one.

Such former trademarks are numerous, including: *aspirin, cellophane, cola, cornflakes, cube steak, dry ice, escalator, high octane, kerosene, lanolin, linoleum, mimeograph, Murphy bed, nylon, raisin bran, refrigerator, shredded wheat, thermos, trampoline, yo-yo, monopoly,* and *zipper*. As an example, the term *escalator* was first used as a trademark (Escalator® [moving stairs]) but, over time, the public stopped using the term as a trademark (an adjective, or modifier, such as in *Escalator® stairs*) and started to designate any moving stairs, regardless of the manufacturer, as *escalator* and thus, the trademark term became the name of the product.

3.2 *Preadoption investigation*

Once a mark is selected, but prior to its use, a thorough search should be undertaken to determine whether the mark is available for both use and federal registration. Sources of information on existing registered marks are discussed below.

3.2.1 *Records of the U.S. Patent and Trademark Office*

A prospective trademark user is charged with constructive notice of any identical or confusingly similar mark that is federally registered. A search of the PTO records can be conducted online on the PTO database,[4] by hand in the office records, or by means of the Trademarkscan® database[5] (File 226)[6] of Dialog services. Also, File 116 (brand names) of Trademarkscan can be searched.

Private search companies undertake record searches for a fee. These companies include:

- Thompson & Thompson[7]
- Dialog[8]
- Questel/Orbit[9]
- Micropatent[10]
- Corsearch[11]

The companies will search the federal register and pending application records as well as phone directories, yellow pages, industrial directories, and state trademark registers in an effort to determine if a particular mark or a similar mark is already in use.

Also, if use of the mark is contemplated in any foreign countries, the trademark and service mark records of those countries should be searched. Searching of trademark records of countries such as Canada (File 127), France (File 657), Germany (File 672), and the United Kingdom (File 126) can be performed on the Trademarkscan database.

3.2.2 *State trademark records*

The Trademarkscan database (for state records, File 246) can be utilized to search the trademark and service mark records of all states.

Related information can be accessed using Internet searches. Network Solutions' Web site[12] provides a convenient search tool to determine if a proposed mark is being used in a domain name and who owns it (the "WOSIT" button). One can also use a browser to search for directly conflicting Web sites or for business names across the country. The following sites are useful for such searches:

- Big Book[13]
- Switchboard[14]
- GTE Superpages[15]
- World Pages[16]
- ZIP2[17]

3.3 *Misconceptions*

Below is a list of some common misconceptions about trademark protections:

- The fact that an individual has incorporated, qualified to do business under a name, or registered the name in the assumed name records of a particular state does not automatically bestow to that individual the right to use the name as a mark.
- A person does not have an absolute right to use his or her own name as a trademark or service mark (for example, Old McDonald would likely be barred from using his surname as a trademark and

service mark for his own national chain of fast food hamburger franchises).
- Registration in one state (or jurisdiction) of a mark for use as a trademark or service mark does not necessarily allow use of the mark elsewhere.
- Even though a mark appears in an abandoned application or an expired registration, the owner of that mark may still be using it, and, thus, have protectable common law rights against a subsequent user.

4. REGISTRATION OF A MARK IN THE PTO

4.1 *Process*

It is not necessary to obtain either a state or federal registration to be able to protect a mark, as rights in a mark are based upon use, not registration, of the mark. Generally, the owner of a mark is considered to be the first person or company to use a mark, or to file an intent-to-use application in the PTO, for a particular product or service or for related products and services. However, registration of a mark in the PTO is highly recommended, as registration confers significant nationwide benefit upon the owner, even if the actual use in commerce of the mark is limited to a small geographic area—the term *commerce* is broadly construed to mean any commerce that may lawfully be regulated by the U.S. Congress.

The Trademark Act (15 U.S.C. § 1127) defines use in commerce as follows:

The term use in commerce *means the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark. For purposes of this Act, a mark shall be deemed to be in use in commerce:*

(1) on goods when (A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such placement impracticable, then on documents associated with the goods or their sale, and (B) the goods are sold or transported in commerce, and

(2) on services when it is used or displayed in the sale or advertising of services and the services are rendered in commerce, or the services are rendered in more than one State or in the United States and a foreign country and the person rendering the services is engaged in commerce in connection with the services.

4.2 *Advantages of registration*

Registration of a mark on the Principal Register[18] of the U.S. Patent Office allows an owner to:

- prevent registration of the identical or confusingly similar marks
- secure injunctive relief and damages against infringers nationally in federal court (whereas unregistered marks may be protectable only in the specific market where they are used)
- assert the registration in federal court as prima facie evidence of the validity of the registration, of the ownership of the mark, and of the right to exclusively use the mark in commerce
- have the mark treated as incontestable after five years' use
- eliminate the defense of innocent adoption by anyone using the mark after the date of registration, thereby affording nationwide protection to registered marks, regardless of the areas in which the mark is actually used
- prevent the importation of goods bearing infringing or counterfeit marks by recording the mark with U.S. Customs

4.3 *Actual use versus intent-to-use applications*

A dual-application system exists in the PTO that permits the filing of trademark/service mark applications based upon an intent to use the mark, as well as applications based on actual use of the mark in commerce. However, while an application may be filed based on a bona fide intent to use the mark, the applicant will still have to make actual use of the mark in commerce before the mark can be registered.

The intent-to-use procedure encourages the early filing of an application because, while the application is pending, the applicant will have the benefit of constructive-use priority. Thus, subject to the mark actually being registered, the applicant will have prior rights in the mark against all others nationwide (except for those who used the mark before the application was filed, or who filed an earlier application, or who had priority based on a foreign application).

4.4 *Term of a federal registration*

Federal trademark/service mark registrations are valid for a period of ten years and are renewable for ten-year periods as long as the mark remains in actual use.

Additionally, between the fifth and sixth year from the date of a federal registration, the registrant must file a declaration or affidavit that the mark is still in use as of that date (as of the sixth year after registration). An affidavit of use must also be filed in the year prior to the end of each registration term. Failure to file such a statement will cause the registration to be canceled by the PTO.

4.5 *State registrations*

A state registration does not confer the same rights and benefits as a federally registered mark. For example, a state registration is enforceable only within that state while federal registration provides nationwide protection and constructive notice.[19] Usually there is no need to seek a state registration if the mark is registered in the PTO. A state registration should be obtained only if the mark is not registrable in the PTO.

5. INFRINGEMENT OF A MARK

Protection of a mark, whether registered or not, involves actions against other marks that are likely to cause confusion. For a trademark owner to prevail against an accused party, neither the respective marks nor the respective goods or services need to be identical. Instead, likelihood of confusion (the test for trademark infringement) is determined by considering the following factors:

- the strength or weakness of the plaintiff's mark
- similarity of the marks in sound (for example, *SO* found confusingly similar to *Esso*), appearance (*Old Forester* infringed by *Old Foster*), or meaning (*Tornado* for wire fencing held confusingly similar to *Cyclone* [wire fencing])
- similarity of the product or services
- likelihood that the prior owner will bridge the gap between the parties' respective products or services
- presence or absence of actual confusion (actual confusion obviously being the best test of whether there is a likelihood of confusion occurring between two conflicting marks)
- defendant's good faith in adopting the mark
- sophistication of the potential purchasers (buyers of expensive goods may be more discerning purchasers and less likely to be confused between two similar marks for the same goods)
- channels of trade (the goods/services are sold, or are not sold, in the same marketing channels to the same general class of customers)
- similarity of the advertising media

6. THE "CARE AND FEEDING" OF MARKS

Trademarks and service marks are valuable assets, so their proper use, maintenance, and protection should be a paramount concern of the owner. It is critical to avoid misuse of a trademark, which can destroy the legal significance of the mark, for example, misuse leading to genericide, with the unfortunate outcome of a valuable trademark becoming a generic term. There is also the necessity of maintaining trademarks so as to avoid any possibility of creating unfavorable commercial impressions; solid, strong, and maintained trademarks are source indicators that attract business. Proper usage for trademarks and service marks will go a long way to protect marks and prevent genericide:

- Always use the mark as a proper adjective that modifies a noun, such as Cabbage Patch Kids® dolls, Levis® jeans, Xerox® copy machines.

- Never use a mark in the possessive form, in the plural form, or as a verb.
- Avoid prefixes, suffixes, additions, or deletions of the mark.
- Distinguish the mark in use from surrounding text such as a distinctive typeface, quotation marks, all capital letters or, at the very least, capitalize the first letter of each word of the mark.
- For marks registered in the PTO, use the symbol of registration, namely, ®, or the phrase *Registered in the U.S. Patent and Trademark Office or Reg. U.S. Pat. Tm. Off.*
- For unregistered marks, use either the informal notice TM or SM (or the corresponding symbols) or an asterisk indicating *A trademark/service mark of XYZ Company*.

The following ditty was a prize-winning submission at the Coca-Cola Co., which should be kept in mind to promote the proper usage of any mark:

Three laws bind the Kingdom of Coke.
This trio must never be broke:
The "C" should be tall,
Not possessive at all,
And the plural should never be spoke.

7. LICENSES

Never allow a third party to use your mark without entering into a written license agreement, which, at a minimum, enables you to monitor and control the nature and quality of the goods or services in connection with which the mark is being used by the licensee. Otherwise, you may end up with a *naked license*,[20] which could negatively affect the distinctiveness of your mark, possibly leading to the de facto abandonment of the trademark. Also, provide in any license agreement for the licensee to notify you of potentially infringing marks so that you may police your mark, as unauthorized uses of your mark will similarly negatively influence your scope of protection.

An assignment of a mark must be in writing and, whether registered or not, must include "*the good will of the business associated with the mark*" or the assignment is invalid. The basis for this provision is that a mark is merely the symbol of good will (that is, the owner's reputation for quality in connection with the goods or services sold under the mark). An assignment of a mark without the accompanying good will is an assignment in gross[21] and is invalid. Also, an intent-to-use application cannot be assigned as there is nothing to assign until the mark is in actual use.

8. CONCLUSIONS

When properly managed, maintained, protected, and used, trademarks are a valuable form of IP rights. In a comprehensive and coordinated IP strategy, trademarks can augment other forms of IP rights protection, for example, patents and trade secrets, and therefore should not be overlooked as additional options in a layered IP portfolio. A single product, such as crop variety, can have multiple forms of IP rights protection, including patents, trade secrets, and trademarks. It is therefore important to understand what a trademark is, how to select a strong mark and establish rights, the importance of registration, and the necessity of policing the trademark, whether to maintain the integrity of licensees or to identify potential infringers. Finally, strong trademarks are distinct and specific indicators of source. Protecting this function, an owner never wants to find his or her mark in a dictionary. That would mean the mark had joined the ranks of the unfortunate victims of genericide, like the yo-yo. ■

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1 For copyright information, go to www.copyright.gov; for patent information, go to www.uspto.gov/main/patents.htm. The U.S. Patent and Trademark Office has a very informative Web site at www.uspto.gov/web/menu/tm.html.

2 See www.uspto.gov/web/offices/tac/notices/guide299.htm.

3 Registration No. 1,709,019.

4 www.uspto.gov.

5 http://library.dialog.com/bluesheets/htmlaa/blo246.html.

6 See library.dialog.com/bluesheets/html/blo226.html.

7 www.t-tlaw.com.

8 www.dialog.com.

9 www.questel.orbit.com/patents/.

10 www.micropat.com/trademarkwebindex.html.

11 www.corsearch.com.

12 www.networksolutions.com.

13 www.bigbook.com.

14 www.switchboard.com.

15 www.superpages.com.

16 www.worldpages.com.

17 www.zip2/com.

18 A trademark or service mark may be registered with the united states patent and trademark office on either the principal or supplemental registers. Arbitrary, fanciful, and suggestive marks are on the principal register, while suggestive marks with secondary meaning are on the supplemental register: "A certificate of registration of a mark upon the principal register provided by this act shall be prima facie evidence of the validity of the registered mark and of the registration of the mark, of the registrant's ownership of the mark, and of the registrant's exclusive right to use the registered mark in commerce on or in connection with the goods or services specified in the certificate, subject to any conditions or limitations stated in the certificate." 15 u.s.c. § 1057 (b).

19 Constructive notice is a notice to the public of the registrant's claim of ownership of the mark.

20 Naked licensing means the licensing of trademarks without that trademark owner's retaining the right to approve the said use of the mark in connection with the licensee's goods or services. As a result, the trademark would be deemed abandoned (*Barcamerica International USA Trust v. Tyfield Imports, Inc.*, 289 F.3d 589-598 [9th Cir. 2002]).

21 Assignment in gross: A mark is a symbol of the mark owner's goodwill in the goods or services associated with the mark. The rule both under the common law and the Lanham act is that a mark cannot be assigned apart from the goodwill in the mark. An assignment in gross is an assignment of a mark without the associated goodwill. This rule is intended to protect the public from the deception that might arise if the assigned mark becomes associated with goods or services of a different nature or quality than was previously the case. An assignment in gross is invalid, and the assignee acquires no rights by such an assignment. See www.inta.org/index.php?option=com_content&task=view&id=174&itemid=132&getcontent=1.

The Statutory Toolbox: Plants

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ABSTRACT

Different forms of intellectual property protection are available for agri-biotech inventions: utility patents, plant variety protection, plant patents, trade secrets, geographic indications, trademark, and copyright. Each form has its own strengths and weaknesses. In general, stronger protections require meeting more stringent requirements. The three most important regimes for agri-biotech inventions are utility patents, plant variety protection, and trade secrets. A careful consideration of the relative demands and benefits of each regime will allow custom-tailored approaches to suit the needs of the inventor and the nature of the invention.

1. INTRODUCTION

Several intellectual property (IP) regimes protect agricultural biotechnology. They may be used alone or in combination. In general, the easier it is to obtain a particular form of IP protection, the weaker the protection it affords. Conversely, the more robust the protection, the more stringent are the requirements for obtaining it. This chapter provides an overview of the various forms of IP that are available for protecting agricultural biotechnology innovation.

2. PATENT AND RELATED REGIMES

Patent and somewhat patent-like IP protection regimes provide the most important protection for agricultural biotechnology innovation. In general, a patent grants an inventor of a novel, nonobvious, and useful invention an exclusive monopoly of fixed duration in exchange for public disclosure of the invention. Patent and related regimes offer the strongest IP protection. It is not mutually exclusive, and concurrent protection under multiple regimes is permitted. This section describes the utility patent, plant variety protection, and plant patent regimes, exploring the advantages and disadvantages of each regime.

2.1 *Utility patents*

The first regime, the utility patent, provides the most extensive coverage for inventions. In the context of agricultural biotechnology, the utility patent may be obtained to protect everything from genetically modified seeds and genetically modified plants, to transformation methods. Under the U.S. statute governing utility patents:

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.*[1]

Plants are eligible subject matter for utility patent protection under the category of "compositions of matter."

Kesan JP. 2007. The Statutory Toolbox: Plants. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2.1.1 *Scope of protection*

In the United States, utility patents grant a broad right to exclude others from making, using, offering to sell, selling, or importing into the United States, the patented invention.[2] Unauthorized exploitation of the patented invention by others within the patent term constitutes patent infringement. The broad scope of protection afforded by utility patents provides great flexibility for tailoring protection to various plant innovations.

Utility patents may cover individual components of a plant, including the plant's genome, cells, cell culture, and tissues, as well as methods for making the plant. For example, Monsanto, an agrichemical corporation, holds U.S. patents on Roundup Ready® soybeans, which are genetically modified to withstand the company's broad-spectrum herbicide, Roundup®. The company creates Roundup Ready® soybeans by inserting a gene sequence that allows the plant to survive the herbicide. Monsanto's utility patents allow the company to claim protection not only for methods of producing the Roundup Ready® soybeans, but also for the DNA molecule that encodes the herbicide-resistant trait, for the herbicide-resistant plant cell, for the seed of the herbicide-resistant plant, and for the final Roundup Ready® soybean plant itself.

A utility patent may also cover multiple varieties at once. And if the applicant meets the disclosure requirements discussed below, the patent can cover an entire species or genus. Moreover, the scope of the protection is broader than the specific plant variety developed. Under the patent law's doctrine of equivalents, trivial variations to an invention that may not fall within the literal terms of the claims of the patent may nevertheless infringe as an equivalent of the claimed invention.

2.1.2 *Requirements for obtaining a utility patent*

To obtain the protection of a utility patent, an applicant must meet the highest threshold for acquiring IP protection: an invention must be *new*, *useful*, and *nonobvious*.[3] First, it is considered new if it is not already known to the public.[4] An invention fails to meet the novelty requirement if it was in public use, was described in a printed publication, or was covered in a preexisting patent. In the United States, there is a one-year grace period on the bar on public use and printed publication. Second, an invention must be useful, that is, capable of providing a specific benefit.[5] Failure to identify a specific use for a gene sequence renders the gene sequence ineligible for patent protection. Finally, an invention must be nonobvious, that is, the invention is not obvious to a person of ordinary skill in the art. The nonobvious requirement takes into account the scope and content of the prior art and the level of ordinary skill in the pertinent art. Patent may be denied if the invention is a combination of previously known components A, B, and C, and the idea to combine the components A, B, and C were obvious to a person of ordinary skill in the art.

At minimum, a patent application must contain specifications and at least one claim. In the specifications, an applicant must disclose in writing what the applicant believes he or she has invented. The specifications must describe the invention in sufficient detail to enable others of ordinary skill in the pertinent art to practice the invention.[6] For example, in an application claiming DNA as the invention, a description of the DNA is adequate if it includes a definition of the physical properties, formula, chemical name, or structure of the claimed invention; a description that merely states that DNA is involved in the invention falls short of the requirement. In situations where the starting materials required to practice the invention are not readily available to the public, the applicant may also be required to place the materials in a depository in order to fulfill the enablement requirement. The written description of the invention must also reveal what the inventor believes is the best way to practice the invention.

The claims in a patent define the boundaries of a patentee's right to exclude. The patent application must therefore describe what the inventor claims as his invention, by including

> *…one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*[7]

Ideally, claims should be both broad enough to afford the patentee a wide scope of protection, and narrow enough to avoid invalidation by the prior art. In general, claim language that contains fewer limitations provides broader patent protection than claim language that includes many limitations. Consider the following two simplified claims for a bucket:

A claim that reads:

A bucket comprising a wooden circular bottom, wooden side walls, and a stainless steel handle

provides narrower protection than a claim that reads:

A bucket comprising a bottom, side walls, and a handle

A competitor's metal bucket with a square bottom would fall outside the claim language of the first example, but would infringe the second example by falling within its claim language.

Additionally, claims may be classified as either independent or dependent. Independent claims generally are the broadest claims and do not refer to any other claim in the patent. Dependent claims, on the other hand, incorporate other claims by reference and add additional limitations. Consequently, dependent claims provide a narrower scope of protection than independent claims. Consider the following example:

I claim:

1. a bucket comprising a bottom and side walls
2. the bucket of claim 1 further comprising a handle
3. the bucket of claim 2 wherein the bottom and side walls are wooden
4. the bucket of claim 2 wherein the bottom is circular

In this example, claim 1 is the independent claim. Claims 2 through 4 are the dependent claims that rely on claims that have come before. Ultimately, a patent covers only what the applicant describes and claims in the patent application.

2.1.3 *Procedure for obtaining a patent*

a) Patent protection in the United States. In the United States, utility patents are administered by the Patent and Trademark Office (PTO), an arm of the U.S. Department of Commerce. The PTO receives and examines applications and has power to grant patents if it is convinced that the invention is new, useful, nonobvious, and meets other conditions and requirements as set forth in the statute.[8] The first step in acquiring a patent is to file a patent application with the PTO. Thereafter, a series of communications between the applicant and the PTO follows. Six months to two years after the filing date of the patent application, the PTO will send communications to the applicant known as an Office Action. This communication notifies the applicant of whether the claims have been allowed and provides reasons for rejections of claims. The applicant then has a chance to respond to the PTO within a time specified in the Office Action, typically three months. The applicant may amend the application to overcome the rejections. Two to six months after the PTO receives the applicant's response to the Office Action, the PTO may send another Office Action to the applicant or it may send a Notice of Allowance. A Notice of Allowance indicates that the PTO has allowed all of the claims in the application. A patent will issue after the applicant pays an issue fee.

Once granted, utility patent protection lasts for a term of 20 years, measured from the date the patentee filed the application. It is not subject to exemptions from enforcement. During the term of the issued patent, the patent holder must pay periodic maintenance fees to the PTO.

b) International patent protection: The Patent Cooperation Treaty (PCT).[9] In the current global economy, an inventor may wish to procure patent protection for his or her invention in more than one country. A patent confers rights, however, only in the jurisdiction in which the patent application was filed. Outside of the country where the patent is issued, others are free to use the invention without incurring patent infringement liability. A patent that issues in the United States, for example, confers no automatic patent protection for the invention in France. To protect an invention internationally, an inventor must secure a patent in each country in which he or she desires protection.

Many nations have adopted international agreements that make the process of obtaining multiple patents easier. One of these agreements is the Patent Cooperation Treaty (PCT). The PCT, administered by the World Intellectual Property Organization (WIPO), is an international agreement that streamlines the process of securing patents for an invention in multiple countries. A patent applicant may seek simultaneous patent protection in multiple countries by filing a single application and designating the countries where protection is desired. While PCT does not alter the substantive requirements of patentability in each country, it does eliminate the duplicative effort wasted in filing separate patent applications for the same invention.

An inventor who wishes to take advantage of the PCT, first files an application in his or her home patent office, designated the Receiving Office. The home office conducts an initial prior art search and gives the applicant the opportunity to request an international preliminary examination. The preliminary examination, while not binding, indicates the patentability of the invention, which may assist the applicant in deciding whether to commit to an expensive filing abroad. In the next step, called the "national stage," an applicant has 30 months to convert the PCT application into parallel patent applications in the countries in which he or she desires patent protection. From there, the patent application process proceeds according to the procedures established by each designated country.

2.1.4 *Rights of the inventor*

A patent grants its owner the right to exclude others from making, using, offering for sale, and selling the patented invention without the patent owner's permission. Patents are personal property and therefore may be licensed or assigned to others, including companies. An assignment transfers the rights of the patent from the current owner to a new owner. In contrast, a license grants a revocable permission to engage in conduct that would otherwise constitute patent infringement without transferring ownership of the patent. Licenses may be either exclusive (issued strictly to one licensee) or nonexclusive (issued to several licensees at once).

2.2 *Plant variety protection*

While utility patents provide the most robust protection for plant innovation, only a few countries afford utility patent protection for agricultural biotechnology. A more common regime is plant variety protection, also known as plant breeder's rights. In general, plant variety protection provides a sui generis form of IP protection to breeders of new varieties of plants.

2.2.1 *International protection: UPOV–The International Convention for the Protection of New Varieties of Plants*

Many countries with a system for protecting new varieties of plants have based it on the International Convention for the Protection of New Varieties of Plants (UPOV Convention).[10] Originally adopted in Paris in 1961 with the objective of providing IP protection for new plant varieties, the UPOV Convention has undergone several revisions, first in 1972, again in 1978, and most recently in 1991. The International Union for the Protection of New Varieties of Plants (UPOV), an intergovernmental organization headquartered in Geneva, Switzerland, administers the UPOV Convention.

The UPOV Convention defines a minimum scope of protection that enables plant breeders to prohibit the unauthorized exploitation of their protected variety. Under the UPOV Convention, the authorization of the breeder of an eligible plant variety is required to produce or reproduce, condition for the purpose of propagation, offer for sale, sell, export, import, and stock the propagating material of the protected variety. Where the plant breeder has not had a reasonable opportunity to exercise his or her rights as to the propagating material, the same rights are extended to the harvested material of the protected variety. The rights also attach to varieties "essentially derived" from the protected variety, varieties "not clearly distinguishable from the protected variety," and varieties that "require the repeated use of the protected variety."[11] The Convention explains that "essentially derived varieties" are those that

…may be obtained, for example, by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual

from plants of the initial variety, backcrossing, or transformation by genetic engineering.[12]

To obtain plant variety protection, UPOV must examine an application to ensure that the proposed variety meets the conditions for protection. To qualify for UPOV protection, a plant variety must be:

(i) distinct from existing, commonly known varieties,
(ii) sufficiently uniform,
(iii) stable, and
(iv) new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection[13]

Once granted, UPOV dictates that plant breeder's rights shall last for at least 20 years; for trees and vines, the term should endure for no less than 25 years from the date of the grant.

UPOV also defines acts that are exempt from the plant breeder's rights. The plant breeder's permission is not required for acts done privately and for noncommercial purposes, experimental use of the protected variety, and acts done for the purpose of breeding other varieties. In addition to the compulsory exceptions, an optional exception allows farmers to save harvested seeds for replanting.

Member nations of the UPOV Convention agree to adopt all measures necessary to implement the plant breeder's rights as outlined in the Convention and to extend to foreign nationals the same rights it provides to its own citizens. Implementation of the Convention entails the establishment of legal remedies and enforcement mechanisms for breeder's rights, as well as the designation of an authority entrusted with the power to grant such rights to applicants. UPOV provides the basic framework for plant variety protection. However, since countries are free to tailor their laws to domestic circumstances when implementing the provisions of the UPOV Convention, different countries have adopted slightly different versions of the plant variety protection regime.

2.2.2 *Protection in the United States: The Plant Variety Protection Act (PVPA)*

The United States is a member of UPOV, having implemented the UPOV Convention in 1981. Plant variety protection certificates, issued by the Plant Variety Protection (PVP) Office of the U.S. Department of Agriculture (USDA), supply patent-like protection for new varieties of seed-bearing plants and may be obtained to protect new plant varieties. Governed by the Plant Variety Protection Act (PVPA), rights are granted to

[T]he breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, […] subject to the conditions and requirements of this Act.[14]

The PVPA protects discrete varieties from unauthorized exploitation by others. Following the UPOV Convention, a PVP certificate grants its holder the right to exclude others from selling, offering for sale, reproducing, importing or exporting the protected variety, and from using the protected variety to produce (as distinguished from to develop) a hybrid or different variety. As per the UPOV Convention, protection under the PVPA extends not only to the protected plant variety, but also to "essentially derived varieties," narrowly defined in the PVPA to include two generations of derivation. The PVPA defines the term as a variety that:

- *…is predominantly derived from another variety (referred to in this paragraph as the "initial variety") or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety*
- *is clearly distinguishable from the initial variety*
- *except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.* [15]

Inclusion of essentially derived varieties within the limits of the breeder's rights guards against acts that border on blatant copying. Essentially derived varieties delineate a zone of protection around the protected variety that captures plants produced by inducing minor changes to a protected variety. As an example, a hybrid variety of corn produced from a protected variety may exhibit cosmetic differences that make the hybrid distinct from its parent; but as an essentially derived variety, the hybrid nevertheless falls within the scope of PVP protection for the parent.

As required by the UPOV Convention guidelines, the PVPA includes several exceptions that shield certain acts from infringement liability. Private noncommercial use of a protected variety does not constitute infringement.[16] Saving seed for replanting *"a crop for use on the farm*" and sale of such seeds *"for other than reproductive purposes"* also do not constitute infringement.[17] Also, the PVPA explicitly provides a research exemption. The statute states that "*use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act.*"[18]

Furthermore, though not an exemption from infringement liability, the PVPA is subject to a requirement that allows the secretary of USDA to declare a compulsory license allowing use of the protected variety for two years, in exchange for a royalty, if such action is deemed necessary for the public interest to maintain a sufficient food supply. The many exceptions to the PVPA allow others, under certain circumstances, to exploit a protected plant variety without the owner's authorization and therefore diminish the strength of plant variety protection.

As a trade-off for the narrower scope of protection, the PVPA demands a lower threshold for obtaining protection. Unlike the utility patent, the PVPA does not call for rigorous disclosure of the claimed invention, nor does it impose a nonobvious requirement. Instead, applicants for a plant variety protection certificate must show that the variety qualifies for protection, must provide a description of the variety, and must deposit seed in a repository.

To qualify for protection under the PVPA, a plant variety must be new, distinct, uniform, and stable. The statute defines each of these terms. First, a variety is "new" if "*the variety has not been sold or otherwise disposed of to other persons*" for more than one year before the date the applicant filed the application for PVP.[19]

Second, a variety is "distinct" if

… *the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application*. [20]

Moreover,

… [*t*]*he distinctness of one variety from another may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence*.[21]

Third, a variety is "uniform" when

… *any variations are describable, predictable, and commercially acceptable.*[22]

Finally, a variety is "stable" if

… *the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety, with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.*[23]

Once a plant protection certificate issues, the term of protection lasts for 20 years from the date of issue of the certificate, or 25 years in the case of a tree or vine.[24] Unlike utility patents and plant patents, which must issue under an individual inventor's name, a plant variety protection certificate may issue in the name of a corporation, which allows a corporation to file under its own name. Additionally, as a requirement for maintaining PVP, the certificate holder must periodically replenish the repository of

seeds of the protected plant variety. The PVPA does not, however, require payment of maintenance fees for the certificate. When compared to a utility patent, the scope of protection under the PVP regime is limited. But one advantage of the PVPA is the immediacy of protection: as soon as a plant variety protection application is filed and the fee is paid, provisional protection attaches to the plant variety. By marking the seed with protection notices "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited," the seed owner acquires protection prior to the issuance of the plant variety protection certificate.[25]

2.3 *Plant patents*

Plant patent protection is the narrowest of the three patent and patent-like IP regimes available to agricultural innovation. The scope of protection extends only to asexually reproduced plant varieties. In general, the U.S. statute grants plant patents to one who

> … *invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state*…[26]

For example, a person who discovers and asexually reproduces a new pineapple variety may obtain plant patent protection. If he or she later discovers a second variety of pineapple that is separated from the first by a single trait, the second variety may also obtain plant patent protection.

The plant patent regime affords protection against unauthorized asexual reproduction of protected plant varieties. A plant patent grants its holder "*the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts*…"[27] To qualify for plant patent protection, a plant must be produced asexually, through means such as grafting, cutting, budding, layering, and inarching.

The cornerstone of plant patent protection is asexual reproduction, but asexual reproduction also severely limits the protection afforded and is therefore its Achilles' heel. The asexual reproduction requirement effectively limits infringement to the narrow circumstance where stock from the patentee's original parent plant is obtained and asexually reproduced. Independent breeding of a variety that closely resembles the subject of a plant patent escapes infringement liability. So too does seed propagation and sexual crosses of the plant, since such acts fall outside the scope of plant patent rights. Because its scope of protection is exceptionally narrow, a plant patent ordinarily should not be the sole source of protection for a plant innovation.

The requirements for obtaining a plant patent are, arguably, the least strict of the three patent and patent-like regimes. In the United States, the Patent and Trademark Office administers both plant patent and utility patents. Like a utility patent application, a plant patent application must meet the patent law's nonobvious requirement. Applications for plant patents must also fulfill a disclosure and claiming requirement. The plant patent disclosure requirement may be met by a description that "*is as complete as reasonably possible*"[28] and a color drawing of the plant. Plant patents need not disclose how to make or use the claimed invention. The claiming requirement restricts the plant patent to a single claim to the whole plant.

Plant patent protection shares some of the requirements for PVPA protection, but there are some differences. Like plant variety protection, a variety must be new and distinct—new, meaning that the plant variety was not sold or used more than one year prior to the application date, and distinct meaning that the characteristics of the variety are clearly distinguishable from those of existing varieties. Unlike plant variety protection, however, plant patents do not require that the plant variety be uniform and stable. Whereas PVPA protection is unavailable for plants that do not breed true, such plants may receive protection under a plant patent.

If the requirements are met, the PTO issues a plant patent, which offers a term of protection of 20 years from the date of patent application. Like a utility patent, there are no exceptions to enforcement. Also like a utility patent, the patent

holder must pay periodic maintenance fees to the PTO.

3. OTHER FORMS OF IP PROTECTION IN PLANTS

3.1 *Trade secrets*

Along with utility patents and plant variety protection, trade secret protection represents another essential tool for protecting plant innovation. Most significantly, trade secret protection is available for inventions that do not otherwise qualify for protection under a patent or patent-like regime.

In general, the purpose of trade secret protection is to uphold commercial morality by preventing the unauthorized use and disclosure of secret information, while leaving other parties free to independently develop the same matter. The subject matter protected by a trade secret coincides with the subject matter protected under patent regimes. Typically, protection attaches to information that is used in business, gives a competitive advantage, and has been kept confidential.

Unlike patents, trade secret protection arises instantly and requires no formal application or review process. Once trade secret protection is established, it grants recourse against one who wrongfully acquires the secret information. To recover for trade secret misappropriation, however, the trade secret owner must show that the information was protected by reasonable measures to ensure the secrecy of the trade secret. The requirement of maintaining the confidentiality of the information is critical: trade secret protection evaporates if the underlying information is no longer a secret. The cost of maintaining a trade secret is therefore largely the cost of maintaining secrecy measures. Keeping a trade secret may involve continuous and costly expenditures on measures to prevent the unauthorized use or disclosure of the information.

Unlike other IP regimes, trade secrets provide protection for an indefinite period rather than for a fixed term of protection. So long as the underlying information continues to be a secret, the information remains protected as a trade secret. Some trade secrets, most notably the secret formula for the beverage Coca-Cola, have been maintained as trade secrets for a very long time indeed. However, trade secret protection can end at any time, since once the underlying information is no longer a secret, the trade secret protection disappears. Loss of trade secret protection may result from disclosure, successful reverse engineering, or independent development by others. Unlike patent protection, trade secret protection provides no recourse against one who reverse engineers or independently discovers the same matter. This uncertainty of protection is the risk borne by one who chooses trade secret protection.

In the context of plant innovation, trade secret protection is a mixed bag. For seed companies, protecting plant varieties under trade secrets alone may prove difficult. Maintaining the secrecy of information is challenging because crops are grown in open fields and seed is sold on the open market with no assurances of confidentiality. Hybrid seed varieties are the easiest to maintain as a trade secrets. Since the exact characteristics of the parental lines of a hybrid cross are difficult for others to ascertain, the owner of the hybrid plant variety may maintain the parental lines as a trade secret and sell only the seed resulting from the cross of the parental lines. Trade secret protection might also be employed to protect know-how, or the methods and techniques of the plant breeder. Additionally, trade secret protection may be used to protect an invention during the patent examination period in order to protect an invention until a patent issues.

Most importantly, trade secret protection is instrumental for protection of innovations that do not otherwise qualify for protection under patent and patent-like protection regimes. Trade secret protection extends to the same subject matter covered by patents and requires only secrecy. Consequently, trade secret protection is vital for protecting matter where patent and patent-like protection is unavailable.

3.2 *Geographic indications, trademark, and copyright protection*

To a much lesser extent than patents (and to some extent trade secrets), the protection provided under geographic indications, trademark, and

copyright may also be used to protect plant innovations. The first of these three, the geographic indications regime, is not traditionally protected under U.S. law, but is recognized under a treaty of the World Trade Organization. Geographic indicators communicate to consumers the association between a product and the territory from which it originates, which may indicate the product's quality, reputation, or other characteristic. The most prominent example of geographic indicators is the designation given to wines, for example *champagne* and *Bordeaux*. Geographic indicators may be used to differentiate among plants originating from different territories.

The second regime, trademarks, focuses on communicating to the consumer the association between a product and the source of the product, such as its manufacturer. This may reflect on the product's quality or authenticity. Trademarks may differentiate one plant breeder's product from another breeder's products, stopping competitors from using the good name a plant breeder has built in its popular varieties. The leading international treaties governing trademark protection include the Paris Convention, the Madrid Agreement, and the Madrid Protocol, all of which are administered by WIPO.

The last of the regimes, copyright, protects works "*fixed in any tangible medium of expression*."[29] Copyright may be used to protect works of authorship such as descriptions of processes, training materials, and brochures, as well as artistic renderings of plant varieties and other ancillary materials. While copyright protects the expression of an idea, the copyright does not protect the underlying idea itself. Anyone is free to use the ideas contained in a copyrighted work. Therefore, while a copyright may protect the written expression that describes a new plant variety, the copyright does not offer protection for the plant variety itself. Internationally, the minimum substantive standards of protection for copyrights are set forth in the Berne Convention, a multinational agreement established in 1886, and in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), an agreement administered by the World Trade Organization.

4. CONCLUSION

In the context of agricultural biotechnology, several IP regimes are available to provide protection for plant innovation. The three most important regimes are utility patents, plant variety protection, and trade secrets. Through careful consideration of the relative demands and benefits of each regime in terms of the protection it offers for different types of plant innovation, individual approaches may be custom-tailored to suit the needs of the inventor and the nature of the invention. ■

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1 35 U.S.C. § 101

2 35 U.S.C. § 271(a)

3 35 U.S.C. §§ 102–103

4 35 U.S.C. § 102

5 35 U.S.C. § 101

6 35 U.S.C. § 112

7 35 U.S.C. § 112

8 35 U.S.C. §§ 102–103

9 See also in this *Handbook*, chapter 10.7 by AM Schneiderman.

10 The acronym UPOV originates from the French name for the organization, Union internationale pour la Protection des Obtentions Végétales.

11 "International Convention for the Protection of New Varieties of Plants," art. 14, 19 March 1991, available at www.upov.int/en/publications/conventions/1991/w_up911_.htm.

12 See note 11.

13 UPOV, "International Union for the Protection of New Varieties of Plants: What It Is, What It Does," www.upov.int/en/about/pdf/pub437.pdf.

14 7 U.S.C. § 2402(a)

15 7 U.S.C. § 2401(a)(3)

16 7 U.S.C. § 2541(e)

17 7 U.S.C. § 2543

18 7 U.S.C. § 2544

19 7 U.S.C. § 2402(a)(1)

20 7 U.S.C. § 2402(a)(2)

21 7 U.S.C. § 2401(b)(5)

22 7 U.S.C. § 2402(a)(3)

23 7 U.S.C. § 2402(a)(4)

24 7 U.S.C. § 2483(b)
25 7 U.S.C. § 2567
26 35 U.S.C. § 161
27 35 U.S.C. § 163
28 35 U.S.C. § 162
29 17 U.S.C. § 102(a)

Plant Breeders' Rights: An Introduction

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ABSTRACT

Based on the averages, there is a good chance that your country has decided to fulfill its TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement commitments by selecting an "effective sui generis system" over patents for plants, something more commonly known as plant breeders' rights. This chapter attempts to explain what plant breeders' rights are by describing the organization and function of the plant breeders' rights system. Covering the objectives, scope, protection requirements, and examination provisions, the chapter compares the plant breeders' rights system with the patent system and attempts to clarify specific puzzling issues. These include concerns that the latest UPOV Act does not address farmer seed savings (the choice is left to individual countries, with virtually all countries choosing to allow seed saving). Plant breeders' rights are less puzzling once the intent and structure of the system are understood. The system is, in fact, one with very specific, if narrow, objectives.

1. INTRODUCTION

Guild members in mid-15th century Venice, averse to direct competition from former apprentices, passed a law prohibiting the apprentice from entering the trade until about 18 years had lapsed. That edict, according to intellectual property (IP) historians, marked the origins of patents. Indeed, the duration of a patent (20 years from date of filing the application) is said to be modeled after that apprenticeship period in long-ago Venice. Yet some easily copied creations were not granted similar IP protection, in Venice or anywhere else, until many centuries had passed. Plants are one example of this. Food, fiber, and ornamental crops (F_1 hybrids excepted) carry in themselves the ability to regenerate true to form, whether sexually or asexually. Anyone holding a seed or a cutting immediately possesses all the skills of the master to recreate the variety of plant from which the seed or cutting came. Yet not until 1930 (the U.S. Plant Patent Act) did legal restrictions apply to the use of plant materials for regenerative purposes, and even then protection only applied to asexually propagated plants (excluding tubers). An additional 30 years passed before a harmonized format for legislation covering IP protection for all plant varieties emerged. That is the International Convention for the Protection of New Varieties of Plants, or UPOV in its French acronym, an international treaty first adopted in 1961 and revised several times, the latest in 1991. The form of intellectual property created by UPOV is known widely, if informally, as plants breeders' rights (PBR). This chapter describes the acts and modes of operation of PBR under UPOV-compatible national legislation. While every effort is made here to be complete and accurate, it would be impossible discuss all of the considerations needed to appreciate every possible contingency. Persons wanting to learn more should refer to the text of UPOV and other official documents, such as

Lesser WH. 2007. Plant Breeders' Rights: An Introduction. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

at the UPOV Web site.[1] The *Handbook* chapter PBR in the Developing World, discusses the effects of PBR laws and the available alternatives at the national level.

2. WHAT ARE PLANT BREEDERS' RIGHTS?

PBR is a patent-like system that allows the plant variety owner to prohibit specific unauthorized uses of the variety. PBR laws apply only to plants, and hence are among the class of sui generis systems, that is, special purpose systems. Laws applying to computer chips (that is, *mask works* … the set of templates used to manufacture chips) form another sui generis system. In fact, sui generis systems have been applied to everything from aeronautics to Xerox® machines. These systems differ significantly from patent laws. The differences between the two systems—and the similarities—are explained below.

PBRs, like patents and other forms of IP law, are forms of national legislation. That is, protection applies only in countries where protection has been sought and granted. Thus, the owner of a sunflower variety protected in the United States would have no legal control over how that variety was used inside Canada. Critically, however, the variety owner could prevent the importation into the United States of the variety, including (in most cases but depending on the specific country's sui generis laws with regard to plant varieties) grain, plants, plant parts, and, in some countries, even manufactured products produced using the protected variety. In the case of a U.S. PVP-protected sunflower variety, the variety owner could not prevent it from being planted, grown, harvested, or sold inside Canada, but U.S. PVP-protected sunflower seed, sunflower meal, sunflower oil, and similar products could be prevented from entering the U.S. stream of commerce.

PBR under the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) is a component of the World Trade Organization (WTO). Signatories of WTO (currently about 150) are committed to comply with the TRIPS requirements of a harmonized minimum level of IP rights protection. Although the TRIPS text is quite exhaustive in most regards, only a single sentence refers to PBR. Article 27.3(b) reads, in part, that WTO members must provide plant variety patents, "*an effective sui generis system,*" or both. Most countries new to protecting plants are opting for PBR over patents. PBR is clearly a sui generis system, but what constitutes "effective" is less clear.

3. WHAT ROLE DOES UPOV PLAY?

If PBR is based on national law, what role does UPOV, an international convention, play? Essentially, UPOV establishes a framework law that may be adopted by countries into their own national laws. After having done so, a country could submit its national law to the governing body of UPOV for evaluation and, if the law was found to have similar critical elements, the country could become a UPOV-signatory nation. In practice, there is usually an informal assessment done by UPOV prior to final diplomatic submission. UPOV does provide a mechanism for harmonizing national laws and providing standardized definitions/interpretations of terms. UPOV also requires nondiscrimination against foreign applicants of other Union members (National Treatment, Article 4 of 1991 Act). However, that Article has largely been supplanted by the geographically broader national treatment requirements of TRIPS (Article 3). UPOV member states have training and other technical support available to them, although an annual membership fee based on national income is imposed. Countries can and do have PBR systems without joining UPOV, but little is known about their operation and few countries have implemented them. Since its inception, UPOV has adopted four acts (1961, 1972, 1978, and 1991). Members may at their discretion adopt a more recent Act, but older acts are closed. Presently, the 1991 Act is the only one now open to new members. There are some important differences between the 1978 and 1991 acts, to which essentially all current members belong. These differences are discussed below. All terms and references here refer to these acts. There are some national-level differences, but for the most part identifying them involves a greater level of detail than is possible here.

4. HOW DO PBRS WORK?

PBR systems, like other IP systems, have three major components:

1. Definition/identification of protectable subject matter
2. Requirements that must be met to receive protection
3. Rights of the variety owner

4.1 *Identifying what can be protected*

As a sui generis system, protection is limited to plant "varieties," but this term lacks a standard definition. The definition in the 1991 Act (Article 1(vi)) reads in part:

a plant grouping . . .

- defined by the expression of the characteristics …
- distinguished … by the expression of at least one of the said characteristics and
- *[having] suitability for being propagated unchanged*

Beyond its technical relevance, this definition is significant since it departs from the language of earlier acts. The 1978 Act lacked any such definition, while the 1961 Act (Article 2.2) refers to a variety as "*any cultivar, clone, line, stock, or hybrid which is capable of cultivation….*" Certainly, one purpose for defining variety is to distinguish what is protectable under UPOV from those "plant genetic resources" that fall under the Convention on Biological Diversity (CBD). As a general matter, a plant variety under UPOV would also be a plant genetic resource as defined by the CBD. Furthermore, the international convention typically (but not universally) allows the more recent convention to supercede the prior one. The CBD was ratified in 1992 and went into effect in 1993. However, the CBD (Article 16.2) does provide for the "*adequate and effective protection of intellectual property rights*," so PBRs would seem to operate independently of national laws enacted under the CBD, although exceptions could arise. There might be conflict, for example, over traditional farmer-bred varieties, often referred to as landraces. Landraces are certainly genetic resources and, arguably, plant varieties. However, as a practical matter, heterogeneous landraces rarely satisfy the uniformity and stability requirements for PBR protection, so a conflict in practice seldom arises. This does not mean that a landrace is specifically excluded from PBR protection, or that one could not be protected. Rather, the UPOV protection requirements demand more specific attention to a landrace (such as backcrossing), so the issue of whether, or not, landraces qualify for PBR protection actually seldom arises. As to UPOV, it is quite evident that the system is intended for planting materials, whether they are food crops or horticultural varieties, that will be sold on a commercial basis.

Another area of potential overlap is with the offering of patents and PBR for a plant. The TRIPS Agreement specifically allows patents for plants, and, in the United States, both forms of protection have been available for some time. The matter has, however, not been so straightforward in E.U. countries, due to the adoption of the European Patent Convention (EPC). The EPC (Article 53(b)) excludes protection for "plant or animal varieties," raising the question of just what the appropriate definition of *variety* is. Rulings on this question have seesawed back and forth for decades, but the current (and likely sustainable) rule is that a plant variety is in a fixed form regarding all of its characteristics. An invention that is applicable to a number of varieties is not a plant variety and is thus patentable. This interpretation, while not binding in other countries, is of relevance since Article 53(b) wording has been adopted into the patent laws of a number of other countries.

4.1 *Protection requirements*

To be eligible for protection under UPOV-based laws, a variety must be (Article 5, 1991 Act, Article 6, 1978 Act):

- new
- distinct
- uniform
- stable

These requirements are often abbreviated as DUS. Newness (or novelty) requires that the applicant variety has not been "*sold or otherwise*

disposed of to others" for more than one year in the country of application or for four years (six for trees or vines) elsewhere. This requirement assures that the public is not giving away exclusivity rights to something already available, while recognizing that some limited use or testing will typically be required prior to application.

Uniformity and stability necessitate a certain amount of backcrossing, so that the variety reproduces true to form across individual plants (uniformity) and across generations (stability). Stability and uniformity serve the important function of making a variety identifiable after propagation. The two also serve important commercial needs. UPOV has sometimes been criticized for promoting genetic uniformity through the stability and uniformity requirements. The text reads "*sufficiently uniform in its relevant characteristics*" (Article 8, 1991 Act) and "*stable [in] its relevant characteristics*" (Article 9, 1991 Act). That is, stability and uniformity are required only to a degree, and only in certain characteristics. The requirements are variable and limited, beyond which a protectable variety can be as heterogeneous as is feasible from the prospective of UPOV. Commercial requirements may necessitate broader uniformity, but this is not relevant to UPOV. Rather, distinctness is the driving characteristic: "*A variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application*" (Article 87, 1991 Act). The wording in the 1978 Act (Article 6.1(a)) is nearly identical, except for the inclusion of "*by one or more important characteristics.*" That is, the variety must be distinguishable by one or more characteristics, such as flavor, color, or virus resistance. What characteristics are considered to be distinguishing ones is a matter of national interpretation.

4.3 *Rights of variety owner*

Under the 1978 Act (Article 5.1), the permission of the owner is required for:

- production, for purposes of commercial marketing
- offering for sale or offering marketing rights to reproductive or vegetative propagating material

To those activities, the 1991 Act (Article 14.1) added the following activities for which permission of the owner must be given:

- production or reproduction (multiplication)
- conditioning for the purposes of propagation
- exporting
- importing
- stocking for any of [these] purposes

The specificity of these rights enhances the ability of the rights owner to exclude access, the only right granted by PBR and other IP rights systems. For example, under the 1991 Act, it is sufficient to show unauthorized reproduction, while the 1978 Act required proof of intent to "*commercial[ly] market*" the material. Similarly, under the 1991 Act (Article 14.2) protection is extended to "*harvested materials, including entire plants or parts of plants.*" This means, for example, that the blooms from an unauthorized propagation of a rose variety overseas can be barred access. Under the 1978 Act (Article 5.4), such an extension of protection was optional. Finally, under Article 14.3 in the 1991 Act, a signatory country may choose (but is not required) to extend protection to "*products made directly from harvested material of the protected variety.*"

Two important exceptions to these rights exist. First, protected varieties may be used for breeding and experimental purposes (Article 15.1, 1991 Act and Article 5.3, 1978 Act). This is a right mandated by UPOV, and typically referred to as *breeders' rights*. The freedom to use the variety resulting from the breeder's effort, however, differs between the two acts. It is an important and arcane enough issue to warrant separate treatment.

The second major exception to the rights listed above is the right of a grower (farmer) to retain the crop as a seed source for a subsequent season. This right is absolute under the 1978 Act because, as there is no commercial marketing involved, it is not prohibited. The 1991 Act (Article 15.2) makes this right (typically known as the "farmer's privilege") optional. This Article

is sometimes misconstrued as the elimination of the farmer's privilege, when what it really does is allow each nation to choose. At present, almost all countries have chosen to retain the farmer's privilege. A notable distinction is the European Union, which requires farmers to pay a royalty on saved seed. "Small" farmers are exempted. Note also that this right is completely different and separate from Farmers Rights as defined by the Food and Agriculture Organization of the United Nations (FAO).

Under UPOV, the PBR protection period is a minimum of 15 years, which extends to 18 years for woody plants under the 1978 Act (Article 8). The 1991 Act (Article 19.2) extends the periods to 20 and 25 years respectively.

4.3.1 *Testing (examination) methods*

According to the 1991 Act, "*Any decision to grant a breeder's right shall require an examination for compliance with the [protection] requirements*" (Article 12, 1991 Act). The wording of Article 7, 1978 Act, is similar. Signatory countries nonetheless have substantial latitude in how to conduct the examination. The distinctness requirement does, however, require a comparison with "*any other variety whose existence is a matter of common knowledge at the time.*" Thus, at a minimum, a national examination system must maintain (or have access to) a large database of variety descriptions, both protected and not protected, including varieties used both inside and outside the country. Beyond that, countries exercise considerable flexibility. The E.U. nations, for example, carry out a two-year field trial where the applicant variety is compared to an established reference variety. Distinctness is recognized only in specified characteristics by crop, and sometimes a quantitative basis is defined by a "crop committee." For example, an onion variety may be distinct in resistance to sprouting if 3% fewer sproutings occur than in the reference variety after X months of storage. As a variation of this approach, some countries (such as Canada) require the applicant to conduct the growouts (field evaluation of the variety) under the supervision of the plant variety office. Most PBR offices are within a ministry of agriculture. Using the opposite approach is the United States, where growouts are rarely undertaken. Instead, the claim of the applicant is essentially taken at face value. Moreover, distinctness may be claimed in any characteristic, including in those of no practical value. Improper claims of distinctness are resolved in court between the parties. To date there have been few if any court cases resulting from improper claims. From an economic perspective, the U.S. approach is simpler and less costly, while allowing more rapid access to new varieties. Because a variety is protected, however, does not necessarily mean it has agronomic merit. Cosmetic breeding ("cosmetic" traits do not contribute to the productivity of the crop, for example, flower color for pulses) raises costs, although the proliferation of available varieties would reduce their market prices. Choosing a single approach, or choosing to adopt a combination system, is a significant national decision. The U.S. approach does rely more on an efficient and transparent court system, something not available everywhere. To emphasize that point, a study done of Argentina's PBR act (one of the first in a developing country) determined that such a system of PBR would not be effective until the rights could be adequately enforced.

4.3.2 *Initial and dependent varieties*

The 1991 Act (Article 14.5) does add a significantly new component: that of essentially derived varieties. This component provides an exception to breeders' rights: protected materials may still be used in a breeding program, but if the resultant variety is judged to be essentially derived, it cannot be commercialized without the permission of the initial variety's owner. Before considering the technical aspects of this article, it is perhaps helpful to consider several justifications. If the background or development breeder spends 15 years breeding disease resistance from a wild relative into a commercial variety, then under the 1978 Act provisions, the resultant variety could be used as a basis of subsequent breeding, and within a few years competitive varieties would appear. The development breeder would then have difficulty recovering the costs of the 15 years of work, meaning that, as a practical matter, background breeding would have to be left to the public

sector. The owner of a leading commercial variety would be in a similar situation regarding the insertion of a genetically modified trait by another party. Under the 1978 Act, if herbicide resistance had been produced by cross-breeding patented genes into that leading commercial variety, then the resulting genetically modified herbicide-resistant variety could be commercialized, with nothing owing to the original variety owner. Yet that original variety owner would be prevented from using the patented genes in its breeding program, thus producing a distinct asymmetry of rights. Article 14.5 is intended to correct this imbalance by establishing two levels of protection:

- Initial varieties are those on which essentially derived varieties depend. If the initial variety is protected, these essentially derived varieties can be bred from an initial variety but not commercialized without permission from the variety owner. Essentially derived varieties are often referred to informally as *dependent varieties.* If the background-bred variety were an initial variety, any minor derivative varieties would be dependent and, in practice, could expect to pay royalties. UPOV (Article 14.5(b), 1991 Act) uses terms such as "*predominately derived*."
- Other varieties retain the expression of the "*essential characteristics*." Essentially derived varieties may be produced in a number of ways, including by selection, back-crossing, or transformation by genetic engineering. Several UPOV-associated committees have used words such as "*the preponderance of genetic material*." Just how initial and derived varieties are distinguished can be quite critical, but this may not be clearly determined until there are actual decisions settling disputes revolving around this issue. We do know that many national PBR offices are treating the matter as an infringement, that is, the self-identified initial-variety owner is left to sue the purported dependent-variety holder, and it is up to the courts to resolve the counterclaims. This approach relieves a national office from having to making difficult distinctions, but could prolong the process of identifying operational definitions.

5. HOW DO PBRS COMPARE WITH PATENTS?

There are more similarities than differences between patent and PBR systems. Both operate by temporarily privatizing something that would otherwise have been freely available in the public domain. A fee can be assessed for access as well as for any rewards derived through market sales. In their particulars, however, critical differences exist between PBRs and patents.

5.1 *Protection requirements*

Protection requirements for patents include novelty, inventive step (nonobviousness under U.S. law), and utility (or industrial application). The concept of novelty in the two systems is similar, although most patent systems operate with absolute novelty, or no prior public disclosure. Inventive step in the patent system is similar to the distinctness requirement in the PBR system. Patents have always operated with a dependency-type system similar to the initial variety concept in the 1991 UPOV Act, except that in the patent system there are no statutory (text-based) statements about the dependency relationship or how dependency might be achieved. A dependent patent could, for example, be an improvement on an existing product or process or a new use for an existing product. The new product/new use could be protectable in its own right, so that neither owner could use the other invention without permission. These details are worked out between interested parties.

The utility requirement, stated as simply as possible, means that some use for the product must be identified. When applied to patents for genes and gene fragments, the utility requirement has raised serious issues that generally do not exist for PBR. Protected varieties, as noted, are intended for sale and, under many examination systems, must display some practical merit. Uniformity and stability have no comparable requirements under patent law.

5.2 *Protectable subject matter*

With respect to protectable subject matter, the patent and PBR systems are quite different from each other. Under patent acts, everything is pat-

entable except for identified exceptions. One common exception is for "*plant and animal varieties.*" PBRs cover all genera and species, with certain minimums under the several acts, as follows:

- 1978 Act (Article 4): on adoption, three rising to at least 24 genera or species within eight years
- 1991 Act (Article 3): for new members on adoption, at least 15 genera or species, rising to all genera and species within ten years

5.3 *Other components*

PBR systems are distinct from patents in allowing an option, under the 1991 Act, for farmers to save seed for subsequent seasons. Under patents, such actions would constitute infringement. The breeder's right is statutory with PBR and hence is relatively clear in its scope. National patent systems do allow some research on patented inventions, but the form and extent of research allowed is based on case law and so this is more difficult to assess. The difference in this matter between patents and PBR is one of clarity alone; however, this makes research use under PBR a more clear-cut process than for patented inventions. Provisions for farmer's privilege (where allowed) and breeders' rights are generally considered to give holders of PBR certificates weaker protection than do patents. This helps explain why, where the choice is available, commercial breeders often prefer patents, or patents plus PBR, over PBR alone.

Patents are, however, typically far more costly to apply for and to maintain. The difference is not in the application fees structure, which may in fact be lower for patents, but rather, a patent usually requires an attorney's assistance to prepare the application. PBR applications are typically completed by the breeders. Adding the elaborate translation requirements under some patent laws, and the annual maintenance fees can also make patenting a costly process, compared with PBR.

6. CONCLUSIONS

Although some legal ambiguity does still exist within PBR legislation, the objectives of the system are specific, and the laws and provisions, if clearly understood, are manageable. The PBR system shares several features with more conventional patent systems, but the two systems differ in several crucial respects. As a sui generis system, PBR laws apply only to plants and plant materials. But they work, like patents, to prohibit unauthorized use of these materials.

UPOV establishes a framework to guide signatory nations in adopting PBR provisions in their own national laws. The acts have been amended several times; currently, most nations are operating under either the 1978 or the 1991 versions.

To be eligible for protection, a plant variety must demonstrate novelty, distinctiveness, uniformity, and stability. If protected, a potential user must seek permission from the owner before producing, selling, importing, or exporting the variety or, in some cases, products made from or with that variety. A few important exceptions to this apply; for example, a breeder's exemption allows researchers to use the variety for experimental purposes, and farmers are generally allowed to retain the variety for seed. In an important new component of the 1991 Act, if research produces a variety judged to be essentially derived from a protected variety, it cannot be commercialized without the permission of the initial variety's owner. ■

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1 www.upov.int.

Plants, Germplasm, Genebanks, and Intellectual Property: Principles, Options, and Management

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ABSTRACT

In ever-increasing numbers, institutions are establishing technology transfer offices (TTOs). These offices serve a variety of functions, all of which must be integrated to cost effectively transfer technologies and to benefit the institutions. A critical function of the TTO is to proactively manage intellectual property (IP) issues pertinent to crops. Crops can be covered by more than one form of IP rights protection, often simultaneously. These rights protections include trademarks, trade secrets, plant and utility patents, and plant variety protection (PVP). Closely related is the importance of careful and organized genebank management, a critical component of an overall IP and tangible property management system. PVP provides one type of protection that allows TTOs to responsively serve clients and generate revenue. PVP is a form of IP rights protection for crops with potentially global applications, and either a PVP office, or a PVP subsection in the TTO, would be wisely established by an institution. In addition, this chapter provides important information to assist in establishing a national PVP office and in the selection and implementation of various types of IP rights protection for crops and germplasm.

1. INTRODUCTION

Plants affect people's everyday lives in terms of quality and cost—the cost of food, feed, fiber, fuel, and other necessities. Plants provide raw materials for industry, such as vegetable oils, rubber, and drugs and other health care items. By 2020 the Earth's population is likely to reach 9 billion. To meet the increasing demand, annual global food production will have to increase to more than 3,000 million metric tons from the current 1,800 million metric tons. At the same time, productive farmland is, and will continue to be, diverted at an increasing rate to nonfarm uses, and access to water will continue to be a major limiting factor for agricultural productivity.

To address the challenge of meeting the needs of the world's growing population, plant breeders are developing improved plants that can produce more, while using less land and less water. As trained professionals whose endeavor is developing plants that are genetically equipped to produce higher yields of quality products, plant breeders will contribute significantly to meeting these challenges. While producing higher yields, these improved plants will also be more resistant to pests and diseases, so they can potentially reduce the need for large (and expensive) applications of fertilizers and crop protection chemicals. Finally, these plants reduce the need for additional irrigation from precious water resources, thereby contributing to further conservation.

The breeding of new plant varieties is thus an economically important activity that contributes in many different ways to the social and economic well-being of societies. In many cases, new plant varieties are absolutely essential for human survival. However, there are many

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challenges associated with crop breeding. For example, experience has shown that a breeder has difficulty recovering his financial investment when he sells his initial supplies in the first years of a new variety's life. The breeder's competitors can secure supplies of propagating material and, in a short time, be in a position to compete with the breeder, thus profiting from the many years of effort invested by the breeder. In this way, the rewards of the plant breeder's innovative efforts can be rapidly lost to himself or herself. The initial phase of protection is therefore critical, because developing new varieties in most plant species may take between ten and 20 years.

These new varieties are crucial to the needs of modern society. They contribute to a varied diet and provide for a wide choice of ornamental and amenity plants. Generating sufficient variety, however, requires substantial investment in crop breeding programs. Accordingly, many countries, while continuing to invest in public sector plant breeding research, have established open free-market systems in which exclusive rights of exploitation (patent-like protections) are granted to the breeders of new varieties of plants.

This chapter presents a general overview of the types of IP protections that are available for plants. It then focuses on plant variety protection (PVP) as one key example of plant IP rights protection, an option that can be broadly applied to the needs of developing countries.

2. DEFINITIONS

Before discussing some specific issues in relation to crops, germplasm, and genebanks, it is important to have a common understanding of what is meant by certain words:

- *breed.* To develop new or improved strains of organisms, chiefly through controlled mating or pollination and the selection of offspring for desirable traits.
- *breeding line*. Genetic group that has been selected and bred for special combinations of traits.
- *enhancement*. The process of improving germplasm accessions by breeding, while retaining the important genetic contributions of the accessions. This process may entail simple selection.
- *gene.* The fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides in a particular position, on a particular chromosome, encoding a specific functional product.
- *genebank*. A genebank is a special facility that stores living samples of the diversity of crop varieties and their wild relatives. These samples are usually in the form of seeds or other plant parts. Some of the plants that genebanks hold are extinct in the wild. The value of the genetic resources conserved in genebanks encompasses not only their current use value and expected future use value, but also the option value associated with the flexibility to respond to some unknown future events.
- *genetic resource.* Often used as a synonym to germplasm, this is a seed, plant, or plant part that is useful in crop breeding, research, or conservation because of its genetic attributes. Genetic resources are maintained for the purposes of studying, managing, or using the genetic information they possess.
- *improved material.* An elite breeding line.
- *landrace.* A population of plants, typically genetically heterogeneous, commonly developed in traditional agriculture from many years of farmer-directed selection and specifically adapted to local conditions.
- *public domain.* Public ownership status of information not protected by patents or copyrights.
- *wild species.* A species that has not been subject to breeding with intent to alter them from their wild state.

3. IP ISSUES THAT AFFECT GENETIC RESOURCE MANAGEMENT

It is useful to recall that plant breeding is a knowledge-based activity. Consequently, it is a nonexhaustive activity. In other words, the results of applying the knowledge are not decreased if shared with others. What is lost in sharing, however, is *market value*. In other words, a plant breeder who

has invested millions of dollars over many years cannot extract value if others appropriate the new variety and sell it at the mere cost of seed production. The free distribution of varieties provides the breeder with no incentive to invest. IP systems remedy this situation by providing a level of protection to breeders.

IP rights is a broad term for the various rights that the law provides for the protection of economic investment in creative effort. The principal categories of IP protections relevant to agricultural research are patents, plant variety rights, trade secrets, copyrights, and trademarks.

3.1 *Patents*

Patents are a statutory form of protection that allows an inventor rights of exclusivity on the sale or use of his or her invention for a limited period of time, in a particular territory, in exchange for a full public disclosure of the invention.

In the case of plants, there are two forms of patenting. The first is called a plant patent. It applies only to materials that are asexually propagated, such as pineapples and bananas. The second is called a "utility patent." This does not protect the plant per se, but rather the invention that is embodied in the plant (for example, a method for conferring insect resistance through the incorporation of resistant genes into the plant).

3.2 *Plant variety protection*

Plant variety protection (PVP) is another form of IP protection for plants. PVP gives the breeder exclusive rights to a new and distinct plant variety so that the breeder can exploit it.

The breeder is defined by the 1991 UPOV (International Union for the Protection of New Varieties of Plants) Convention as the person who bred, or discovered, and developed a variety. Therefore, protection is not limited to breeders who produce a variety as a result of crossing parent plants and selecting from the progeny. The term *breeder* also includes a person who discovers a mutation and converts that discovery into a cultivated variety by a process of selective propagation. Discovery itself, however, does not constitute breeding.

The PVP Act (PVPA), enacted in December of 1970 and amended in 1994, provides legal IP rights protection to developers of new varieties of plants that are sexually reproduced (by seed) or are tuber propagated. Bacteria and fungi are excluded. The PVPA is administered by the U.S. Department of Agriculture.

A Certificate of Protection is awarded to an owner of a variety after an examination shows that the variety is new and distinct from other varieties and is genetically uniform and stable though successive generations. The term of protection is 20 years, for most crops, and 25 years for trees, shrubs, and vines. The owner of a U.S.-protected variety has exclusive rights to multiply and market the seed of that variety.

The characteristics of the PVP systems are summarized in Table 1 and are compared both to plant patents and utility patents. A detailed discussion of PVP and its global applicability is published by Blakeney and colleagues.[1]

3.3 *Trade secrets*

U.S. trade secret laws have been used to protect in-house breeding materials, such as the inbred lines of maize used as parents of hybrids. These laws do not, however, protect against independent discovery or reverse engineering of products by the purchasers.

It should be remembered, moreover, that genetic resources have a *dual property* nature: they are physical material (tangible property) that may be associated with human-made improvements (IP). This dual nature is the reason for genetic resources to be, on the one hand, physical property in the form of germplasm and, on the other hand, IP in the form of modified genetic information constituting inventions, trade secrets, and new plant varieties.

3.4 *Copyrights*

Copyrights are becoming more important for protecting IP in the field of plant breeding because the databases that hold information about plant genes can often be copyrighted. Such copyrights

Table 1: Comparison of Plant Variety Protection Systems

Action or stipulation	UPOV 78	UPOV 91	TRIPS Compatible Patent Law[2]	Utility Patents (since 1985; United States)	Plant Patent Act (since 1930; United States)	PVP Act[3] (since 1970; United States)
Protects	Varieties of selected genera and species as listed	Varieties of all genera and species	All plant species and enabling technologies	Plant genotypes not normally found in nature	Asexually reproduced plants, including cultivated, mutant, and hybrid	Sexually reproduced plants
Excludes					Uncultivated and tuber-propagated plants	First-generation hybrids, uncultivated plants
Requires	Novelty, distinctness, uniformity, stability	Novelty, distinctness, uniformity, stability	Novelty, inventiveness, enablement	Novelty, utility, nonobviousness, enablement	Novelty, distinctness, stability	Distinctness, uniformity, stability
Disclosure			Description of novel characteristics and genealogy, enabling disclosure, deposit of novel material	Enabling disclosure, best mode disclosure, deposit of novel material	As complete as possible photographs or drawings	Description of novel characteristics and genealogy, seed deposit
Claims			Not determined	Varietal claim, generic claims, claims to plant genes, gene transfer vectors, processes for producing plants, and so on	Single varietal claim	Single varietal claim
Rights	Prevents others from producing for commercial purpose, offering for sale, marketing	Prevents others from producing or reproducing, conditioning for the purpose of propagation, offering for sale, selling or other marketing, importing, exporting, stocking for any purposes detailed above	Prevents others from making the patented product, using the patented process, or using, offering for sale, selling or importing for those purposes the patented product or the product obtained by the patented process (extends to harvested material)	Prevents others from making, using, or selling claimed invention, or from selling a component of the claimed invention	Prevents others from asexually reproducing, selling, or using claimed plant	Prevents others from importing or selling, sexually or asexually reproducing, distributing without proper notice, producing a hybrid or new variety, using the claimed plant
Exemptions	Exemptions for breeding and for farmers to save own seed mandatory	Exemptions for breeding except where new variety is essentially derived; optional farmers' exemption and only for use on same farm and subject to a license and/or fee; private use and research	Breeders' rights and farmers' rights, in principle compatible with TRIPS but not yet tested		Does not protect sexual reproduction of claimed plant; does not protect plant products	Exemptions for developing a new hybrid or variety and for farmers' saving and sale of seed; compulsory license provision
Duration of protection	15 years for most crops (20 years for grapevines and trees)	20 years for most crops (25 years for grapevines and trees)	20 years from date of filing	20 years from effective filing date (after 8 June 1995); 17 years from issue date (prior to 8 June 1995)	20 years from effective filing date (after 8 June 1995); 17 years from issue date (prior to 8 June 1995)	Protected while application is pending, plus 20 years from issuance date for most crops (25 years for vines and trees)
Priority				First to invent in the United States	First to invent in the United States	First to file in the United States or another UPOV member country
Double protection	Protection by both patent and PVP not allowed	Protection allowed by both patents and PVP				

Source: Modified from Krattiger and Potter.[4]

do not, however, affect trade in products developed using the protected information.

3.5 *Trademarks*

Trademarks can be used to protect brand names, such as Monsanto's Roundup Ready®. But trademarks protect only the names and other symbols denoting products or technologies, not the technologies themselves. Still, trademarks may give customers a proof of quality, and so they may be as important as variety protection.

4. "NON-IP" MATTERS AFFECTING GENETIC RESOURCES MANAGEMENT

As indicated above, there are tangible property rights that have a bearing on the ownership of genetic resources. The Convention on Biological Diversity (see below) affirmed the sovereign rights of nations over their genetic resources. Such ownership is a tangible property right on the ownership of the actual material.

There exist, however, a number of other non-IP matters that affect the day-to-day lives of genetic resource specialists working in the field. These most typically include indigenous knowledge issues and access to and transfer of materials.

4.1 *Indigenous knowledge*

The formal IP system of patents, PVP, copyrights, and so on is based on a set of statutory (legislative) rules. The current system allows so-called *prior art* to be used as a way of determining whether novelty exists with regard to an invention. The current formal system does not adequately allow for indigenous knowledge to form the basis of prior art or allow indigenous people to be the inventors or breeders. This has led to significant controversy in the international community. Both WIPO (World Intellectual Property Organization) and UPOV are actively reviewing and debating this topic to try to develop a mechanism that would prescribe a role for such knowledge within the formal system. One noteworthy example within a national program is the PVP Office of the Philippines' mechanism for allowing the registration of descriptors for indigenous materials. These descriptors are reviewed as part of the examination process for awarding a PVP certificate.

4.2 *Material transfer agreements*

When genetic resources are transferred, it is increasingly common for them to be accompanied by an MTA. Such a document forms a contractual relationship between the shipper and the recipient. It is common for MTA agreements to attach terms and conditions regarding both the approved use of genetic resources and the rights to ownership of such materials or their derivatives.

MTA agreements can appear in a number of forms. While the most common is a conventional sheet of paper, it is also possible for the material to come with language included on the bag. The use of so-called bag-tag language is becoming increasingly common. At issue, however, is whether the "shipper" who applies the MTA language actually owns title to the materials and has the right to allocate ownership rights.

5. INTERNATIONAL TREATIES

Generally, plant genetic resources are governed by national, regional and international laws, which regulate ownership, access, and benefit sharing. Internationally, these concerns are regulated by treaties such as the CBD, the International Union for the Protection of New Varieties of Plants (UPOV) Convention, the International Treaty of Plant Genetic Resources, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

5.1 *The Convention on Biological Diversity (CBD)*

The CBD is the central instrument related to international biodiversity. It broadly delimits the rights of states and other relevant actors over biological resources and affirms the sovereign rights of states to exploit their own resources pursuant to their own environmental policies. The sovereign rights of states over their own biological resources are limited by the recognition that these resources are a common concern of humankind.

The Convention also provides a broad framework for member states' policies concerning access, development and the transfer of technologies. It also acknowledges the necessity for all parties to recognize and protect IP rights in this field. The Convention further recognizes both the dependence of local communities on biological resources and the roles that these communities play in the conservation and sustainable use of these resources. Finally, it points to the need for equitably sharing the benefits that arise from the use of traditional knowledge, innovations, and practices.

5.2 *UPOV*

The UPOV Covention is the only international treaty focusing on PVP. It recognizes not only the rights of individual plant breeders who have developed or discovered plant varieties that are new, distinct, uniform, and stable, but also accords certain rights to farmers. Under the 1978 version of the Convention, farmers are permitted to reuse propagating material from the previous year's harvest, and they can freely exchange the seeds of protected varieties with other farmers. Plant breeders are also allowed to use protected varieties to breed and commercialize other new varieties.

The latest revision of the Convention, adopted in 1991, has further strengthened the rights of commercial plant breeders. These revisions include the obligation for member states to provide protection to all plant genera and species. Furthermore, it extends breeders' rights to all seed production of a protected variety, even though countries can decide on their own internal laws regarding this issue. In some cases, the revision grants to commercial breeders the rights to the harvested material of the variety and extends protection to varieties that are "essentially derived" from a protected variety.

5.3 *The International Treaty on Plant Genetic Resources for Food and Agriculture*

The International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by consensus of the member states of the United Nations Food and Agriculture Organization (FAO) in November 2001. The Treaty envisions a multilateral system to facilitate access to key genetic resources, with minimal procedural and administrative costs. Initially, the treaty applies to 35 crops and some 80 forages that are under the control of member governments and that are not subject to IP rights. Thus, the treaty includes practically all the crops that humanity depends on for its food supply. The treaty invites all holders of listed plant genetic resources to join the multilateral system. The list itself can be changed with the consensus of the parties to the treaty.

The multilateral system is intended to be efficient, effective, and transparent. It aims to ease access, not only to plant genetic resources for food and agriculture, but also to information about those resources, so that any benefits that may arise from their use can be shared fairly and equitably.

In this context, it is worth dwelling briefly on the difference between *farmers' rights* and *farmers' exemption/privilege*. Because the terms are often used interchangeably, there has been significant confusion regarding their use. *Farmers' rights* is a term developed by FAO under the Revised Undertaking for Plant Genetic Resources. Resolution 5/89 of the treaty states, "*…rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources.*" Resolution 3/91 states that these rights are to be "*implemented through an international fund on plant genetic resources that will support plant genetic conservation and utilisation programmes, particularly, but not exclusively, in the developing countries….*"

The difference is further elaborated in the FAO Treaty. However, no specific future action is targeted here; instead, the treaty gives voice to a general equity objective. These areas are still the subject of much debate, and the mechanism with which to ensure both participation and benefit sharing has not yet been elucidated.

The concept of farmers' exemption or farmers' privilege in PVP legislation, on the other hand, hinges on the notion that a farmer has a right to "fair use" of his or her own produced seed. Most national legislations embrace this notion of fair use, as do UPOV's model laws, and allow farmers to use seed produced on their own

farms for further sowing. Only if the farmer sells or trades the seeds is an infringement of the PVP holder's rights committed. Article 15 of UPOV 1991 states that:

a) [Compulsory exception] The breeder's right shall not extend to:
   (i) Acts done privately and for non-commercial purposes;
   (ii) Acts done for experimental purposes; […]

b) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest that they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

5.4 *The TRIPS Agreement*

TRIPS was the result of an initiative by developed countries to introduce more stringent IP rights trade rules. The agreement sought to extend the security of IP rights internationally. Article 27.1 of the TRIPS Agreement implies that patents may be available in biotechnology fields, a position that Article 27.3 consolidates with regard to granting IP rights in biotechnology, particularly as it relates to plants.

6. SPECIFIC ISSUES RELATED TO GENEBANK MANAGEMENT

A genebank manager addresses both the many technical aspects relevant to the use of genetic resources and issues related to the ownership of genetic resources. As outlined below, these issues usually come in different phases of the work.

In accordance with the CBD, incoming material must be acquired with the consent of the nation that "owns" these resources. This is achieved through a germplasm acquisition agreement (GAA) or an MTA that clearly indicates the rights that the owner is giving to the genebank in terms of using and distributing such materials.

In-house materials may include those acquired prior to the CBD. These may be in the form of genebanks, botanic gardens, and so on. While the ownership of in-house materials is still contentious, the law is clear that such materials may be used freely without prior permissions. It is very important here to distinguish between "genetic resources" collected in nature and "improved materials." IP rights will attach only to the latter. Indeed, a sound knowledge of the biology of the materials and the ownership and legal rights associated with them is essential.

Outgoing materials are those materials the genebank manager distributes to others, either for research, direct use, or for use in improvement programs. This is often when problems arise. Carefully using appropriate MTAs is the most effective way to deal with these issues. The MTA should reflect a range of matters: international law, policy of the organization, nature of the material, nature of the recipient, nature of the acquisition of the material, and conditions relating to incoming MTA on the material (see examples included in this *Handbook*).

Genebank management has recently become a very sensitive issue. An organized, stepwise approach is vital for effectively managing a genebank and for avoiding difficulties. Potential ownership issues about genetic resources must be clearly analyzed, and documentation procedures for the acquisition and distribution of such materials must be effective and thorough.

The legal issues surrounding genebanks have changed dramatically over the last decade. Such changes will continue, and genebank managers must be alert to the effects of these changes. When appropriate, managers should seek professional advice about how these changes affect their respective institutions. Genebank managers must not, however, lose sight of their crucial social role: they guard and preserve the basic building blocks upon which human survival and food security depend. They work not only for this generation but for generations to come.

7. PVP: IP PROTECTION FOR CROP VARIETIES

PVP addresses a specific need that applies broadly across the globe, in both developed and developing countries. So-called PVP regimes are implemented in order to:

- provide breeders (both public and private sectors) with an opportunity to receive a reasonable return on past investments
- provide an incentive for continued or increased investment in future breeding research
- recognize the legal right of the innovator to be recognized as such
- acknowledge his or her economic right to remuneration for his or her efforts

In order to foster these laws and agreements within the global economy, UPOV was formed through a union of states. These states agreed to grant exclusive exploitation rights to the breeders of new plant varieties on an internationally harmonized basis. UPOV developed a set of model laws that provided a general legislative framework for PVP. Indeed, some provisions of TRIPS refer to the use of UPOV standards as an effective mechanism for complying with WTO standards. One very effective aspect of this arrangement is the provision for mutuality, which allows cross protection between jurisdictions for states that are members of the UPOV system. Countries often use the model law produced by UPOV as a framework for developing their own legislative standards. This is not to say that the system is wrinkle free. For example, the differences between protected varieties and other forms of plant genetic material (including genetic resources and landraces) has yet to be established.

The U.S. system is a useful model and because of the UPOV system's efforts toward harmonization, most of the provisions in the U.S. PVP system are consistent with those in other jurisdictions. It should be noted that many jurisdictions have patent laws allowing for the protection of plants. This is complementary to the PVP legislation. It is possible, and increasingly common in the United States, for protection to be taken on the variety, and, in addition, for a patent on the inventive nature of the product and/or process to be filed. Finally, the new variety name is usually trademarked. (For more information about the U.S. PVP system, see section 3.2.)

The model law of UPOV, and effectively of all national legislatures, also allows a government to issue a compulsory use license. In effect, if a country has a compelling need to multiply a protected variety, then the government can issue a license for its use. The PVP holder would, however, still have the legal right to be given a reasonable royalty payment.

To qualify as a protected variety, the plant variety coming out of a breeding program must be able to demonstrate:

- distinctness
- uniformity
- stability

The way in which these criteria are met is described in more detail in section 7.3 below.

7.1 *PVP application process*

PVP application forms and the supporting documentation, such as the UPOV crop guides, will guide the applicant (and examiner) through the steps of describing the history, breeding origin, and variety, making seed deposits, paying fees, and, if all is as required, obtaining a PVP certificate. If application materials exist, the relevant ministry of agriculture will have them; if application materials are not available, this chapter provides information to help develop them.

Anyone who is the owner, breeder, developer, or discoverer of a unique cultivar of a sexually reproduced or tuber-propagated plant may apply for PVP. This applies to any citizen in any UPOV member country. The applicant may be an individual, a public institution, or a corporation.

The protection works by prohibiting a person from selling, marketing, offering, delivering, consigning, exchanging, or exposing the variety for sale without explicit consent of the owner. In addition, a person is prohibited from soliciting an offer to buy the variety, or transfer or possess it in any manner. It is also illegal to import or export the variety, sexually multiply it, propagate it

by tuber, use the variety in producing (as distinguished from developing) a hybrid, or condition the variety for the purpose of propagation. It is worth adding here that plant parts (flowers, pollen, and so on) are also protected. This is critical in reviewing infringement actions to determine where the material has been used.

7.2 *Exemptions*

In general, there are two exemptions to the protection provided: 1) a research exemption and 2) a farmer's exemption (also called farmer's privilege).[5]

A *research exemption* allows for breeding to develop a new variety; a *farmer's exemption* allows for the saving of seed for the sole use of replanting the farmer's land. However, if the farmer sells or trades the seeds, he infringes on the rights of the PVP holder. The controversies surrounding this provision turn largely on the definition of terms. It should be noted that neither plant patents nor utility patents provide these exemptions.

7.3 *Examination standards*

The owner must prove the distinctness, uniformity, and stability of the new variety. The burden is entirely on the applicant.

For distinctness, the applicant may:

- list the single variety he or she believes is most similar to the new variety and describe how the new variety differs from it
- list a group of varieties that are similar to the new variety and describe how it differs from varieties within that group
- describe how the variety differs from all other known varieties in the crop kind

The PVP office maintains databases of both public and private varieties of crops. The examiner uses these and other sources to determine which, if any, varieties are indistinguishable from the new one. If the examiner finds varieties that appear to be indistinguishable from the application variety, the applicant will be notified that supplemental data is necessary. To obtain additional data, applicants may perform additional field or greenhouse replications and may use DNA profiling and other analyses to substantiate distinctness. In the United States, the PVP office does not perform tests to confirm the distinctness of a variety. That responsibility rests with the applicant.

For uniformity, a statement must report the level of variability in any characteristic of the variety. Variation, which is predictable, describable, and commercially acceptable, may be allowed.

For stability, a statement of genetic stability is required, showing the number of cycles of seed reproduction for which the variety has remained unchanged in all distinguishing characteristics.

Special mention should be made of essentially derived materials. Good examples are so called "sports." If PVP protection has been obtained on a potato variety that has a red skin after decades of breeding, and then someone selects a field sport with a white skin, the new white skin material is determined to be essentially derived from the original variety and will be protected under the 1991 UPOV act.

7.4 *Enforcement*

The owner of a protected variety may bring civil action against persons infringing on his or her rights, and the owner may ask a court to issue an injunction to prevent others from further violations. The owner of the protected variety must bring suit in such cases—the USDA will not take that action. In the United States, IP protection for plants is provided through plant patents, PVP, and utility patents. Plant patents provide protection for asexually reproduced (by vegetation) varieties excluding tubers. PVP provides protection for sexually (by seed) reproduced varieties including tubers, F_1 hybrids, and essentially derived varieties. Utility patents currently offer protection for any plant type or plant parts. A plant variety can also receive double protection under a utility patent and PVP.

7.5 *Contents of a complete application and exhibit forms*

A PVP application consists of a completed and signed form that includes Exhibits A, B, C, and E (Exhibit D is optional):

A) Exhibit A (Breeding History)

B) Exhibit B (Statement of Distinctness, previously called "Novelty Statement")
C) Exhibit C (Objective Description)
D) Exhibit D (Additional descriptive Information)
E) Exhibit E (Statement of Ownership)

Also required is a sample of at least 2,500 untreated viable seeds, capable of propagating the application variety, and, for a tuber-propagated variety, verification that a viable cell culture will be deposited. A check for the filing fee is also required.

7.5.1 *Exhibit A: Breeding History*

The applicant is required to provide the following:

- full disclosure of the genealogy back to publicly known varieties, lines, or clones, including the breeding method
- details of subsequent stages of selection and multiplication used to develop the variety
- statement of uniformity reporting the level of variability in any characteristics of the variety (commercially acceptable variability is allowed)
- statement of genetic stability showing the number of cycles of seed reproduction for which the variety has remained unchanged in all distinguishing characteristics
- information about the type and frequency of variants observed during reproduction and multiplication
- information about the frequency of off-types (in other words, impure lines) observed or known to occur

7.5.2 *Exhibit B: Statement of Distinctness*

The applicant is required to give a summary of the variety's distinctness, stating clearly how the application variety may be distinguished from all other varieties in the same crop. If the variety is most similar to one variety or group of varieties, the applicant must (1) identify these varieties and state all differences objectively, (2) attach statistical data for characters expressed numerically and demonstrate that these are clear differences and (3) submit, if helpful, seed and plant specimens or photographs (prints) of seed and plant comparisons that clearly indicate distinctness.

7.5.3 *Exhibit C: Objective Description of Variety*

The PVP office has prepared forms for the applicant to provide a botanical description of the variety for most crops. These forms list the botanical characteristics for a kind of crop and the degree of expression of each characteristic. These forms also provide a list of recommended varieties that the applicant should compare to the application variety. The applicant needs to complete the form for his or her variety as thoroughly as possible.

7.5.4 *Exhibit D: Optional Supporting Information*

The applicant may provide additional information, specimens, and/or materials in support of the claims of the application.

7.5.5 *Exhibit E: Statement of Ownership*

The applicant is required to furnish a statement for the basis of the applicant's ownership. The PVP office has prepared a form to simplify this requirement. The form also includes a statement to verify that the applicant is eligible to file for PVP in the United States.

7.6 *Steps needed to start and operate a national PVP office*

You may be reading this chapter because you are in the process of setting up a PVP office. If that is the case, then the topics below will help you effectively and efficiently establish the office.

The basic operation of this office and its actions can be translated into the following steps:

1. **Setting up the office.** The initial setting up of the office will have a physical component (obtaining the necessary space, equipment, and other physical resources) and a legislative component (setting up the laws and regulations, and examining guidelines).
2. **Appointing the staff.** A registrar for the PVP office, a number of examiners, and support staff, both clerical and technical, will need to be appointed.
3. **Training the staff.** The PVP office staff needs to be trained in both the technical

processes related to the examination and the legal and clerical matters related to issuing and registering the certificate.

4. **Establishing the formal procedure.** The office must set up formal procedures, such as law enactment, rule approval, and examination standards.
5. **Notifying the public that the office is functional.** Once the PVP office is functional, staff must inform the public that they may avail themselves of the services the office provides.
6. **Distributing information and application material.** As part of the public awareness campaign, staff should make information and forms publicly available. In an increasing number of jurisdictions, application forms are available online at the PVP office Web site.
7. **Informing and educating the public about how to apply.** Attorneys and agents may need to be educated about the actual mechanics of preparing and submitting applications.
8. **Receiving application.** The filing date is a critical component of the application process, and detailed rules should inform applicants about the application filing date.
9. **Reviewing the applications.** This is the heart of the process. Applications are reviewed (1) for compliance with general applications standards and (2) for technical content.
10. **Examinations standards and their application.** The 1991 UPOV act, the rules, and possibly the examiner's manual provide an objective set of standards that can be applied to particular applications. The importance of such objectivity for the credibility of the system cannot be overstated.
11. **Communicating with the client.** Effective communication with the applicant is absolutely essential. All correspondence must be consistently dated, numbered, and sent by registered or certified mail.
12. **Communicating with policy-makers.** When establishing the office, it will be crucial to keep in very close communication with senior policy-makers. The act and regulations will need legislative action, and they must also be consistent with other domestic laws. Regulations will also often need to comply with WTO requirements.
13. **Storing deposits.** Facilities must be arranged for storing exhibits of the materials.
14. **Preparing certificates.** A format and style must be established for the production and registration of PVP certificates.
15. **Dealing with disputes.** The legislation and regulations will usually contain provisions allowing for applicants who are refused a PVP certificate to appeal the decision either through the PVP office and/or through the judicial system.
16. **Sample deposits.** An appropriate, adequate system must be in place for applicants to deposit seed or plant materials. This facility may belong to the ministry of agriculture in most countries or may be managed by a related organization. The facility should meet appropriate international seed storage guidelines and have adequate mechanisms for safekeeping/security of the seed samples.

8. CONCLUSIONS

It is clear that a PVP regime effectively harmonized across different countries would significantly lower the costs for users, and hence increase returns on plant-breeding investments. This would undoubtedly lead to more varieties and more choices for farmers. A costly regime, on the other hand, discourages smaller national companies from filing for PVP protection and increases the cost of participating in foreign markets that, in turn, favors large multinational companies with the resources and infrastructure to operate across multiple national regimes.

All of the IP protection mechanisms discussed in this chapter depend upon enforcement by national governments. If a law is only as good as its enforcement, then a regulatory body such as a PVP office is only as good as the people who

implement the regulations. In order to reinforce national policy initiatives in many countries, a comprehensive, in-depth training program is recommended to equip personnel with the information and experience required to establish the long-term health of a PVP system. This training could be combined with a coordinated effort to regionalize the PVP system through jointly training administrators from a number of countries, which would increase cooperation and harmonization within the region.

Of course, different people within the system require different training. As a starting point, all participants, whether officers, management, or even individuals in breeding companies, need to be brought to a certain minimum level of competence in the application of the regulations. A general program, such as a Web-based training course or other distance-learning approaches, could help to achieve this goal. For management staff, tailored workshops could be used to expose staff members to areas of conflict and to increase their knowledge of the importance of PVP in the development of plant breeding businesses. These courses and workshops could be augmented by an internship program, in which selected individuals would be given more intensive training through collaboration with public and private institutions from countries with well-established PVP systems. These highly trained individuals could form a core group that would then further develop staff expertise. ■

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1 Blakeney M, JI Cohen and S Crespi. 1999. Intellectual Property Rights and Agricultural Biotechnology. In *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (ed. JI Cohen). pp. 209-227. CAB International Press; Blakeney M. 1999. Agricultural Research and the Management of Intellectual Property. In *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (ed. JI Cohen). pp. 228-40. CAB International Press.

2 Modified from Helfer LR. 2002. Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments FAO Legal Papers Online, No. 31. www.fao.org/Legal/Prs-OL/lp031.pdf.

3 The initial PVP Act of the United States was not UPOV compliant, but in 1980 the United States acceded to UPOV 1978 and later to UPOV 1991. A further jump in investment was seen after 1986 when the U.S. Patent and Trademark Office established that plant varieties were patentable subject matter.

4 Krattiger AF and RH Potter. 2002. The Status of Plant Variety Protection Issues in the Asia-Pacific Region: An Overview. *Asian Seed* 9(5): 17–20.

5 Farmer's exemption or farmer's privilege should not be confused with "Farmer's Rights". Farmer's rights is a concept that became popular during the 1980s through the FAO Revised Undertaking for Plant Genetic Resources (Resolution 5/89) in an attempt to recognize and reward the *"...rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources..."* (see www.fao.org/docrep/X0255E/x0255e03.htm for a detailed history). The term now constitutes a central element in the International Treaty on Plant Genetic Resources for Food and Agriculture where it is called "Farmers' Rights." ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf.æ

Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm: Legal Aspects of Sui Generis and Patent Regimes

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ABSTRACT

This chapter outlines the range of plant variety protection regimes that currently exist internationally, including the International Convention for the Protection of New Varieties of Plants, the Convention on Biological Diversity, the Agreement on Trade-Related Aspects of Intellectual Property Rights, and the International Treaty on Plant Genetic Resources for Food and Agriculture. The chapter commences with a history of intellectual property laws affecting plant breeding and the genetic modification of plants. It explores the trend toward the harmonization of international standards and concludes with an examination of the impact of these developments upon germplasm exchange, international agricultural research, and food security.

1. INTELLECTUAL PROPERTY RIGHTS AND AGRICULTURE

The first international intellectual property (IP) convention was the 1883 Paris Convention for the Protection of Industrial Property. In this instrument, agriculture was envisaged as an area of enterprise in which property rights could be secured, thus Article 1(3) of the Paris Convention declared that:

> *Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.*

Given the state of technology in 1883, the inclusion of these agricultural subjects within the Paris Convention was for the purpose of protecting trademarks and indications of source.

The first inclusion of biological agricultural innovations in an IP statute was in the U.S. Plant Patents Act of 1930, which created a sui generis system confining protection to asexually reproduced plants, so confined because of the view that sexually reproduced varieties lacked *stability*.[1] The Act also excluded tuber-propagated plants principally because of a concern that protecting such plants would lead to monopolies in basic foodstuffs such as potatoes.[2] Applicants for plant patents were required to asexually reproduce the plant for which protection was sought, to demonstrate the stability of the characteristics of the plant being claimed. Section 161 required that new varieties be "*distinct.*" The statute did not define this requirement, although the Senate Committee report accompanying the act stated that "*in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties*" and that it was not necessary for the new variety to constitute "*a new species.*"[3]

Legislation similar to the Plant Patents Act was adopted in Cuba in 1937, in South Africa in 1952, and in the Republic of Korea in 1973.

Blakeney M. 2007. Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm: Legal Aspects of Sui Generis and Patent Regimes. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2. INTERNATIONAL STANDARDS FOR SUI GENERIS PVP

As with other categories of IP, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. The Congrès Pomologique de France, held in 1911, had called for special protection for plant varieties. This agitation continued in the 1920s and 1930s, culminating in the founding, in Amsterdam in November 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). At its Semmering Congress in June 1956 a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of new plant varieties. In February 1957, the French government issued invitations to 12 western European countries[4] to attend a diplomatic conference in Paris in May of that year to consider establishing such a system. Participation was limited by the French to those states who were known to have similar concerns to it on this subject. The conclusions of the 1957 Paris conference were set down in its Final Act, adopted in May 1957. This recognized the legitimacy of breeders' rights and established as the preconditions for protection that a variety had to be distinct from pre-existing varieties and sufficiently *homogenous* and *stable* in its essential characteristics. The act defined the rights of the breeder and acknowledged the principle of the independence of protection. At the second session of the conference, held in Paris in late 1961, the International Convention for the Protection of New Varieties of Plants, or Union pour la Protection des Obtentions Végétales (UPOV), was adopted. Article 4(1) applied the Convention to "*all botanical genera and species,*" but it was envisaged that the Convention would have a gradual introduction. A list of 13 genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, Lucerne, red clover, ryegrass, lettuce, apples, and roses or carnations. Article 4(3) required each member state, upon entry into force of the Convention, to apply it to at least five genera from this list and, within eight years, to all the listed genera.

Article 27 of the 1961 Convention provided for its periodic review, with the first revision scheduled for 1972. Within the first 19 years of its life, the UPOV Convention had attracted the accession of only 12 states. A reason identified for the reluctance of states to adopt the Convention was the stringency of its provisions, in particular the obligation of states to select either patent or UPOV-style protection for plant varieties, but not both. Article 2 of the Convention was amended to permit the accession of countries, like the United States, which had laws allowing for the double protection of varieties under both patent and UPOV-style sui generis laws. The list of genera, annexed to the 1961 Convention was removed. This list had contained mainly species from temperate climates. Under the new Article 4, member states agreed to apply the Convention to at least five genera, rising to 24 genera within eight years. Additionally, a grace period was introduced to permit the marketing of varieties for up to 12 months prior to submitting an application for plant variety protection (PVP).

A further broadening of the UPOV Convention occurred with the 1991 revision. The 1991 Act requires states to protect at least 15 plant genera, upon becoming members, and to extend protection to all plants within 10 years (Article 3(2)). In response to demands from breeders in developed countries, the 1991 Act removed the prohibition against dual protection. The 1991 Act recognized *breeders' rights* to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as were not "*essentially derived*" from protected varieties (Articles 14(5) and 15). The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has, however, proved highly controversial in practice. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.[5]

From the perspective of farmers, probably the most contentious aspect of the 1991 Act was the limitation of *farmers' rights* to save seed for propagating "*on their own holdings*" the product

of the harvest that they obtained by planting a protected variety on their own holdings, "*within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder*" (Article 15(2)). Unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes. This is criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.[6]

A number of developing countries have resisted the adoption of the 1991 Act as the standard for PVP laws. The foreign ministers of the *Organization for African Unity* issued a statement at a January 1999 meeting calling for a moratorium on IP protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities.

3. THE UPOV SYSTEM

In most countries the implementation of the UPOV Convention requires domestic legislation.

3.1 *Scope of plant breeders' rights*

Generally, the *plant breeders' rights (PBRs)* conferred by domestic legislation modeled on UPOV are defined as the exclusive right to do or to license the following acts in relation to propagating material of the plant variety:

- produce or reproduce the material
- condition the material for the purpose of propagation
- offer the material for sale
- sell the material
- import the material
- export the material
- stock the material for all of the purposes described above

3.2 *Exceptions*

Excepted from these rights, under the UPOV Convention, are acts performed privately and for noncommercial purposes, for experimental purposes, or for the purpose of breeding other plant varieties. As was mentioned above, seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land is considered not to be an infringement by legislation based on UPOV 1991.

Legislation may also provide that PBRs are not infringed when propagating material is used as a food, food ingredient, or fuel, or for any other purpose not leading to or involving the production or reproduction of propagating material.

Also, it may be provided that PBRs are exhausted following the sale of propagating material by a grantee unless there is a multiplication of the material after the sale.

3.3 *Duration of plant breeders' rights*

The general duration of PBRs, provided by legislation implementing UPOV 1991, is to be 25 years in the case of trees and vines and 20 years for any other plant type. This duration period commences on the date of grant of PBRs in the variety. Where a plant variety is declared to be essentially derived from an initial variety, the total duration of protection for the dependent or essentially derived variety generally can last for no longer than the duration of the protection of the initial variety.

3.4 *Application for plant breeders' right*

Eligible applicants are usually plant breeders who are citizens or residents of the country in which they are applying for the permit, if the variety is bred in the country. On the other hand, a country might permit anyone, domestic or foreign, to apply for a variety under the country's laws.

Ineligible applications will generally involve varieties previously sold in the country.

3.5 *Form of application*

The form of application for PBRs will be prescribed by the national legislation. It will provide that an application must contain:

1. the name and address of the applicant
2. the name and address of the agent, if any, making the application on the applicant's behalf
3. a statement to that effect if the applicant is the breeder of the variety

4. if the applicant is not the breeder of the variety, details of the applicant's right to make the application
5. a brief description, with a photograph, if appropriate, of a plant of the variety sufficient to establish a *prima facie* case that the variety is distinct from other varieties of common knowledge
6. the name, and any proposed synonym, for the variety
7. particulars of the location at which and the manner in which the variety was bred, including particulars of the names by which the variety is known and sold in the country and particulars of any PBRs granted in the country or in another country that is a signatory to the UPOV Convention
8. particulars of any application for, or grants of, rights of any kind in the variety in any other country
9. the name of an approved person who will verify the particulars of the application and who will supervise any test growing of the variety required under Section 37 of the Act and who will verify a detailed description of the variety; and
10. such other particulars, if any, as are required by the approved form.

3.6 *Application fee*

An application fee will usually be prescribed under the legislation.

3.7 *Acceptance or rejection*

The authority or official that is responsible for the administration of the relevant law will be required to decide, as soon as is practicable after an application is filed, whether to accept or reject the application. Where the authority or official is satisfied that the application is prior in time to any other application and that it complies with the requirements of the legislation and establishes a prima facie case for treating the plant variety as distinct from other varieties, the application must be accepted. Upon acceptance, the applicant must be notified that the application has been accepted and public notice of the acceptance must also be given. Similar notification obligations apply when an application is rejected.

3.8 *Variation of application*

After an application for PBRs has been accepted, but before concluding the examination of that application, the authority or official may permit an applicant to vary an application, subject to the payment of a prescribed fee.

An application is usually permitted to be withdrawn by an applicant at any time. If this occurs after public notice of the application, the authority or official must, as soon as is practical, give public notice of the withdrawal.

3.9 *Detailed description of the plant variety*

Whenever it is practical, but not later than 12 months after an application has been accepted, or within such further period granted by the authority or official, the applicant is usually required to give a detailed description of the plant variety to which the application relates. Failure to supply this description will result in the application being deemed to have been withdrawn. The detailed description must be in writing and in an approved form, containing particulars of:

1. the characteristics that distinguish the plant variety from other varieties, the existence of which is deemed a matter of common knowledge
2. any test growing carried out
3. any test growing outside the country that tends to establish that the variety will, if grown in the country, be distinct, uniform and stable; and
4. other such particulars that may be prescribed.

3.10 *Objection to an application for PBRs*

The administering authority is usually obliged to give public notice of the detailed description as soon as is practicable after it has been received. A person may object to an application for PBRs if they can establish that their commercial interests would be affected by the grant of PBRs to the applicant and that the authority cannot be satisfied that the various substantive requirements of the law have been met by an applicant.

The objection must set out the particulars of the manner in which the person believes his or her commercial interests would be affected and the reasons why the person considers that the authority cannot be satisfied that the various substantive requirements of the law have been met.

3.11 *Inspection of application and objections*

A person may, at any reasonable time, inspect an application for PBRs over a plant variety, or an objection lodged in respect to that application. Upon payment of a prescribed fee, a copy of an application or an objection to an application is to be provided.

3.12 *Test growing of plant varieties*

In the case of an application that has been accepted, or an objection to such application, or a request for revocation of PBRs, the authority may require a test growing, or a further test growing, of the variety. In such case, notice may be required to be provided to all relevant persons. The notice, in addition to telling the applicant, objector, or grantee of the authority's decision, must specify the purpose of the test growing and may require the person to supply the authority with sufficient plants or propagating material and with any necessary information to permit the authority to arrange a test growing, or to make arrangements for an approved person to supervise the test growing and to be supplied with plants or propagating materials. The expense of a test growing must be borne by the applicant, objector, or person requesting revocation of the PBR. Provision may be made for a test growing outside the country of a plant variety that was bred outside the country.

3.13 *Provisional protection*

Where an application for PBRs is accepted, the applicant is taken to be the grantee of that right from the date that the application is received until the application is disposed of. During this period of provisional protection, the applicant is prevented from commencing any infringement action with respect to the PBRs, until such time as the application is finally resolved in the applicant's favor.

3.14 *Declarations of essential derivation*

Where a person is the grantee of PBRs over a particular plant variety (the initial variety) and another person is the grantee of, or has applied for, PBRs in another variety (the second variety) the grantee of PBRs in the initial variety may seek a declaration that the second variety is an essentially derived variety of the initial variety. A plant variety is defined to be an essentially derived variety of another plant variety if:

1. it is predominantly derived from the other plant variety
2. it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and
3. it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.

The application for essential derivation must be in an approved form and contain such information relevant to establishing a prima facie case of essential derivation. If the authority is satisfied, or not satisfied, as the case may be, that a prima facie case has or has not been established, the applicant and the grantee of PBRs in the second variety must be informed and provided an opportunity to rebut the prima facie case. The authority may order a test growing in order to rebut a prima facie case of essential derivation.

3.15 *Grant of PBRs*

Where an application for PBRs in a plant variety is accepted, the law will provide that following examination of the application. The authority must grant the right to the applicant where it is satisfied that:

1. there is such a variety
2. the variety is registrable within the law
3. the applicant is entitled to make the application
4. the grant of that right is not prohibited by the law
5. the right has not been granted to another person
6. the name of the variety complies with Section 27

7. propagating material of the variety has been deposited for storage, at the expense of the applicant, in a genetic resource center approved by the authority
8. a satisfactory specimen plant must be supplied to a prescribed herbarium; and
9. all fees have been paid.

PBRs are granted by the issue of a certificate in approved form.

3.16 *Effect of a grant of PBRs*

If a person is granted PBRs over a plant variety, the grantee will take precedence over any other person who was entitled to make an application for the right in the variety. Such person is not prevented, however, from applying for a revocation of rights or to seek administrative review of the authority's actions in relation to the grant of PBR or to request the authority to make a declaration that the variety over which rights were granted was essentially derived from another plant variety. Where it has been determined that another person was entitled in law or equity to an assignment of the right to make an application for the PBRs, that person may be entitled to an assignment of the PBRs.

Where the relevant Minister for Agriculture considers it appropriate, PBRs may be granted subject to conditions. The Minister would probably take the advice of any Plant Breeders' Rights Advisory Committee established under the law.

3.17 *Revocation*

There may be provision for the revocation of PBRs, or a declaration that a plant variety is essentially derived from another plant variety, if the authority becomes satisfied that facts had existed that, if known before the grant of the right or the making of the declaration, would have resulted in the refusal to grant the right or make the declaration. Revocation may also result from a failure to pay prescribed fees. Within a prescribed number of days of the decision to revoke, the grantee or transferee of PBRs may be provided with particulars of the grounds of proposed revocation.

Applications for revocation may be made by a person whose interests are affected by the grant of PBRs over a plant variety or by a declaration of essential derivation. In the event of revocation or surrender of PBRs, particulars of revocation or surrender will usually be entered in the PBRs Register and published.

3.18 *Compulsory licensing*

National laws usually require the grantee of PBRs in a plant variety to take all reasonable steps to ensure reasonable public access to that plant variety. This requirement is considered to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand. For the purpose of ensuring reasonable public access, the law may permit the relevant authority to license an appropriate person to sell propagating material of plants of that variety, or to produce propagating material of plants of that variety for sale, during such period as the authority considers appropriate and on such terms and conditions (including the provision of reasonable remuneration to the grantee) as the authority considers would be granted by the grantee in the normal course of business.

A person may make a written request to the authority for the grant of a license where a person considers that a grantee is failing to ensure reasonable public access to a plant variety and that failure affects that person's interests. The request must set out particulars of the alleged failure and of the effect upon the person's interests. The authority is then usually required to provide the grantee an opportunity within a prescribed period to satisfy the authority that the grantee is providing reasonable public access to a plant variety, or that he or she will comply within a reasonable period of time. Where the authority decides to grant a license, a public notice will be issued identifying the variety, detailing the particulars of the license that is proposed to be granted and an invitation to persons to apply for a license. The authority is usually required to consider all applications and publicly notify the proposed licensee, as well as notifying each of the applicants.

3.19 *Infringement of PBRs*

Generally speaking, PBRs in a plant variety are infringed by an unauthorized person:

1. performing acts that are included in the PBRs
2. claiming the right to perform one of those acts; and
3. using the name of a registered variety in relation to another plant or another plant variety.

An infringement will not occur where the act complained of is exempted from the operation of the law. A defendant in an action for infringement of rights may counterclaim for revocation of the rights on the grounds that the variety was not a new plant variety or that facts existed that would have resulted in the refusal of the grant of those rights.

3.20 *Remedies*

In an infringement action, a nominated court may grant an injunction subject to any terms that the court thinks fit and, at the option of the plaintiff, either damages or an account of profits. Where a person satisfies the court that at the time of the infringement he or she was not aware of that right, and had no reasonable grounds for suspecting the existence of the right, it may refuse to award damages or order an account of profits.

3.21 *Administration*

Most laws provide for the establishment of the Office of the Registrar of Plant Breeders' Rights, which is responsible for the general administration of the Act and for the maintenance of the Register of Plant Varieties.

The office of the Registrar will usually issue an official Plant Varieties Journal in which all public notices are to be published.

3.22 *Genetic resource centers and herbaria*

The law may provide for the nomination of genetic resource centers for the storage and maintenance of germplasm material.

4. PATENTS ON PLANTS, VARIETIES, SEEDS, AND OTHER PROPAGATING MATERIAL

As mentioned above, PVP laws were developed in response to industry calls for sui generis protection of agricultural and horticultural innovations. However, a seed-saving exception for farmers was included as a public policy safeguard, an early reflection of food security concerns. Such a safeguard does not generally exist in patent statutes, and this absence was an inducement for seed companies to shift their attention to the patent system as a means of protecting their innovations. This shift in attention also coincided with the development of modern biotechnologies.

Patent protection was not originally considered to be a particularly effective system for the protection of plant varieties. Prior to the development of modern biotechnology, the breeding of a new variety could not be said to involve an inventive step, and such innovations as were made could be considered to be obvious rather than inventive. However, with the extension of patent protection to recombinant DNA methods for producing transgenic plants and their resulting products, patents have been assuming increasing significance in PVP. The broader ambit of patent rights is one particular advantage of this form of IP protection, covering, as it does, plants, seeds, and enabling technologies. Plant variety rights are highly specific to the variety, and their scope is limited by reference to the physical (propagating) material itself, combined with the description of the variety given in the documentary grant of the rights.

4.1 *European prohibitions on patentability*

Article 53(b) of the European Patent Convention (EPC) excludes plant varieties, as well as "essentially biological processes" from the scope of patentable subject matter. This raises, in the first instance, the definitional distinction between *plants* and *plant varieties*. The UPOV Convention defines plant variety in terms of a plant grouping within a single biological taxon of the lowest known rank. The grouping can be:

- defined by the expression of characteristics (such as shape, height, color, and habit) resulting from a given genotype or combination of genotypes
- distinguished from any other plant grouping by the expression of at least one of these characteristics

- considered as a unit with regard to its suitability for being propagated unchanged

The first consideration of the distinction between plant and plant variety by the Technical Board of Appeal of the European Patent Office (EPO) occurred in 1984 in the *Ciba-Geigy* determination.[7] This case concerned a plant that had been treated with a chemical compound to confer on the plant a degree of protection from the toxic side effects of certain herbicides. The Examination Division had refused the patent application on the basis of Article 53(c). This was reversed by the Technical Board of Appeal, which, applying the definition of plant variety in the UPOV Convention, stated that "*Article 53(c) prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety… Plant varieties in this sense are all cultivated varieties, clones, lines, strains and hybrids.*"[8] In this case the claims covered merely the application of a chemical treatment and not plant varieties as such.

This approach was applied by the Technical Board of Appeal in the case *Lubrizol (Hybrid Plants)*[9] where the Board held that "*the term* plant varieties *means a multiplicity of plants which are largely the same in their characteristics (that is, homogeneity) and remain the same within specific tolerances after every propagation or every propagation cycle (that is, 'stability').*"[10] The Board then ruled that as the hybrids in issue were not stable, they did not fall within the excluded category of plant varieties.

The European Directive on the Legal Protection of Biotechnological Inventions (the Directive) permits the patentability of inventions concerning plants, where "*the technical feasibility is not confined to a particular plant … variety.*"[11] Patent claims can therefore be made with respect to plant groupings, or as stated in Recital 31 to the Directive,

Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is not excluded from patentability even if it comprises new varieties of plants.

This qualification was addressed by the Technical Board of Appeal in *Novartis/Transgenic Plant*.[12] The application concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had denied registration. The denial was supported by the Technical Board of Appeal on the ground that Article 53(b) denied the patentability of an invention that could embrace plant varieties.

In its decision in December 1999, the Enlarged Board of Appeal indicated that it would favor the application because, in substance, it did not involve an application for a plant variety. This determination contains some useful guidance on the legal definition of plant varieties. The Enlarged Board of Appeal noted that the definitions of plant variety in the UPOV Convention and the Council of the European Union (EU) Regulation on Community Plant Variety Rights refer to "*the entire constitution of a plant or a set of genetic information,*" whereas a plant defined by a single recombinant DNA sequence "*is not an individual plant grouping to which an entire constitution can be attributed.*" The Enlarged Board observed that the claimed transgenic plants in the application were defined by certain characteristics that allowed the plants to inhibit the growth of plant pathogens. No claim was made for anything resembling a plant variety. The board noted that in the case of PBRs, an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired characteristic could be bestowed on plants by inserting a gene into the genome of a specific plant. The board observed that the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering.

4.2 *Patentability outside of Europe*

Outside of Europe the prohibition against the patenting of plant varieties is absent. In the United States, for example, the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act in its decision in *Pioneer Hi-Bred*

International Inc. v. J.E.M. Ag Supply Inc.[13] The defendants objected that Pioneer had obtained both patent protection and certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter in the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that "*when two statutes are capable of coexistence, it is the duty of the courts ... to regard each as effective.*"

The patenting of plant varieties in Canada was upheld by the recent Canadian Federal Court of Appeal case of *Monsanto Canada v. Schmeiser*.[14] This case concerned the cultivation by a farmer of canola that contained chimeric genes conferring tolerance to glyphosphate herbicides. Monsanto had patented the canola and had marketed these genes in its product Roundup® Ready Canola. Schmeiser had cultivated canola derived from plants on his land that he claimed had developed the tolerance from wind-borne genetic pollination. The trial court found that cultivation of a plant was not an infringement of patented genes contained in that plant; however, the majority of the Federal Court of Appeal agreed with Monsanto that this was infringing use.

Counsel for Schmeiser raised the moral question of whether it was right to manipulate genes in order to obtain better weed control or higher yields. The Federal Court of Appeal ruled that his was a question for the parliament to consider and that the court's job was to "*interpret the Patents Act as it stands.*"[15] The majority explained that, "*Under the present Act, an invention in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science. Where Parliament has not seen fit to distinguish between inventions concerning plants or other inventions, neither should the courts.*"[16]

As the minority judge pointed out that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), in Article 27.2(b), permits the exclusion of plants from patentability but that plant varieties might be patented. The *Novartis* determination, among others, argues that the addition or modification of genetic material to confer disease resistance is not the creation of a new plant variety. If the view of the majority in Schmeiser that the patenting of a cell confers exclusive patent rights over a plant in which that cell is included, then the Article 27.2(b) exception becomes meaningless.

The Joint Communication of the African Group to the TRIPS Council[17] suggested that Article 29 of the TRIPS Agreement seemed to be the most suitable for an appropriate modification to deal with the issue of patenting plant variety rights, by including the requirements for equity, disclosure of the community of origin of the genetic resources and traditional knowledge, and demonstration of compliance with applicable domestic procedures. Thus the Group suggested that Article 29 be modified by adding the following as paragraph 3:

Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.

4.3 *IP and the research exemption*

Plant breeders have tended to stress the necessity of being able to freely access genetic material, including that which is IP protected. This is why the UPOV Convention contains a broad breeders' exemption. Patent law tends to have a much narrower research exemption, and it is often limited to noncommercial scientific or experimental use.

The narrowness of the research exception in patents law is illustrated by the recent U.S. decision in *Madey v. Duke University,*[18] which held that a university that undertook commercial research contracts could not avail itself of the defense. The ambit of the experimental research exception in patents law in the United Kingdom was examined in *Monsanto v. Stauffer*.[19] In that case, Stauffer had developed a market variant, called Touchdown®, of Monsanto's successful patented weed-killer Roundup® for which Stauffer had obtained provisional clearance from relevant authorities. In order

to obtain final clearances, Stauffer had established tests at its own research farm and also organized a series of tests outside the farm, where interested parties could observe the results. Monsanto moved for an interlocutory injunction, on the grounds of patent infringement, which was granted by the patents court, negating the ground that tests done outside the research farm to check the product in different soil and climatic conditions amounts to an experimental use. The Court of Appeal, although it agreed that tests done outside could not qualify for an experimental-use exception, exempted all trials carried out at Stauffer's research farm and at laboratories and greenhouses in the United Kingdom. The Court limited the interpretation of the word *experimental* in accordance with the size, scale, recipient, and methodology of the experiment. This case has raised uncertainty as to how far university researchers can apply the experimental-use exception to agricultural field trials.[20]

Another illustration of the relative narrowness of the experimental-use exception in patents law, compared with PVP laws, is that while a protected plant variety is covered by a single title, plant-related biotechnological inventions are likely to be protected by a patent and, in some cases, several patents. The patents may cover not just plants, but also seeds, genes, and DNA sequences. The effect of patents is to restrict access to the patented "*products*." It has been argued that "*locking up*" genetic resources with patents is a bad thing because innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as is possible. The International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty) introduced a number of provisions to deal with this concern. The provisions are laid out below.

Apart from patents, the restrictions on access to breeding material may have causes other than IPRs. For one thing, some countries have chosen to provide exception for certain categories of plant genetic resources they consider to be strategically important from the Multilateral System to be set up under the Treaty. Also, some developing countries have been exercising their rights under the Convention on Biological Diversity (CBD), administered under the United Nations Environment Programme (UNEP), to regulate access to their genetic resources, and in doing so have restricted the free flow of those resources. This practice may well be detrimental to those countries and others, in terms of long-term food security.[21]

But beyond the issues of how specific IP rights privatize genetic material needed for breeding is the association of IP rights with the privatization of agricultural research, the shrinkage of nonproprietary public sector research, and the increased concentration of ownership of breeding material, research tools, and technologies in the hands of a small number of giant corporations.[22] Not only does this privatization trend toward greater restriction on access reduce the free circulation of breeding material, but it can also make public policy aimed at enhancing food security harder to put into practice. This is true because it is much more difficult for governments to influence companies than the public institutions they partly or wholly fund.

4.4 *Ethical issues relating to the patentability of life-forms*

There is a substantial body of literature on the ethical implications of permitting the propertization of the "*building blocks of life*" or at least to "*reduce the value of life and nature to the merely economic.*" The Joint Communication of the African Group to the TRIPS Council on taking forward the review of Article 27.3(b) of the TRIPS Agreement,[23] stated that patents on life-forms were unethical and "*contrary to the moral and cultural norms of many societies in Members of the WTO.*" The Joint Communication invoked the exception in Article 27.2 for protecting *ordre public* and morality as justification for outlawing patents on life-forms.

An important question for which empirical work is required concerns the impact of oligopolization in the biotechnology market on the capacity of international institutions to provide public goods to developing countries in the agricultural sector. The proprietization of enabling technologies, as well as genetic resources, raises concerns about the capacity of the public agri-

cultural research system to fulfill its public-good mission in contributing to the elimination of food insecurity. As Drahos observed, "*in biotechnology and agriculture, it is likely that much research will end up as an international rather than public good and that it will be distributed according to complex licensing structures.*"[24]

In addition to the possible adverse impacts this market concentration might have upon the vigor of competition, the market dominance of these private corporations also has an important influence upon the sort of biotechnological research that is undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research toward northern concerns and away from southern health problems[25] and southern food priorities?[26] Will the owners of IP rights in key enabling technologies make them available to public research institutions on affordable terms?[27]

Article 27.2 of the TRIPS Agreement permits members to disallow the exploitation of inventions "*which is necessary to protect ordre public or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment…* ." Member states would have to show that the commercial exploitation of the specific invention would be contrary to *ordre public* or morality. In light of the interpretation and application of the equivalent provision within the European Patent Convention, and recently reinforced in the Directive, it is unlikely that this exception would permit a general exclusion of living material from patentability. It is also questionable whether patent offices are the proper bodies to adjudicate the application of moral and ethical issues to the patent system.[28] In any event, the patent offices have abstained from exercising moral judgments in this area. Thus, for example, in *Greenpeace v. Plant Genetic Systems NV*,[29] in an opposition to an application for a patent directed to transgenic plants engineered to be resistant to the herbicide Basta®, Greenpeace argued that it was immoral, and therefore in breach of Article 53(a) of the European Patent Convention, to "*own*" plants that were the common heritage of humankind. The Appeal Board of the EPO sustained the Examination Division's view that it was not the proper forum for discussing the advantages and disadvantages of genetic engineering. Similarly, in *Novartis/Transgenic Plants*[30] the Extended Board of Appeal of the EPO considered the debate over genetic engineering to be too controversial for the board to sustain Greenpeace's opposition to the patent. The Extended Board of Appeal noted that the Directive was an indication that the European Parliament considered there to be some benefit in genetic engineering.

5. PVP, PLANT GENETIC RESOURCES, AND THE TRIPS AGREEMENT

Access to the plant genetic resources of a country is governed by an evolving composite of national legislation pursuant to CBD, TRIPS, UPOV, and the Treaty.

The interrelationship between these instruments has been addressed by the Council on TRIPS pursuant to its review of Article 27.3(b), which commenced in 1999. At a March 2001 meeting of the Council on TRIPS, the chairman set out a list of key issues that had arisen in the review of Article 27.3(b) (IP/C/M/26). These included:

- technical issues relating to patent and PVP under Article 27.3(b)
- technical issues relating to the sui generis protection of plant varieties
- the relationship to the conservation and sustainable use of genetic material
- the relationship with the concepts of traditional knowledge and farmers' rights

Article 27.3(b) of the TRIPS Agreement permits the exclusion from patentability of :

plants and animals, other than microorganisms, and essentially biological processes for the production of plants and animals, other than nonbiological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

However, Article 27.3(b) provides no guidance on what is meant by *effective*, the debate in the TRIPS Council having focused upon which sui generis systems satisfy the obligation. A sui

generis option in the IP context is usually taken to refer to a specially coined IP right, outside of the traditional categories of IP protection. UPOV has advanced its system as the principal workable example of a sui generis PVP system. It is interesting to note that the drafters of the TRIPS Agreement, who felt free to import into the agreement provisions from other named international instruments, such as the Paris, Berne, and Rome conventions and the Washington Treaty on Integrated Circuits, desisted from specifically importing provisions from the UPOV Convention in the area of plant varieties.

The failure of the drafters of TRIPS to define what was meant by sui generis leaves considerable scope for nations in the range of legislation that they may implement in compliance with this provision. One option is to include the benefit-sharing and informed-consent provisions of the CBD in a UPOV-style statute. A problem with doing so is that although the CBD provisions would apply in the countries that introduce them, they will not apply in countries that do not introduce them. In the countries that do introduce the provisions and also adopt an approach based on UPOV 1991 or patents, there is no guarantee of benefit sharing and informed consent, or even of the right to save seed.

The Doha Ministerial Declaration of November 2001, in Clause 19, provided:

We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

5.1 *Technical issues relating to patent and PVP under Article 27.3(b)*

The following technical issues are suggested by the terminology of Article 27.3(b):

- What is a patentable invention for the purposes of Article 27.3(b)?
- What are microorganisms for the purposes of Article 27.2?
- What are plant varieties for the purposes of Article 27.3(b)?
- Should there be a research exception in relation to patents over plant material?

5.1.1 *What is a patentable invention?*

IP law attempts to draw a distinction between inventions and discoveries. The latter are not protectable. This distinction may be made in the relevant legislation. For example, European laws based on the Directive, which specifically provides in Article 3.2 that "*Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.*"

Of course, it is equally open to a court or a legislature to rule or provide that genetic material is not patentable, even in its isolated or purified form, on the grounds that it is a mere discovery. Indeed, nothing in the TRIPS Agreement obliges countries to deem the isolation of genetic materials to be inventions. A number of developing countries exclude the patentability of genetic materials (Mexico), or of materials existing in nature (Argentina, Brazil, and the Andean Group Decision 486).

5.1.2 *What are microorganisms for the purposes of Article 27.3(b)?*

Article 27.3(b) permits WTO Members to exclude from patent protection plants, animals, and essentially biological processes for the production of plants and animals. Members are specifically not permitted to exclude from patent protection microorganisms and nonbiological and microbiological processes. The language used in Article 27.3(b) implies that a clear distinction can be made between plants and animals on the one hand and microorganisms on the other. However, there is no commonly accepted definition of *microorganism,* either in science or in patent office practice. The lack of any definition permits great variations between members in practicing this exclusion.

The practice of patent offices in developed countries suggests that there is no perceived need for a definition: the key issue for protection being not its subject matter, but whether or not the invention meets the patent-granting criteria.

An invention involving biological material will be regarded as lacking an inventive step if it: (1) merely identifies the biological material; and/or (2) merely identifies the natural function of the biological material. An invention will demonstrate an inventive step if it takes the form of a significant technical application of an identified function of the biological material. This technical application must go beyond a mere simple replication of the natural function of the biological material, and the technical application must represent a significant technical advance on the prior art. What about processes and uses?

An invention involving biological material will be regarded as being capable of industrial application if it can be shown that the invention is capable of being used in a manner that provides a demonstrable public benefit. Public benefit means that the invention must be capable of being used in a manner conducive to public health and to social, environmental, and economic welfare.

5.1.3 *What is a plant variety for the purposes of Article 27.3(b)?*

As noted above, a crucial issue in the establishment of a sui generis regime would be the definition of the protected subject matter. Article 27.3(b) of the TRIPS Agreement requires the protection of "plant varieties," but does not provide (as in the case of inventions) a definition thereof. Therefore, national laws have ample room to determine what is to be deemed a plant *variety* for the purposes of protection. Which are the possible definitions? The law may require certain characteristics for a *protected* variety that may not be essential for a scientific definition.

5.2 *Technical issues relating to the sui generis protection of plant varieties.*

Article 27.3(b) provides no guidance on what is meant by *effective*, the debate in the TRIPS Council having focused upon which sui generis systems satisfy the obligation.

Sui generis systems are generally defined as those that fall outside of the traditional categories of IP protection and are created to deal with a unique category of creativity. The UPOV system has been urged by the industrialized group of countries as the principal workable example of a sui generis PVP system. In excess of 50 states have acceded to the UPOV Convention.

Developing countries in the TRIPS Council have argued that the TRIPS Agreement is in tension with the CBD, particularly with the provisions in the latter convention concerned with informed consent to biological materials and equitable benefit sharing following access.

A communication to the WTO from Kenya, on behalf of the African Group, to assist the preparations for the 1999 Ministerial Conference, suggested that:

"*After the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any sui generis law for plant variety protection can provide for:*

(i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;

(ii) the continuation of the traditional farming practices including the right to use, exchange and save seeds, and sell their harvest;

(iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.

This African proposal is reflected, in part, in clause 19 of the Doha Ministerial Declaration of November 2001 mentioned above.

In order to help countries devise an appropriate sui generis system, the International Plant Genetic Resources Institute (IPGRI, now Bioversity International) came up with a list of key questions that decision makers should take into account.[31] These are as follows:

- What kind of domestic seed industry exists?
- What kind of public breeding sector exists?

- What kind of seed supply system is in place?
- To what extent is farm-saved seed used in the country?
- What is the current capacity of breeders?
- What do local breeders want to do in the next 5–10 years?
- Are external inputs to agriculture low or high?
- What are the country's production needs and objectives?
- What is the country's biotechnology capacity?
- What are the goals and realistic expectations of the biotechnology sector?
- What kinds of strategic alliances will the country want to enter into in the next 5–10 years and how involved will other countries be?

The fact that the answers to these questions will vary widely from one country to another suggests that, as with patents, one size is unlikely to fit all.

6. THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Plant genetic resources for food and agriculture (PGRFA) were freely exchanged by the international agricultural research institutes of the Consultative Group on International Agricultural Research (CGIAR), as well as by their national counterparts, on the basis that they were "*the common heritage of humankind.*" This principle was embodied in the International Undertaking on Plant Genetic Resources for Food and Agriculture (the Undertaking) adopted by the Food and Agriculture (FAO) Conference in 1983. The Undertaking was adopted as a nonbinding conference resolution. In subsequent years the principle of free exchange was gradually narrowed by the impact of IP rights upon agriculture. In November 1989, the 25th Session of the FAO Conference adopted two resolutions providing an "*agreed interpretation*" that plant breeders' rights were not incompatible with the Undertaking. The acknowledgment of plant variety rights obviously benefited industrialized countries that were active in seed production. In exchange for this concession, developing countries won endorsement of the concept of farmers' rights. A further resolution in 1991 recognized the sovereign rights of nations over their own genetic resources. Agenda 21, promulgated at the Rio Earth Summit in 1992 called for the strengthening of the FAO Global System on Plant Genetic Resources. Resolution 3 of the Final Act to the CBD noted that the access to ex situ germplasm collections, such as those maintained by the CGIAR, and the realization of farmers' rights were the province of the Undertaking. The 1993 FAO Conference called on member states to harmonize the Undertaking with the CBD. Negotiations for revision of the Undertaking to take account of both the CBD and the TRIPS Agreement commenced in November 1994 and were consummated with the adoption of the Undertaking as the Treaty.

6.1 *The main objectives and innovations of the Treaty*

The objectives of the Treaty are stated in Article 1 to be "*the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.*"

Article 4 of the Treaty requires signatories "*where appropriate*" to "*promote an integrated approach to the exploration, conservation and sustainable use of plant genetic resources for food and agriculture.*" Article 10.2 contains the agreement of the Contracting Parties to "*establish a multilateral system, which is efficient, effective and transparent, both to facilitate access to [PGRFA] and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis.*" Facilitated access to PGRFA is to be provided in accordance with the conditions prescribed in Article 12.3. Paragraph (d) of this provision provides that the recipients "*shall not claim any intellectual property or other rights that limit the facilitated access*" to PGRFA, or their "*genetic parts or components,*" in

the form received from the Multilateral System. This, of course, does not prevent IP rights being claimed in relation to germplasm that is modified by the recipient.

Article 13.1 recognizes that benefits accruing from facilitated access to PGRFA shall be shared fairly and equitably under this Article. Article 13.2 envisages that this sharing of benefits includes the exchange of technical information, access to technology, capacity building, and the sharing of monetary benefits from commercialization.

Article 28 provides that the Treaty would enter into force 90 days after accession by 40 countries. Until that date, the Undertaking would remain operative. Having acquired the necessary accessions in March 2004, the Treaty entered into force in June 2004.

The establishment of the Multilateral System was the principal innovation introduced by the Treaty. This asserts the primacy of national sovereignty over biological resources, but, in fact, imposes limitations on countries on their ability to restrict access to other states. Facilitated access has to be provided to the crops, listed in Annex I, that account for a significant part of human nutrition. Member states are obliged to make available all passport data and, subject to applicable law, any other associated nonconfidential descriptive information. In relation to material that is under development by farmers or breeders at the time when access is requested, the Treaty gives the country of origin the right to delay access during the period of development. Two compromises were necessary to secure this right of access: first is the limitation imposed by Article 12 upon recipients seeking IP rights in material obtained under the Treaty; second is the right of donors to receive some form of benefit sharing. Benefit-sharing mechanisms under the Treaty include the exchange of information, access to and transfer of technology, capacity building, and the sharing of benefits arising from commercialization.

The CGIAR Centres signed agreements with the FAO in 1994, placing the acquisitions to their germplasm collections after that date under the trusteeship of the FAO. Under the Treaty, new agreements were invited to determine that the access provisions of the Treaty would govern the Centres' germplasm collections that fell within Annex I list that were collected after the entry into force of the Treaty.

6.2 *Farmers' rights and food security*

Article 9 of the Treaty implements the proposal that was developed under the Undertaking for the recognition of farmers' rights. The policy behind this recognition is stated in Article 9.1, namely that:

The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

The principal contribution of traditional farmers to agrobiodiversity has been their conservation of landraces, which are crop varieties that are primitive cultivars, developed by local farmers to deal with the local climate and diseases and to cater to local tastes and food-preparation practices.[32] This development may involve the interbreeding of locally occurring undomesticated plants with cultivated plants, as well as the exchange of different genotypes among farmers and farms.[33]

6.3 *Traditional knowledge and food security*

A significant contribution has been made by the knowledge of indigenous peoples and traditional farmers in the development of new crop types and biodiversity conservation. These groups have been an important agency in the conservation of plant genetic resources and the transmission of these resources to seed companies, plant breeders, and research institutions. The contributors have not typically been paid for the value they have delivered, whereas breeders and seed companies have resorted to IP rights to recover their development expenditures.

The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify. It has recently been suggested that "*the value of farmers' varieties is not directly dependent on their current use in conven-*

tional breeding, since the gene flow from landraces to privately marketed cultivars of major crops is very modest"[34] because "*conventional breeding increasingly focuses on crosses among elite materials from the breeders own collections and advanced lines developed in public institutions.*" On the other hand, those collections and advanced breeding lines are often originally derived from germplasm contributed by traditional groups.

An increasingly significant economic value of biodiversity is the extent to which it provides a reservoir of species available for domestication, as well as genetic resources available for the enhancement of already domesticated species. The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived from wild species and landraces.[35]

Traditional knowledge is particularly important in the development of farming systems adapted to local conditions and farming practices. This may enable the utilization of marginal lands, contributing to food security by enabling access to food in remote areas, as well as contributing to the management of the environment by preventing erosion, maintaining soil fertility, and maintaining agricultural biodiversity.

Farmers in subsistence systems have tended to utilize a diverse selection of crop species in order to assure their annual harvests and thus to guarantee a minimal level of production and to prevent food shortage. Seed production in many instances has been on the collection of and domestication of locally known wild varieties. Modern agricultural practices depend on crop species that promote productivity and resistance to disease that can only be maintained with the continuous input of new germplasm. The diversity of landraces and the associated information on their specific qualities contribute invaluable information to formal breeding processes. It has been noted that the loss of biological diversity is paralleled by the loss of traditional knowledge. Where a plant variety becomes extinct, then the entire body of knowledge about its properties is condemned to irrelevancy.

An assumption of Article 9.1 is that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The traditional knowledge of local and indigenous communities is similarly perceived. As a means of remunerating these groups for their past contributions to the development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration.

Inevitably, any calculation of the equitable share that traditional farmers and indigenous communities might enjoy under a farmers' rights or traditional knowledge regime will be arbitrary. However, the IP system is no stranger to arbitrary calculations, thus the 20-year length of a patent term is intended to provide an opportunity for the compensation of all inventors, whatever the area of technology. Similarly the 25-year exclusivity, which the UPOV Convention provides for new varieties of trees and vines, takes no account of variations in R&D costs between the different varieties.

The principal ways in which plant genetic resources are translated into food and agriculture production is through plant breeding and plant patenting. Standing at the heart of a farmers' rights regime is the concept of equitable benefit-sharing with farmers for their contribution to innovations in plant breeding and plant patenting. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived from wild species and landraces.[36]

Article 9.2 of the Treaty envisages that "*the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments*" and that national legislation should include measures relating to:

- protection of traditional knowledge relevant to plant genetic resources for food and agriculture
- the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture

- the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture

Article 9.2 obliges the Contracting Parties to the Treaty "*to take measures,*" subject to their national legislation to protect and promote farmers' rights. The content of these rights is defined in the balance of that provision and embraces the protection of traditional knowledge, equitable benefit sharing, and the right to participate in decision making. The Treaty leaves open the legal context within which farmers' rights are to be enacted.

Finally, Article 9.3 provides that the Article shall not be interpreted "*to limit any rights that farmers have to save, use, exchange, and sell farm-saved seed/propagating material.*"

National legislation on farmers' rights tends to combine one of the versions of UPOV with some of the access principles of the CBD. The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, which was adopted by the Organization of African Unity (OAU), Heads of States Summit at Ouagadougou in June 1998, adopts a sui generis regime based on UPOV 1991. However, most national statutes prefer access legislation combined with UPOV 1978 (for example, the Andean Community's Common System on Access to Genetic Resources, 1996; Costa Rica's Biodiversity Law of 1998; India's Community Intellectual Property Rights Act of 1999; Kenya's Seeds and Plant Varieties Act of 1975).

7. ASSESSMENT OF THE RELATIONSHIP BETWEEN IP AND FOOD SECURITY

The role of IP in eliminating food insecurity has to be placed in its proper policy perspective. Development experience over the last 50 years attributes rural poverty and food insecurity in developing countries to development strategies that overlooked the importance of the development of the agricultural sector, particularly the production of staple foods.[37] Thus the enhancement of food security in developing countries requires a package of policies that address the supply, distribution and consumption aspects of the food chain. The FAO has noted that the policy options that are available to poor countries are constrained by a number of factors including: (1) limited resources for public spending programs; (2) the dilemma between remunerative prices for producers and prices that a large number of poor households can afford, thus making the option of border protection less attractive despite high bound tariffs; (c) major constraints on foreign exchange availability leading to pressure to boost production of export crops.[38]

Where IP could make its greatest contribution is in the incentivization of beneficial agricultural innovations. Historically, the strongest incentives have been those arising from the marketing of hybrid seeds that provide higher yields, with the commercial benefit to the seed marketer that the seeds of the offspring cannot be used by the farmer because these seeds do not breed true-to-type. As is discussed above, the evidence for incentives to breeding research for crop plants is limited—in developing countries even more so—whether PVP and patenting will be useful in encouraging a national seed industry. Barton suggests that a developing country "*is probably best-off adopting minimum compliance with TRIPS, which requires at least some form of sui generis protection for plants—although there is the possibility that a number of nations with similar agricultural conditions could combine their markets in some way that encouraged private investment. Moreover, use of UPOV-style laws might help in commercializing varieties developed by the public sector*."[39]

The question of whether a developing country will adopt a sui generis PVP system or a patent-based system, to comply with Article 27.3(b) of the TRIPS Agreement will depend upon the technological sophistication of agricultural research in that country. ■

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IP and Information Management: Libraries, Databases, Geographic Information Systems, and Software

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ABSTRACT

The last decades have seen a revolution in knowledge management, library services, and information resource database configurations. The use of integrated computer networks and the ability to produce and distribute information have had far-reaching implications for IP (intellectual property) protection. In order to demonstrate IP laws and their application, this chapter will use, as its primary example, Geographic Information Systems and Remote Sensing (GIS/RS), a technology that presents interesting and complex IP issues.

1. INTRODUCTION

The management of databases and library volumes is becoming increasingly complex. In many organizations, library staff are responsible for the storage and retrieval of information, as well as the development of new books or articles. Library staff face ever-increasing challenges regarding the intellectual protection (IP) rights that apply to these various materials.

IP is a term that refers to creations of the mind: inventions; literary and artistic works; and symbols, names, images, and designs used in commerce. U.S. law allows for various sorts of IP protection.

Much of this chapter focuses on a technology that creates a unique IP management challenge: Geographic Information Systems (GIS) and Remote Sensing (RS). GIS/RS is a particularly interesting example of intellectual property because it combines and interfaces a series of different component parts: hardware, software, and other protectable components (including maps, survey data, aerial photographs, information from land records, and so on). Each of these components may carry its own IP protections and restrictions through various licenses. As a result, the final product will also have various IP protections and restrictions attached to it. In other words, GIS/RS systems are affected by IP issues in relation to databases and software, as well as in relation to the technologies that create entirely novel sets of data. These are not always straightforward: for one thing, many different intellectual property and licensing terms appear to have overlapping meanings. Box 1 at the end of this chapter provides a list of the most common technical and legal terms encountered in the context of data, databases, GIS, and software.

In almost all countries, various forms of IP protection are available for the protection of data and data-related products. These are copyrights, trademarks and trade secrets. Thus:

- Symbols, names, and images used in commerce can be protected by trademarks.
- Creative works can be protected by copyrights.

Dodds J, S Somersalo, SP Kowalski and A Krattiger. 2007. IP and Information Management: Libraries, Databases, Geographic Information Systems, and Software. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

- Information can be protected by keeping it a trade secret.

GIS/RS is protected by copyrights and trademarks and, to some extent, trade secrets.

2. COPYRIGHT AND THE PUBLIC DOMAIN

A copyright protects an original work and allows the author the exclusive right to:

- reproduce the work exclusively
- prepare derivative works
- distribute copies by sale, transfer of ownership, lease, renting, or lending
- perform the work publicly
- display the work

Generally, the types of works that are protected by copyright are: literary works; musical works (including accompanying words); dramatic works; pantomimes and choreographic works; pictorial, graphic, and sculptural works; motion pictures and other audiovisual works; sound recordings; and architectural works.

2.1 *Public domain*

Works in public domain are not protected by copyright and are publicly available. They may be used by anyone, anywhere, any time, without permission or license. A work may enter into the public domain if its term of copyright protection has expired. In the United States, works of the U.S. government are all in public domain (Title 17 U.S.C. § 105); they cannot be protected by copyrights. However, U.S. government employees may produce copyrighted work not created during the course of their official duties. If U.S. government works are disseminated in foreign countries, such works may be copyrighted to the extent allowed by the domestic laws of those countries.

It is very important to note that authors are not required to give notice that their work is copyrighted. Therefore, it is the responsibility of the potential user to determine whether or not a work is in public domain. This may become an issue for example in a case where a private work has been included in a government publication by permission of its author. Under U.S. law, such private work is not in the public domain, and therefore one using the government publication may still need permission, or license, to use such private portions of the publication.

2.2 *Fair use exemption*

Section 107 of the U.S. Copyright Act states that an author's original creation is subject to "fair use": that is, the work can be used in special cases without permission for purposes of criticism, comment, news reporting, teaching, scholarship, or research. This exemption is one of the most important copyright limitations. *De facto* fair use should never be assumed. Fair use is determined on a case-by-case basis, taking into consideration the purpose and character of the use, the nature of the copyrighted work, the amount and substantiality of the portion of the work used in relation to the work as a whole, and the potential effect of the use on marketing and distribution of the work.

2.3 *Copyright registration*

Copyright is automatically granted at the creation of a work. Registration of the copyright with the U.S. Copyright Office is not necessary, but a copyright cannot be enforced, or damages collected for improper use, unless it is registered. Currently, the cost for registering a copyright is $30.

2.4 *Copyright duration*

In the United States, a work that is created and fixed in tangible form for the first time on or after 1 January 1978, is automatically protected from the moment of its creation for the lifetime of the author, plus an additional 70 years after the author's death. In case of a joint work, the term lasts for 70 years after the last surviving author's death. For works made for hire, and for anonymous works, the duration of copyright is 95 years from publication or 120 years from creation, whichever is shorter. A work that was copyright registered or published with a copyright notice before 1 January 1978 can be protected at most for 95 years from the date of securing.

It is important to note that duration of copyright varies somewhat from country to country. In European Union member countries the

copyright, generally speaking, protects the work for the lifetime of the author plus 70 years. In Japan the protection is generally lifetime plus 50 years. In Mexico the protection is lifetime plus 100 years.

2.5 *First sale doctrine*

The first sale doctrine, codified at 17 U.S.C. 109, limits the rights of copyright holders to control the distribution and display of copies of their works. The owner of a particular copy is entitled to "sell or otherwise dispose of the possession of that copy" and to "display the copy publicly ... to viewers present at the place where the copy is located." Therefore, the first sale doctrine gives the copyright owner the right to control only the first sale of the work. The owner of a lawfully made copy may in turn dispose of it by any means. The first sale doctrine is the legal basis for public libraries, which lend copies that they have previously purchased. The first sale doctrine does not, however, allow anyone except the copyright owner to make more copies. The Digital Millennium Copyright Act of 1998 authorizes the creation of digital copies for archival and preservation purposes nonprofit libraries and archives. The right to distribute such copies requires authorization from the copyright owner.

2.6 *Copyright ownership*

Generally speaking, the author of a work owns its copyright. In case of work for hire, the employer is considered to be the author and the owner of the copyright.

In the case of GIS/RS, if all work (including aerial photography and geographical data entry) is completed by the employees of a company under the terms of their employment, then the work-for-hire requirements would be fulfilled and the company would own any relevant copyrights. It is important that companies have written agreements (with appropriate work-for-hire language) with any independent contractors that they hire.

If, at the time of creation, the authors intend to combine their contributions into an inseparable or interdependent whole, the resulting work is considered a joint work and the authors are considered joint copyright owners. Each copyright owner has an equal right to exploit her or his copyrights. A company can license or obtain an assignment for the copyright of the joint work from only one of the authors. If, on the other hand, at the time of creation the authors did not intend their works to be parts of an inseparable whole, the resulting work is considered a collective work and the authors are considered collective copyright owners. A collective copyright owner only owns copyrights for the material that she or he added to the final product.

2.7 *Work for hire*

A work for hire is defined in copyright law as that which is prepared by an employee within the scope of his or her employment, or a work specially ordered or commissioned for use as a contribution to a collective work, a part of a motion picture or other audiovisual work, a translation, a supplementary work, a compilation, an instructional text, a test or the answer key to a test, or an atlas. The parties must expressly agree by signing a written instrument that the work shall be considered a work made for hire.

In academic environments, the terms of employment typically require inventors to assign *ex ante* their patentable inventions (but not necessarily their copyrightable works) to the university. If a company hires consultants who are also academics, it is important that their consultancy contracts explicitly state that the contracting institution owns all work done by the consultant. The following is an example of such a clause:

Property and Property Rights. Consultant agrees that any computer programs, software, documentation, copyrightable work, discoveries, inventions, or improvements developed by Consultant solely, or with others, resulting from the performance of Services pursuant to this Agreement, are the property of Contractor, and Consultant agrees to assign all rights therein to Contractor. Consultant agrees that the Services constitute a Work for Hire as such term is used and defined in the Copyright Act. This provision shall survive expiration and termination of this Agreement.

2.8 *Assigning and licensing copyright*

The owner of copyright may transfer the copyright wholly or partially to another party. A transfer is usually done by an assignment or by licensing. With an assignment the copyright owner sells his or her rights to the assignee, while with a license the copyright owner retains the ownership but grants the licensee a right to use the copyrighted material according to the limitations in the agreement.

It is important to realize here that copyright includes numerous rights (for example, a right to reproduce the work, a right to prepare derivative works, and a right to distribute copies). Therefore, the copyright owner can transfer the copyright via an assignment or a license partially or wholly. The copyright owner may, as well, transfer the copyright on an exclusive or a nonexclusive basis. The transfer of exclusive rights is not valid unless that transfer is in writing and signed by the owner of the rights. Transfer of a right on a nonexclusive basis does not require a written agreement.

As an example, the author and copyright owner of a database, could transfer to a company a right to copy and distribute the database. However, the author could also transfer a right for another company to make a derivative work using the database. Either of these rights granted could be exclusive or nonexclusive ones. Probably both of them would be made via a license.

Works by the U. S. government, including maps, are not eligible for U. S. copyright protection. A map, in pictorial form, would not lose its copyright protection if its information were to be digitized and stored in an electronic database. However, a geographical information system whose data have never existed in a coherent pictorial form would be considered a compilation.

2.9 *Databases*

A compilation is only copyrightable if its facts have been selected, coordinated, or arranged in such a way that the resulting work, as a whole, constitutes an original work of authorship (joint work, see Section 2.6). Copyright is meant to reward originality, not effort. Therefore, not all databases are protectable under copyright law. An example of a compilation that did not have the requisite originality for being protectable under the Copyright Act was a telephone catalog, for which the telephone company has simply selected names and arranged them in alphabetical order. Such a database is not original or creative and would not warrant protection.[1] It is, however, important to note that there is no requirement of novelty; therefore, the data or information that is used for the compilation may well be known. The way to select, organize, and arrange the information has, however, to amount to some minimal originality or creativity.

Copyright Act Section 102(b) reads, in part: "*in no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.*" This clause has been interpreted to mean that the individual data in a database are not protected under the Copyright Act. Therefore, even if a database may be copyrighted, a user may use data extracted from it. However, the original data/images that were used to develop the new work must not be passed to any third party or used in a way inconsistent with the terms and conditions under which they were given. In order to prevent such use, the copyright owner usually includes preventing clauses into the licensing agreements.

2.10 *Maps*

Even if a map's geographical features are not protectable by copyright law, the map may still be original enough to warrant copyright protection, depending on what information it includes, from which sources the information was collected, and how the information is represented in pictorial form.

2.11 *Photographic Images*

GIS/RS may use aerial photographs instead of maps. A photograph may be protectable under the Copyright Act if it exhibits a certain amount of uniqueness. The U.S. Court of Appeals, 11th Circuit, has stated that copyright law protects "*the selection of lighting, shading, timing, angle and film*" of a photograph.[2] Copyright protection does not, however, extend to physical facts the photograph expresses.

3. TRADE SECRETS

Under U.S. law, spatial databases are granted fewer IP protections than even the most mundane cloak-and-dagger international spy novel. Therefore, keeping the database a trade secret may be the best way to protect it. A generally accepted definition of *trade secret* appears in the 1939 Restatement of Torts. The subject matter of a trade secret must be secret, and only known to those involved in the particular business in which it is used. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by anyone as his or her secret. Matters that are completely disclosed by marketed goods cannot be trade secrets, either.

4. IP PROTECTION FOR SOFTWARE

4.1 *Protection*

A software program is potentially covered by two types of statutory IP protection:[3]

- The software code is protected by copyright
- The algorithm of the software, if original, is protectable in the United States (but not in most other countries) by patent

Because software algorithms cannot be copyrighted, it is possible for a third party to reproduce the flow and function of the software program and (provided he or she did not derive the new code from the original code) legally use and sell the resulting software.

Patents may offer better protection from competition, but they have several drawbacks:

- Patents are expensive to file and prosecute (and software patents are often even more expensive than the average utility patent). Depending on the number of countries where patent protection is sought, the cost of a patent may amount anywhere from $10,000 and beyond.
- The algorithm must be demonstrably original.
- The patent laws of most countries do not cover software.
- By the time the patent is issued, the program may well have become obsolete.

4.2 *Licensing*

Both copyrights and patents can be licensed for commercialization. Some software licenses in the United States are combined copyright-and-patent licenses. Generally, copyright-alone licenses for software are of limited value unless the program in question is very large and was developed over many years and is therefore difficult for a user to replicate.

A number of different types of licenses are applicable to software:

- **end-use licenses.** The licensee may use the software but not distribute it. These licenses are almost always nonexclusive. The licensor may or may not provide a source code.
- **nonexclusive distribution licenses.** The licensee may distribute the software, either as code or in hardware form (such as a semiconductor). The licensor usually provides a source code.
- **exclusive distribution licenses.** The licensee will distribute the software to end-users and will also improve and support the software. The licensor always provides a source code.
- **open-source licensing.** The software is provided free to users, usually over the Internet. There are many different forms of open-source licenses, each with different restrictions on use.[4] Two of the most common are described below:
- **minimally restrictive.** The licensee may use, improve, sell, and even establish proprietary rights to any improvements he or she makes to the software, provided that he or she acknowledges the licensor's ownership of the copyright.
- **quite restrictive.** The licensee may use and improve the software, but any improvements or modifications to the software must be made available to other licensees under the same conditions. Any licenses the licensee grants to his or her improvements must carry the same obligations and restrictions for the licensees; that is, the rights granted originally to the licensee who made improvements to the originally copyrighted product has to flow through to the improved versions.

4.3 *Collaboratively developed software*

Software created for later distribution or commercialization is a special case. Software programs often have a number of authors and frequently incorporate software that was written by third parties and obtained either formally (through license agreements or open-source licensing) or informally (such as through colleagues).

Technology transfer offices should make sure ahead of time that they are legally able to license software programs, especially if they hope to grant exclusive licenses. In order to determine the legality of licensing, the following questions must be considered:

- Does the potential licensor own the copyright for the primary software program? Are all authors obliged to assign their copyrights to the potential licensor? To ensure this, the potential licensor should:
  - have in place clear policies that delineate under which circumstances students and employees must assign their copyrights to the licensor
  - have written agreements with any other authors (such as consultants or students) that software produced under the consulting arrangement will be assigned to the potential licensor
- Is there any code in the program that was written by a third party? If so, the licensor should:
  - find out from whom or what the code was obtained and whether copyright permission has been granted by this party; learn what restrictions, if any, have been imposed on making and/or distributing *derivatives* of the software that incorporate the original code
  - if the code was obtained from an open source, determine what type of open-source license was involved and what *restrictions* have been imposed on the distribution of the code

Technology transfer offices should take steps to educate creators of commercializable software about ownership issues. A lack of knowledge about IP rights may lead to an unmarketable product.

The Uniform Computer Information Transaction Act (UCITA) standardizes the rules for licensing digital information, including software. UCITA is, however, very controversial and at this point only two states (Virginia and Maryland) have implemented it.

4.4 *Shrink-wrap and click-wrap licenses*

Shrink-wrap and click-wrap licenses are common in software licensing. Shrink-wrap licenses are enclosed in the plastic shrink-wrap packaging of software products; they inform the buyer that if he or she does not agree with the terms of the agreement, he or she should return the software and its packaging to the retailer. Click-wrap licenses appear on the screen before the software installation begins, and typically read: "*Before downloading this software, you must read and agree to the following license terms and click the 'I Agree' button to accept.*" In the United States, these types of licenses are enforceable.

5. INTERNATIONAL ASPECTS

Sometimes, data is obtained from multiple jurisdictions, each with its own laws. IP protection for databases is stronger in Europe than it is in the United States. The European Union Database Directive, adopted by the European Parliament in 1996, grants two rights to the makers of databases:

1. The right to prevent unauthorized use of the database
2. The right to prevent unauthorized acts of extraction and reutilization of the contents of a database

The first right, which is similar to that provided under the U.S. Copyright Act, protects databases that are sufficiently original in their selection or arrangement of data. This right does not, however, protect the data itself.

The second right is a sui generis right that prohibits the extraction or reutilization of any database that has required a substantial effort to obtain, verify, or present. Under this second right, there is no requirement for creativity or originality.

A database is protected for 15 years from the date of its creation. If substantial changes are made to the content of the database, the modified database will be protected for an additional 15 years. Protection under the directive is available only to nationals of member countries of the European Union. Other countries will obtain such protection only if they offer comparable protection to databases of European national and if a bilateral agreement is reached.

6. CONCLUSIONS AND TWO HYPOTHETICAL SITUATIONS

Library and database management professionals are faced with a wide range of IP issues regarding who owns what and how and by whom various media can be used. There is no need to obtain permission to use a work if it is in public domain or if a license or agreement allows the intended use. Nor is it necessary to obtain permission to use facts from a copyrighted source, because the Copyright Act does not protect facts. However, charts, graphs, or figures that use these facts may be copyrighted. It is extremely important to know who the owner of a copyrighted work is: the potential user needs to know whether it is a work for hire or a collective work. Also, it is important to carefully inspect the terms of any licensing agreement in order to determine what rights the licensee will have. In order to place these critical conclusions into perspective, Box 2 presents hypothetical examples of the various IP issues that emerge from library and database issues, and Box 3 offers examples from software development and use. ■

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1 *Feist Publications Inc. v. Rural Telephone Service Company Inc.* 499 U.S. 340 (1991)

2 See *Leigh v. Warner Bros., Inc.* 212 F.3d 1210,1215. [11th Cir. 2000]

3 This section is based on a text graciously supplied by Lita Nelsen, Director, M.I.T. Technology Licensing Office.

4 Further details on open-source licensing can be obtained from the Open Source Initiative at www.opensource.org.

5 www.uspto.gov/web/offices/tac/notices/examguide4-06.htm.

Box 1: Common Technical and Legal Terms Related to IP and Information

author. either the person who creates a copyrightable work or the employer of the person who creates a copyrightable work as a work for hire (see Section 2.7) (The word ***author*** in copyright law includes not only writers of novels, plays, and treatises, but also those who create computer programs, arrange data in telephone books, choreograph dances, take photographs, sculpt stone, paint murals, write songs, record sounds, and translate books from one language to another.)

book. a printed literary composition

collective work. a work, such as an issue of a periodical, anthology, or encyclopedia, in which a number of contributions, each a separate and independent work in itself, are assembled into a collective whole

compilation. as defined by Section 103 of the Copyright Act, "***a work formed by the collection and assembling of preexisting material or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship***"

copyright assignment. the giving away or selling, by the copyright owner, all rights to the copyright

copyright license. a license by which an owner retains ownership to a copyright but allows another person to use or sell the copyrighted material under defined conditions (for example, for a certain purpose, for a certain period of time, or inside a limited geographical area)

copyright. an intangible, incorporeal right granted by statute to the author (or originator, in the case of certain literary or artistic productions), whereby he or she is invested for a specified period of time with the sole and exclusive privilege of multiplying, publishing, and selling copies of the work

creative works. works in which the content does not change, whether the work is in printed, recorded, or electronic form (Materials such as books, sound recordings, downloadable songs, downloadable ring tones, videocassettes, DVDs, audio CDs and films, are usually ***single creative works***. Creative works that are serialized, that is, the mark identifies the entire work but the work is issued in sections or chapters, are also considered single creative works. A theatrical performance is also considered a single creative work, because the content of the play, musical, opera, or similar production does not significantly change from one performance to another.[5])

data. organized information often collected for a specific purpose and generally used as the basis for adjudication in case of litigation

database or data bank. a computer-readable compilation of data and/or information, arranged for ease of search and retrieval

design. the visual ornamental characteristics embodied in an article of manufacture

electronic copy. a computer-readable copy of data or information

facts. a statement or assertion of verified information about something that is the case or has happened (From a more legal perspective, a fact is an actual thing or happening [which must be proved at trial by presentation of evidence and which is evaluated by the finder of fact].)

Geographical Information System (GIS). a computer system capable of assembling, storing, manipulating, and displaying geographically referenced information

image. a reproduction of the form of a person or object, especially a sculptured likeness (An image can be an original visual image or a copy of the original image; for example, it can be a digital image of a painting or a digital image made from a slide of the painting printed in a book.)

joint work. collaboration between two or more authors in which their contributions are joined into a single cohesive work.

CONTINUED ON NEXT PAGE

Box 1 (continued)

patent license. an agreement between licensor and licensee allowing the licensee to practice the invention with agreed provisions while the licensor retains the ownership of the patent

photograph. an image, especially a positive print, recorded by a camera and reproduced on a photosensitive surface

public domain. the realm in which there are no laws that restrict a work from use by the public at large

text. the body of a printed work, as distinct from headings and illustrative matter (on a page) or from front and back matter (in a book)

trade secret. any valuable business information that is not generally known and is subject to reasonable efforts to preserve confidentiality

transfer of copyright. the transfer of any or all of the copyright owner's exclusive rights or any subdivision of those rights (Transfers of copyrights are normally made by contract; usually by a license or an assignment.)

work. something that has been produced or accomplished through the effort, activity, or agency of a person

work for hire/work made for hire. a work prepared by an employee within the scope of his or her employment or a commissioned work that all parties agree in writing to treat as work for hire (The real person, partnership, or corporation for which the work is prepared is considered to be both the author and the owner of copyright from the moment the work is created.)

Box 2: Hypothetical Example: Library and Database Issues

Let us imagine that a librarian is in the process of assembling a work that recounts and reflects upon a research institution's 50-year history. In order to complete this project, the librarian will use various materials that may or may not carry IP restrictions:

(A) photographic images stored in the institution's archives for 20–50 years

Although the organization has had physical custody of these images for as long as 50 years, they are still protected by copyright.

(B) photographic images taken by staff members and donated to the library

If the photos were taken in the course of the employee's duties, they are the property of the institution. If taken outside of work, they may have been given to the institution with attached terms and conditions.

(C) photographic images of the institution taken by a commercial photographer

The commercial photographer may have issued a use license to the institution, thereby preventing further use of the images.

(D) articles written by staff members, some of whom are now retired

If the articles were written during the course of an employee's duties, they are owned by the institution. If they were written after the employee's retirement, the following questions should be asked: Did the employment or separation contracts assign copyright to one party or another? Is the information contained in the article based on knowledge that the author acquired while an employee?

(E) a foreword written by a retired director general, who has been awarded a Nobel Prize

The author owns copyright over the document and should sign a waiver or copyright assignment document so that the material can be legally used.

(F) reproduction of key research articles published by scientists in peer-reviewed journals

It is very likely that the peer-reviewed journals requested and were granted the copyright over the authors' material; the institution will therefore need permission from the owners of the journals to reproduce these articles. Such requests are almost always granted so long as there are no clear competition issues identified.

(G) a text written by professional media consultants on the history of the institution

The consultants should sign contracts indicating that all intellectual property developed during the term of the consultancy is property of the institution.

(H) data (generated by the institution's employees in cooperation with colleagues around the world) showing that the institution is still producing Nobel-Prize-quality data

Care must be taken that the disclosure of data does not infringe on the IP rights of the scientists or their institutions. The terms of the agreement with the external scientists (there had better be one!) may also limit the institution's data ownership and distribution rights.

(I) a special 50-year anniversary logo

The logo may be trademarked.

In many cases, the most important IP protection is common sense. If the probability of a dispute over IP infringement is extremely low, the institution might choose to judiciously cut corners.

The institution can, of course, seek protection for the final document, regardless of whether it is in print or electronic form. However, the IP protection of the final document must not infringe upon the IP ownership of its collective authors.

Box 3: Hypothetical Example: Software Issues

Now, let us consider another example: a GIS/RS project to create maps that will assist in cultivating new plant varieties, conducted by an employee of a research university. In order to develop the project, the principal researcher has to deal with various types of materials, each with its own IP restrictions.

(A) a soil map of country X (obtained from government X)

The U.S. government does not, of course, have copyright on the maps it produces; this may or may not be the case for the IP laws of country X. It will be necessary to draw up a material transfer agreement (MTA) that delineates the specialist's rights of use. The agreement might include a reach-through clause that gives the government of country X rights over new materials created through the project.

(B) a meteorological dataset (purchased from the Meteorological Office of country X)

The principal researcher should check to make sure that there is no specific language in the license that would prohibit commercial use of the dataset (a research-only license) or restrict its distribution.

(C) photographic images of the area of interest (from a commercial source)

As mentioned above, purchased materials almost always come with restrictions; see the previous paragraph.

(D) information on the agricultural performance of a certain plant variety (obtained from an international development organization)

Just because information comes from an international development organization does not mean that it is not protected. The organization may require potential users of this information to sign a material transfer agreement.

(E) a topographical map of country X (obtained informally from a collaborating scientist)

Informally shared information usually leads to IP conflicts. The employer of the collaborating scientist may have ownership rights to the map. If the employer is a U.S. university, it will probably protect its intellectual property and sell information only when it sees fit to do so. There is also a chance that the government of country X has rights to the map.

(F) a software program bought by the principal researcher, using university grant money

The software may have been licensed with an "educational use only" license

(G) data collected in the field by the principal researcher

Since the principal researcher is a university employee, the university may claim ownership over any data he or she collects.

(H) a data manipulation algorithm developed by the principal researcher during the course of his or her employment

As mentioned above, the university may claim ownership over the algorithm, since it was developed during the course of his or her duties as an employee of the university.

Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals

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ABSTRACT

The chapter discusses the meanings of data protection and data exclusivity in the context of the provisions of the Trade-Related Aspects of Intellectual Property Rights agreement. In addition, it outlines the relationship between data exclusivity and patent protection and briefly reviews the possible costs and benefits of introducing data exclusivity laws. Finally, the chapter explains that countries need to consider the costs and benefits when negotiating bilateral trade agreements that might require the introduction of these laws.

1. INTRODUCTION

The development of a new drug or agrochemical, such as a pesticide, usually requires extensive testing, inside the laboratory or in the field, on animals, humans, plants, or the environment, depending on the nature of the drug or chemical.

The way in which these tests are undertaken are, at least in the later stages, governed by rules set by the regulatory authorities. These rules are designed to ensure the safety, quality, and efficacy of products being developed for use by humans or in the environment (in the case of agrochemicals). In the United States, for instance, this regulatory authority is the Food and Drug Administration (FDA) for medicines and vaccines and is the Environmental Protection Agency (EPA) for agrochemicals.

Meeting the requirements, which is necessary for permission to place products on the market, involves a considerable cost. Studies on pharmaceutical industry data, albeit disputed by some, have suggested that the average total development cost of a new drug is on the order of US$800 million, of which about 60% would be incurred in the conduct of trials (a substantial portion of these trials would be required for regulatory approval).[1] In agrochemicals, it has been estimated that the average development cost is more than US$180 million.[2]

Because of the size of the required investment in clinical test data, the pharmaceutical and agrochemical industries argue that the use of such data by third parties (other than the regulatory authority) must be prevented. If the regulator, relying on test data provided by the originator company at great expense, allows an equivalent product to enter the market, originator companies would have no incentive to incur the heavy costs necessary to bring new products to market in the first place. In practical terms, a rule that prevents use of the data by a third party (or the regulator relying on that data to approve a third party's generic product) also has the effect of providing exclusivity to the originator product. This is principally because the cost of replicating the investment in trials to satisfy regulatory requirements would be sufficiently prohibitive to deter a potential competitor. In the case of medicines, even if the cost were not prohibitive, there are also ethical concerns about repeating trials (that

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include an untreated control group) with a drug known to be efficacious.

This chapter seeks to explain the quite complicated issues related to data protection and data exclusivity and how they are treated in different jurisdictions. Particular consideration is given to the position of developing countries who are contemplating, or being obliged to contemplate, data protection or exclusivity regimes.

2. WHAT IS THE DIFFERENCE BETWEEN DATA PROTECTION AND DATA EXCLUSIVITY?

The modern debate about *data protection* and *data exclusivity* largely derives from differing interpretations of what the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) says on the subject.

The relevant article (Article 39(3)) says:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

There are unreconciled views on what this paragraph, the subject of protracted discussion when the agreement was negotiated, means in practice.

It is important to note that Article 39, as a whole, constitutes the section of the agreement "protection of undisclosed information" that relates broadly to what are generally known as *trade secrets*. Article 39(2) is a general clause about World Trade Organization (WTO) members' obligations with respect to trade secrets. Article 39(3) covers such obligations in the particular case where such trade secret data are submitted to governments or government agencies as a precondition for obtaining marketing approval.

Article 39(3) essentially imposes three obligations on governments:

1. To protect data on new chemical entities, the collection of which involved considerable effort, against unfair commercial use
2. To protect such data against disclosure, except where necessary to protect the public
3. To protect such data against disclosure, unless steps are taken to ensure that the data is protected against unfair commercial use

The first obligation is simply about protecting data submitted to regulatory agencies against unfair commercial use. No time limit is specified. Examples of unfair commercial use could include, for example, the government itself using the data for a commercial purpose or various kinds of dishonest commercial behavior. The World Intellectual Property Organization (WIPO)[3] provides a set of model provisions on protection against unfair competition.

The second and third obligations concern protecting data against disclosure to third parties, in the case of one or another exception. Although there is some lack of clarity, arising from the generality of the wording, about when disclosure would be justified by the exceptions (particularly in the third case), the essential point is that the obligation creates a presumption that the regulatory authority would not disclose data, without due reason, to a third party. Again, no time limit is specified. The purpose of avoiding disclosure is to avoid unfair commercial use. The third obligation implies, therefore, that disclosure is acceptable provided it can be ensured that disclosure will not lead to unfair commercial use.

Most observers regard what is referred to in TRIPS Article 39 as "data protection," dealing as it does with the protection of undisclosed information or trade secrets. Article 39(3) does not create *new* property rights, nor a right to prevent reliance on the test data submitted by an originator for the marketing approval of an equivalent product by a third party, except where unfair commercial practices are involved. The article is an articulation of widely accepted legal precepts regarding trade secrets and unfair competition, not an invitation to create a new intellectual property right for test data.

However, industry groups and some developed countries, for example, the United States and the European Union, have argued that Article 39(3) requires countries to create a regime of "data exclusivity," a form of time-limited intellectual property right. In the United States and countries in the European Union a data exclusivity regime for both medicines and agrochemicals was adopted prior to the TRIPS agreement (for example, in 1984 in the United States and in 1987 in the European Union, for medicines). For a period of five years from marketing approval of an originator product, no other company may seek regulatory approval in the United States of an equivalent product based on data submitted by the originator company without the latter's approval. During the period of exclusivity, regulators cannot use (rely on) the originator's data to approve a generic product, even if the product is demonstrated to be exactly equivalent in chemical composition and in its behavior within the body.

The European Union now provides more extensive exclusivity, up to 10 years, for medicines. Unlike TRIPS provisions for data protection, data exclusivity regimes often extend beyond new chemical entities. For instance, in the United States only chemical entities never previously approved are entitled to exclusivity for a five-year period, but new uses or indications of an already approved entity are also entitled to exclusivity for three years. In the European Union, exclusivity is provided to new medicinal products, not just new chemical entities. Details of the European Union and United States regimes are described in Sanjuan.[4]

In the United States, agrochemicals have been entitled to a ten-year exclusivity period; the period is five years for medicines. This difference exists because the act that introduced data exclusivity for medicines in 1984 (known as Hatch-Waxman) also introduced a provision allowing for patent extensions of up to five years to compensate for the loss of patent life in meeting regulatory requirements (principally the time lost compiling the test data required by the FDA). Thus the term of data exclusivity for medicines was reduced as a trade-off.

In addition, the United States provisions for agrochemicals allow for a further five years of exclusivity during which the originator data may be relied on to approve a generic product, provided compensation for the use of the data is paid to the originator.

In summary, a data exclusivity regime relates to how long the regulatory agency may be prevented from relying on originator's data to approve the products of potential generic competitors. Data exclusivity does not relate to the question of disclosure to third parties and trade secrets dealt with in TRIPS Article 39(3) (and 39(2)) in which no time limits are specified.

3. DATA EXCLUSIVITY AND PATENTS

If the patent period has expired, or there is no patent on a product, data exclusivity will act independently to delay the entry of any generic companies wishing to enter the market until the period of data exclusivity is over. It should be noted that in most cases the period of data exclusivity may have no material effect if it is within the patent period, because exclusivity is protected by the patent.

However, the data exclusivity right is a much stronger right than a patent because, unlike patent law, there are no exceptions or flexibilities that allow governments to tailor the law to national circumstances. For example, there is no ability for governments to provide the equivalent of a compulsory license, or data exclusivity may act as a barrier to compulsory licensing of a patent on the same product by preventing marketing authorization for a compulsory licensee. Data exclusivity is attractive to originator companies because unlike a patent, data exclusivity is automatic (rather like copyright). No fees are incurred for application or maintenance of the right, and there is more limited scope than exists in patent law for legal challenges, which are expensive to mount and to defend. For these reasons pharmaceutical companies are strong proponents of data exclusivity regimes. Whatever the benefits, which depend on exclusivity extending beyond the patent term, the costs to these companies are very low.

4. COSTS AND BENEFITS

The claimed benefits of data exclusivity relate, to a great extent, to the additional incentives offered to companies in the long and expensive process of pharmaceutical R&D. Data exclusivity gives companies an incentive to extend the original use of the product (for example, to a wider population, by age or geography, or in new indications for therapeutic use) where, for one reason or another, no patent protection is available. Data exclusivity provides an additional opportunity for originator companies to recoup their investments where marketing approval is given late in the patent life, so that the protection afforded extends beyond patent expiry. Experts argue that data exclusivity offers benefits to domestic innovators in developing countries, and, in particular, that it provides incentives for research to identify new uses for existing unpatented products and for originator companies to introduce products into developing countries, since, in effect, exclusivity would protect the companies from generic competition.

On the other hand, in developing countries where there is little or no innovative research capacity, the benefits of data exclusivity are likely to be limited. In those circumstances, data exclusivity would not promote R&D and the benefits to the companies themselves, and a potential addition to the R&D incentive, would be small because of the limited market potential in most developing countries. However, data exclusivity would allow additional periods of exclusivity for originator products, and it therefore would correspondingly delay the onset of generic competition. Specifically, exclusivity would preclude possible reductions in the cost of medicines in the developing country, keeping healthcare costs higher.

Data exclusivity is likely to have the largest effect in countries where, for historical or other reasons, there are many products with no current patent protection that may gain rights to exclusivity. For example, in many developing countries there are numerous medicines that are not patented (even if they *are* patented in developed countries). This is often the case in developing countries where TRIPS-based laws have only recently been introduced (for example, India only introduced TRIPS-compliant laws in 2005 on the expiry of its transitional period allowed under TRIPS). In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. By contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[5]

5. BILATERAL TRADE AGREEMENTS

Earlier drafts of the TRIPS agreement, which was in negotiation for nearly a decade before coming into force in 1995, contained, in addition to language closely following the final form of Article 39(3), text reflecting the U.S. five-year data exclusivity regime, which had been enacted in 1984 in the Hatch-Waxman Act. The North American Free Trade Agreement (NAFTA[6]), which was agreed in 1992, contained a close equivalent of Article 39(3) followed by a paragraph preventing the regulator from relying on the originator's data for a reasonable period, normally meaning not less than five years.

From the point of view of supporters of data exclusivity, the TRIPS agreement was, therefore, in this particular respect, something of a backward step. Although supporters of data exclusivity argued that exclusivity, taking account of the negotiating history, was what TRIPS Article 39(3) really meant, most observers have noted that the fact that a specific clause on data exclusivity along the lines of NAFTA was omitted from the final agreement indicated the opposite. If TRIPS had meant to sanction "data exclusivity," it would have done so explicitly, as does NAFTA.

The United States in particular has sought, in post-TRIPS negotiations, to insert the language of NAFTA on data exclusivity, or even stronger provisions, in negotiating bilateral free-trade agreements with developing countries. Countries that have reached such agreements include Bahrain, Jordan, Morocco, Chile, the Dominican Republic, and the countries of Central America. Negotiations are ongoing with Thailand, Ecuador, Peru, and Columbia.

Most United States bilateral treaties involve agreement to the five-year rule as it is followed in the United States. In other cases, such as the Central American Free Trade Agreement (CAFTA), approved in 2005, the five-year rule applies also to a product approved in another party to the agreement—that is, marketing approval in Country A deters generic entry in country B for a period of five years. If the originator seeks marketing approval in Country B within five years, there will be an additional five years of data protection in Country B from the time of obtaining marketing approval, providing a maximum exclusivity of up to 10 years. CAFTA also obliges parties to provide extensions to the patent term on the grounds of unreasonable delays in granting a patent (for example, five years from filing) or unreasonable delays in procuring marketing approval.

Developing countries need to consider the extent to which the demands for data exclusivity in bilateral trade agreements reflect the lobbying of the pharmaceutical industry in developed countries, particularly the United States, where there are close and legally institutionalized links between the industry and negotiators, in particular through the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15). This Committee evaluates successive free trade agreements as to whether or not they meet the objectives of U.S. intellectual property-based industries. The committee's objectives do not include consideration of what measures might be in the best interests of developing countries.

6. CONCLUSIONS

This chapter has sought to explain the meaning of data protection and data exclusivity in the context of pharmaceuticals and agrochemicals. The protection of commercially valuable data held by governments is a duty of government, formalized in the TRIPS agreement, essentially to protect such data against unfair commercial use. Data exclusivity, by contrast, is a time-bound form of intellectual property protection that seeks to allow companies to recoup the cost of investment in producing data required by the regulatory authority. The effect of data exclusivity is to prevent the entry of generic competitors, independent of the patent status of the product in question. The costs and benefits of data exclusivity depend on the particular economic circumstances of countries. In developing countries with little innovative capacity, the benefits may be less obvious than the costs in terms of reduced competition in the market for medicines or agrochemicals. These costs and benefits need to be considered in the context of bilateral trade agreements, particularly with the United States, where data exclusivity is likely to be part of the package of intellectual property measures governments are asked to accept. ■

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2 CropLife International. 2004. Position Paper: On the Protection of Safety and Efficacy Data for Existing and New Crop Protection Chemicals. CropLife International: Brussels. www.croplife.org/librarypositionp.aspx?wt.ti=Position%20papers.

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5 Satyanarayana K, S Srivastava and NK Ganguly. 2006. Data Protection Issues in India. *Indian Journal of Medical Research* 123:723–726. medind.nic.in/iby/to6/i6/ibyto6i6p723.pdf.

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Regulatory Data Protection in Pharmaceuticals and Other Sectors

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ABSTRACT

Generating data to secure regulatory approval in sectors, such as pharmaceuticals and agricultural chemicals in which product safety and efficacy is paramount, has become ever more extensive and expensive. There is thus a need to provide an incentive to undertake such data-generation efforts by protecting the investment in them against free riding. Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognizes as an intellectual property right the need for such protection in those sectors. This chapter discusses how certain jurisdictions, and in particular the European Community, have implemented the TRIPS requirement involving regulatory data protection regimes. Such protection is not provided by the patent system, which instead protects invention.

1. INTRODUCTION

When a company or institution spends the time and money to demonstrate that a product is safe and efficacious, the investment pays off, in part, by protecting the data generated through this effort. This protection has become crucial in highly regulated sectors, such as pharmaceuticals and agricultural chemicals, where product safety and efficacy are paramount. The importance of protecting such data is reflected in their recognition by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 39.3, as intellectual property (IP) rights. The need for such protection has arisen because the testing required to secure regulatory approvals has become more extensive and expensive. Thus, greater incentives for undertaking such work are needed, especially since no other forms of protection may be available for a product that regulatory agencies have authorized for the market.

The protection of data generated for regulatory purposes prevents direct or indirect use of the data filed in support of a marketing authorization by subsequent applicants seeking marketing authorization for the same product. The protection applies unless the subsequent applicant has obtained the consent of the party that first filed the data and obtained the original marketing authorization. It is often uneconomic for subsequent applicants to generate their own data independently, so this exclusivity effectively confers a de facto right in favor of the first applicant. However, the protection is for a limited time, so that subsequent applicants can use it after an appropriate period. This avoids the need for repetitive testing, which whether on animals or people, is undesirable both from economic and ethical points of view.

2. REGULATORY DATA PROTECTION VERSUS OTHER FORMS

2.1 *How regulatory data protection differs from confidential information protection*

Although the protection of regulatory data has its origins in laws regulating confidential information

Cook T. 2007. Regulatory Data Protection in Pharmaceuticals and Other Sectors. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

(including trade secrets), and indeed is addressed in the same article of TRIPS that mandates the protection of confidential information, it is a separate right that requires separate analysis.[1] The two types of IP right are different, and a balance between private and public interests struck in one should not affect how that balance is struck in the other. For example, while there would seem to be no compelling reason why the protection afforded to confidential information should ever be limited in duration, the term of regulatory data protection *ought* to be limited.

Some experts might argue that there is no need for a separate legal regime to protect regulatory data because the data can be protected under the law governing confidential information. Indeed, viewed from an English common law perspective, regulatory data is typically confidential in nature and is communicated to regulatory authorities with an obligation of confidence. However, trade secrets law has proved inadequate for protecting data filed with regulatory authorities. First, the issue has not been about the disclosure of data but about its use (although freedom of information considerations today make a limited measure of disclosures inevitable, which can undermine its confidential nature.) Second, it is unclear whether regulatory authorities in fact do "use" the data in a way that is subject to the law of confidential information, especially when officials merely rely on the existence of such data and do not actively refer to it. Third, even assuming that such reliance does constitute use, is there some "public policy" or "implied permission" defense that permits this use?

On this third point the various *Cimetidine* cases,[2] each of which was decided effectively on public policy or implied-permission grounds, demonstrated the difficulties faced by those who file confidential regulatory data in the common law countries of England, Australia, and New Zealand. When regulators assessed in these cases an application for approval of an equivalent medicinal product by a generic competitor, the original data filings could not be protected via traditional concepts of confidential information. The law of confidential information could not prevent the regulatory authority from referring to the originator's file or from relying on the mere fact of the earlier authorization.[3] Thus the decision of the House of Lords in the English *Cimetidine* case confirmed that the information was confidential and that a breach of confidentiality would have occurred if the information had been disclosed to third parties or the information used for purposes unrelated to the function of the regulatory authorities. But that was not the case. Instead, the regulatory authorities had been using the data to carry out the regulatory function. The legal decision went on to confirm that regulatory authorities have a right and duty to make use of such information. The court observed that "*the licensing authority should not be deterred from exercising its rights and powers so as to ensure public safety…*"

2.2 *Regulatory data protection versus patents*

Some experts argue that the protection of innovation in regulated areas, such as pharmaceuticals and agrochemicals, ought to be left to the patent system, and that no other system of protection is needed. This objection, however, fails to recognize that proving safety and efficacy for regulatory authorities is a very different matter from demonstrating that an invention is patentable. From a regulatory perspective, much of the required expenditure of time and money is directed to R&D that rarely yields patentable inventions.

Indeed in some cases, patent protection for a product approved by regulatory authorities may be very weak or impossible to obtain, especially when the patent protection is not for a new chemical entity or other new active substance but is instead for a new physical form, new formulation, new synthetic process, or new use of an old substance. Such "second generation" patents are at greater risk of successful attacks on their validity, because patent validity depends less on the work done to bring inventions to market, or to prove that inventions are safe and efficacious, than on the discovery of the invention in the first place. Such patent validity considerations are wholly unrelated to regulatory data protection, which may therefore provide the sole protection for a medicinal product. The ability of patents to give only limited protection—and thus to

provide a limited incentive for completing the important work required to secure a marketing authorization—was recognized in the English patent case *Merck & Co. Inc.'s Patents.*[4] Having found invalid certain patents for the medical uses of alendronate, a compound used to treat medical disorders of excess bone destruction, the trial judge observed:

Accordingly I hold both patents invalid. I do so with some regret. Merck [has] only had a few years' exclusive exploitation of alendronate. [The company] must surely have had to make a very considerable investment and incurred considerable risk in bringing [the product] to market. And mankind is better off as a result. But the patent system does not confer monopolies on those who develop obvious or old products, even if they have never been exploited. A workable system for that might be a good idea, particularly in the field of medicine and analogous fields.

The framework for such a workable system has existed for some time in the law of regulatory data protection, which in the United Kingdom provided longer effective protection than did the patents at issue in this case.[5] However, the regulatory data protection system for medicinal products, at least in Europe and as mandated by Article 39.3 of TRIPS, provides for only limited compensation for the shortcomings of the patent system. This is because regulatory data protection is available only for data filed in support of a new active chemical and not (with one exception only recently introduced) for data filed in support of a new indication, new formulation, or new dosing schedule of an already-authorized active chemical. The exception, discussed further below, extends the total period of data protection for all uses of a medicinal product by one year, if one or more new therapeutic indications are authorized that are held to bring significant clinical benefits in comparison with existing therapies. To fail to protect data filed in support of a new indication, new formulation, or new dosing schedule of an already authorized active chemical has two baleful consequences. It not only discourages development work on existing medicinal products, but also encourages work on new medicinal products that may be no better in practice than those they replace. This robs from investments in public health since the "innovations" add no benefit to the public but still require resources to be spent for new research and market authorization. Clearly, the pursuit of better IP protection in this case is a perverse incentive. A revised approach is needed, one that recognizes the differences between regulatory data protection and patents. In short, the former differs from patents in three ways: (1) its apparently shorter duration; (2) the lack of any need to comply with conventional concepts associated with patentability, such as novelty and obviousness; and (3) it protects only the regulated product. Table 1 lays out these differences in more detail.

Notwithstanding the fundamental conceptual differences between the two systems of protection, some links between the systems have been created. The regime in the United States for granting authorizations for medicinal products (and as required to a degree, by many bilateral trade agreements between the United States and third countries) provides that, when a patent protects a product, in most cases the term of regulatory data protection is extended for 30 months or longer. In Europe, however, if there is no sample submission to the regulatory authorities (which itself would constitute an infringing act under applicable patents in Europe), the mere application for a marketing authorization does not constitute an act of patent infringement. In fact, a marketing authorization may be granted to any party that complies with the applicable technical requirements without, thereby, infringing any patent[6].

2.3 *Regulatory data protection versus other forms of marketing exclusivity*

Rights protecting regulatory data need to be distinguished from and contrasted with other types of marketing exclusivity conferred for other reasons. Because both provide a form of market exclusivity, the distinctions are not always very clear.

Internationally, one example of market exclusivity that contrasts with regulatory data protection is the exclusive marketing rights conferred

under Article 70.9 of TRIPS for pharmaceuticals and agricultural chemical products in those countries that did not provide full product patent protection for such chemicals when TRIPS came into force.

Another type of marketing exclusivity is available in both Europe and the United States for *orphan* medicinal products. Because of their small potential market, these products require incentives for development over and above the norm. In a sense, the exclusivity for orphan medicinal products could be said to protect indirectly the data submitted by the entity that secures the first such orphan-drug authorization, but it goes much further. During the term of orphan-drug marketing exclusivity, a second applicant will not be able to obtain market authorization even if it submits its own data. Thus orphan-product status does not simply protect regulatory data but confers true marketing exclusivity.

As is to be expected for a right that has only recently been developed and is only now starting to be analyzed in detail, there was considerable international variation in the protection afforded to regulatory data. This was the case when the text of TRIPS was finalized in 1994 and it remains the case today in 2007. In consequence, Article 39.3 leaves much latitude in relation to its national implementation (see Box 1).

Table 1: Patents and Regulatory Data Protection Contrasted

	Patent	Data Protection
Protects	claimed compound and analogues, and/or uses, and/or formulations, and/or synthetic processes	compound (and sometimes formulation) which has an authorization to market
Prevents	• manufacture, sale, use, or import of a claimed product or the direct product of a claimed process • use of a claimed process • indirect infringement	grant to a subsequent applicant of an authorization to market based on originator's data
Relevant excepted use	- private and noncommercial use - use for purposes of securing regulatory authorization - experimental use relating to the subject matter of the invention (outside the United States)	any use which does not require an authorization to market
Period of protection	20 years from application	variable, but typically 5–10 years from the first authorization to market
Requires	patentability: novelty, inventive step, sufficiency, etc.	demonstration of safety and efficacy

Box 1: Article 39.3 of TRIPS

Propositions as to the scope of Article 39.3 TRIPS

The importance of regulatory data protection and its international recognition as a sui generis type of intellectual property right are embodied in Article 39.3 of TRIPS. This embodiment, together with Article 39.1 and Article 39.2, (which are expressed in somewhat different terms and mandate the protection of confidential information) provides:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10 *bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or government agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

   a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally dealt with the kind of information in question;

   b) has commercial value because it is secret; and

   c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Note: For the purpose of this provision, "*a manner contrary to honest commercial practices*" shall mean at a minimum practices such as breach of contract, breach of confidence, and inducement to breach, and includes the acquisition of undisclosed information by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or steps are taken to ensure that the data are protected against unfair commercial use.

To date, there have been no cases brought under the WTO (World Trade Organization) dispute-resolution mechanism in relation to Article 39.3 to provide guidance. Nonetheless, the following propositions about the minimum thresholds of protection that it mandates can be advanced:

- Article 39.3 addresses two issues: *use* of the data in its first sentence and *disclosure* in the second. However the data to be protected are in each case the same.

- In each case the data protected are *required* "*as a condition of approving the marketing of pharmaceutical or of agricultural chemical products,*" suggesting that this does not require that data submitted for these products for other purposes, or submitted as a condition of approving the marketing of other types of product, be protected. (The European Community, for example, also provides for regulatory data protection in other fields, such as animal feedingstuffs and biocidal products but TRIPS does not recognize it).
- In each case, the data protected are *required* "*as a condition of approving the marketing of … products which utilise new chemical entities.*" The expression *new chemical entity* is not defined. Thus this provision does not necessarily impose a patent standard of novelty, and indeed it should not be expected that it do so, given the different nature of the right. In any event, if one were to apply a patent standard of novelty, would this be absolute (worldwide) or relative (local)? TRIPS is silent on this issue with regard to patents, and although over time there has been a trend to absolute novelty, it has by no means been universally adopted. It should be noted that the term *new chemical entity* is widely used in a regulatory context. Accordingly, a new chemical entity could be regarded as an active substance approved for the first time within a particular regulatory framework, since the same chemical may have activity within the context of different regulatory frameworks. Moreover, because in some regulatory systems the term *new chemical entity* is in practice limited to "small molecules" (as opposed to the "large molecules" that designate biotechnology products, such as therapeutic proteins, and are usually termed *new active substances* in such systems), the term ought to be regarded as comprising new active substances. However, this does not mandate the protection of new data, no matter how much effort their origination has involved, for an old, or already authorized, chemical entity or active substance, although such protection ought to be regarded as desirable on public policy grounds.
- In each case, the origination of the data protected must "*involve a considerable effort.*" This no doubt would cover safety and efficacy data, such as that generated in the course of clinical trials for pharmaceuticals or field trials for agricultural chemicals, but it leaves open the question of what other data should also be protected on these grounds.
- In relation to prohibited use, the use must be "*unfair commercial use.*" This expression is not defined, but clearly excludes noncommercial use, such as for public health and safety. As to commercial use, such as that made when a subsequent applicant relies on the existence of such data (whether or not actually referred to), or to be more accurate, when the regulatory authority assesses the second applicant's application in light of the data provided by the original applicant, the issue is whether or not such use is unfair. It is in this context that such matters arise as the appropriate term of protection and whether or not the protection should be an exclusive right or merely a remuneration right (and thus available for compulsory licensing).
- In relation to disclosure, such data must be protected except in two cases: where it is either "*necessary to protect the public*" or where "*steps are taken to ensure that the data are protected against unfair commercial use.*" Thus, in these two alternative cases there is

no absolute prohibition on the disclosure of such data. The first permitted exception, namely that of "*[necessity] to protect the public*" appears narrow in scope and should not properly be equated with transparency, which is the principle behind disclosures under freedom of information considerations. Thus in relation to disclosures for purposes of transparency, TRIPS would appear to require that "*steps [be] taken to ensure that the data are protected against unfair commercial use.*" This would appear to require the regulatory authority not to treat information disclosed for such purposes as detracting from the undisclosed nature of the underlying data. Indeed, in the European medicinal products regime, the Notice to Applicants expressly provides that the information set out in a European Public Assessment Report (EPAR) cannot be used to apply for a marketing authorization for a medicinal product on a bibliographic or published data basis (see also Box 2 at the end of this chapter).

The Background to and Negotiating History of Article 39.3 TRIPS

Before TRIPS came into force on 1 January 1995, regulatory data was already protected throughout the European Community and in the United States by statutory provisions for both pharmaceuticals and agricultural chemicals. Since 1987, the member states of the European Community have provided protection for data filed in support of marketing authorizations for medicinal products, and since 1991 for data filed in support of marketing authorizations for plant protection products. Similarly since 1982, the United States has had its own regulatory data protection provisions for pesticides, and since 1984, such provisions for medicines. Moreover, as discussed earlier, in both jurisdictions the case law had made plain the limitations of the law of confidential information as a means for protecting regulatory data.

Moreover, TRIPS was not the first multinational agreement to mandate that its Member States provide regulatory data protection. This honor fell to the North American Free Trade Agreement (NAFTA)[7], paragraphs 5 through 7 of Article 1711 of which provide:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.
6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

The "*not less than five years*" term of protection that the North American Free Trade

Agreement (NAFTA) accepts in Article 1711(6) as "*reasonable*" reflected, no doubt, the U.S. position regarding pharmaceuticals,[8] but such a term is now widely regarded on the research-based side of the pharmaceuticals industry as inadequate. However, the NAFTA formulation has a significant place in the history of regulatory data protection because it is the first to reflect the principles of regulatory data protection in treaty language and because its language parallels that found in TRIPS.

3. THE E.U. AND U.S. IMPLEMENTATIONS OF ARTICLE 39.3 TRIPS

3.1 *Background*

Although the obligations mandated under Article 39.3 are generally expressed, it is instructive to consider how they have been implemented by the world's two major trading blocks—the European Union and the United States—especially since it has become increasingly common for each to try to impose its own IP norms on trading partners through regional or bilateral trade agreements.

3.2 *Pharmaceuticals*

A variety of national regulatory data protection regimes for pharmaceuticals have emerged. The regimes differ both in terms of the length of protection and the categories of data protected. For example, European Community Member States previously provided (depending on the country or the regulatory route followed) six or ten years protection for data filed in support of an authorization for a new pharmaceutical chemical entity, but none for data relating to a new indication for an already-authorized pharmaceutical. For new chemical entities authorized as pharmaceuticals in the European Community after October 2005, second applicants may apply for a marketing authorization eight years after the first authorization is granted, but such authorization cannot be granted less than ten years after the date of such first authorization.[9] In each case the protection runs from the first authorization in the Community. Under the new system, the ten-year period is extended by a further year if authorization for a significant new indication for the pharmaceutical is secured before the eight-year period expires.

In the United States, a second applicant cannot (assuming no patents cover the product) apply for such an authorization until five years after the first marketing authorization.[10] Assuming a typical review period of 18 months, the result is a total effective protection period of six and a half years. However, the more usual situation is that the relevant regulatory authority (the U.S. Food and Drug Administration (FDA)) has been advised that one or more patents apply to the pharmaceutical in question, in which case the link between the regulatory regime and the patents regime comes into play (see section 2.2).[11] This link exists in the United States but not in the European Union.

In the United States, a company wishing to market a generic version of a pharmaceutical by relying on the first applicant's regulatory data must certify one of the following to the FDA: (1) no patent applies, (2) the relevant patent has expired, (3) approval is sought only after the patent expires; or (4) there is a patent but it is asserted to be invalid or not to be infringed. Once a generic manufacturer provides a certification that it considers the patent to be invalid or not infringed (a "Paragraph IV Certification"), the manufacturer must notify the patentee, which then has an immediate right to sue for patent infringement. A patent infringement action filed within 45 days of notice delays approval of the first generic authorization for 30 months.[12] The practical result of the linkage is thus to extend the effective regulatory-data protection period by at least 30 months to seven and a half years, even when the Paragraph IV certification proves to be correct and the listed patent turns out to be either invalid or not infringed. Thus at first sight the duration of protection in the United States for data filed in support of an authorization for a pharmaceutical as a new chemical entity may seem less than that afforded by the European Community. In practice however, the difference is much less, especially because of this patent linkage.

Moreover, in the United States, data based on new clinical investigations (other than

bioavailability studies), relating to an already-authorized product, that are essential to a further authorization (such as that required for a new indication) are protected for three years. Although the protection for new data in support of a new indication for an old product is apparently more generous in the United States than in the European Community, which provides for an extension of only one year, it is important to appreciate that in the European Community the protection is extended for all indications and not just, as in the United States, for the new indication.

3.3 *Agricultural Chemical Products*

In general, the agricultural-data protection systems for authorizations in the European Community and the United States provides for a longer period of protection than for pharmaceuticals. They also give a considerably higher level of protection for new data used in relation to old active compounds than that mandated in the pharmaceutical systems.

The system in the European Community, subject to special provisions for products already on the market when the system came into force, provides for ten years of Community-level protection for a new active compound.[13] The system also provides ten years of protection at a national level (running from the first such authorization in the Community) for data filed in support of a formulated plant protection product containing an already authorized active compound. However, these periods of protection are subject to provisions intended to promote data regarding vertebrates to be shared, so that duplicate testing on animals can be avoided. Failing agreement on this issue, Member States are empowered to compel sharing of such data, which typically involves arbitration over compensation. As a result of these compulsory licensing provisions, test data derived from vertebrate animals does not benefit from exclusivity. The conferred data protection can to this extent thus be seen as a remuneration right rather than an exclusive right.

For pesticides, in the U.S. regulatory data for old and new products is protected for a ten-year period.[14] For a further five-year period, others can use the data only when the would-be users have offered to compensate the first filer of the data (in the absence of agreement as to the level of compensation, there are provisions for arbitration), but after this 15-year period there is no restriction on use. Thus the protection for the last five years of the 15-year period of protection is not exclusivity but remuneration.

3.4 *Regulatory data protection in bilateral and regional trade agreements*

NAFTA is an example of a regional free trade agreement, but since the negotiation of TRIPS, both the United States and the European Community have entered into a number of bilateral trade agreements with third countries. There have also been some regional trade agreements. Such agreements typically contain chapters addressing IP, including regulatory data protection. The approach of the European Community Trade Agreements, such as that with the Ukraine, is simply to require the trading partner to harmonize its laws with European Community standards. In contrast, the U.S. free trade agreements (FTAs) contain specific provisions to tighten up matters left vague by the TRIPS Agreement. Several FTAs are in force, including one with Australia. The texts of several others have been finalized, and negotiations are under way on a number of others.[15] The texts spell out the approach to be adopted in implementing the TRIPS standards. The obligations, expressed as mutual obligations, usually require the other party to adopt at least some elements of the U.S. implementation. This is the approach in the provisions concerning regulatory data protection.

In most cases, the FTAs that the United States has negotiated specify minimum five-year periods of regulatory data protection for pharmaceuticals and ten-year periods for agricultural chemicals. Some countries permit the granting of marketing approval based upon the existence of an approval for the same pharmaceuticals in another country. In some of these cases, the FTAs require the second country to protect the regulatory data filed in the first country for the same length of time as the first country does, or for an independent period.[16] Protection is sometimes required for test data submitted in support not

only of authorizations for pharmaceutical products incorporating new chemical entities, but for any pharmaceutical product.[17] In comparison, Europe offers such protection for new data filed in relation to an old active compound in a pharmaceutical product only when such data is filed in support of one or more new indications that bring a significant clinical benefit. However, regulatory data protection in the European Community for data filed in support of an authorization of a new pharmaceutical chemical entity is longer than the minimum five years required under the FTAs.

Several of the FTAs also require the parties to adopt the U.S. system for pharmaceutical products: the patent holder is notified of any attempt by a second applicant generic company to apply for a marketing authorization before patent expiry.[18] Indeed, in many cases, the regulatory authority is prohibited from granting a marketing authorization before patent expiry.[19] The impact of the FTA provisions requiring a link between marketing approval and patent protection, which is not mandated by TRIPS, depends very much upon the precise mechanism involved. Some mandate mere notification. Others mandate that no authorization be granted while patents continue in force, the effect of which is to increase considerably the effective period of protection. Moreover, unless they have an incentive to challenge patents in the form of their own brief period of generic exclusivity as provided by the U.S system, they may be unlikely even to try, because all they will achieve is to clear the path for other generic competitors.

4. CONCLUSIONS

Regulatory data protection provides an important incentive for developing safe and efficacious pharmaceuticals and agricultural chemicals. It is an incentive that patents alone cannot provide. The obligations in TRIPS Article 39.3 concerning the protection of regulatory data are broadly expressed and permit numerous flexibilities of implementation. However, the United States and the European Union, as the two major trading entities, have each developed specific implementations of these obligations, each with its own carefully crafted checks and balances. Each adopts a different approach to protecting regulatory data for pharmaceuticals and for agricultural chemicals. Each is also in the process of extending its specific approach to implementing these obligations to some of its trading partners. They are doing this through trade agreements that specify the minimum standard of IP protection that the parties must afford. It is important, therefore, to be aware of the differences between the U.S. and European Community systems for protecting regulatory data for pharmaceuticals and agricultural chemicals, the different checks and balances within such systems, and the reasons for and consequences of such differences. Such differences make it dangerous to cherry-pick only certain aspects of such systems, or indeed to try to merge and harmonize their respective features into one system, for doing so is likely to result in an upward harmonization that will produce a system of regulatory data protection that is more stringent than that provided by either system on its own. ■

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1 Article 39.2 TRIPS mandates the protection for confidential information. There are, however, considerable disparities in the manner in which countries comply or enforce this protection (even within the European Community), in the remedies conferred (for example, are they are enforced in the criminal or civil courts?), and in the legal bases for such laws (are they contractual or, as tends to be the case in common law jurisdictions, equitable? Or are they seen as a species of unfair competition, as tends to be the case in civil law countries?)

2 *Smith Kline & French Laboratories Ltd. v Attorney General* FSR 418 (1989), *In re Smith Kline & French Laboratories Ltd.* 1 AC 64 (1990) (England), *Smith Kline & French Laboratories (Australia) Ltd. v Secretary to the Department of Community Services and Health*, and *Alphapharm Ltd. v Secretary to the Department of Community Services and Health* FSR 617 (1990), relating respectively to New Zealand, England, and Australia.

3 Likewise in the United States, *Ruckelshaus v Monsanto Co.* (467 U.S. 986, 1019–20 (1984)) shows the reluctance of the courts to impose an unqualified restriction on regulatory authorities' use of the data filed with them. *Ruckelhaus* was analyzed extensively in the Australian *Cimetidine* case *Alphapharm Ltd. v Secretary to the*

Department of Community Services and Health [1990] FSR 617.

4 *Merck & Co. Inc's* FSR, p. 498 (2003).

5 However, one of the patents in issue in this case was for a new dosing schedule (seven days as opposed to one, with a concomitant difference in dose), and neither the old regulatory data protection law in Europe, nor the current one that replaces it, protects new data in support of a new dosing schedule for an old active compound, as was confirmed under the old law in the unsuccessful challenge to the grant of a marketing authorization to a second applicant in *The Queen on the application of Merck Sharp and Dohme Limited v The Licensing Authority (acting by the Medicines and Healthcare products Regulatory Agency, and Approved Prescription Services (U.K.) Ltd., Generics (U.K.) Ltd. and Arrow Generics Ltd*. EWHC 710 (Admin, 2005) (Moses J, 28 June 2005).

6 The earlier regulatory data protection regime in Europe as introduced by the amendments made in 1987 by Directive 87/21/EEC to Directive 65/65/EEC allowed Member States the option not to confer regulatory data protection for medicinal product "after patent expiry" and thus undermine the effect of regulatory data protection in such countries. However, although some countries, such as Denmark, initially availed themselves of this option, they rapidly abandoned it. The current regulatory data protection regime in Europe, which applies to active compounds the application for the first marketing authorization of which was made since November 2005, provides no such option.

7 NAFTA was signed on 12 August 1992 and entered into force (subject to transitional provisions) on 1 January 1994.

8 Although, as observed in Section 3.2 where the pharmaceutical is the subject of a patent, this can in practice prove to be rather longer.

9 For specifics of the current European Community system for the regulatory data protection of medicinal products see Box 2 of this chapter.

10 See the Federal Food Drug and Cosmetic Act (21 U.S.C. 355), "New Drugs," and in particular the amendments here introduced by the Drug Price Competition and Patent Term Restoration Act 1984 (Hatch-Waxman Act).

11 Such declarations are listed in the so-called Orange Book, the electronic version of which is available at www.fda.gov/cder/ob/.

12 There is an exception to this in the unlikely event that a final judgment disposes of the patent in less than 30 months. The U.S. system also provides an incentive to be the first applicant to file a Paragraph IV Certification: no other such applicant can go to market until 180 days after the first applicant to file such a certification goes itself to market or disposes of the patent in a final judgment.

13 See Articles 13 and 14 of Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market.

14 See the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a), "Registration of pesticides."

15 Details of those U.S. FTAs signed to date and the progress of the others can be found at www.ustr.gov/Trade_Agreements/Bilateral/Section_Index.html.

16 For example United States-Australia FTA Article 17.10, CAFTA Article 15.10, United States-Jordan FTA Article 4(22), United States-Bahrain FTA Article 14.9.

17 For example United States-Jordan FTA, Article 22 Footnote 10, United States-Singapore FTA, Article 16.8.

18 For example United States-Chile FTA Article 17.10, United States-Singapore FTA Article 16.8(4), CAFTA Article 15.10(3).

19 For example United States-Singapore FTA, United States-Chile FTA, CAFTA, United States-Australia FTA, United States-Morocco FTA.

20 Namely, "*any substance or combination of substances presented as having properties for treating or preventing disease in human beings*" or "*any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunologic or metabolic action, or to making a medical diagnosis*."

21 *Separate* is here meant in the sense that an authorization secured under one system cannot form the basis for securing another authorization in the other system. One exception to this is provided by Article 3(3) of the Regulation, which allows Member States to apply the Article 10 abridged authorization procedure to grant a national authorization for a generic medicinal product of a reference medicinal product first authorized by the Community.

22 The centralized system has long been obligatory for medicinal products produced by most biotechnological processes, and has with effect from 20 November 2005 been obligatory also for medicinal products for human use containing a new active substance for the treatment of AIDS, cancer, neurodegenerative disorder, and diabetes, and for medicinal products that are designated as orphan medicinal products. It is optional for other new active substances and for medicinal products shown by the applicant to constitute "*a significant therapeutic scientific or technical innovation or that the granting of authorisation in accordance with [the] Regulation is in the interests of patients or animal health at Community level*." This latter provision provides a theoretical possibility of securing an entirely new period of data protection via the centralized route in relation to an active compound that has already been authorized via the national route.

23 See Article 14(11) and 89 of the Regulation, paralleling part of Article 10 of the Directive, as amended, and Article 2 of the amending Directive.

24 See Article 6 of the Regulation, incorporating by

reference, inter alia, Articles 10, 10a and 10b of the Directive, as amended.

25 Moreover by New Article 10(5) "*... where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication*." The precise application and scope of this provision (which was added at the final stage of the legislative process and for which there are no *travaux preparatoires*) is yet to be established. The EMEA takes the view that the expression *well-established substance* means that the product no longer benefits from data exclusivity, and that the new period of data protection can be granted independently at any time after the initial protection period has expired, but can only be granted once.

26 Case C-368/96, *R v Licensing Authority, ex parte Generics (UK) Ltd*. 2 CMLR 181 (1999).

27 The proviso under the old regulatory regime stated, "*However, where the medicinal product is intended for a different therapeutic use from that of the other medicinal products marketed or is to be administered by different routes or in different doses, the results of appropriate toxicological and pharmacological tests and/or of appropriate clinical trials must be provided*."

28 In Case C-106/01, *v R v Licensing Authority, ex parte Novartis* the abridged authorization that the ECJ held to be lawful concerned a formulation of an active that was suprabioavailable to the formulation that had been authorized for longer than the data protection period but was bioequivalent to a formulation for the same active that had been authorized for less than that period. In Case C-36/03, *v R v Licensing Authority, ex parte Approved Prescription Services* the abridged authorization that the ECJ held to be lawful concerned a pharmaceutical form of an active compound that was different to the pharmaceutical form that had been authorized for longer than the data protection period but was the same as that for the same active that had been authorized for less than that period. In Case C-74/03, *SmithKline Beecham plc v Laegemiddelstyrelsen*, the abridged authorization that the ECJ held to be lawful concerned a different salt of the active moiety to that in the originally authorized product.

29 Whether or not such a mechanism was in effect implicit in the old regulatory regime was the subject of a challenge to a Commission Decision under the old regulatory regime concerning a human growth hormone product in Cases T-15/04 & T-105/04 *Sandoz GmbH v Commission of the European Communities*. However as the product in question (Omnitrop (somatropin)) has now received an authorization under the new regime, this litigation may well not continue.

30 See www.emea.eu.int/pdfs/human/ewp/309702en.pdf and www.emea.eu.int/pdfs/human/bwp/320700en.pdf for already-adopted general guidelines and the listing at www.emea.eu.int/htms/human/biosimilar/biosimilardraft.htm for various draft guidelines including specific draft guidelines as to recombinant EPO, G-CSF, human insulin, and somatropin.

31 C-440/93, *R v Licensing Authority of the Department of Health (Norgine intervening) ex parte Scotia Pharmaceuticals Ltd*. 3 CMLR 657 (1995).

32 "*The Parties acknowledge that, at the time of entry into force of this Agreement, neither Party permits third persons, not having the consent of the person that previously submitted information concerning the safety and efficacy of a product in order to obtain marketing approval in another territory, to market a same or similar product in the territory of the Party on the basis of such information or evidence of prior marketing approval in another territory.*" [Footnotes 17 and 18 in original Annex].

33 "*As an alternative to this paragraph, where a Party, on the date of entry into force of this Agreement, has in place a system for protecting information submitted in connection with the approval of a pharmaceutical product that utilizes a previously approved chemical component from unfair commercial use, the Party may retain that system, notwithstanding the obligations of this paragraph*." [Footnotes 17–19 in original Annex].

Box 2: Regulatory Data Protection for Medicinal Products in the European Community (extracts)

Introduction

This section sets out in detail the provisions relating to regulatory data protection for medicinal products for human use in the European Community.[20] Parallel provisions, which differ with regard to certain specifics involving regulatory data protection, apply to veterinary medical products. The legal basis for such provisions changed as from:

- 30 October 2005, the date by which Member States were mandated to bring the provisions of Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (for medicinal products in the national systems) into effect
- 20 November 2005, the date on which the relevant provisions of Regulation 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use (for medicinal products in the centralized Community system), and replacing those under Regulation 2309/93, comes into effect.

The relevant extracts from the Directive as amended are set out at the end of this Box. However, it should be noted that certain aspects of the former provisions (notably the period of protection and the nonavailability of extended protection for new uses) continue to apply to medicinal products for which an application for authorization was submitted before such dates, and since much of the litigation concerning the scope and effect of the old provisions informs the interpretation of the new ones, it is appropriate also to bear in mind the old provisions when discussing the new ones. Moreover, it is convenient to analyze these issues by reference to the Directive, dealing with medicinal products in the national, decentralized, and mutual recognition systems, rather than by reference to the Regulation, which deals with the generally separate, from a regulatory perspective,[21] centralized system,[22] because the substantive law in each case is the same as a result of the Regulation either repeating,[23] or in some cases incorporating by reference the relevant provisions of the Directive.[24]

This Box does not address the separate system of protection that may also be available in some cases under Regulation (EC) No 141/2000 (the Orphan Medicinal Products Regulation).

General Principles

The regulatory data protection provisions for medicinal products operate by providing an exception, after a specific period, to the requirement for someone seeking a marketing authorization for a medicinal product to provide the results of toxicological and pharmacological tests or the results of clinical trials for such medicinal product if such a medicinal product has already been the subject of an authorization. Thus these provisions enable the authorization of a generic version of an already authorized product after such period and without such data. Such an authorization may conveniently be termed an *abridged authorization*.

Term of Protection

Where a medicinal product has been the subject of an authorization submitted before November 2005, then the periods of protection under the old regime (old Article 10(1)(a)(iii)) apply, by which a product must have been authorized within the Community, in accordance with Community provisions in force, for not less than a six or ten-year period, and be marketed in the Member State for which the application is made. The ten-year period applies to medicinal products authorized under the centralized procedure of the Regulation and its predecessor, throughout the Community, and also in respect of authorizations secured nationally in those Member States that elected to apply it, namely Belgium, France, Germany, Italy, Netherlands, Sweden and the United Kingdom The six-year period applies to authorizations secured nationally in other Member States. This is the regime that will continue in effect for abridged authorizations for some time to come.

(Continued on Next Page)

Box 2 (continued)

Where a medicinal product is the subject of an authorization submitted after October 2005, then the periods of protection under the new regime apply. By new Article 10(1), an application for an abridged authorization cannot be filed until a period of eight years after the first marketing authorization in the Community has been granted, but a product so authorized cannot be placed on the market less than ten years from the first marketing authorization in the Community. This ten-year period is extended to 11 years when, during the first eight years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications that, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. The first requests for abridged authorizations under the new regime cannot be filed before November 2013.

Variations and Line Extensions of an Already Authorized Medicinal Product: New Indications, New Strengths, Pharmaceutical Forms, Administration Routes, Presentations, and so on

As noted earlier, the new ten-year period of protection available to medicinal products the subject of an authorization submitted after October 2005 will be extended to 11 years where, during the first eight years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.[25] No such provision existed under the old regulatory regime, it having been established in the *Generics* case[26] that new indications for an already authorized active did not secure a new period of protection running from the date of authorization of such new indication, and that accordingly an abridged authorization for a particular medicinal product could be granted with respect to all indications already authorized for that particular medicinal product as at the date of such abridged authorization. This case also established that new dosage forms, doses, and dosage schedules likewise did not secure a new period of protection running from the date of authorization of such new dosage forms, doses and dosage schedules, and that accordingly an abridged authorization for a particular medicinal product could be granted in respect of all dosage forms, doses and dosage schedules already authorized for that particular medicinal product as at the date of such abridged authorization.

The decision in the *Generics* case was based on the determination under the old regulatory regime that the product the subject of the abridged authorization was properly to be regarded as "*essentially similar,*" as the term was used in Article 10(1)(a)(iii), to the originally authorized product, if it satisfied "*the criteria of having the same qualitative and quantitative composition in terms of active principles, of having the same pharmaceutical form and of being bioequivalent, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety and efficacy*." Subsequent cases under the old regulatory regime established that even where there might not be such essential similarity, the proviso to Article 10(1)(a)[27] allowed for bridging data to be filed, or for bridging data filed by the originator to be relied on, provided that the originally authorized product and the product that is the subject of the abridged authorization had the same active principle.[28]

These principles have been retained under the new regulatory regime by virtue of new Article 6 and Article 10(1). Article 6 clarifies the issues of interpretation addressed in the *Novartis* and *Approved Prescription Services* cases by introducing the concept of the global marketing authorization which covers "*any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions*." Article 10(1) requires the applicant for an abridged authorization to demonstrate that the medicinal product that is the subject of the application "*is a generic of a reference medicinal product which is or has been authorized under Article 6 for not less than eight years in a Member State or in the Community*." The definition of *generic medicinal product* under Article 10(2)(b) preserves the concept of essential similarity as refined by ECJ case law in *Generics* and subsequent cases.

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Box 2 (continued)

New Combinations

New Article 10b replaces old Article 10(1)(b) and concerns medicinal products containing active substances used in the composition of authorized medicinal products but not hitherto used in combination for therapeutic purposes. In such a case, the results of new preclinical tests or new clinical trials relating to that combination shall be provided, but it is not necessary to provide scientific references relating to each individual active substance. The matter has not been the subject of litigation, but it has generally been accepted that, by virtue of this provision, a new combination has its own period of data protection calculated from the date of the first marketing authorization for that particular combination in the Community, as if that new combination were a new active substance.

Biological Medicinal Products

New Article 10(4) provides a framework that did not exist under the old regulatory regime.[29] It would enable guidelines to be established by which biological medicinal products could be authorized without full results of toxicological and pharmacological tests, or the results of clinical trials, on the basis of an earlier authorization for a "biosimilar" product. The EMEA is at present developing such guidelines, but so far the only specific guidelines that have so far been published concern certain specified recombinant proteins.[30]

Bibliographic Applications

New Article 10a replaces old Article 10(1)(a)(ii) and, as before, allows for an authorization to be sought without full results of toxicological and pharmacological tests or the results of clinical trials but which does not refer to an authorized reference product where "*the active substances of the medicinal product have been in well-established medicinal use within the Community for a period of at least ten years, with recognised efficacy and an acceptable level of safety*". It is under this provision that authorization can, for example, be sought for medicinal products containing active substances such as aspirin for the relief of pain. The narrow scope of the provision was emphasized under an earlier version of the provision under the old regulatory regime in the *Scotia* case.[31]

Relevant Provisions of Directive 2001/83/EC on the Community Code in Regard to Medicinal Products for Human Use as Amended by Directive 2004/27/EC

Article 6

1. No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No. 2309/93.

   When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).

Article 10

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he [or she] can demonstrate that the

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Box 2 (continued)

medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

   (a) "reference medicinal product" shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

   (b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters, or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

4. Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided.

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Box 2 (continued)

The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in the Annex and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Article 10a

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in the Annex. In that event, the test and trial results shall be replaced by appropriate scientific literature.

Article 10b

In the case of medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with Article 8(3)(i), but it shall not be necessary to provide scientific references relating to each individual active substance.

Article 10c

Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

Box 3: Regulatory Data Protection Provisions of the United States-Australia FTA Articles 17.10: Measures Related to Certain Regulated Products

1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party.

(b) If a Party requires, as a condition of approving the marketing of a new agricultural chemical product, including certain new uses of the same product, the submission of undisclosed test or other data concerning safety or efficacy of that product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for ten years from the date of the marketing approval of the new agricultural chemical product by the Party.

(c) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously submitted information concerning safety or efficacy, to market the same or a similar product on the basis of evidence of prior marketing approval in another territory, or information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least five years, and ten years for agricultural chemical products, from the date of marketing approval by the Party, or the other territory, whichever is later.[32]

(d) For the purposes of this Article, a *new product* is one that does not contain a chemical entity that has been previously approved for marketing in the Party.

(e) If any undisclosed information concerning the safety or efficacy of a product submitted to a government entity, or entity acting on behalf of a government, for purposes of obtaining marketing approval is disclosed by a government entity, or entity acting on behalf of a government, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article.

2. With respect to pharmaceutical products, if a Party requires the submission of: (a) new clinical information (other than information related to bioequivalency) or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later.[33]

3. When a product is subject to a system of marketing approval in accordance with paragraph 1 or 2, as applicable, and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1 or 2, as applicable.

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Box 3 (continued)

4. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:

   (a) that Party shall provide measures in its marketing approval process to prevent those other persons from:

      (i) marketing a product, where that product is claimed in a patent; or

      (ii) marketing a product for an approved use, where that approved use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner; and

   (b) if the Party permits a third person to request marketing approval to enter the market with:

      (i) a product during the term of a patent identified as claiming the product; or

      (ii) a product for an approved use, during the term of a patent identified as claiming that approved use, the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.

SECTION 5

Institutional Policies and Strategies

IP Strategy

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ABSTRACT

This chapter gives an overview of the aims of an IP (intellectual property) strategy and discusses management issues involved in implementing such a strategy. Other chapters in this *Handbook* provide more-detailed information about managing intellectual property; the purpose of this chapter is to provide an integrated framework for giving IP rights the balanced consideration they deserve.

1. INTRODUCTION

IP (intellectual property) strategy can mean many things. In order to understand the relevance and implications of the term, we first need to look at what is meant by the terms *intellectual property* and *strategy*, how they work in combination, and the implications of an IP strategy for organizations. For some people, it means the tactics used to manage an IP rights program, with detailed attention to licensing, filing, and litigation strategies. For others, the term refers to a general business strategy that uses IP rights to manage technology. Still others might assume that an IP strategy is only a concern for large for-profit corporations and irrelevant to smaller or not-for-profit organizations. However, an IP strategy, and the informed use of IP rights, is important to organizations of all sizes.

2. INTELLECTUAL PROPERTY

IP rights are commonly regarded as simply a means of protecting innovation, with the assumption that this protection benefits the innovator.[1] However, such a view emphasizes too strongly the private benefits that can accrue to IP rights holders while neglecting the important public benefits provided by an IP system. Viewed broadly, an IP rights system has several components that contribute to the system's overall effectiveness. These roles need to be kept in balance, so that private interests do not dominate the public interest. Nor should public interests, considered in the short term, dominate the long-term private interests that drive the system.

IP rights are beneficial in a number of ways. By providing incentives or rewards for innovation, by packaging or defining intellectual assets, and by diffusing technical information and controlling intellectual assets, they are a powerful engine for innovation. In contrast to these utilitarian functions, IP rights also can be seen to protect a natural, even moral, right of inventors to their creations, a view that has its origins in Lockean conceptions of property.[2]

Whatever theoretical justifications are used to support them, the difficulty with IP systems is in striking the optimal balance between private rights and public benefits. From a public-policy perspective, this goal is elusive, and even after several hundred years of debate by economists, political leaders, and inventors, a precise way of balancing these competing concerns has yet to be found.

Pitkethly R. 2007. IP Strategy. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

IP systems play a significant but uncertain role in policy measures used to encourage investment in innovation. Fritz Machlup is often cited, for example, to support the view that the uncertainty inherent in the patent system makes that system difficult both to implement and to abolish.[3] But Edith Penrose made this same point seven years earlier in her study of the international patent system: "*If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them.*"[4] Penrose was referring to the 19th century debate about patents, and Machlup and Penrose's earlier discussion of the 19th century patent system controversy dealt, in large part, with the debate over its abolition.[5] However, they observed in the same article that "*little, if anything, has been said for or against the patent system in the 20th century that was not said equally well in the 19th.*" That statement is also likely to be true for the 21st century.

Indeed, despite the longstanding theoretical uncertainty about IP rights systems, they have proved remarkably resilient in the countries that have implemented them. It is arguable that IP rights systems are, so far as we can tell, better than any of the alternatives that have been proposed over the years. Of course, this raises the possibility of interpreting IP strategy as that at the national not corporate level. In fact, there are many interesting examples that could be studied in support of this claim.[6] The U.S. Constitution, for example, provided for IP rights from its inception.[7] And Japan's rapid modernization from a feudal society in the 1850s to an industrialized nation by the early 1900s included the relatively rapid adoption of an IP rights system.[8] Even in the United Kingdom, the gradually evolving patent system had a role to play in the first industrial revolution.[9] Patent systems are known to support the interests of industrialized nations, and in most cases such systems also played a role in encouraging early industrialization efforts. This suggests that some form of IP strategy, at a national level, is relevant to all nations regardless of their level of industrialization.

2.1 *Organizational roles of IP rights*

Although the different justifications for IP systems and the different national strategies for implementing them are worthwhile topics, this chapter has a more pragmatic goal, to help provide an understanding of the practical implications of the various IP systems. Accordingly, it considers the four practical roles of an IP system. These are (1) acting as an incentive system for innovation, (2) packaging intellectual assets, (3) diffusing technical information, and (4) controlling intellectual assets.

An IP system's role of providing incentives or rewards for innovation is achieved through protecting that innovation by restricting use by others. The restriction, by protecting the inventor, enables them to command monopoly prices and benefit from the innovation to a greater extent than would be possible without such protection. This has implications for strategy in that potential restrictions on use confer control, and that control can be exercised not just to limit but also to expand the market for an innovation.

With technology-based innovation, IP systems also help package and define intellectual assets. Intellectual assets, by definition, start as tacit ideas, literally embodied in the inventor. IP rights, and particularly patent specifications, facilitate these tacit inventions by providing a more easily transmissible and protectable embodiment for these intellectual assets. This ability to enable previously tacit or secret information to be identified and made the subject of transactions and communications is a critical function of Intellectual property, and this dimension of IP rights has strategic implications. For example, this function facilitates licensing. Kenneth Arrow's information paradox, where transactions in confidential information are made more difficult where trust is absent, can be eased by the use of IP rights and the laws of contract.[10]

An IP system—especially a patent system—plays a key role in diffusing technological information. The threat of free riders and competition may tempt an innovator to keep an invention secret. Historically, there have been cases, notably the Chamberlen family's secret use of obstetric forceps in their medical practice for more than 130 years, where society has been denied

life-saving technologies because an invention was kept secret.[11] Modern analytical methods and job mobility make such tactics less likely today, but an IP system still has an important role in both facilitating the publication of inventions and making information easier to find. The challenge is, of course, that an IP system must be arranged so that the rights granted to innovators do not end up costing the rest of society more by unduly hindering access to other innovations.

Finally, intellectual property rights may be thought of as a means of, not just protecting, but, *controlling*, the underlying intellectual assets. This is particularly critical when IP rights are considered from the point of view of organizations or individuals with a concern for the public interest. The fact that IP rights give the power to prevent use means that they also give the right to license use, which enables IP rights holders to exert significant control over their innovations. The extent of that control will depend on a number of other factors (see section 4 below). If an organization ignores or fails to obtain IP rights, it risks abdicating control over an invention. In the case of a fundamental invention, this may have major strategic implications.

This point is illustrated by the different ways in which penicillin and the subsequent cephalosporin antibiotics were protected by patents. When penicillin was discovered in 1929, chemical product patents were not available in the United Kingdom. At the time, some felt that the discovery and work associated with penicillin's production should not be subject to patent protection. As a result, neither penicillin itself nor the initial production methods were patented by the discoverer, Alexander Fleming, in London and the developers in Howard Florey's team in Oxford. In contrast, the crucial factor in the widespread use of penicillin in the latter part of the 1940s turned out to be the development of bulk fermentation methods of production, and these were patented by their inventors in the United States.[12] As a result, the potential for control over the commercialization of penicillin largely belonged to the U.S. companies involved. Several years later, scientists from Florey's research group in Oxford discovered and developed the cephalosporin group of antibiotics. Patents were obtained by the National Research and Development Organization (NRDC), which was then responsible for commercializing university-based inventions.[13] Using the royalties derived from licensing these patents, the two main inventors, Guy Newton and Edward Abraham, set up two charitable trusts, the E. P. Abraham Research Fund and the Guy Newton Trust, which still today support medical, biological, and chemical research in Oxford.

The point behind these two stories is that, in the first case, control and financial benefit were effectively ceded to subsequent developers of critical enabling technology. In the second case, patents were used to not only retain that control but also to put financial proceeds under the inventors' control—in this case, for charitable purposes. A similarly significant financial decision was made by the NRDC many years later when it did not patent the initial discovery of monoclonal antibodies by Georges Köhler and César Milstein. In retrospect, this arguably forfeited several million British pounds of potential royalty income. However, it is worth noting César Milstein's comment about his approach to patenting and licensing his laboratory's work:

Within our laboratory we established a set of principles. The public interest should come first, the scientific interest of the inventors, second, and making money should be considered only in the light of the first two priorities.[14]

But did the first two principles receive the priority they could have had if there had been more interest in the commercial aspects of the laboratory's work? Indeed, such principles do not preclude the use of IP rights. They simply suggest how the rights might be used. More importantly, the public may benefit when those who are obliged to be concerned with the public interest exercise control over their innovations. Intellectual property represents one of the few means of control available to scientific and research establishments, even for those organizations not directly involved in commercializing their research.

More generally, it is much more useful to consider IP rights as a means of control,

rather than as a barrier to be placed in the path of the competition.

3. STRATEGIC MANAGEMENT THEORY

Having considered the roles that intellectual property can play, the nature and scope of IP strategy should be considered. There are many definitions of *strategy* from a business perspective. A common, widely applicable definition is provided by business historian Alfred Chandler:

Strategy can be defined as the determination of the long-run goals and objectives of an enterprise and the adoption of courses of action and the allocation of resources necessary for carrying out these goals.[15]

The word *objectives* is used in the plural, and it is important to realize that organizations may have multiple objectives. Businesses tend to be thought of as unidirectional, as devoted solely to the pursuit of profit, or maximizing shareholder value. In reality, most organizations have multiple objectives and pursue more than just profit. In the case of not-for-profit organizations, this is usually explicit. Objectives such as widening access to medicines, eradicating disease, and improving social conditions may constitute primary objectives for organizations, and these objectives may make profit seeking impossible. However, whatever the organization and whatever the objectives it sets for itself, the resources it has under its control must still be managed to best effect. For a company to say it will forego profit by not bothering to exploit a resource may sound acceptable, if financially inefficient. For an organization to say it will forego the chance to save lives by not bothering to exploit a resource can hardly be seen in the same light. Indeed, if not-for-profit organizations opt out of the global IP system, they may not be the biggest losers. This point once again highlights the importance of intellectual property and of understanding its challenge, which lies in the need to balance the management, control, and use of resources with the achievement of the organization's objectives. Intellectual property is a resource. As such, it should not be thrown away—even with the best of intentions. As with many aspects of intellectual property, it is no surprise that the choices may not always be clear and are almost always controversial; the challenges should be expected to be unexpected.

A conventional view of business strategy might divide the subject into a consideration of the *external* environment, in which the business competes, and the *internal* resources it uses to compete. In the early 1980s, studies of strategy tended to concentrate more on external environment, including work originating in industrial organization economics. This work, emphasizing barriers to entry, by authors such as Bain[16] and Mason,[17] eventually led to Porter's work on industry structure analysis.[18] Porter considered IP rights primarily as examples of barriers of entry, though they also form "isolating mechanisms" necessary to preserve competitive advantage.[19] However, concentration on such external issues as the choice of where to invest and compete made the strategic analysis of the day less directly relevant to IP issues. In the latter half of the 1980s and 1990s, the development of the resource-based view of companies, with their internal focus on managing the resources of an organization, gradually drew the field of strategy closer to that of IP management.[20]

The resources of the organization essentially comprise the organization's staff, its financial resources, any tangible assets, and the intangible or intellectual assets that the organization controls. The aim of strategy is to manage the resources available in order to achieve the objectives set. Since in most cases resources are tradeable assets, any organization in possession of valuable resources is obliged to put those resources to the best use possible, even if they lack direct relevance to the organization's immediate objectives.

A publicly acknowledged failure to make the best use of a company's assets may result in a bid for control of the company by those who feel they can extract more value from resources than managers have. Even with not-for-profit organizations, not making the best use of the resources available is a serious failure.

IP rights are one of an organization's intangible resources, and thus they need to be exploited to the fullest extent consistent with the organization's objectives. How this should be done may

not always be clear, but what is certain is that no resource should just be given, or thrown, away.

One final aspect of general strategic-management theory that is relevant to the study of intellectual property is the concept of managing added value. In any business where resources are employed and processed through a value chain of parties—each adding some small amount of value before the product reaches the end customer—the relationship between the organization and those with whom it buys and sells is crucial. Just as important is how the value created by the entire chain of parties is distributed among the parties in, or closely associated with, the chain. If the innovator tries to capture the entire added value in the business, perhaps by using particularly effective IP rights, the innovator may find it impossible to get any distributors to sell the product. The innovator might then be forced to rely on direct sales, resulting in a loss of competitiveness. Equally, if each business or licensor involved in a production chain insists on a substantial proportion of the final retail price, the royalty stacking produced may make the goods concerned uncompetitive. While the concept of the value chain is inherent in a number of strategic models, whether at the industry level[21] or business-unit level, the "value net" advocated by Brandenburger and Nalebuff deals nicely with the issue of how value added is distributed over a network of parties involved directly, or indirectly, with a business.[22]

In considering how to exploit and appropriate the benefits of a given piece of intellectual property, consideration must always be given to how the dynamics of an industry, the access to complementary assets, and the strength of IP rights will affect the ability of any one party to appropriate the benefits of the innovation.

4. IP STRATEGY

Having identified IP rights and how they fit into the larger scheme of strategic management, the immediate question is what exactly an IP strategy requires beyond the general exhortation to make the best use possible of the resource.

A simple taxonomy of IP strategy to divide the field is needed, just as the larger field of strategic management is divided into internal and external resources. On the one hand, there are activities external to the organization that involve interaction with other parties. On the other hand, there are internal activities concerned with management within the organization. The word *strategy* tends to invoke images of competitive action, but the internal perspective on IP strategy must not be neglected in favor of the external, since both are directly concerned with the value and allocation of resources.

A further distinction to be drawn is that between IP *strategy* and IP *management*. This might be likened to the difference between strategy and tactics; the difference is between the general principles and aims that govern the courses of action (strategy) and the actual implementation of those courses of action (management).

4.1 *External IP strategy*

The key components of an external IP strategy are the issues of exploitation and what might be termed litigation, licensing, and learning. In a sense, litigation and licensing are opposites, since one denies and the other allows what would otherwise be an infringement of IP rights. The fact that both are choices within an IP rights holder's range of strategies illustrates the power of control provided by an IP strategy. The possessor of an IP right has the power to stop, allow, or even encourage the use of that right, depending on the strength of the IP rights concerned.

Regarding litigation, perhaps the main distinction to be drawn is between litigation tactics, for example, deciding in which country to litigate against multiple infringers or deciding which arguments to use. In contrast, litigation strategy involves, for example, deciding whether to resist or grant licenses to infringers, so that litigation can be settled before it reaches court. Especially where IP rights held overseas are infringed, IP rights holders may be persuaded to solve infringement by granting licenses to convert local infringers into licensees. This may not, however, always be the best course of action; certainly the best licensees may not always be found among former infringers. The infringers may have deliberately infringed with the aim of

acquiring licenses on advantageous terms. Indeed, a focus on litigation strategy may encourage the IP rights holder to make poor decisions about whom to grant a license. Moreover, while a patentee's options may be more limited when operating overseas, a litigation strategy should not be decided by the infringers but by the IP rights holder. Wherever possible, any decision about licensing should be driven by licensing considerations rather than by a desire to avoid litigation. For institutions and organizations whose main aim is to maximize the use of their innovations, litigation should be secondary—far behind exploitation and licensing.

When seeking to exploit intellectual property, an organization has at least three main options. First, it can sell the technology outright and exit from the field (except perhaps for providing technical advice during a transitional period). Or it might choose to exploit the technology in-house, using its resources to develop and market products and services. Finally, an organization could choose to license-out the technology.

In all cases, the implications of each approach must be considered. The organization aims to make the greatest use of resources under its control. In the case of intellectual assets, such as a patented technology, a key question must be what resources are required to successfully exploit the technology. Teece has suggested that firms need more than IP rights: success in a competitive market requires strong IP rights plus access to "complementary assets."[23] For most technologies, getting from laboratory to market or to the patient, recipient, or other beneficiary of the technology requires much more than just inventing and announcing the technology. Process development, testing, trials, approval, production engineering, production facilities, distribution chains, and marketing skills are just some of the resources required to exploit a technology. Not all organizations have the needed resources. Even those that do have the resources may only possess them in limited markets, putting international exploitation beyond their reach. So, if we assume that a new technology is well protected using IP rights, then the question remains as to whether the organization has the complementary assets needed to exploit the technology. Leaving aside the question of whether the innovator keeps most of the benefits from the innovation, the key issue is whether the innovation can be exploited to the fullest extent by the organization at which it was invented.

Indeed, if a new invention gives substantial advantages over existing technologies, it can be assumed that the invention will be a technological success. What cannot be known is whether the organization inventing it will be more successful than its competitors in making the invention widely available. Organizations with limited resources, the case for all but the very largest multinational firms, are very unlikely to be able to exploit new products or services quickly. This means that the organization's assets will have to be used or traded in order to acquire the needed resources. Especially for smaller organizations with limited staff, finances, and physical assets, the only resource likely to be sufficiently scaleable to expand to meet the resources needed for overseas exploitation will be the intellectual property associated with the invention.

The returns from out-licensing technology are inevitably less than the potential proceeds from exploiting those assets in-house. But licensing can make access to markets and technical fields possible. Thus, the cost of such licensing may be well worthwhile, since the amount of value added will likely be substantial, relative to costs. Even for a not-for-profit organization, some form of contract that effectively trades returns for opportunities to exploit is all but unavoidable.

There are, however, two potential concerns with licensing agreements. Licensing is just one option on a continuum of possible interactions between organizations, ranging from sale, purchase-through-licensing, and joint ventures and alliances to full acquisition and merger of the organizations. These options should be considered as alternatives to licensing if in-house exploitation or outright sale of the technology is impossible. For an organization with limited resources, licensing may be the easiest option, but it may not necessarily be the most efficient for maximizing control and returns available to the innovating organization.

Outright sale involves loss of control and, more importantly, may fix the returns available. As an alternative to an outright sale, some form of exclusive license may be preferable, since contracts can be written to include options enabling the innovator to benefit from unexpected increases in revenue and new opportunities to exploit the invention. This approach essentially applies the concept of real options to help the organization limit its downside risk, while still allowing the organization to take advantage of any unexpected upside advantage. Another way of achieving this real option effect is to license technology to a spinout company formed by the organization to develop the technology independently. Forming a spinout, however, requires raising additional financing from other sources, with the original organization recouping its investment from the eventual capital appreciation of its shares in the company. But the demands on those involved in the spinout are arguably greater than those involved with exploitation either through licensing or sale. That is true because the interests of investors, industry, and those in the organization must all be reconciled. Such a spinout strategy may, however, provide higher returns to the organization and, because outside investment could be generated, the strategy may enable exploitation on a scale that would have been impossible either by licensing or by selling the technology to existing companies. Spinouts can be used by any organization, including public sector organizations such as universities. Indeed, there are many examples of their use by technology transfer offices (TTOs).[24]

The objective of all licensing or sale of intellectual assets is for the organization to extract the maximum benefit from the innovation so that it can achieve its objectives. This means seeking the maximum benefit not just for immediate opportunities but also for future opportunities, such as overseas expansion. IP strategy cannot be short sighted, in terms of either markets or time. Just as a patent attorney drafting claims will frame them as broadly as the prior art allows, enabling the full scope of patent protection to be obtained and not unnecessarily restricted as new uses of the invention develop, means a TTO should construct contracts and licensing arrangements to take advantage of all possibilities. In fact, such practices should be a normal part of the responsible strategic management of an organization's intellectual assets.

One final aspect of licensing, equally important to not-for-profit organizations, is the issue of learning, or technology diffusion. In a competitive market, out-licensing by a technological leader will give access, not only to the technology licensed, but to learning opportunities.[25] Where the aim is to diffuse technology as widely as possible, such dual access may be a positive advantage. On the other hand, where the aim is to maintain a competitive advantage over those who might learn by licensing-in, it may prove a considerable disadvantage that is not outweighed by the income that licensing brings. Licensors of intellectual assets may need to balance the effects of learning with the potential revenue from licensing.

Finally, one sometimes neglected aspect of licensing concerns network externalities where the worth of a technology to users increases the more users it attracts. In such cases, even in a competitive situation, it may be preferable for an organization to license-out or otherwise make the technology available even at low or below cost, since this will generate a large user base and encourage further adoption of the technology. (An organization should, of course, be aware of any competition law restrictions that might be relevant.) In such cases, the reluctance to license-out the technology may actually lead to a competitive disadvantage, even though it is thought that the innovation is being protected and exploited. Once again, the lesson here is that the control that IP rights give is more important than the mere ability to prevent exploitation by others; too restrictive an attitude toward IP rights can act to an organization's disadvantage.

4.2 *Internal IP strategy*

IP strategy involves not just external issues but a variety of internal issues related to resources within an organization. A few of these issues that are particularly relevant to IP strategy are: valuation, information, coordination, and education, including the management of researchers in their

roles as creators and preservers of intellectual property within an organization.

4.2.1 *Valuation*

The valuation of intellectual property reflects the nature of the IP system in general. Despite the best efforts of economists, it is often arguable how valuable the IP system is for any general class of innovations. Likewise, despite the best efforts of managers and accountants, it is often unclear exactly how valuable a particular intellectual property right is, despite the fact that deciding to obtain or preserve the right implies a specific value.[26] If organizations are to go to the expense of obtaining and protecting intellectual property, especially intellectual property that requires a complex application procedure such as overseas patent applications, then the considerable costs have to be justified.

It is easy enough to justify long-established legal fees to preserve an established income stream, for example, from licensing a successful piece of intellectual property. However, far more often IP managers will be required to make decisions about incurring costs for intellectual property of unknown value. Such decision making in the early stages of the life of a patent, for example, is inevitably problematic because the decisions require speculation about the invention's future prospects. After all, such predictions about the future can certainly be wrong.

In response, two potential approaches can be taken. The first is simply to adopt a portfolio management view of innovation and to assume that, although much expenditure on R&D and IP protection may be wasted, there will be enough successes to more than pay for the failures. While this approach is adopted often by larger companies that can afford such an approach, such an approach is not easy to sustain when financial pressures mount and organizations are looking for short-term costs to cut. The consequence of such financial pressures are that companies operating near the margins of profitability may find that their IP rights coverage is patchy, reflecting fluctuations in their financial position. In unfortunate cases, financial hardship coincides with the creation of a valuable innovation, which then is left unprotected and less exploitable than it might have been.

The second approach is to adopt a case-by-case analysis of each development, taking into account all the information that is available about the innovation's future prospects. The key feature of such an analysis is the fact that the absence of current revenue early in the life of an invention should not count against it as much as its absence later in the invention's life. Of course, it is easy to value a stable income stream once an invention has become successful. The essence of valuing early-stage innovation is to be aware that such IP rights represent *real options* on the future extra income that might be derived from the IP rights that protect the invention.[27] But calculating patent values, taking such real options into account, is not straightforward. In practice, patent attorneys and IP managers make implicit valuations of this sort whenever they justify preserving an IP right that is currently unproductive, as long as they foresee some chance of it producing an income stream in the future.

In terms of evaluating alternative courses of action, some form of valuation is essential for assessing the potential outcomes against the potential costs. Strategy is thus intimately linked to valuation. However, beyond such assessments, there is the more general issue of the values driving the objectives of the organization. Issues may exist where the values of the organization drive decisions that are not solely based on a financial analysis. That said, even where such plural strategic objectives and nonfinancial values are involved, financial analysis might still be a perfectly valid basis for making many IP-related decisions.

Valuation is a critical, unavoidable element of IP management and strategy. This, however, does not make valuation any easier to carry out reliably when making important strategic decisions.

4.2.2 *Information*

One of the roles of IP rights is to diffuse information. The patent system, for example, promotes the public benefit by forcing inventors to disclose their inventions to the world in return for the grant of patent rights. Of course, publishing such information has its drawbacks. Publishing

provides a source of information of great use to the organization and also of use to competitors.

Besides publications, researchers should conduct patent searches along with literature searches. Though academic publications might be issued before related patent applications, often the patent application is the only, or the first, publication available related to a competing technology. In addition to establishing what already exists in the prior art, patent searching can give a very good view of the technological trajectory of organizations and thus has strategic importance for dealing with competitors or when negotiating licenses or other deals. Patent and other IP-related information thus play, not just a technical, but a strategic role.

Strategy is almost always formulated with reliance on imperfect information. Consequently, any access to information that can inform decisions is a valuable resource.

4.2.3 *Coordination*

Those involved in managing intellectual property need coordination, and such coordination is essential to the strategic process of "allocating resources" identified in Chandler's definition of strategy. The problem often encountered in the strategic management of intellectual property is that the range of people, skills, and qualifications required is such that no one person or group of people can easily carry out, in an integrated way, all the tasks required. The range of skills needed will include those of legal specialists, such as patent attorneys skilled in drafting and prosecuting patent and trademark applications; lawyers specializing in intellectual property who can assist with litigation or licensing contracts; and R&D managers who can provide suitable incentives and motivation to keep personnel involved in obtaining and protecting IP rights. Other personnel such as licensing managers, who may not be legally or technically qualified but have substantial commercial experience, also have a significant part to play in managing intellectual property.

Finally, senior managers are needed to guide and oversee the overall strategic management of the organization's intellectual property. The person ultimately responsible for intellectual property in a company might come from a legal, business, or technical background. However, since it would be unusual for any one of such managers to have all the requisite skills to manage intellectual property, an essential feature of good IP rights management is good communication and coordination among those who, as a group, possess the requisite skills. Communication and coordination are key concepts to keep in mind when assembling staff to provide the skills for the organization. These concepts are especially important when making decisions about where to locate staff or find outsource specialists.

For example, locating patent attorneys near to the R&D scientists the attorneys are meant to interact with will facilitate the process of patenting and technology transfer. Conversely, isolating a specialist IP department from the strategic management of the organization will not help integrate the management of intellectual property into the strategic thinking of the organization as a whole. Compromises may have to be reached to reconcile conflicting demands of the R&D lab, IP legal department, and the organization's headquarters. The aim, however, should be to enable R&D, IP law, general law, and general strategy to work together efficiently.

4.2.4 *Education*

Finally, there must be a minimum level of IP awareness training for all staff, especially the majority who are not IP specialists. Such training is necessary to avoid employees compromising valuable intellectual property because they do not know, for example, that publication before filing a patent application invalidates the application. IP training can also serve to improve communication between researchers and IP specialists. Training sessions can provide a forum for publicizing the organization's policy on incentives offered to employees to support the process of obtaining and preserving IP rights. Preliminary research results in the United Kingdom and of the common experience of those working as in-house patent attorneys show that, while most managers have heard of patents, they have only a limited knowledge of more-detailed information, such as what type of disclosure will prejudice a patent application.

The aim of an organization's IP awareness activity should therefore be to dispel such ignorance without trying to turn all employees into patent attorneys, thus ensuring that employees are reasonably equipped to preserve the organization's IP interests.

5. INSTITUTIONAL DIFFERENCES IN IP STRATEGY

Governments, public sector organizations, spin-out companies, small and medium enterprises (SMEs), and large companies all need to pay attention to IP issues. However, the issues that each will be concerned with will differ from institution to institution, as will the various IP strategies and practices the institutions adopt.

5.1 *Governmental IP strategy*

In addition to having institutions to administer IP laws, most industrialized nations will need an IP policy, for dealing with trade-related IP aspects, as part of their general trade and industry policies. However, any national government intellectual property or patent office has both an administrative role and an *internal* policy-making and promotional role. The first IP systems in the U.K. resulted not from external trade pressure, but from the original goal of encouraging innovation. Today, battles commonly are fought to choose between trade pressures that protect external intellectual property and the perceived local, short-term advantages of minimizing such protection and free riding on such external intellectual property. This conflict can lead to insufficient attention being paid to one of the original roles of IP systems: promoting innovation and diffusion of inventions. In the face of such distractions local innovators will fail to take advantage of the information that IP systems can diffuse (for example, through patent information systems) and will also likely fail to be influenced by, or even aware of, innovation-promoting incentives. Thus, one of the most important things a government can do is to provide an effective, enforceable system for protecting and promoting local innovation that not only provides the infrastructure to administer the system and spread knowledge, but also actively promotes the use and benefits of the IP system to potential users.

Such promotion can be carried nationally by the central government, as illustrated by the promotional activities of the Danish patent office[28] and the traveling seminars of the U.K. patent office.[29] Promotional activities can also be undertaken at the local government level, as has been shown by the Tokyo metropolitan government's IP center, which not only promotes IP awareness but can even help pay for some IP work and applications.[30] Obviously, exactly how awareness is promoted and which aspects of intellectual property are emphasized will vary from country to country. In any case, an IP system that potential users are unaware of is guaranteed to be ineffective, since it will serve only the interests of the few who are aware of the benefits.

5.2 *Public sector IP strategy*

IP strategy might appear to be of interest only to for-profit commercial organizations. Granted, the innovation-promoting role of IP rights may be less relevant for a public sector organization involved in R&D as a matter of government policy, than for a private company seeking a commercial return. However, the controlling and intellectual-resource-management aspects of IP strategy are nonetheless highly relevant to any institution—particularly public institutions that have a duty to manage their resources as best they can to achieve their public objectives. Government services, such as health services, government research departments, university research laboratories, and other public sector institutions involved in creating intellectual property will certainly need to formulate an IP strategy. They will need to ensure that staff are aware of the organization's valuable IP assets and that these assets need managing and preserving as much as any other assets of the organization. An IP strategy can also help to ensure that any liabilities that might be incurred by the use—especially the inadvertent use—of intellectual property owned by other parties are minimized.

Given, for example, the IP management functions within a university or government

research laboratory, an IP strategy is likely to emphasize protecting and exploiting intellectual property through licensing or spinout companies.[31] Noncontractual and nonlitigious aspects of work, such as drafting patent applications, may be outsourced to patent attorneys in private practice. So one key role of a public organization involved in R&D—especially collaborative R&D—will be to manage the IP elements that govern research contracts.

In the case of public or charitably funded research organizations, the absence of an IP strategy is likely to result in the organization effectively giving away its IP assets to others. Ignoring the need to manage IP resources is as serious a failing as neglecting to manage an organization's physical or human resources.

5.3 *Spinout and SME company IP strategy*

Small companies, especially those in the very early start-up phase of their existence, may not have the resources to employ any specialist staff (such as qualified patent attorneys). However, one might argue that companies at that stage of their existence have the largest portion of their overall value embedded in intellectual property. As such, an IP strategy is one of the most essential elements of a company's overall strategy, and because of limited resources and information, the IP strategy will be difficult to formulate. Thus, because small companies lack resources and the complementary assets mentioned above, these companies, including IP spinouts, run the risk of failing to appropriate returns from their innovations.

To counter this potential loss of advantage, smaller companies need to spend what may seem like a disproportionate amount of their resources on protecting and exploiting their intellectual property. If necessary, these organizations should rely on external sources of advice and help to accomplish such protection and exploitation. A risk, which may be unavoidable at times, is that cash constraints may limit the ability of a company to protect and exploit its intellectual property. Thus, the company may be unable to reap as much of the benefit from its innovations as it otherwise might.

By investing in the initial innovations to extract more value from them, a small company can use protected intellectual property to generate the financial and other resources needed to grow the business. A spin-out company may likely find it difficult to extract the maximum value from its innovations, especially if its IP rights are weak. However, as the company gradually increases the resources available to it, its ability to exploit subsequent innovations should improve. An IP strategy is not something that a small company cannot afford to have, but rather something it cannot afford to be without.

5.4 *Large-company IP strategy*

Large companies might be considered to have the simplest task when it comes to IP strategy, since they are likely to have enough resources to deal with IP issues promptly and, very often, in-house. But large companies face IP strategy problems that smaller companies or public institutions are unlikely to encounter.

First, a large company is likely to have been built on the strength of its past technological successes. Most forms of intellectual property (apart from trademarks) have a limited lifetime, so past success is no guarantee of future success. Indeed, the ability of a company to reap large financial rewards from out-licensing previously neglected IP assets may just be a prelude to the company's demise, unless some of those proceeds from past success are invested in the future. Repeating success is never easy, especially in areas where technological uncertainty can undermine technical and commercial ability. In the absence of continued investment, decline is inevitable, since IP rights erode and technology gradually becomes obsolete. No company, however large, can afford to rest on its technological laurels.

Second, communication and integration may present a challenge. One benefit of being a small company is that all the key personnel involved in IP issues probably work in the same building and interact with each other every day. For a large company, especially one with a separate in-house IP department, IP specialists must be continuously encouraged to communicate with those inventing and exploiting innovations within the company. Moreover, the IP department must communicate

well with senior management and convince it of the importance of IP management.

A third challenge is that IP departments within a larger company may be tempted to focus on internal department interests, rather than on the interests of the company as a whole. This might result in too many patent applications being filed or excessive licensing of technology that should instead be kept in-house.

None of these challenges should force larger companies to outsource such IP management functions; they are just good reasons to make sure that IP is properly managed. In terms of communication alone, the benefits of keeping IP management functions in-house can be considerable if IP departments are managed well.

6. IMPROVING IP STRATEGY

IP strategies inevitably differ with size and type of organization. As we have seen, the key elements of an IP strategy involve both external and internal factors. External factors include issues of licensing and litigation; internal factors include issues of valuation, information, coordination, and education. All these aspects of IP strategy should concern all types of institutions to some extent, though emphasis will vary. Public institutions may tend to concentrate more on licensing, information, and education. Spinouts and small companies will be more concerned with external issues of licensing and litigation, and, consequently, valuation. Large companies will be concerned equally with all issues, and the companies may be more aware of IP issues due to their in-house IP departments.

Each kind of institution can take basic actions to improve its own IP strategy. For governments, these might include:

- promoting awareness of intellectual property, from both a creator's (potential innovators) and a user's (potential infringers) perspective
- promoting use of information contained in patent and other IP databases to both source technology and inform further innovation
- providing both central and local sources of advice and assistance with innovation exploitation, especially in overseas markets
- providing basic education in innovation exploitation to IP lawyers (Although they may be the first point of contact for IP advice for many, they are generally only legally and not commercially trained. Having someone to whom companies could refer to for specific advice would help.)
- organizing a network of innovation-support centers to provide communal TTO/IP advice (Infrastructure to exploit innovations exists internationally; the problem in many countries is getting from the inventor to the overseas licensee. Such centers might not be able to do all the work of normal TTOs, but would be able to coordinate IP exploitation and protection.)
- involving external trade organizations, which can help market technology overseas for those companies/organizations without the resources to do so
- taking steps to enable organizations to use, protect, and exploit nontechnological intellectual property—in particular copyright and trademarks, including collective and certification trademarks and designations of origin—even where technological innovation is less common or absent

For public sector institutions and research laboratories, basic actions to improve IP strategy might include:

- promoting an awareness of intellectual property from the innovator's perspective, including its value to the institution
- promoting use of the information contained in patent and other IP databases to inform further innovation
- providing sources of advice and assistance with intellectual property and innovation exploitation, especially in overseas markets
- giving a manager within the organization specific responsibility for IP management

- combining the role of IP manager with that of TTO manager in order to control the exploitation of technology produced by the organization and to provide advice on research contracts with external organizations (This approach will work in an R&D-related organization)
- taking action to facilitate good communication between IP generators and IP managers, as well as between IP managers and those controlling the organization overall

Spinouts and other small and medium enterprises could undertake these actions:

- promoting awareness of the basics of IP law and IP exploitation among staff so that everyone knows what crucial errors to avoid
- encouraging organizations to spend money in order to preserve and exploit commercially valuable intellectual property, where doing so is obviously economically justifiable
- encouraging companies to use IP information sources, such as patent and trademark databases, to supplement literature searches and to inform companies of competitors' activities both at home and abroad
- enabling companies to manage and provide incentives for those inventors who are the source of a company's intellectual property and who may well be the source of future intellectual property
- being prepared to form alliances and licensing deals to supplement the company's resources and to exploit markets earlier than would otherwise be the case, especially in the early stages of a company's life, during which period resources are scarce (Such licensing should not be so late that competitors have sunk investments into developing their own competing technology, nor so early that the value of the company's technology would not be fully appreciated or valued.)
- being prepared for the exploitation of a succession of innovations (The company's ability to fully exploit its inventions should gradually increase over time as proceeds from the exploitation of initial inventions are reinvested.)

With public sector institutions and research laboratory scientists activities to improve IP strategy could include:

- ensuring that laboratory notebooks are properly kept and that any publication is preceded by an assessment of patentability and commercial potential
- ensuring that all research staff are aware of the basics of IP law, especially that publishing technology before an application is filed may preclude patent protection
- ensuring that all research staff are familiar with IP-related staff in the organization or, if necessary, external TTO or patent attorneys who can provide expert advice at short notice
- ensure that all scientists entering collaborative agreements with other institutions have such agreements vetted by IP experts before they are signed

Finally, larger companies will need to bear in mind the following points:

- Even though a large company may have access to all the resources required for successful IP exploitation, these may be rendered useless by inadequate communication among the various people involved. Action should be taken to facilitate good communication between IP generators and IP managers, as well as between IP managers and those controlling the organization overall.
- Intellectual property should be considered both a source of technology to exploit and a means of exploiting technology: a "Not Invented Here" attitude to externally sourced technology can be shortsighted.

7. CONCLUSION

IP strategy encompasses a far greater range of issues than can be dealt with here. Strategic issues connected with intellectual property—in particular, the interaction between the strength of

IP rights and access to complementary assets, as well as the specialist nature of the skills required to manage it—are particular to IP management. However, IP strategy can fit within a number of conventional strategic-management theoretical frameworks, particularly the resource-based view of the company, with its consideration of intangible assets as a resource of the organization, and also game theoretical considerations of value-added distribution. As with any other resource, intellectual assets should be used to best advantage to pursue the organization's objectives.

IP systems are always controversial, because they appear to be cases of means justifying ends: they use something generally considered undesirable (monopoly, even if temporary) to achieve something desirable (technical or commercial progress). Nonetheless, IP-rights systems are now institutionally embedded in many societies to such an extent that abolishing them or even weakening them would be extremely difficult without coordinated international cooperation. Such cooperation is highly unlikely to occur. Thus, whatever views are held of the system, organizations have no option, for now, but to work as best they can within it.

The following is an essential tenet for any organization, including not-for-profit organizations: that if innovators do not use the IP rights at their disposal to try to influence or control the exploitation of their own inventions, then others will do it for them. If this happens, the organization's inventions may be exploited in ways that do not conform or contribute to the organization's objectives. ■

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IP Management Policy: A Donor's Perspective

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ABSTRACT

This chapter describes how the Wellcome Trust, a major charitable funder of biomedical research, manages intellectual property arising from Wellcome-sponsored research. The trust recognizes that the development of new health technologies requires the enlightened management of intellectual property through partnerships involving funders, scientists, institutions, and companies. This chapter explains how the charitable mission of the trust influences its decision-making process. The chapter includes case studies to illustrate the concerns of the trust and to identify key procedures.

1. THE WELLCOME TRUST

The Wellcome Trust is an independent, U.K.-based biomedical research charity. In the year 2006–2007, the trust will invest nearly US$1 billion in biomedical research, both in the United Kingdom and internationally. The Wellcome Trust was established in 1936 after the death of Sir Henry Wellcome. In his will, Sir Henry vested the entire share capital of a drug company he founded, The Wellcome Foundation, into the Wellcome Trust. The Wellcome drug company was absorbed, by a series of mergers, into GlaxoSmithKline, and, in the process, the trust diversified its investment portfolio. The trust no longer has a significant shareholding in GlaxoSmithKline but operates entirely independently of the drug company.

The mission of the trust is to foster and promote research to improve human and animal health (see Box 1 for a statement of the organization's mission and general policy). Funding by the trust supports a wide range of work in the biomedical arena, including basic science, technology transfer, medical humanities, and public engagement with science. In order to support scientific research of the highest caliber, grant schemes include not only career-based schemes for scientists, from Ph.D. studentships to fellowships, but project and program grants, equipment grants, and infrastructure initiatives.

The majority of trust funding goes to researchers in U.K. academic institutions, but the trust has also always supported research for tropical diseases, particularly in developing countries. Support schemes are available for U.K. researchers who wish to carry out tropical medicine research in the developing world, as well as for researchers, based in developing world institutions, who are conducting research in public health or infectious diseases.

2. IP MANAGEMENT

When considering IP (intellectual property) management, the trust's key aims are (1) to ensure that intellectual property arising from the research that it funds is prudently used to

Ballantyne Z and D Nelki. 2007. IP Management Policy: A Donor's Perspective. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Box 1: Wellcome Trust Policy on Intellectual Property and Patenting

Note that the policy is currently under revision and is expected to be approved in spring 2007.[1]

Preamble

The mission of the Wellcome Trust is to foster and promote research with the aim of improving human and animal health. This is the driving force behind all of the Trust's activities, and the basis for its policy on the protection and use of intellectual property rights. The aim of this policy is to provide a clear statement for Trust-funded scientists on the Trust's position on the protection and provide a clear statement for Trust-funded scientists on the Trust's position on the protection and use of intellectual property through patents; and to inform other Trust activities, particularly those relating to genomics.

In developing this policy, the Trust has considered a wide range of issues, in particular the role of intellectual property rights in creating the best conditions for research and in translating that research into tangible healthcare benefits. The Trust supports the appropriate protection and use of intellectual property where this will maximise healthcare benefits and enable biomedical research to flourish.

In order for research advances to qualify for intellectual property protection, the legal criteria for patent protection must be fulfilled. This means that, to be patentable, the results of research must describe an invention that is:

- novel, i.e., not described elsewhere before
- non-obvious, i.e., involving a step sufficiently inventive that most people working in that field could not have predicted it
- capable of industrial application, i.e., described in such a way that it can be made or used.

Patents, including those covering genes and their products, are no exception, and the Trust is supportive of these if there is sufficient information to indicate that the DNA sequences in question can be used to develop healthcare benefits. The Trust does not support the patenting of raw DNA sequences in the absence of such information. This is in line with EU law, which states that a gene sequence, whether partial or complete, is only patentable when it has been isolated and its function described.

The Trust is particularly concerned about patents and patent applications which are unreasonably broad and opportunistic, e.g., when there is limited functional data available to support those patent claims. The Trust may challenge such speculative patents if it believes that they are being applied for or used in ways that could be detrimental to research or limiting to the development of healthcare benefits.

As a charity the Trust is under an obligation to ensure that useful results from the research that it funds are applied for the public good. Technology Transfer at the Wellcome Trust aims to bring together researchers, universities, industry and investors to help ensure that promising lines of research yield practical healthcare benefits. Given the importance of these issues and the potential health gains which should flow from genomics research, the Trust will continue to keep this policy under review.

achieve health care benefits and (2) to maintain and promote a supportive environment for future biomedical research. The trust has historically taken an open and innovative approach to IP management, some examples of this are discussed below.

Other donors, of course, will have different perspectives, mechanisms, and processes for achieving their respective missions. The trust's approach to managing intellectual property has developed in a way that the trust considers appropriate for achieving its own objectives. This chapter is not intended to set out any form of best practice. The authors' aim is simply to present experiences, from their work in technology transfer at the trust, that might be instructive to other practitioners.

3. MANAGING INTELLECTUAL PROPERTY FROM TRUST GRANTS

The trust awards the majority of its grants based on its standard grant conditions.[2] The trust does not normally seek to own intellectual property arising from the research it funds, but the trust does require a sponsored academic and research host-institution to establish agreements with personnel involved in the research that vest in the institution any intellectual property generated. Under the trust grant conditions, the institution must also have established systems for identifying and managing intellectual property generated under a trust grant (for example, a system for invention disclosures and evaluation by the institution's technology transfer office or the equivalent function).

If trust-funded intellectual property is generated, the grant conditions require the host-institution to consider whether protecting the intellectual property is an appropriate way for that research to benefit the public.[3] The usual rationale for doing so is that attracting further research and development funding—which may likely be from a third-party commercial organization such as a venture capital company or a pharmaceutical or biotechnology company—requires protecting the intellectual property, often through a patent filing. Such patent filings offer a potential limited monopoly to any party who might wish to develop the intellectual property.

In some cases, of course, IP protection may not be the best way to obtain a public benefit. Instead, allowing immediate and unprotected access to the research results may directly improve public health or enable other researchers to build upon the results with the aim, for example, of aiding related health research through the creation of large data sets (see also section 7.1.3 below). Alternatively, the research results may be of insufficient value on their own, making patenting worthless.

3.1 *Exploiting Intellectual Property*

Since part of the mission of the trust is to improve human and animal health, translating research successes into health care applications is essential. In the vast majority of cases, further development and investment in the results of trust-funded research are necessary for it to have a health impact. Under the trust's grant conditions, the host-institution has the responsibility to decide whether the exploitation of trust-funded intellectual property is an appropriate way to achieve public benefit. If the institution decides that exploiting the intellectual property is appropriate, then before it grants any rights to the intellectual property, it must first seek the agreement of the trust on this matter. The trust's consent would normally be contingent upon the institution accepting the trust's standard revenue and equity-sharing terms.

Under the trust grant conditions, if the trust reasonably considers that the institution is not adequately protecting, managing, or exploiting trust-funded intellectual property, the trust has the right to take over such activities instead. In addition, to ensure that potential grant recipients can adhere to the trust's policies, the applicant(s) and institution are required to disclose at the grant application stage whether the research will use any technology or materials that are subject to agreements with third parties (such as companies or other research institutions) that might affect the research institution's ability to develop the potential trust-funded intellectual property as envisaged.

3.2 *The consent process*

During the consent process, the institution provides as much detail as possible about the proposed method of exploitation (such as draft license terms, material transfer agreements, and collaboration agreements). In the case of a proposed transfer of intellectual property into a spinout company, the institution should provide the draft shareholders' agreement and the company's articles of association. The trust will assess on a case-by-case basis whether the terms set out an appropriate means by which the intellectual property can achieve a public benefit. If the proposed development route and associated agreement terms are determined to be consistent with the trust's public benefit objectives, the trust will normally enter into a benefit-sharing arrangement with the institution and with any other involved parties. This can include a percentage share of milestone and/or royalty payments. In the case of spinout companies, it will usually involve a share of the equity of that company.

Because of its charitable status, the trust is required to assess any benefit-sharing terms and their public benefit impact. It is a fundamental principle of English charity law that any "private benefit" coming to an individual or company from a charity must be necessarily incidental to the public benefit resulting from the implementation of the charity's objectives. Accordingly, where the trust's charitable funding gives rise to valuable intellectual property and that value is to be shared with other parties, such as the researcher, the host-institution, and a licensee, it is important that those parties receive only a portion of the total value of that intellectual property. The amount should be appropriately related to the amount that the party has contributed to the creation and further development of the intellectual property. The trust must also receive an appropriate share of the value of the intellectual property that its funding helped create.

Because most of the host-institutions that receive funding from the Wellcome Trust are themselves U.K. charities (for example, universities) and are governed by equivalent charity law, the research institutions themselves will consider the public and private benefit balance when establishing any IP exploitation agreement. The consent process, therefore, is usually straightforward, since the proposed exploitation terms will likely be consistent with the trust's objectives.

4. EXAMPLES OF TRUST IP MANAGEMENT

4.1 *Material transfer agreements*

When a trust researcher requires biological materials from a third party, the consent of the trust is required if the relevant material transfer agreement (MTA) grants any rights over trust-funded intellectual property. The trust has often encountered what it considers to be *reach-through* clauses in such agreements that give the provider of the material a payment-free license, for commercial purposes, to any invention made through the recipient's use of the materials. The trust considers this unacceptable in a situation in which the provider of the materials makes no inventive contribution to new intellectual property created by the recipient other than providing materials. In such situations, although a case-by-case approach is taken, the trust will often recommend that either (1) the license for such intellectual property, to the provider, be limited to a nonexclusive, noncommercial research license, or, (2) if the provider has significantly contributed to the new intellectual property and is considered to be a suitable partner for developing it further, the provider should be granted a time-limited option to negotiate a commercial, royalty-bearing license (with the ability for the institution to license the invention to other partners, if license terms cannot be agreed to within the time period). However, where the recipient files patents on inventions that are directly and principally related to the materials, it is usually appropriate for the provider to be granted a nonexclusive license to use the patents solely in connection with the materials, so the provider can continue to use its own materials. Offering the provider a time-limited option to negotiate an exclusive license of such patents can be appropriate in many cases.

4.2 *Pipeline agreements*

Pipeline agreements usually give a company an exclusive license to all future intellectual property arising from, for example, an institution's departments. This type of arrangement is problematic for the trust because should any trust funds be going into such a department, the automatic license prevents the trust from assessing, on a case-by-case basis, whether the proposed exploitation plan of the new intellectual property is a suitable way of achieving a health-care benefit. The breadth of the pipeline arrangement often makes it unlikely that an automatic license to a company would be the most appropriate route of exploitation, particularly if the company's resources are limited and the license field is much wider than that of the company's focus. In such cases, the trust will normally agree with the relevant institution that, prior to granting any license of trust-funded intellectual property to the company under the pipeline agreement, the institution will request the trust's approval of an exploitation plan and the license terms. However, such an arrangement may be considered acceptable if the pipeline arrangement is appropriately narrow, the anticipated intellectual property can be well defined, the company in question is suitably qualified and resourced to exploit the relevant intellectual property, and revenue sharing terms with the host-institution can be agreed on in advance.

4.3 *Licensing arrangements*

The trust commonly consents to the grant of exclusive license, or even the assignment of a patent, to a university spinout company. The trust recognizes that exclusive licensing or assignment will often encourage further investment in and development of trust-funded intellectual property because it gives the investor or developer a competitive advantage. Where appropriate, the trust also uses co-exclusive licensing (the grant of licenses to a small number of partners—typically less than five) to balance incentives for commercial investment in product development, manufacturing, and distribution with wider public access to the new product.

Sometimes, the patent in question is relatively broad. It may address a number of diseases, or it could be widely used by third parties to develop health-care applications without an unnecessarily negative impact on their respective markets or applications. In such cases, the trust may conclude that there is a risk that a single licensee (especially in the case of a resource-limited, early-stage spinout) would be unable to fully exploit the patent across all applicable fields. In addition, if licensing is not carefully handled in such cases, there is a further danger that the research fields would be unnecessarily inhibited. Thus, the trust would normally propose a program of nonexclusive licensing, or careful, selective field-of-use licensing as a more appropriate means of achieving a public benefit.

5. PUBLICATIONS

The trust grant conditions require that the results of research funded by the trust be published in an appropriate form, although it is accepted that publication may be reasonably delayed to allow IP protection. The trust sees publication as a key process in maintaining an active, healthy research base and allows scientists to keep up-to-date with the latest discoveries, makes it possible for their research findings to be challenged and tested by their peers, and lets other scientists build upon and benefit from the new knowledge. Indeed, in the right circumstances, publication alone can therefore be a means of achieving a public benefit.

In 2003–2004, the trust commissioned two reports on the scientific research publishing market.[4] They concluded that although many scientific articles were available electronically, publishers' access policies posed potential barriers to dissemination, and journal subscriptions were a heavy cost burden on institutional libraries and researchers. After these reports were issued, the trust added a new condition to its grants that requires all trust-funded researchers to deposit a copy of their scientific publications relating to trust-funded research into PubMed Central (a free-access, digital repository of full-text, peer-reviewed biomedical journals that was developed by and is maintained by the U.S. National Library of

Medicine). The trust is also part of a consortium composed of medical-research charities and government-funding bodies that is funding and developing a U.K. counterpart of PubMed Central. This initiative aims to ensure that research is disseminated as widely as possible and that both access to articles and long-term preservation of the archive is ensured.

6. IP AND TECHNOLOGY TRANSFER AWARDS

Technology Transfer at the trust makes translation awards to facilitate the development of early-stage health-care inventions to the point at which they can be further developed, usually by a commercial company. Funding through these awards aims to fill what the trust considers to be the funding gap between basic research outcomes in academic research and the point at which the research is sufficiently developed to attract investment by venture capital firms or potential commercial licensees. Trust translation awards may be made to companies, usually early-stage spinouts, or to academic host-institutions. Funding for spinout companies is normally in the form of a program-related investment. With this type of funding—permissible for charities—a "charitable investment" is made into a specific research project with the primary aim of achieving the mission of that charity. Such funding provisions enable the trust to offer charitable funds to commercial vehicles where there is an ongoing research and development project for particular health care applications. While receiving a potential return on such a program-related investment is not the primary objective of making such an award, it is nonetheless important (for balancing public and private benefits arising from charitable assets) for the trust to receive an appropriate share of any benefits that might result from the program-related investment. Accordingly, Technology Transfer normally structures its translation awards into companies as convertible loans rather than as grants.[5]

Because of the critical nature of this stage of the development of a technology, appropriate IP generation, identification, filing, ongoing monitoring, and prosecution are vital. As part of the application process for a translation award, Technology Transfer requires information about whether patents have already been filed, on the technology in question, or will be filed in the course of the funding. The application also typically requires disclosure of information about freedom-to-operate issues related to the relevant technology.

For translation awards in areas of particular high-strategic interest or relevance to the trust, Technology Transfer may make strategic translation awards available. Through such awards, Technology Transfer will often actively participate in project management, including the management of intellectual property that might arise. This involvement may even include assistance with finding commercial partners or further funding. Funding agreements tend to be much more customized for strategic translation awards, but a number of commonly used provisions have been developed to address IP issues that may arise. Two broad categories are addressed in these provisions: 1) keeping the research field open and 2) ensuring the appropriate management and exploitation of intellectual property for a health-care benefit:

1) Keeping the research field open:
   (a) a prohibition on enforcing trust-funded intellectual property against universities/research institutions carrying out non-commercial research
   (b) the grant or reservation of a license for research purposes (which may be sub-licensable) to the trust or relevant institution(s)

2) Ensuring appropriate management and exploitation of intellectual property for a health-care benefit:
   (a) formation of an IP management group, comprising the researchers, independent experts, and representatives from the trust, to provide opinion and guidance on IP strategy
   (b) terms to ensure that the results of research that have a potential developing country application are developed for

such purpose and made available in the developing world

6.1 *Case studies*

6.1.1 *Typhoid vaccine*

With Trust funding, the company Emergent (Europe) Limited is testing its one-dose oral typhoid vaccine in healthy Vietnamese adults and children in preparation for proof-of-concept and phase III studies in the southeast Asia region. Emergent owns the underpinning intellectual property in the vaccine. Typhoid has both a developed-world travellers' market and a less-profitable developing-world endemic market, so the Trust wanted to ensure that the developing world market would benefit from the development of the vaccine. Terms were therefore negotiated, giving timescales within which the vaccine has to be launched in developing world markets. If launch does not take place within the relevant timescale, and there are no concrete plans to do so within a reasonable time, the Trust can acquire the rights to manufacture and sell the vaccine in those countries.

6.1.2 *Drugs for malaria*

The Trust, the Medicines for Malaria Venture, and the Singapore Economic Development Board agreed to fund the Novartis Institute for Tropical Diseases (NITD) to carry out a program of drug discovery in the field of malaria, the main aims being to find a one-dose cure for Plasmodium falciparum and a curative modality for Plasmodium vivax. Novartis agreed to make contributions in kind to the cost of the program.

NITD owns, (or in the case of intellectual property generated by collaborators, has rights to acquire rights to), all intellectual property generated during the funded program, but the Trust and MMV have a noncommercial research license to enable basic research on any findings of the program. If NITD decides not to file or prosecute such IP, the Trust and MMV may, so that valuable IP protection is not lost. In addition, NITD has agreed to covenants not to sue for infringement of the program patents any not-for-profit institutions that may carry out noncommercial research. NITD cannot develop and commercialize products comprising Trust-funded IP without the consent of the Trust and MMV. Consent, not to be unreasonably withheld, is subject to a benefit-sharing arrangement. In the event that NITD puts development on hold for certain periods, or fails to make any sales into developing countries within a certain period following launch, the Trust and MMV have the option to take over the necessary IP rights, to ensure that developing countries benefit from the outcomes of the research.

7. IP MANAGEMENT FOR SPECIAL INITIATIVES

The trust has been involved in a number of large initiatives to create data resources (principally DNA sequence information) for the scientific community. In each case, IP management has been considered from the outset as a key aspect of the resource. In the case of DNA sequencing, the trust's position is that basic DNA sequence information should be placed in the public domain as soon as it is practical to do so without limitations on use.

7.1 *Case Studies*

7.1.1 *The human genome project*

The Wellcome Trust Sanger Institute, which is largely funded by the Trust, took a major role in the Human Genome Project for its part in sequencing almost one-third of the human genome. The participants in the Human Genome Project decided that all the information produced by public human-sequencing centers should be made immediately and freely available to the biomedical-research community, via the Internet, without seeking any IP rights and without restrictions on how the information could be used. These principles were enshrined in an agreement on human sequencing brokered at a strategy meeting sponsored by the Trust in Bermuda in February 1996 and extended to data on other organisms at a later meeting.

7.1.2 *The SNP Consortium*

In partnership with several large pharmaceutical and technology companies, the Trust is a major funder of the SNP Consortium, which aims to

produce a high-quality map of human genetic markers, known as single nucleotide polymorphisms (SNPs). An SNP is a site in DNA where there is a change in a single "letter" of the DNA code. Sometimes this change in a single letter can cause a visible effect or cause a disease, but even if there is no obvious effect, knowing the location of the change can still be useful. The SNP map may be used to identify specific genes involved in disease processes, to develop novel diagnostic tests, and to predict individuals' responses to medical therapy.

As SNPs by themselves are only a small factor in the development of new drugs, the map was considered to be a precompetitive resource that would be of huge benefit to the biomedical research community. The consortium therefore agreed to put the SNP map into the public domain. Consortium members have access to the data on the same terms as other users: there is no preferential access. To keep the SNP map freely available to the public, the consortium filed patent applications on SNPs as evidence of dates of discovery (so that these would act as prior art to any subsequently filed patent). The patent applications would be abandoned prior to grant.

7.1.3 *The international HapMap project*

The Trust, through the Sanger Institute, is a major participant in the HapMap consortium, which is made up of members from the United Kingdom, Japan, United States, Canada, Nigeria, and China. The HapMap consortium aims to build a map of haplotypes, or "blocks" of SNPs that are inherited together in humans, to aid in pinpointing genetic variations associated with disease. These data represent a valuable precompetitive resource for the biomedical research community, and it was decided to make SNPs and haplotypes available to the public as they were identified. There was a concern that in the early stages of the project, when data were not sufficiently dense to derive haplotypes, third parties could combine HapMap data with their own data and file patents on haplotypes. These filings could prevent the HapMap Project from continuing. Accordingly, data were initially released under a "click-wrap" nonexclusive license,[6] which required researchers accessing the database to agree (by clicking a box on the HapMap Web page) to the following standard terms of access:

1. not to restrict access to or the use of HapMap data by others
2. not to file composition-of-matter patents on SNPs, genotypes, or haplotypes based on HapMap data
3. not to file patents containing claims to particular uses of any SNP, genotype, or haplotype data based on HapMap data unless such claims do not restrict, or are licensed on such terms that do not restrict, the ability of others to use at no cost the HapMap data for other purposes
4. to share data with other licensees only under the same license

The main disadvantage of this approach was that HapMap data could not be shared with other large-scale genomic databases. In December 2004, following release of over 1 million SNPs by the HapMap project, a further release into the public domain of 1.6 million SNPs by Perlegen Sciences Inc. and the development of new haplotype analysis tools, the consortium decided that sufficient data were in the public domain to constitute prior art and that derivation of haplotypes and haplotype tag SNPs from HapMap data would be considered to be obvious and not patentable. The click-wrap license was therefore abandoned.

8. CONCLUSIONS

The trust's primary aim when considering IP management is whether it is an appropriate mechanism for achieving part of the trust's mission, namely improving human and animal health. Practically, this translates into a focus on promoting a healthy research community and exploitation of research for health care outcomes. By encouraging exchange of research results, making large-scale databases freely available for researchers, and discouraging restrictions on the research use of inventions, the trust aims to keep the research-base broad and to benefit from the exchange of ideas. The role for commercial (or noncommercial) exploitation is recognized

and encouraged, provided that there is a clear health care benefit as the ultimate outcome. The trust sees intellectual property as a useful tool for achieving these aims and encourages the intelligent management of intellectual property by its grantees to ensure that trust-funded research achieves its full potential.

The trust also recognizes that, on the whole, given the inherently varied nature of research and the diversity of health care applications that may arise, potential intellectual property emerging from trust funding should be considered on a case-by-case basis to determine how to best disseminate, protect, and develop the results. For this reason, the trust has a devoted group, Technology Transfer, to manage these processes and considerations. The trust is also in the advantageous position of being a significant funder in the area of biomedical research. This position offers the opportunity to contribute its perspective as a charitable funder to both governmental policies and institutional mechanisms for managing intellectual property. The trust's collaborators, partners, and IP developers recognize the trust's charitable motives and are usually accommodating to the trust's IP policies and related goals with respect to health impacts. This accommodation is critical because the trust recognizes that the development of new health technologies requires the enlightened management of intellectual property through partnerships of funders, scientists, institutions, and companies. ■

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1. Please visit www.wellcome.ac.uk for the latest policy version.
2. www.wellcome.ac.uk/doc_WTD004055.html.
3. Trust-funded IP includes all IP created, exemplified, or developed in whole or in part from the research that the Trust funds. Trust-funded IP does not normally include copyright in artistic works, books, articles, scientific papers, lectures, or audio or visual aids to the giving of lectures or teaching.
4. The Wellcome Trust. 2003. Economic Analysis of Scientific Research Publishing. *SQW Limited*, A Report Commissioned by the Wellcome Trust: London. www.wellcome.ac.uk/assets/wtd003184.pdf.

   The Wellcome Trust. 2004. Costs and Business Models in Scientific Research Publishing. *SQW Limited*, A Report Commissioned by the Wellcome Trust: London. www.wellcome.ac.uk/assets/wtd003182.pdf.
5. www.wellcome.ac.uk/assets/wtx024257.doc.
6. Click-wrap licenses are similar to the shrink-wrap licenses common with software. If one wants to access data online, one has to click a box that typically states something like "I agree to these terms" before one is let through to the online database.

Making the Most of Intellectual Property: Developing an Institutional IP Policy

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ABSTRACT

An institutional IP (intellectual property) policy forms the very foundation of IP management and, as such, serves as the starting point for a system of institutional best practices. The IP policy should be entirely consistent with the mission of the institution. Whether the role of the institution, as defined by its mission, is primarily disseminator of knowledge through teaching and publication, generator of research, technology transfer engine, or promoter of economic development through education and service and/or through technology transfer, the institutional IP policy should be drafted and enforced in a manner consistent with the mission. Doing so will bring efficiency and clarity to IP management, since all the components of the policy, including IP ownership, patenting, confidentiality, and disclosure can be written into the policy. Moreover, the intellectual property will serve the mission in a way that strengthens the institution's credibility, reputation, and public image.

1. INTRODUCTION

Establishing an IP (intellectual property) policy is necessary for several important reasons. IP rights, including patents, copyrights, trademarks, and industrial property rights *attach* to research, administrative, and scholarly (including courseware) work products. Therefore, any public sector institution entering into research contracts with private sector entities will encounter IP issues. These matters will also need to be addressed in cases involving government-funding agreements, which often carry provisions for the disposition of intellectual property.

Of course, most universities already have IP policies in place in a number of areas. Faculty and students have an interest in publishing scholarly works, and publishing carries with it copyright ownership issues. Most often publishers require assignment of copyright, but what about the interests of the author or the institution? Lectures and course curriculam are also copyrightable. Who owns these? The faculty or the university? These same concerns govern other ostensibly more-complicated IP areas. For example, universities have an interest in owning or controlling the work product of nonacademic employees. Is there an operable *work for hire* doctrine that governs the country where the university is located? If not, agreements transferring ownership to the university must be in force.

These kinds of issues will grow increasingly relevant for public sector research institutions as they become more involved with national and global IP systems. Indeed, for a university wishing to adopt a technology transfer program structured around licensing, a conceptually solid, pragmatic IP policy will be an essential building block for the program. It is the foundation upon which all other IP activities and initiatives are built. For developing countries, putting an IP policy in place is an especially important step for protecting their interests. When a university in a developing country commercializes an invention, an IP policy can

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be used to establish an equitable basis for resolving issues related to ownership, disclosure, and the distribution of income. In fact, the World Intellectual Property Organization (WIPO) has documented that universities and R&D institutions in developed countries, and also some countries in Asia and Latin America can generate significant income from sources such as:

- royalties and fees from licensed patents from staff innovations and inventions
- consultancy
- research contracts
- sponsored research
- university-owned companies and joint ventures[1]

Remember that it is too late to begin formulating IP policy when negotiations about IP have already begun. As Lita Nelsen, Director of the Massachusetts Institute of Technology (M.I.T.) Licensing Office, observes, "Although policies will change over time as the program evolves, the major issues must be decided in advance. Otherwise, a new program is likely to stall or fail altogether in an entangled committee indecision and policy ambiguity."[2]

2. MATCHING THE MISSION TO IP POLICY

Certain steps should be considered when establishing an institutional IP policy. Initially, administrators of the institution will need to assess its mission. This will involve examining not only the university's mission statement but also prioritizing the institution's roles with respect to the mission. These may include:

- disseminator of knowledge through teaching and publication
- generator of research
- technology transfer engine
- promoter of economic development through education and service and/or through technology transfer

Such considerations will help establish an institutional IP policy that supports mission priorities. For example, if the top priority is education and dissemination of knowledge, then IP policy should favor faculty ownership or release of intellectual property into the public domain, with less emphasis on IP protection. If R&D activities are the institution's top priority, then the institution should have greater control of intellectual property (for example, more-flexible licensing arrangements with industry, to encourage industry funding, or more emphasis on industry needs). If the institutional mission emphasizes technology transfer and commercialization, then even greater institutional control of intellectual property may be most appropriate. This would involve IP strategies geared towards commercialization through inducing investment (exclusive licensing preferred), more-flexible royalty sharing with inventors to induce disclosures, and choosing the best commercial partners for any given technology. Finally, if the institutional mission priority is economic development, then a more-balanced IP ownership policy that promotes technology transfer, driven by economic development opportunities, may be preferred. Such an approach might focus on licensing regional companies and encouraging local spinouts by providing incubator facilities. Since economic policies will drive development and implementation of the IP policy that most supports economic growth, there should also be built-in flexibility to accommodate changes in economic climate.

An exemplary case of an organization's mission matching its IP policy can be found at the Drugs for Neglected Diseases Initiative (DNDi). Its mission statement proclaims that "*[t]he mission of DNDi is to develop safe, effective and affordable new treatments for patients suffering from neglected diseases, and to ensure equitable access to these*."[3] This mission provides the framework for the institution's IP policy (see Box 1).

Note that DNDi explains how it "*will pursue creative and innovative strategies to make the fruits of research projects readily available*" in terms of its approach to managing intellectual property. This type of language provides for a flexible intellectual property management style that is consistent with its core mission. Strong IP policies, such as DNDi's, incorporate such language to allow the institution to operate without being constrained by its own IP policies.

3. FORMS OF INTELLECTUAL PROPERTY/IP RIGHTS COVERED

Designers of an institution's IP policy will need to define IP categories and the IP rights covered. Covered categories might include patents, copyrights, trademarks, industrial rights and designs, plants, computer software, video, multimedia, or courseware.

It will be important for policy designers to understand the criteria the university will use to decide when to seek IP (generally patent) protection, and what happens if patent protection is not sought. To handle the latter, a procedure for waiving title back to inventors/authors in such an event needs to be developed. Furthermore, attention will need to be given to deciding which rights should be granted back to the university (grant-backs), such as use for education and research.

4. OWNERSHIP OF INTELLECTUAL PROPERTY

Of course, issues relating to ownership are central. Such issues include the role of federal/local/state laws that directly relate to IP ownership, as well as the legal rights of employers/employees, contract obligations, and so forth. The prevailing customs of the country where intellectual property is developed also need to taken into account. There are a number of possibilities for ownership:

Box 1: Drugs for Neglected Diseases Initiative (DNDi) Intellectual Property Policy

III. Intellectual Property and DNDi's Work: Basic Principles

In implementing the IP strategy, DNDi will adhere to the following basic principles:

DNDi will ensure that the results of the work carried out under its auspices are disseminated as widely as possible and its products made readily available and affordable in developing countries. Where the acquisition of IP is not necessary to promote its mission and goals, DNDi will make all possible efforts to ensure that the results of its work are placed and remain in the public domain. However, it is possible that promoting DNDi's mission and goals will sometimes require outputs to be protected by IP (see Sections IV and V). Given the costs involved, patenting is likely to be the exception rather than the rule. Other nonpatent types of IP such as confidential information ("trade secrets") and copyrights will also need to be considered.

To make the results of its work useful and encourage the research community to engage in additional or follow-on research in the field of neglected diseases, DNDi will seek—whenever possible and without undermining its rationale for acquiring IP—to disseminate its research through publications, presentations, the Internet (emulating the Human Genome Project), and other appropriate channels.

DNDi does not seek to finance its research and operations through IP rent revenues. Although they will constitute an exception rather than the rule, patents might be sought to strengthen DNDi's ability to ensure control of the development process and to negotiate with partners.

When IP is generated through DNDi-sponsored research projects, it should be used to achieve DNDi's mission. To this end, DNDi will pursue creative and innovative strategies to make the fruits of research projects readily available to patients affected by neglected diseases. This will require avoiding prohibitively costly approaches, restrictive IP strategies, or other issues that may inhibit or delay the rapid adoption of the invention to the benefit of developing countries.

- inventor/author owns
- university owns
- company providing research funds owns
- government providing research funds owns
- public domain, that is, no one owns

In designing an effective institutional IP policy, the inventor's/author's rights for IP assigned to the university should be clearly defined and could include a formula for sharing cash royalties earned, sharing of equity interests taken by university in a spinout, or retention by inventors/authors of personal rights to use intellectual property they develop (generally these are copyrights). Normally, a university would own "any intellectual property that is made, designed, discovered or created by a member of staff, students, guest researchers, etc., in the course of their employment and responsibilities or which makes significant use of the institution's resources (including institution-administered funds or R&D institution-funded time, facilities, or equipment) in connection with its development."[4] The policy of M.I.T., for example, states that the university owns all intellectual property that arises under research grant funding or from significant use of M.I.T. facilities.[5] In order to avoid potential disputes, the policy should clearly state what constitutes "institutional resources." In the case of sponsored research, whether private or government, the usual approach to resolving ownership issues is to make them dependent on the terms of the grant, agreement, or prevailing law. Usually, the agreement would give the university ownership. It would also be a good idea to specifically address the ownership of intellectual property that students and visiting researchers generate. At M.I.T. faculty researchers and visiting scientists (including scientists who are assigned to M.I.T. for a limited period of time) must sign an Inventions and Proprietary Information Agreement prior to beginning work. It is highly recommended that universities have such IP forms.[6]

An institutional IP policy should also consider whether the institution will reserve a shop right in intellectual property created by faculty, students, and staff but not owned by the institution. (Under the shop right rule, an employer is granted an irrevocable, nonexclusive license to inventions that originate with employees not hired to invent when such employees invent during working hours with the employer's materials and facilities.[7]) Such intellectual property could include publications, software, theses, works of art, or student works. To address this issue, it will be important to ask for what purposes such a shop right is reserved. For example, would it be for internal use only, or, possibly, for Internet delivery for distance learning programs?

An institutional IP policy should also cover *stranded IP* by establishing a default for intellectual property not covered by the policy.[8] In other words, what intellectual property is owned by the inventor, author, or institution? Despite efforts to be clear about these matters, disputes are probably inevitable. A carefully crafted institutional IP policy will therefore consider establishing an IP disputes-resolution committee. It is better to set this up in advance of potential disputes so that it can be used to deal with problems as they arise.

Indeed, an IP policy should seek to harmonize the conflicting interests of all the stakeholders. WIPO suggests that "in order to harmonize the various conflicting interests of stakeholders and achieve broad-based objectives, an intellectual property policy for universities and R&D institutions should address some of the following issues:

- coverage of intellectual property policy
- ownership of intellectual property
- disclosure of intellectual property
- marketing, commercialization and licensing of patents
- distribution of income
- rights and obligations of an inventor and the institution
- other pertinent issues[9]

Again, despite such efforts and the best intentions of all involved, conflicts of interest will likely arise. For example, the goals of sponsored research may conflict with the aim of the university to disseminate research results quickly and widely. Or there may be other legitimate but opposing goals between the institution and private interests that put researchers in conflict with their

employer. Universities and R&D institutions must therefore develop policies and procedures for the disclosure and management of conflicts of interests.[10]

It is also difficult to ensure compliance with policies related to the disclosure of inventions. A comprehensive review procedure is often used in the private sector, but the resources and time required for such procedures make them impractical for the university. The best way to ensure compliance, therefore, is to educate researchers about the potential value—to the university and themselves—of their discoveries. Enlightened self-interest has always been an effective motivator.

5. ADMINISTERING THE IP POLICY

Identification of who shall administer and enforce institutional IP policy is another key ingredient of the policy. Possible administrators include:

- vice president for research
- technology transfer office
- IP office
- provost

A patent committee that will address patent policy issues, and make decisions on patent filings, may also be established.

6. BUILDING, IMPROVING, AND SELLING THE IP POLICY

For more mature institutions, officials, at some point, will need to assess whether to design and implement a new policy or revise an old one. An initial step in this assessment might be to take a snapshot of "what is" so that the effectiveness of existing policies, contractual commitments, and legal constraints can be determined.

When pursuing these efforts, it would be wise to gain the support of the highest levels of administration and to determine a path of least resistance for the process, perhaps via the faculty senate or the administrative committee. In addition, it will be critical to persuade faculty of the need to change the IP policy or to implement a new one. Gaining such backing will lend importance, urgency, and credibility to the endeavor. Policy developers may want to make available for comparison other universities' policies in order to show that any suggested changes are not out of the mainstream. Providing such material, and opportunities for informed discussion and debate as to the pros and cons of suggested changes to the IP policy, will ease anxieties and highlight the benefits the changes will provide. Indeed, throughout the entire process, it will be important to focus on the positive aspects that any changes to the policy may bring.

The IP policy will have to be "sold," both inside and outside the institution. Educating stakeholder communities as to *what the policy is* and *why it is* will promote acceptance. However, to be successful, the proper pitch must be made. This will most likely involve:

- making the policy comprehensible to the reader
- providing incentives for participants
- establishing IP management as a service to the community
- applying the policy with consistency
- showcasing the benefits

One of the primary benefits of the policy will be shared licensing revenue, and a firm, cut-and-dried policy will be music to everyone's ears. It should be straightforward with very few exceptions. M.I.T., for example, gives the inventor(s) one-third of net royalties (after taking 15% for administration and any unrecovered patenting costs for the case). The remaining funds are shared between academic departments and the university general fund under a formula involving patenting costs for unlicensed cases.[11] WIPO's recommendations are equally clear:

100% of the revenue goes to the institution until all out-of-pocket expenses associated with protection and exploitation of the patent or copyright have been reimbursed. Such expenses include fees associated with patent filing and copyright registration and any other continuing costs associated with licensing and other commercialization of the intellectual property. Thereafter, the net income is shared between the inventor and the institution; the general trend is that the inventor's percentage share decreases whereas that of the institution increases as total net

revenue increases. For example, one U.S. university gives the inventor 50% for the first $100,000 of net revenue, 40% for the next $300,000, 30% for the next $600,000 and 25% for net income in excess of 100,000.

7. M.I.T.'S IP POLICY

M.I.T. provides a vigorous example of institutional IP policy. The main missions of the institution are the dissemination of knowledge, education and research, but the institution also is committed to public service, which involves technology transfer, as is shown in this excerpt from M.I.T.'s IP policy (see Box 2).

M.I.T.'s IP policy on ownership of intellectual property is carefully laid out. For example, ownership of patents is either (1) assigned to M.I.T. if the invention occurs from sponsored research or is made with significant use of M.I.T. funds or facilities or (2) owned by the inventor(s) if the inventions are made on the inventor's own time, without use of facilities, and are outside of the M.I.T. programs the inventor is assigned to work on. If appropriate, and with no outside obligations, M.I.T. will waive ownership to inventors (see Box 2).

This statement from M.I.T.'s IP policy clearly articulates the various foreseeable situations wherein IP ownership issues might arise. Significantly, these details are all placed within the purview of the overarching institutional mission of M.I.T. The policy goes on to explain, for example, that, with regard to copyrights to scholarly publications, textbooks, and course materials, these copyrights are owned by the authors. However, M.I.T. owns "work for hire" made by staff. In other words, M.I.T. owns, by assignment or as work for hire, copyrightable works developed by faculty and staff under sponsored research or with significant funds or facilities of M.I.T.

For ownership of mask works and tangible research property, the policy is the same as for patents. The ownership of data is not specifically covered, but it is treated as M.I.T. owned under the same situations as for patents and copyrights.

Technology transfer, which is a by-product of M.I.T.'s primary missions of education and research, is conducted to fulfill institutional goals:

- to foster continuing public support for basic research by showing public benefit (namely, new products)
- to stimulate more industrial support for research
- to foster community support by creating jobs and new companies
- to help students learn entrepreneurial attitudes
- to enable faculty to see the practical results of research

8. SPECIAL PLANT ISSUES

The International Maize and Wheat Improvement Center's (CIMMYT) policy on intellectual property[12] is exemplary. The policy shows how a public sector research institution involved in crop improvement seeks to achieve a balance between the institutions express mission of serving the greater global public interest and acknowledging issues relating to IP rights protection. The CIMMYT IP policy articulates these concerns, providing a coherent, comprehensive, and comprehensible statement that is the foundation of an institutional IP policy that is consistent with and true to the institutional mission:

As a publicly-funded international research institute, CIMMYT regards its research products as international public goods. Yet, in the current political and legal environment, producing and keeping the products of its research in the public domain, free for use and development both by scientists and farmers, have become increasingly problematic. It is in this context that CIMMYT has examined, and will continue to examine, its policies and practices in regard to intellectual property rights. CIMMYT's commitment to the resource-poor remains as strong and passionate as ever. As a direct consequence of this commitment, CIMMYT has a responsibility to be alert to changes in the political, legal and market environments. When necessary, CIMMYT must also be ready to adopt new tools and strategies in order to keep faith with its mission.[13]

Box 2: M.I.T.'s Policy on Intellectual Property

13.1 Intellectual Property

M.I.T. Policies and Procedures

The aim of the Institute's policy on patents, copyrights, and other Intellectual Property is to make available Institute technology to industry and others for the public benefit, while providing recognition to individual inventors and encouraging the prompt and open dissemination of research results.

13.1.1 Ownership of Intellectual Property

With the exception of student theses as described below in Section 13.1.3 (Ownership of Copyrights in Theses), rights in patentable inventions, mask works, tangible research property, trademarks, and copyrightable works, including software ("Intellectual Property"), made or created by M.I.T. faculty, students, staff, and others participating in M.I.T. programs, including visitors, are as follows:

a) Inventor(s)/author(s) will own Intellectual Property that is:

i) not developed in the course of or pursuant to a sponsored research or other agreement (the faculty advisor, administrative officer, or the Office of Sponsored Programs contracts administrator can advise on the terms of the agreements that apply to specific research); and

ii) not created as a "work-for-hire" by operation of copyright law (a "work-for-hire" is defined, in part, as a work prepared by an employee within the scope of his or her employment) and not created pursuant to a written agreement with M.I.T. providing for a transfer of copyright or ownership of Intellectual Property to M.I.T.; and

iii) not developed with the significant use of funds or facilities administered by M.I.T. ("significant use" is discussed in Section 2.1.2 of the Guide).

b) Ownership of all other Intellectual Property will be as follows:

i) ownership of Intellectual Property developed in the course of or pursuant to a sponsored research or other agreement will be determined according to the terms of such agreement;

ii) ownership of copyrightable works created as "works-for-hire" or pursuant to a written agreement with M.I.T. providing for the transfer of any Intellectual Property or ownership to M.I.T. will vest with M.I.T.;

iii) ownership of Intellectual Property developed by faculty, students, staff, and others participating in M.I.T. programs, including visitors, with the significant use of funds or facilities administered by M.I.T. will vest with M.I.T.

Importantly, with regard to access to germplasm resources, CIMMYT encourages the availability of such resources in a manner consistent with its greater mission of serving the poor of developing countries.

This commitment is reiterated several times in CIMMYT's IP policy, which is clearly articulated within the overall context of the guiding principles that establish the foundation of the CIMMYT global mission (see Box 3).

This theme is repeated again in the CIMMYT IP policy, making CIMMYT's mission the predominant determinative factor throughout the entire document (see Box 4).

In addition to the provisions found in the CIMMYT IP policy, other provisions that would be applicable to plants and IP issues are related to:

- genetically modified plants
- essentially derived varieties
- hybrid crops (issues relating to inbred parental lines)
- designated and nondesignated germplasm as per the treaty, under the FAO
- status of land races
- freedom to operate
- access issues relating to the Convention on Biological Diversity

These issues relate directly to how crops are actually improved, that is, by:

- conventional crossing of preexisting varieties
- introgression of genes from wild germplasm resources
- genetic engineering via plant transformation

9. CONCLUSIONS

The establishment—or revision—of institutional IP policies is a great tool for advancing internal institutional discussions on the role and function of intellectual property. Once finalized, an effective IP policy should fulfill three fundamental criteria:

1. It should be based on and reinforce the core mission of the institution the policy serves. The mission drives IP management, not vice versa.
2. It should indicate areas of flexibility that allow an institution to pursue creative deals and arrangements.
3. It should be a succinct statement, as opposed to a detailed list of procedures. The latter can be accessed elsewhere, while the IP policy should be the basis of regularly updated IP strategies and serve as a guiding principle for the management of intellectual property.

Following the above criteria will allow you to successfully navigate the sometimes choppy seas of the IP system, and the end results of such a voyage will certainly be worthwhile. ■

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1 www.wipo.int/freepublications/en/intproperty/848/wipo_pub_848.pdf.

2 Lita Nelsen, Director, M.I.T. Licensing Office, personal communications.

3 See, also in this *Handbook,* chapter 17.8 by J Banerji and B Pecoul. See also the latest version of DNDi's IP policy. www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=87&ArticleId=320&TemplateId=1; The Medical Research Council of South Africa also follows an exemplary IP policy. innovation.mrc.ac.za/ippolicy2.pdf.

4 www.wipo.int/freepublications/en/intproperty/848/wipo_pub_848.pdf.

5 See *supra* note 2.

6 web.mit.edu/policies/13.1.html.

7 A shop right is "*an implied-in-law nonexclusive license of a patent from an employee to the employer. A shop right is generally implied when an employee who is not specifically hired to invent uses the employer's facilities to invent, usually while on the job. The shop right rule grants to such an employer the royalty-free right to use the invention of the employee. It is based on the employer's presumed contribution to the invention through materials, time, and equipment.*" (McCarthy JT,

Box 3: CIMMYT Intellectual Property Policy

IV. OBJECTIVES AND OPERATING POLICIES

1. CIMMYT will manage intellectual property issues with:
   - integrity;
   - equity;
   - responsibility; and
   - accountability.

2. In the pursuit and management of intellectual property rights, CIMMYT will be guided by:
   - its mission; and
   - its special responsibilities to the resource poor arising from its role as a provider of germplasm, technologies, and information.

However, the CIMMYT IP policy does not leave the articulation of its mission and its views on IP issues so general. The policy also specifically states how it views IP issues within the context of the CIMMYT mission. Hence, the IP policy is built upon, and indeed interwoven with, the mission:

IV, 4. On occasion, CIMMYT may enter into contracts that provide for the acquisition and management of confidential materials. CIMMYT may also seek to protect the products of its research by obtaining intellectual property protection through patents, plant breeders' rights, copyrights, trademarks, statutory invention registrations or their equivalent, and/or trade secrets to serve the resource poor in the following kinds of situations:

1. to support public and private partnerships which pursue mission-based research or which develop and apply research results;

2. to assure ready access by others to research products developed or funded by CIMMYT;

3. to avoid possible restrictions arising from "blocking" patents and to ensure CIMMYT's ability to pursue its research without undue hindrance;

4. to facilitate the transfer of technology, research products and other benefits to the resource poor including, where appropriate, through commercialization or utilization of research products; and/or

5. to facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to CIMMYT's research and in furtherance of its mission.

Box 4: CIMMYT Intellectual Property Policy

IV, 8. In seeking intellectual property rights, CIMMYT will be guided by its commitment to serve the resource poor, rather than by opportunities to obtain recurring revenues. To the extent that financial returns are generated via intellectual property, they will be used by CIMMYT to support its efforts to implement the FAO Global Plan for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture, adopted by 150 countries in 1996.

RE Schechter and DJ Franklyn. 2004. *McCarthy's Desk Encyclopedia of Intellectual Property,* Third Edition. The Bureau of National Affairs, Inc.: Washington, DC.).

8 Stranded IP is IP that is not covered by the formal policy. No policy is perfect, so certainly not all IP will be covered explicitly. If the IP is not covered, then there is a presumption that the university owns it, that the creator owns it, or that it must be reported to the technology transfer office and a determination made as to who owns it.

9 www.wipo.int/freepublications/en/intproperty/848/wipo_pub_848.pdf.

10 See also in this *Handbook*, chapter 5.8 by AB Bennett.

11 See *supra* note 2.

12 www.cimmyt.org/Resources/Obtaining_seed/IP_policy/htm/IP-Policy_Eng.htm.

13 www.cimmyt.org.

Ownership of University Inventions: Practical Considerations

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ABSTRACT

Several factors help to establish who owns a university invention and what rights the university may, or may not, have. These factors include whether (1) there are express or implied agreements to assign ownership, (2) the inventor is employed by the university, (3) the invention was made within the scope of employment, and (4) where and when the invention was made. Under U.S. law, individuals own their inventions, except where there is an express agreement providing for assignment of ownership of inventions to an employer or where an implied agreement to assign is found because the employee was hired or assigned to invent or solve a specific problem or served the employer in a fiduciary capacity. Therefore, in addition to implementing clearly delineated policies, it is critically important for a university to absolutely require all employees and visitors to sign invention assignment agreements (IAAs) on their date of arrival. It is unwise to rely on policy statements to determine whether or not a university employee owns his or her invention: universities should always obtain signed (express) agreements, and both the employee and the technology transfer office should retain copies. Research contracts with the government and other sponsors should have a checklist item on the existence of IAAs for the principal investigator and other researchers (whether or not a university should have undergraduates routinely sign IAAs is up to each university). Upon termination of employment, personnel should be asked to sign an exit form indicating that they have disclosed all inventions falling within the terms of the IAA to the university licensing office.

1. INTRODUCTION

Who owns an idea? A prototype? A patent? To a free-thinking university researcher, assigning inventions to an employer could seem illogical. So what can a university administrator do to minimize friction, between an employer and an employee, related to patent ownership? When is the law black and white? When gray?

The starting point of the law is that individuals own their inventions, *except*: (1) where there is an *express agreement* providing for assignment of inventions to an employer; and (2) where an *implied agreement* to assign is found because the employee:

(a) was hired or assigned to invent
(b) was hired or assigned to solve a specific problem
(c) served the employer in a fiduciary (president of a commercial company, for example)

Where no written agreement exists and no implied contract to assign is found, the inventor will own the invention, subject to the employer's "shop right" to use the invention if the invention was made with the employer's resources or facilities. The often-discussed, but frequently misunderstood *shop right* refers to an employee's

Weidemier BJ. 2007. Ownership of University Inventions: Practical Considerations. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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obligation to accord an employer a royalty-free, nonexclusive license to practice the employee's invention, if the employee, even if *not specifically hired to invent,* uses the employer's facilities to make the invention. In other words, a shop right is an implied-in-law license of a patent from an employee to an employer. What differentiates the shop-right license from the agreements discussed above is that there is no assignment of patent rights from employee to employer; the employee retains full title to the patent.

2. APPLYING THE RULES

But, how are these rules applied? Is a professor hired to invent? The following scenarios provide a framework for analyzing the practical application of the above rules in the daily business of a university licensing office.

2.1 *Example 1: The unreasonable inventor*

The day Professor Z started work at the university, she signed a clear, unambiguous invention assignment agreement (IAA; see Box 1 for a sample), along with his W-2 form. She signed a three-year federal contract to perform "research in the area of solar light bulbs." She invented a solar light bulb while working in her university laboratory between 9 a.m. and 5 p.m. on a Wednesday. She has refused to assign the invention to the university, because as she says, "After all, it was my idea."

There is no question under the law that Professor Z must assign her invention to the university. In order to compel the assignment of an employee invention, pursuant to a written IAA, an employer must show: (1) that the invention was conceived during the term of employment; (2) that the assignment was governed by a valid, binding, and enforceable contract; and (3) that all conditions in the assignment contract were met by the employer (*Mosser Industries, Inc. v. Hagar*).[1] In this example, all of these elements could be demonstrated.

To diffuse the situation, the university could suggest that Professor Z contact the university's attorney or his own attorney. By seeking professional advice, Professor Z should become convinced that this issue would not be worth fighting. In addition, the university may want to remind Professor Z of any university policy that rewards inventors with royalty revenue from the licensing of university inventions.

2.2 *Example 2: The unreasonable inventor you missed*

Professor Z invented her solar light bulb under the same circumstances as in Example 1 above; however, the personnel clerk was out sick with the flu on Professor Z's first day of work, and the clerk's substitute thought Professor Z only had to sign the W-2 form. Thus, Professor Z never signed an IAA.

Because Professor Z received federal funding, 37 C.F.R. § 401(14) applies regarding election of title by the contractor (the university) within two years of disclosure of the invention. At 37 C.F.R § 401.14 (f), the regulations also require the contractor to have written agreements with its employees (other than clerical and nontechnical employees) requiring (1) the disclosure of all subject inventions promptly and (2) the execution of all papers necessary to file patent applications. Unfortunately, the university is in breach of its federal contract covering Professor Z's invention. Professor Z has hired an attorney, whose wages are being subsidized by Professor Z's potential licensee, who has locked Z into a sweetheart deal. The university scrambles to locate a copy of its latest patent policy, which was revised and mailed to all faculty members last year, and that states:

It is the policy of the university that individuals, through their employment by university, or by participating in a sponsored research project, or using university-administered funds or facilities, thereby accept the principles of ownership of technology as stated in this policy. In furthering such undertaking, all participants will sign invention assignment agreements …

The patent policy also stipulates that inventors/authors will own inventions/materials if they are (1) not developed in the course of or pursuant to a sponsored research or other agreement; (2) not created as a work-for-hire by operation of copyright law and not created pursuant to a written agreement with the university providing for a

transfer of copyright or ownership to university; and (3) not developed with the significant use of funds or facilities administered by university.

The university's lawyer produces the often-cited case of *United States v. Dubilier Condenser Corp.*,[2] which states:

One employed to make an invention, who succeeds, during his[or her] term of service, in accomplishing that task is bound to assign to his [or her] employer any patent obtained. The reason is that he [or she] has only produced that which he [or she] was employed to invent. On the other hand, if the employment is general, albeit it covers a field of labor and effort in the performance of which the employee conceived the invention for which he [or she] obtained a patent, the contract is not so broadly construed as to require an assignment of the patent.

Another early case brought to the university's attention is *Solomons v. United States*,[3] which states:

If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he [or she] cannot, after successfully accomplishing the work for which he [or she] was employed, plead title thereto as against his [or her] employer. That which he [or she] has been employed and paid to accomplish becomes, when accomplished, the property of his [or her] employer.

In this example, the key question in determining the ownership of the invention is whether Professor Z was hired to invent a solar light bulb, or whether her employment was "general." Actually, in this case, on the fateful day she was hired ten years ago, no one had even remotely considered the idea of a solar light bulb. Professor Z was employed to teach several classes and to conduct research generally on solar power. Her first seven years of research were devoted to solar-powered cars.

The hired-to-invent rule clearly envisions that specific job assignments can change during the course of employment and the question of fact turns on the circumstances and current job assignment at the time of invention. Therefore, the change in focus of Professor Z's research from solar cars to solar light bulbs over the ten-year period is relevant. "*An employee, who undertakes upon the direction of his employer to solve a specific problem within the scope of his general employment, is as truly employed and paid for the particular project as if it had been described at the outset in the contract of employment*" (*Houghton v. United States*).[4]

In *Standard Parts Co. v. Peck*,[5] Peck was employed to solve a particular problem, and a written contract required him, "*to devote his time to the development of a process and machinery for the production of the front spring now used on the product of the Ford Motor company,*" in return for US$300 per month, plus several bonuses. The contract was silent on the matter of invention ownership, which became the subject of the lawsuit. The Court found the answer "*inevitable and resistless*": the "*process and machinery*" contracted to be developed for the company belonged to the company, not to Peck, who was otherwise paid for his services.

Whether the work statement in Professor Z's federal contract is specific enough to cover the development of a solar light bulb would be a question of fact under a *Standard Parts* rationale. In *Patent Law Fundamentals* (Section 11.04, Rights of Employer and Employee Inter Se), the analysis goes one step farther; it is stated that "*apparently*" an employer would own inventions if an employee were "*employed to plan and conduct fundamental and practical investigations and such lead directly to an invention*," so long as the employee's area of activity was defined with "*sufficient specificity*."

In *Speck v. North Carolina Dairy Foundation, Inc. et al.*,[6] the inventors were professors and researchers who developed a secret process; they had not signed IAAs. They were paid by the university and acknowledged that the process was developed at the university using university resources. The Supreme Court of North Carolina found that, although there were no signed IAAs, professors and researchers were hired to invent and their invention belonged to the university: "*[T]hey developed the secret process ... while employed as teachers and researchers to engage inter alia in just such research and development for the University.*"[7]

An even more recent university case is *University Patents, Inc. v. Kligman et al*.[8] Dr. Kligman invented a Vitamin A preparation to slow the effects of skin aging. As with Professor Z, Dr. Kligman did not sign an IAA, nor did he sign an invention disclosure statement. Some university resources were used, though Dr. Kligman was not as closely connected to the university as the inventors in the *Speck* case. Animal studies were conducted at the university by Dr. Kligman's wife, Lorraine, pursuant to a Johnson & Johnson contract, and a clinical study was performed at the university's Aging Skin Clinic.

University Patents, Inc., with whom the University of Pennsylvania had contracted to exploit its patents, relied primarily on the university's patent policy set forth in the employee handbook to prove an implied contract to assign. Under the University of Pennsylvania's policy, all inventions resulting from work performed on university time or at university expense were owned by the university.

Pennsylvania law is unclear on the question of whether an employee handbook can create an employment contract. The Court applied traditional patent assignment principles to the more controversial handbook concepts and found that the University of Pennsylvania's handbook "*clearly was not communicated as a definite offer of employment*."[9] The opening comments in the handbook provided in part that, "*we hope that this* ***Handbook*** *will serve as a useful* ***traveler's guide*** *[emphasis added],"* rather than as a contractual legal document.

In April, 1991, the U.S. District Court for the Eastern District of Pennsylvania concluded that a "*jury reasonably could find that an implied contract to assign the patent in question was formed between Dr. Kligman and the University [of Pennsylvania].*"[10] The university conveyed and enforced its patent policy in a rather lax manner over the years, but the court found "*[T]here is evidence, however scant, from which one could find that Dr. Kligman was aware of the Patent Policy since August, 1967, and manifested an intent to be bound by it*."[11] The court cautioned that employers are advised not to rely on handbooks to govern the assignment of patent rights; rather, they should address such issues explicitly in an express IAA. However, the issue of whether professors and university researchers, as a class, are hired to invent when pursuing their field of research was not addressed.

Although involving a different central issue, a third case, *Regents of University of Colorado v. K. D. I. Precision Products, Inc.*,[12] stated that "*[T]he subject of the University's employment was research directed towards the obtaining of patents.*" This supports the concept that university professors and researchers are employees hired to invent.

But with regard to Professor Z in our earlier example, the law is not settled as to whether university professors and researchers are hired to invent. What is the likely outcome for Professor Z? In the university's favor are the following points:

- The failure to have Professor Z sign the IAA was a one-time error, not the result of a pattern of negligence.
- All professors were recently mailed a copy of the patent policy.
- Professor Z's invention fell squarely within her federal contract's statement of work.

In Professor Z's favor are these points:

- She did not sign an IAA.
- It was her first invention, and she had never gone through the procedure before. (see *Mainland Industries, Inc. v. Timberland Machine and Engineering Corp.*[13])

As a practical matter, a university should tighten its process for requiring all regular employees and visitors to sign IAAs on their date of arrival. Before action is taken on new invention disclosures by the university licensing office, staff should double check the existence of such agreements for particular inventors. Research contracts, with the government and other sponsors, should have a checklist item referencing the existence of IAAs for the principal investigator and other researchers.

2.3 *Example 3: Saturday afternoon conception at home*

Professor Z invents the solar light bulb in her driveway on Saturday afternoon after she incurred

a minor hit on the head falling off her son's skateboard. She refuses to assign the invention to the university because, "I invented it on my own time."

In this case, Professor Z properly signed the IAA on her first day of work. Ownership, in this case, would depend on the exact wording of the IAA. As a matter of policy, each university must decide what is fair and what is beyond the scope of the IAA. A university would be most prudent to require inventors to assign this conception-at-home type of invention to the university. Otherwise, university sponsors would be shortchanged by the fact that the invention was conceived in the driveway, even though the inventor most certainly relied for years on government-funded background research at the university and the invention most certainly would have been inspired, at least in part, by that research.

In *Mainland Industries,* the inventor was a salaried employee who did not work specific hours and did not sign an IAA. He was uncertain whether the patentable idea was conceived at home or at the office. The court stated at 665, "*the place where an invention is developed is not determinative of whether the employer or the employee is entitled to a patent.*"

As a practical matter, most likely Professor Z will return to work at the university on Monday morning, will revamp her work schedule and list of priorities toward the goal of making Saturday's idea into a working prototype, and will assign three graduate students to start implementing the idea. Professor Z is now clearly using university-administered funds and facilities to develop the invention, and the university would own the patent rights, under the hypothetical IAA in Box 1.

2.4 *Example 4: The eclectic inventor*

Professor Z, instead of inventing a solar light bulb, as a diversion from her solar projects instead develops a remarkable new fertilizer for tulip bulbs, after borrowing a colleague's lab in the botany department and two research assistants on Tuesday afternoons. A frantic search of the records is futile; Professor Z never signed the IAA.

The *Dubilier* case referenced in Example 2 above presented a similar set of facts. Francis Dunmore and Percival Lowell were employed by the government in the radio section of the Bureau of Standards and performed research and testing in that laboratory. In the fall of 1921, Dunmore and Lowell were considering the problem of applying alternating current to broadcast receiving sets. This project was unrelated to the work of the radio section and not assigned to them by any superior. The employees took on the research independently and voluntarily.

Dunmore and Lowell discovered a remote-control system for airplane bombs and torpedoes and were permitted to pursue their work in the laboratory and to perfect the prototypes after disclosing their discovery to their section chief. Dunmore and Lowell did not sign IAAs, and no one advised them that they would be expected to assign their rights to the United States. Dunmore and Lowell instead assigned the invention to the Dubilier Condenser Corporation.

The Supreme Court held that the work was not part of the work specifically assigned to them, and therefore, the employees had title. The government was granted the royalty-free right to practice the inventions, which is known as a shop right: when "*a servant [employee] during his [or her] hours of employment, working with his [her] master's materials and appliances, conceives and perfects an invention for which he [or she] obtains a patent, he [or she] must accord his master a nonexclusive right to practice the invention*."[14]

In addition to the shop-right issue, *Dubilier* settled the question of whether the character of service calls for different rules regarding the relative rights of the government, as the employer, and its employees. The answer was no, the same principles of employer–employee apply.

These court decisions are all good news for Professor Z. She would probably own her tulip bulb invention; the university would have a royalty-free, nonassignable right to practice it.

The controversy could have been avoided, had the personnel clerk been able to handle Professor Z's paperwork. If Professor Z had duly executed the hypothetical IAA, the university would have owned the tulip bulb invention, because the significant use of university-administered funds and facilities was covered in the standard agreement.

2.5 *Example 5: The precocious undergrad*

Professor Z is filled with joy. After years of lecturing to a sea of bored, young faces, Jane, then a sophomore, appears in the professor's advanced solar class. While chatting after class about Professor Z's long struggle to harness the sun's power in a 60-watt light bulb, Jane asks the key question, "Why not do it this way...?" Jane performs a simple experiment demonstrating that her idea will work. Professor Z puts the lab at Jane's disposal, and Jane spends every free moment for the next year in the lab developing a prototype.

Undergraduates at the university are not routinely requested to sign intellectual property agreements unless they are employed as research assistants. Jane is not in need of employment while at school and never signed the agreement. Students were not issued copies of the patent policy, and frankly, Jane had not even considered the patent-ownership issue.

When Professor Z filed an invention disclosure with the university licensing office citing the federal research support and naming herself and Jane as co-inventors, problems arose. Jane refused to assign her invention to the university and denied that Professor Z was a co-inventor. Professor Z ultimately conceded this issue after the university's patent counsel defined *inventorship* for her, and all agreed that Jane was sole inventor.

In this case, as in *University Patents*, there is no signed IAA, and the university is relying solely on its patent policy. Under the hypothetical policy described in Example 2, the university would own Jane's invention because of her use of significant funds and facilities, regardless of the lack of a signed IAA.

In a court battle, had Jane the financial resources to fight it, the university would have had an uphill battle to prevail. Jane probably could not have been assumed to have had reasonable knowledge of the terms of the patent policy and its applicability to her, and so the university might be left with just a shop right.

If Jane had signed the IAA, the result would be different; most likely the university would own the invention because of her significant use of funds and facilities. Whether or not a university should routinely have undergraduates sign IAAs should be a matter of thoughtful policy making for each university.

2.6 *Example 6: The better-late-than-never agreement*

Professor Z did not sign the IAA on her first day of work. She invented the solar light bulb five years later, and coincidentally two weeks after the discovery received an IAA form, as part of a university licensing office clean-up project, and she signed it.

The courts are divided on whether continuation of employment is adequate consideration for such an agreement when it is signed after the employer–employee relationship has been formed (see *Mirafi, Inc. v. Murphy*[15]). Any agreement after the employer–employee relationship has been formed must have new consideration to be enforceable; *Harsco Corp. v. Zlotnicki*[16] held that an agreement to cover the assignment of invention to the employer, although not executed by the employee until after he made the invention, as agreement used past and present tenses and referred to entire term of employment.

Regarding *General Signal Corp. v. Primary Flow Signal, Inc. et al.*,[17] Dezsoe Halmi was employed by General Signal (GSC) and rose from the position of draftsperson to products development manager. Mr. Halmi was employed for 15 years before he was asked to sign an "Employee Confidential Information and Invention Agreement," which he then signed. The agreement required that he assign, to GSC, his inventions made while working at GSC and for a six-month period following employment.

On April 5, 1983, five days after the six-month period ended, Mr. Halmi recorded the conception of a universal flowmeter that was patented and then manufactured and sold by Primary Flow Signal, Inc., a company that Mr. Halmi established after leaving GSC.

The court found that his continuing employment was adequate consideration for the invention agreement. The court also found that:

The perfection of a flowmeter proved to be a painstakingly intricate process involving extensive testing. It is therefore difficult to believe that after a long and distinguished career with Plaintiff, Mr.

Halmi in his musing five days after the trailer clause expired for the first time came up with the idea for the NTV. Although the word 'Eureka!' has allegedly been uttered by more than one inventor over the years, the concept at issue does not lend itself to such sudden discovery.

The court concluded that the idea must have occurred to Mr. Halmi while employed at GSC, and, therefore, Mr. Halmi was in violation of the invention agreement.

The university can take some steps to protect itself from situations where the IAA is not signed on the first day of employment, or for inventions not reported by employees who leave the university. As mentioned in Example 2, various catch mechanisms can be put in place to ensure that IAAs are on file. If it is discovered that an employee has not signed an agreement, a carefully worded agreement, signed later, provides some assistance in many jurisdictions. The agreement should state that the consideration is the continuation of employment and the continued use of university funds and facilities, and that the entire term of employment is covered. Some additional consideration could be given, for example, the payment of the sum of US$10. Any royalty-sharing right under the university's patent policy should also be cited.

On termination of employment, personnel should be asked to sign an exit form that includes a statement such as this: "I have disclosed all my inventions falling within the terms of the Invention Assignment Agreement to the university licensing office."

2.7 *Example 7: The visiting scientist*

Professor Z corresponds regularly with her college classmate Martin Xcaliber, who is a tenured professor at another university halfway across the country. One hot summer day, Professor Z is feeling stultified in her work and invites Professor Xcaliber to spend some time collaborating in her solar lab. He is compensated through funds from Professor Z's federal contract. The collaboration succeeds, and Professor Xcaliber breaks through the impasse Professor Z had been struggling with for almost a year. He reduces his idea to practice that summer, and the invention is clearly novel and patentable. But he did not sign the visiting scientist IAA from Professor Z's university. His university is claiming ownership and produces a valid, unambiguous IAA, which covers all inventions made during his period of employment, regardless of where conceived or reduced to practice.

Again, the university is in a bit of trouble under its federal contract because this researcher did not sign an IAA. Once again, the university is left relying on a patent policy that states that the university owns inventions made by visiting scientists making significant use of funds or facilities. Professor Xcaliber may never have seen the patent policy document.

The university could argue that Professor Xcaliber should have known that Professor Z's university would have some sort of patent policy and that he should have made reasonable inquiry. No case law was discovered relevant to this situation, but most likely Professor Xcaliber's university would own the invention, with Professor Z's university getting a shop right. This might be a good case to negotiate for joint ownership by the universities. Another possibility for compromise is to recognize the contribution of both universities through a patent cost and license royalty-sharing arrangement. Aside from the equities on both sides, as a practical matter Professor Xcaliber's university may find itself on the other side of a similar situation in the future and may want to generate goodwill.

2.8 *Example 8: The inventor who does not play well with others*

Professor Z was not asked to sign the IAA on her first day of work but, instead, five years later during the licensing office's clean-up project. She replied, "My ideas and thoughts are not for sale." Fearing that Professor Z may be upset, the department head and administration instruct the license office not to insist on the signing.

Without upper-level pressure on the matter of Professor Z's job security, the licensing office can only argue that:

- The patent policy applies in any event, and Professor Z should sign the IAA merely to affirm.

- Licensing of inventions would be blocked by the potential of future ownership disputes between Professor Z and the university.
- The university would take legal steps to pursue its ownership rights to inventions made by Professor Z falling within the patent policy.

3. CONCLUSIONS

Under the hypothetical patent policy stated under Example 2, an employee of a university is required to assign to the university all inventions made with university-administered funds and facilities if the employee signed a clear and unambiguous IAA. Even if no written contract exists, the university may own the invention. It is a question to be decided in view of the circumstances, and the contract may be implied from the relation of the parties.

The principles underlying this policy have evolved from the line of court cases that, in the absence of a written agreement, hold that an invention belongs to an employee-inventor unless the employee was hired to invent or assigned to solve a particular problem (*Standard Parts Co. v. Peck*[18]). In all of the cases, an implied contract to assign was found, because the employee had only accomplished what he was hired to do. The employer also owns the invention if the inventor owes a fiduciary duty to the company (see *Great Lakes Press Corp. v. Froom*,[19] where the relationship of president to company found to be one of special trust).

Where no written contract and no implied contract to assign is found, the inventor owns the invention, subject to the employer's shop right to use the invention if it was made with the employer's resources or facilities.

One expert in IP law concluded that, "[T]he common expectations concerning university employment are not the same as the expectations concerning employees within private industry."[20] It is this author's opinion that the *Speck* court's "*classification of university faculty as persons hired to invent is contrary to the premises upon which higher education is based*."[21] The author suggests that professors are principally encouraged to acquire knowledge only through research. This conclusion is unsupported by the case law, which does not distinguish between university and commercial employees; in fact, the cases of *Speck v. K. D. I. Precision Products Inc.* found specifically that university professors and researchers are, by definition, hired to invent. The Supreme Court stated that government employees are governed by the same rules as private industry employees in *Dubilier.* The logical extension of *Dubilier* is to treat university employees, the bulk of whom perform research under government funding, equivalent to government researchers, and therefore, to be the treated the same as commercial employees.

In *Houghton,* the employee-inventor argued that the hired-to-invent rule should not be applied to cases in which an employer, such as the government, does not seek a monopoly (the essence of a patent). The Court responded vehemently that:

It is unthinkable that, where a valuable instrument in the war against disease is developed by a public agency through the use of public funds, the public servants employed in its production should be allowed to monopolize it for private gain and levy a tribute upon the public which has paid for its production, upon merely granting a nonexclusive license for its use to the governmental department in which they are employed.

Ultimately, without a written agreement, the facts of each case determine ownership; a particular professor may or may not be found to have been hired to invent or to resolve a particular problem. As with any class of employees, probably no blanket statement can be made as to when university professors and researchers are considered to have been hired to invent.

For managing intellectual property, invention, and ownership issues, the best approach is always to require employees and visitors in a position to invent to sign IAAs as often as employees sign W-2 forms. ■

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1 200 U.S.P.Q. 608 (1978).

2 289 U.S. 178, 53 S.Ct. 554, 77 L.Ed. 1114 (1933).

3 137 U.S. 342, 346, 11 S.Ct. 88, 89, 34 L.Ed 667 (1890).

4 23 F.2d 386, 390 (4th Cir. 1928).

5 264 U.S. 52, 59 (1923).

6 311 N.C. 679, 319 S.E. 2d 139 (1984).

7 319 S.E. 2d 139, 143.

8 762 F. Supp. 1212 (1991).

9 762 F.Supp. 1212, 1228.

10 762 F. Supp. 1212, 1234.

11 Ibid.

12 488 F.2d 261, 267 (1973).

13 218 U.S.P.Q. 662, 665 (Ore. Ct. App. 1982).

14 (289 U.S. 178, 188).

15 14 U.S.P.Q. 2d 1337, 1350 (W.D.N.C. 1989).

16 779 F.2d 906, 228 U.S.P.Q. 439 (3rd Cir. 1985).

17 C.A. Nos. 85-0471B, 86-034B (D.C. R.I. 1987).

18 264 U.S. 52 (1923).

19 695 F. Supp. 1440 (W.D.N.Y. 1987).

20 Smith GK. 1985. The Souring of Sweet Acidophilus Milk: Speck v. North Carolina Dairy Foundation and the Rights of University Faculty to their Inventive Ideas. *North Carolina Law Review* 63:1259.

21 See *supra* note 1, p. 1248.

Box 1: Invention Assignment Agreement

Name (please print or type):

In consideration of the sum of One Dollar ($1.00) and:

- my past, present, and/or future employment at UNIVERSITY; and/or
- my past, present, and/or future participation in research at UNIVERSITY; and/or
- opportunities that have been made or will be made available to me to make significant use of UNIVERSITY-administered funds or facilities; and/or
- opportunities to share in royalties and other inventors'/authors' rights outlined in the "Guide to the Ownership, Distribution and Commercial Development of UNIVERSITY Technology,"

A. agree to disclose promptly to UNIVERSITY and hereby assign all rights to all inventions, copyrightable materials, computer software, semiconductor mask works, tangible research property and trademarks ("Intellectual Property") conceived, invented, authored, or reduced to practice by me, either solely or jointly with others, that:

(i) are developed in the course of, or pursuant to, a sponsored research or other agreement in which I am a participant, as defined in Paragraph X of the UNIVERSITY Technology Policy Guide; or

(ii) result from the significant use of UNIVERSITY-administered funds or facilities as "significant use," as defined in Paragraph X of the UNIVERSITY Technology Policy Guide; or

(iii) result from a work for hire funded by UNIVERSITY, as defined in Paragraph X of the UNIVERSITY Technology Policy Guide; and

B. agree to execute all necessary papers and otherwise provide proper assistance, at UNIVERSITY's expense, during and subsequent to the period of my UNIVERSITY affiliation, to enable UNIVERSITY to obtain, maintain, or enforce, for itself or its nominees, patents, copyrights, or other legal protection for such Intellectual Property; and

C. agree to make and maintain for UNIVERSITY adequate and current written records of all such UNIVERSITY Intellectual Property; and

D. agree to deliver promptly to UNIVERSITY, when I terminate employment with UNIVERSITY for any reason, and at any other time as UNIVERSITY may request, copies of all written records referred to in Paragraph C, above, as well as all related memoranda, notes, records, schedules, plans, or other documents, made by, compiled by, delivered to, or manufactured, used, developed, or investigated by UNIVERSITY, which will at all times be the property of UNIVERSITY; and

E. will not to disclose to UNIVERSITY or use in my work at UNIVERSITY (unless otherwise agreed in writing with UNIVERSITY):

(i) any proprietary information of any of my prior employers, or of any third party, such information to include, without limitation, any trade secrets or confidential information with respect to the business, work, or investigations of such prior employer or other third party; or

CONTINUED ON NEXT PAGE

Box 1 (continued)

(ii) any ideas, writings, or intellectual property of my own that are not included in Paragraph A, above, within the scope of this Agreement (please note that inventions previously conceived, even though a patent application has been filed or a patent issued, are subject to this Agreement if they are actually first reduced to practice under the circumstances included in Paragraph A above).

After the date hereof, this Agreement supersedes all previous agreements relating in whole or in part to the same or similar matters that I may have entered into with UNIVERSITY

This Agreement may not be modified or terminated, in whole or in part, except in writing signed by an authorized representative of UNIVERSITY Discharge of my undertakings in this Agreement will be an obligation of my executors, administrators, heirs, or other legal representatives or assignees.

I represent that, except as identified on the reverse side hereof, I have no agreements with, or obligations to, others in conflict with the foregoing.

Witness

_____

Signature (to include first name in full)

_____

Date

Note: This Agreement is completed and signed in triplicate and distributed in the following manner: original copy to the employee's personnel file, second copy to the employee; third copy to the Technology Licensing Office.

The Role of the Inventor in the Technology Transfer Process

ANNE C. DI SANTE, *Director, Technology Transfer Office, Wayne State University, U.S.A.*

ABSTRACT

Without inventors, there would be no technology to transfer. But without technology transfer professionals, there would be limited transfer of technology. Good relations between inventors and technology transfer professionals are therefore essential for the commercialization enterprise to succeed. Relationships should be established long before the transfer services of the technology transfer office (TTO) are required. A healthy relationship will allow technology managers to negotiate both faculty and business concerns about licensing agreements. Making sure that the inventor is sympathetic to the aims of the TTO will also make it much easier for everyone to understand how a technology may meet market needs, recognize potential licenses, and determine whether a licensee is fulfilling its obligations. For all of these reasons and more, a TTO should always go the extra mile to educate, develop, and maintain good working relationships with inventors.

1. INTRODUCTION

The skills of the technology transfer professional are specific and unique to the profession and are crucial for the management and licensing of intellectual property (IP). The successful transfer of a technology, however, cannot be accomplished without the inventor. The challenge for the technology transfer professional is to obtain full support for his or her efforts from the inventor, an individual over whom the technology transfer manager has no real control. In addition to gaining inventor support, the technology transfer professional must expertly handle inventor relations, both with the technology transfer office (TTO) and within the university. The technology transfer professional must also make sure that the inventor has realistic expectations about marketability. This chapter will describe both the various roles the inventor plays in the technology transfer process and the technology transfer professional's many responsibilities with respect to the inventor.

2. INVENTOR AS CREATOR OF TECHNOLOGY

The essential role played by the inventor is to create and develop the technology that will be transferred. No one else will understand the technology as well as the inventor, so the inventor's full cooperation in disclosure and participation in the technology transfer process is necessary. To develop the best working relationship possible with the inventor, the reputation of the TTO and of the technology transfer manager are important. Public relations within the institution are critical for sustaining these relationships and forging new ones.

Di Sante AC. 2007. The Role of the Inventor in the Technology Transfer Process. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Second Edition, Part V: Chapter 2).

The technology professional should strive to ensure that the inventor hears of the TTO before coming up with a great invention. For many reasons,[1] the technology transfer professional needs to learn earlier, rather than later, about the invention. Academic faculty are now significantly more aware of the technology transfer process than they were a decade ago, but a manager should not assume that this is enough to motivate faculty to file invention disclosures. The inventor must be fully aware of the importance of making timely disclosure of an invention to the technology transfer office. However, educating faculty on the *hazards* of premature disclosure (including in publications) may mean more calls to the office about technology not prime for licensing. It is easier to respond *not yet* than to explain that the big one got away.

The technology transfer professional is challenged to develop systems that promote early information delivery, while remaining conscious of the specific academic environment of the university and the pressures on faculty. The procedures developed for information delivery must be relatively easy to access and use, since it is critical that the TTO receive not just timely but full disclosure of the invention. The technology manager may also be faced with a faculty member's concern about confidentiality. For example, the inventor may be willing to disclose to academic peers, even at another institutions, but may view the staff in the TTO as outsiders or as administrative bureaucracy. The technology transfer manager will need to ease these concerns to solicit complete participation of the inventor in the technology transfer process.

3. ROLE IN THE PROTECTION PROCESS

Once the decision to file a patent application has been made, the most frequent question a technology transfer professional will hear is: *"How much of my time will this take?"* While one may be tempted to minimize the efforts needed, it is important to provide realistic estimates in order to prevent unrealistic expectations. Depending on the technology and the detail in the invention disclosure document, inventor input at the drafting and filing stages varies from minimal to substantial.

The inventor and patent counsel should interact early in order to form the critical relationship necessary for a solid patent application. The inventor must be assured of confidentiality and convinced of the value of providing a full disclosure of the technology to patent counsel. In addition to assisting in the drafting process, the inventor is needed for inventorship determinations. For example, many faculty equate inventorship with authorship, so they will list collaborating inventors using the same criteria for naming authors on scientific manuscripts. Fortunately, patent counsel can assume the role of adjudicator for inventorship matters, although the TTO may be required to enlist the assistance of department chairs and other university administrators for difficult cases.[2]

The inventor must be a willing partner during the actual prosecution of the patent application, as well. While the concept of nonobviousness can be difficult to grasp,[3] a skilled patent attorney will work closely with the inventor to develop the responses necessary to overcome this type of rejection. The inventor should be encouraged to read the materials and provide answers to the attorney's questions; after all, the inventor knows the field better than anyone else. Most faculty respond well to patent counsel's translation of the rejection from "patentese" to plain English. Direct questions are easier for the inventor to address than a general "*please read and give me your thoughts on this*" request. While it will cost more in attorney time to have patent counsel read, analyze, and develop questions to address an office action, the investment will prove worthwhile if needed responses are shared from the start.

Filing a patent application and having a patent issue are not the only goals of the TTO. Nearly 100% of the time, the technology transfer professional will also need the inventor to actually transfer the technology to the licensee later in the process. In addition, once the patent is issued and the technology licensed, the inventor may take on the unofficial role of "infringement police officer" by recognizing when a product is sold that may infringe the patent. An inventor should be encouraged to report suspected infringement to the TTO, which can then assign responsibility for pursuing infringers.

Developers of software and multimedia should be well educated about the use of copyright notices; it should be second nature for the appropriate notice to be placed in a new program. Of course, this depends on the specific copyright policy in effect at the institution.

Biological materials with commercial potential are another form of IP not always associated with patent protection. The inventor must understand the difference between transfer to nonprofit research institutions and transfer to forprofit institutions that may use the technology as a product development tool. It is important for the inventor to understand that the value of the material will be maintained if the release of the material is controlled. This control does not prevent the inventor from fulfilling the obligation to provide samples of the materials to those who wish to repeat experiments, as required by many scientific journals, or from meeting federal guidelines on the dissemination of research tools. In the management of biological materials, it is essential for the technology transfer professional and the inventor to design and agree upon a distribution plan that maximizes commercial potential without negatively affecting scientific research.[4]

4. ROLE IN THE TECHNOLOGY TRANSFER PROCESS

The technology transfer process involves many steps, some occurring concurrently. An inventor participates at various levels in each step, although the degree to which the inventor is involved will depend on many factors, including university corporate culture and the players involved.

4.1 *Marketing*

The technology transfer professional cannot expect to understand every industrial sector, market, or niche into which technologies may fit. Most often, it is the inventor who will know both the academic and industrial players in the field. Additionally, the inventor may have a clearer understanding of unmet market need and whether the technology addresses this need. This information may allow the technology transfer professional to perform a general SWOT analysis (strengths, weaknesses, opportunities, threats) with relatively minor market research. An inventor can also prove to be a good source of other marketing information, such as market size, market location, and competitive technology, both in academia and industry. While any numbers should be verified with an outside source, an inventor can be a one-stop source of market information with which to get marketing efforts started.

4.2 *Identification of potential licensees*

A manager can expect an inventor to be contacted by potential licensees because of the inventor's publications, meeting presentations, and industrial contacts. Many inventors call friends in the industry to discuss their research. It is important to encourage the inventor to direct commercial inquiries to the TTO. The referral of these calls to the technology manager will help accomplish many objectives. First, it allows the technology transfer professional to manage the commercialization of the technology by keeping tabs on commercial interest, allowing consideration of all potential licensees when making final decisions. Second, it establishes early in the process who will be the key licensee contact in making the licensing decision. Third, it keeps the inventor from *selling the well* twice. Fourth, by moving the inventor to a secondary role in negotiations, the inventor becomes insulated from licensing decisions, thus allowing the inventor and the industrial scientist to develop and maintain a relationship based on the interests of science—not business. Indeed, the industrial scientist hopefully will become the internal champion within the licensee for the innovation, with the first step in this process involving the inventor.

4.3 *Information to the potential licensee*

Who provides what information to a potential licensee is partly intuitive. For example, the technology transfer professional generally addresses issues regarding the patent application, IP policies, and licensing, while technical questions, prototypes, demonstrations, and materials for evaluation will most likely come from the inventor. With regard

to the latter, the inventor knows the technology best—what it can and cannot do—and thus is in the best position to share such information. The technology transfer manager may wish to encourage the inventor to brainstorm with his/her industrial counterpart on issues that may come up during scale-up. An inventor may become nervous about providing a full disclosure of the technology to industry. The technology transfer professional should work with the inventor to ensure that the time is right in the review process to provide full disclosure, and that the disclosure can be documented in some manner.

4.4 *Licensing negotiations*

An inventor's level of participation in licensing negotiations truly depends on the individual. The decision about how far to involve an inventor rests on the shoulders of the technology transfer professional. The manager must weigh the inventor's personality, interpersonal skills, and knowledge of business negotiations, as well as the inventor's understanding of office policy, knowledge of the licensee, and ability to function as part of a negotiation team. The technology transfer professional should be on guard for signs that the inventor is starting to sway to the side of the licensee during negotiations, which sometimes occurs. Often, the manager can resolve this by investing in discussions with the inventor to identify the underlying reason(s) for the inventor's sympathy towards the licensee's point of view. It is important for the inventor to agree to the deal breakers and to be prepared to walk away from the deal. If the inventor is apprehensive of business negotiations, he/she should remain on the sidelines. If this should be necessary, the technology transfer professional still should keep the inventor updated on the status of license negotiations in order to manage expectations and to preserve a good relationship with the inventor. The inventor, in turn, should be encouraged to keep the technology transfer manager updated on what he/she may have heard from contacts within the company. The technology transfer professional should be notified of any technical updates that occur, especially during the negotiation period, since it may be important to promptly disclose this information to the company. It may be advantageous to routinely schedule discussions with the inventor during negotiations. Such discussions can serve the dual purpose of a negotiation update and a technical update. Prior to signing the agreement, the inventor should identify exactly what materials, know-how, and so on, must be transferred to the licensee. The inventor should also discuss with the licensee how this transfer is best accomplished. The licensee may wish to have access to the inventor once the agreement is in place, for example, by hiring the inventor as a consultant. The technology transfer professional must stay informed of these activities and verify that any obligations of the university under the agreement are fulfilled, and that any new relationships between the licensee and the inventor work within the framework of the license and institutional policies.

4.5 *Licensee diligence and license compliance*

Following execution of the license, the inventor is a major source of information. It is extremely important for the TTO to develop systems to follow license compliance and diligence.[5] In a perfect world, the technology transfer professional would maintain close ties with his or her counterpart at the licensee. Frequently, however, the inventor will have more information than anyone else about technology development by the licensee. In most cases, contact with the scientific counterpart at the licensee is key for good information flow. Indeed, the relationship between the inventor and the scientific counterpart may provide the insight that will help the technology manager determine whether the licensee is diligently pursuing the technology's development. The technology transfer professional should encourage the inventor to inform the TTO of concerns about the voracity of the licensee's efforts (or lack thereof). Specific information about the likelihood of meeting technical milestones is also helpful. Encourage the licensee to involve the inventor (as an observer) in product development discussions. That way, the inventor will stay informed and may be able to help with any technical glitches that might arise when the licensee scales up the technology.

4.6 *When things go well*

When there is an unqualified success in a technology transfer effort, the inventor, licensee, university (including the TTO), and the public all benefit. The inventor might also experience fame and fortune, depending on the discovery. Positive feedback has the potential to reach other faculty and may encourage those who have not yet *tested the waters* of the TTO to disclose an invention. Conversely, success can also bring unwanted attention, often related to the anticipated revenue stream. Disputes may arise about royalty distributions among the inventor, his or her department head, or dean. The university's royalty distribution policy may be challenged. If significant revenue is expected, funds traditionally earmarked for one purpose might be considered for reallocation. A wise technology transfer professional will remain in touch with the inventor to ward off these occurrences and/or to be available for assistance, if needed. When challenges are raised, the TTO may be called upon for suggestions and may be engaged in the discussions, even if its preference would have been to remain neutral.

4.7 *When things go badly*

The earliest signs that a license agreement is not proceeding as planned are usually given (intentionally or not) to the inventor. The technology transfer professional, therefore, should counsel the inventor to recognize trouble spots. It is a good idea to provide pointers to the inventor about what to look for and when to contact the office to relate issues of concern. Better yet, the technology transfer professional should routinely stay in touch with the inventor in order to stay aware of the licensee's R&D efforts. If a license is terminated (for whatever reason), the inventor can help ensure that the institution retrieves from the licensee what is due. Should the technology manager find himself or herself in the unenviable position of terminating a license, the inventor may be instrumental in establishing breach of diligence obligations. Managers should be cautious, however, of the overzealous phone call from the inventor calling for the termination of a license. For example, an inventor who has difficulty moving past the point of research to product development may perceive progression from *research* to *development* as a sign of an incompetent licensee.

If litigation is a possibility, the technology transfer professional may wish to enlist the help of the university's Office of the General Counsel to make sure that the inventor understands the process. Specifically, the inventor needs to know what is expected of him or her as inventor, and what is involved in such a proceeding. Litigation is complex and requires coordination and cooperation. Indeed, should the TTO need to litigate on a matter related to a license, the technology transfer professional and the inventor will both benefit from having previously established a long-lasting, supportive relationship.

5. INVENTOR AS ENTREPRENEUR

With the increased emphasis on the role of technology transfer in economic development activity, managers can expect a change in the relationship when the inventor moves into the role of entrepreneur. Many factors will influence the evolving relationship, including whether it is the inventor or the TTO pushing the entrepreneurial activity. Regardless, it is important for the inventor to recognize that the technology transfer professional's fiduciary duty is to the university. In past cases of third-party licensing, the inventor's interests and the university's were closely aligned. But now the situation is different. Be diligent in notifying the entrepreneur about the university's expectations for him or her to provide appropriate business and legal support. To prevent problems down the road from which it may be difficult to recover, the inventor-entrepreneur must understand the university's conflict-of-interest and conflict-of- commitment policies. The technology transfer professional should encourage the inventor to provide a frequent flow of information to his or her department chair and dean. Concurrently, the technology transfer professional should also provide the appropriate information to the administration, department chair, and dean. The inventor-entrepreneur must recognize that license negotiations with the company must be arm's-length negotiations and that they often require high-level approval, which may delay the execution of the

agreement for weeks. The inventor-entrepreneur has the potential to become a spokesperson for the university's technology transfer efforts. Conversely, the inventor-entrepreneur could become the strongest critic of such activity, depending on how these relationships are managed and balanced.

6. MANAGEMENT ISSUES

6.1 *Other technology transfer roles for the inventor*

The inventor participates in many other technology transfer activities throughout his or her academic career that occur without the involvement of the technology transfer professional. These activities, such as consulting, educating/graduating students, publishing manuscripts, giving conference presentations, distributing posters, participating in a consortium, and becoming involved in sponsored research agreements, may be described as know-how transfer without a license.

While the technology transfer professional may not be involved in any of these activities at the start, some (if not all, at some time) will affect the technology manager's efforts. In these instances, it is best to take the education approach. When possible, educate faculty about the effects of publication or of signing away rights in consulting agreements, and so on. Raising awareness about those effects means more inquiries to the TTO, but early input may prevent impossible situations later.

6.2 *Management of relationships*

It is imperative for the technology transfer professional to keep in mind the numerous groups the inventor needs to deal with in academia: patent attorneys, TTO staff, grants and contracts officers, department chairs, deans, sponsors, academic collaborators, licensees, and students, to name only a few. Remember, both the inventor and the technology transfer professional function within the organization's corporate culture. In addition, the university's corporate culture may be an island in the local culture, subject to frequent analysis and possibly criticism.

It is important for the technology transfer professional to stay high on the inventor's priority list of individuals with whom to nurture a relationship. Faculty, however, are not universally evaluated by the number of disclosures submitted or patents awarded; publications and grants remain the priority. Remember this, and be assured that if the technology transfer professional unconditionally accepts the academic environment, an open, trusting relationship with the inventor will develop over time.

The TTO may be enlisted to function as a go-between, negotiator, or advocate for the inventor with any of the above groups. This is a challenging responsibility, since the TTO needs to maintain its own relationship with each of these groups as well. All potential outcomes and ramifications for both the inventor and the TTO (when assuming this role) need to be considered.

6.3 *Management of expectations*

A significant part of managing the relationship between the TTO and the inventor is making sure the inventor maintains realistic expectations. A former colleague coined this hypothetical disclosure-form question: *"Please indicate the value of this technology: Is it worth millions, billions, or priceless?"* And while this was suggested tongue in cheek, the sentiment does ring true. There is frequently a big disconnect between the inventor and the TTO when it comes to an invention's marketability. The challenge faced by the technology transfer professional is how to tactfully keep inventor's expectations in line with realistic expectations. Soliciting an opinion from another party may help. For example, the technology transfer manager may wish to enlist a trusted faculty member who has experience with transfer technology. A patent attorney or an outside consultant can help deliver the news. Evaluations from industrial representatives may be the only validation an inventor will accept. A manager may wish to identify to whom the inventor best relates and enlist them to help. It is in the best interests of everyone to be realistic from the start. If the inventor's value perception is skewed, his or her chair may also have skewed expectations, and the inventor's dean may be overanticipating, as well.

In these situations, the technology transfer office spends a great deal of time (and political capital) explaining away unrealistic expectations and redefining what is reasonable to expect. Recovery from disappointed expectations may take years, and the gap between expectations and what was actually achieved could possibly end in an office reorganization.

7. CONCLUSIONS

While the technology transfer professional is constantly challenged to manage diverse technology, he or she is further challenged to effectively interact with a diverse group of inventors. While these complex relationships and interpersonal dynamics may be overwhelming at times—both for the inventor and the technology transfer manager—working together can be extremely rewarding. These interactions add an unanticipated dimension to the job of the technology transfer professional that is often enjoyable. ■

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1 See also in this *Handbook*, chapter 8.4 by D McGee.

2 Gates ER and MN Rader. 2001. Disentangling Inventorship. *The Journal of the Association of University Technology Managers*. vol. XIII. www.autm.net/pubs/journal/01/disentangling.html.

3 Terry KR and JE Embretson. 2001. Patent Application Filing in the United States. *AUTM Technology Transfer Practice Manual*, AUTM: Northbrook, Ill.

4 See also in this Handbook, chapter 7.3 by AB Bennett, WD Streitz and RA Gacel.

5 Tretheway JA and H Bremer. Monitoring the License Agreement, *AUTM Technology Transfer Practice Manual*, AUTM: Northbrook, Ill.

Conducting IP Audits

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ABSTRACT

This chapter explains how important it is for a research institute to audit both the intellectual property (IP) that it generates and the third party IP that its researchers utilize. Such an audit will have the practical consequence of enabling the research institute (when appropriate) to secure ownership, maintain, and manage the IP for which it is responsible.

1. INTRODUCTION

For a number of years, intellectual property (IP) rights were considered private rights and not of concern to the public research community. A number of developments have changed this perception. First, genetic materials have been privatized, limiting the genetic materials available for public research. Second, IP rights have been asserted over enabling biotechnologies, which has the potential to thwart the ability of public research institutions to pursue modern biotechnological research. Third, funding for public research institutes has been reduced, making them aware of their need to take an active role in IP management. Indeed, because of the above developments, public research institutes are now using their IP assets to bargain for access to private proprietary rights.

The first step in IP management is to conduct an IP audit. This will identify the IP that the institution's researchers generate, allowing it to be used as an asset and aiding in the identification of the IP of third parties. The latter is particularly important for the institution's ability to avoid liability for the misuse of third-party IP.

2. METHODOLOGY

The usual objectives of an IP audit are to identify relevant IP, establish the ownership of that IP, put in place procedures to manage the IP, and assist in the formulation and execution of the research institute's IP policy.

Of course, before any of these processes can begin, the scope of the audit must be determined. In some cases, an audit might be done to satisfy donor institutions or for external accreditation. On the other hand, it might be prefatory to the research institution's collaboration with the private sector. In each case, those commissioning the audit must determine the objectives. A decision will have to be made about who gets the results of the audit. It may be confined to the board, to donors, to management, or be made available to the public.

The audit may be conducted through:

- online surveys of senior administrative and research staff
- follow-up interviews, by phone or in person, with those staff

Blakeney M. 2007. Conducting IP Audits. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

- analysis of contracts, material transfer agreements (MTAs) and other documents held at the central administration
- analysis of relevant documents identified through interviews

Before the audit, it is often useful to sensitize staff about the relevance of IP to the research institution's operations. This can be achieved through workshops or distributing explanatory material, both of which can be done online. Surveys to identify agreements and activities with potential IP implications can also be administered online. Follow-up interviews will explore this information and identify documents that need analysis. Of course, all of the institution's contracts should be scrutinized for their IP implications.

Keeping the results of the audit confidential will be essential for securing the full cooperation of the institute. After all, the audit might disclose matters that the institute may find damaging to its reputation. More positively, areas of education and training for staff may be identified and the results of the audit translated into best management practices.

3. OWNERSHIP AND CONTROL OF IP

3.1 *Introduction*

A key goal for any IP audit is helping to establish the research institute's ownership and control of the audited IP. This requires examining all documents relevant to: (1) the legal status of the institute; (2) the obligations of personnel under their service agreements and employment contracts, together with their obligations under the institute's IP policy; (3) agreements with research collaborators; (4) agreements with funding bodies and donors; and (5) documents relevant to the research institute's status within any research network.

The ability of a research institute to assert ownership and control over any IP depends upon its legal capacity. In the case of an incorporated institute, this will be set out in its constitution and bylaws (memorandum and articles of association). The laws governing the place of incorporation will usually govern these documents. But if the research institute has international status, its powers may be derived from a headquarters agreement between the host state, donor bodies, and the institute.

Once it has the legal power to exercise dominion over property, including IP, the institute will also have the power to contract with its employees. Typically, IP clauses will be inserted in contracts of employment or in an institute IP policy or code referred to in the employment contract. The simplest of these clauses will oblige an employee to comply with the institute's IP policy, which will typically be available in printed form or on the institute's Web site.

For example, Washington State University's IP policy states:

All employees accept the terms of these policies as conditions of employment or gratis association. Employees shall agree to execute an assignment of their future patentable works and discoveries to the University. These policies may be modified by the administration with approval from the Board of Regents after consulting with faculty and staff of the University.[1]

As indicated below, this policy obliges employees to notify their employers of any innovations that might generate IP rights. For example, Texas A & M's IP policy applies to:

(i) *all persons employed by the System; and*

(ii) *any persons using the System facilities under the supervision of System personnel, including but not limited to visiting faculty and adjunct faculty, unless special terms for management of the work of such individuals are negotiated by the System or the applicable System component. System employees should not enter into intellectual property agreements related to outside employment, such as consulting or summer employment agreements, without affirmative notice to the prospective employer that the intellectual property rights of the System cannot be subordinated to a third party consulting or employment agreement.*[2]

It will be up to the institution to decide what to do with such IP. In some cases, IP rights might be waived. More usually, there is a procedure to

share the benefits of any exploitation of IP. The IP policy of Texas State University is typical:

In those instances where the System licenses rights in intellectual property to third parties, the costs of licensing, including the costs to operate and support a technology transfer office and departmental or institutional intellectual property advisory committees, and the costs of obtaining a patent or other protection for the property on behalf of the Board shall first be recaptured from any royalties or other license payments received by the System, and the remainder of such income (including, but not limited to, license fees, prepaid royalties, minimum royalties, running royalties, milestone payments, and sublicense payments) shall be divided as follows:

- *50% to creator*
- *50% to System*

With the prior approval of the Board … component institution may include provisions in its Handbook of Operating Procedures to adjust the allocation of royalties set forth herein, but in no event shall the creator receive more than 50% or less than 25% of such proceeds.

A similar situation will apply in research institutes operated by government departments. In each case the government department will have to decide whether any IP generated by its employees will be made available to the employee, whether it will be secured by the relevant department for exploitation or, alternatively, made available to the wider research community.

3.2 *Headquarters agreements*

For international research institutes, the agreement between donors and host governments will usually delineate the institute's legal personality. It will usually be designated as "*an autonomous, philanthropic, tax-free, nonprofit, nonstock, benevolent corporation*."[4] There will usually be a term for which the institute is to exist, such as 50 years from the date of incorporation, with a possibility for renewal. It will usually be indicated who owns the assets of the institute at the end of the term. Should an institute establish a collection of biological resources from other countries, biopiracy objections may arise if their ownership is lost at the end of the term.

The headquarters agreement will usually indicate the power of the institute to "*receive and acquire by donation, grant, exchange, devise, bequest, purchase, or lease, either absolutely or in trust, contributions of such properties, real and personal as may be necessary to carry out the objects and purposes*" of the institute. This provision will have no operative effect, as the power will be conferred by incorporation.[5]

3.3 *Incorporation*

Typically, a research institute will be incorporated under the law of the host country. This law will contain provisions about the types of corporations and their powers. Companies are usually divided into nonprofit and profit-making enterprises, and the ownership and assets structure of each may differ. Invariably, the voting rights of the company will be allocated by reference to shares. Management will consist of a board under a panel of directors and a chief executive officer. The powers of the company are usually set out in a constitution or a memorandum of association and detailed in its bylaws or articles of association. These documents should be scrutinized to see what powers the institute has to own and to deal with IP. The documents will also explain the powers of the corporation's officers to enter into transactions on behalf of the corporation. The procedures for terminating the existence of the institute and the disposal of its assets on termination should also be described.

The constitutive documents of a corporation are commonly silent about the fate of intangible property, such as IP, that is generated by the corporation during its life. This is because IP has only relatively recently become a corporate concern. However, where the tangible property is specifically disposed of, it is likely that the intangibles will follow the same route.

3.4 *Charter of the institute*

Public research institutes commonly indicate their public service function in a governing charter. The board, under the corporation's bylaws, will usually promulgate such a charter. As such, the charter will be subordinate to the general operation of the articles of incorporation and confer no powers

that are greater than those defined by the articles of incorporation.

3.5 *Personnel documents*

Typically, the personnel at a public research institute include national staff, internationally recruited staff, visiting scientists, consultants, affiliate scientists, project scientists, collaborative research fellows, and doctoral and postdoctoral students. Asserting ownership and control over the IP that personnel may generate will depend upon the terms of their engagement. For convenience, we can categorize these persons as staff and nonstaff.

3.5.1 *Staff*

The ownership and control of IP generated or held by staff will be handled by a combination of personnel contracts and the institute's personnel policies and procedures. These will usually be gathered in a personnel manual. Given the growing concern about IP staff, some institutes have been requested to sign an IP rights statement or a nondisclosure agreement. At the International Rice Research Institute (IRRI), for example, the statement is an *IPR Agreement* in which staff agree that "*all inventions, improvements, data, processes, technologies, discoveries and other intellectual properties*" generated by them, while employed by IRRI, "*that relate to the research and development programs of IRRI or result from tasks*" assigned to them "*are the sole property of IRRI*."[6]

Publication is a significant issue if a partner desires nondisclosure and the ethos of the institute is to publish its research. Premature publication in articles, research papers, and at conferences and meetings may destroy the novelty of a patentable invention. This is in tension with the desire of researchers to place their scholarship into the public arena. The IP audit can be an opportunity to introduce staff to the impact of IP upon their research. When proprietary technologies are licensed from the private sector, the license agreement may sometimes restrict publication until the commercial opportunities generated by the research have been evaluated. Nonresearch staff and board members should also be bound by a confidentiality obligation.

This list of IP categories embraced by the agreement is presumably intended to be informative and exhaustive for the staff members who sign it:

- The IRRI *IPR agreement* obliges staff to disclose the listed categories of IP "*promptly to IRRI*." A procedure for such disclosure should be established, identifying the person or office to whom/which disclosure should be made.
- The IRRI *IPR agreement* requires that employees assign relevant IP to IRRI and "*do all things necessary, including executing documents*" to assist IRRI in obtaining legal protection for its IP. This is a fairly effective means for IRRI to secure title to the IP generated by its staff.
- The *IPR agreement* also obliges staff to use confidential information only in the performance of duties for IRRI and not to disclose information to unauthorized persons both during employment with IRRI and for a five-year period after the termination of their employment. This provision appears to effectively impose confidentiality obligations.

Staff includes those employed outside the institution, such as those working in the field or attached to other institutions. They are bound by their employment contracts and potentially by the IP policies of the external institutions for which they work. The legislation of the countries where they work may also apply. For example, a number of countries have enacted legislation to regulate access to biological materials that might become the subject of patent applications. A research institute would be in breach of that law if it filed IP applications related to biological material that was obtained without consent.

Usefully supplementing the IPR agreement could be a reference to any institute policy on IP rights and a definition of those rights. Box 1 sets out a comprehensive definition of IP.

3.5.2 *Non-staff*

Research institutes frequently host various categories of nonstaff, such as visiting scientists, consultants, project scientists, collaborative research fellows, and students. Maintaining ownership

and control of the institute's IP can be a particular problem where non-staff are concerned. Without an agreement with them, the institute will be unable to assert control over IP that these visitors might generate or use. Indeed, problems have arisen from the uncertain status of visiting researchers, who in some instances have acquired patent rights over the subject of their research while a visitor. Accommodating researchers funded by outside donors has also been an issue. Uncertainty about the ownership of the research of such donors can be clarified in the institute's IP policy. Accordingly, a number of countries commonly require nonstaff to execute an IP and confidentiality agreement.

3.6 *Policy on IP*

Currently, public research institutes commonly formulate policies to deal with IP ownership and control. The policy is usually agreed to and approved at the board level. As a general principle, the institutes emphasize the free availability of the information, inventions, and biological material that they develop. Institutes are obliged, however, to seek IP protection to ensure the availability of advanced biological technologies or biological materials for developing countries. Some institutes declare that they may seek to protect technologies or materials that they develop for their client communities. Protection may also be pursued to prevent third parties from obtaining IP rights over their innovations. For example, by filing a provisional patent application, knowledge about an institute's innovations will be placed in the public domain. This is intended to destroy the novelty—and hence the patentability—of innovations that are required for the benefit of developing countries. This will prevent such inventions from being appropriated by the private sector.

Box 1: Intellectual Property

Intellectual property means information, ideas, inventions, innovations, art work, designs, literary texts and any other matter or thing whatsoever as may be capable of legal protection or the subject of legal rights and includes the following protections:

- patents
- confidentiality (for information which is of a kind and which has been communicated in such a way as to give rise to a duty of confidentiality)
- copyright vesting in literary works (including computer programs), dramatic works, musical works, artistic works, films, sound recordings, multimedia works, broadcasts, published editions, and certain types of performances
- registered trademarks
- unregistered trademarks used or intended for use in business
- registered designs and designs capable of being registered
- rights of breeders for new plant varieties
- rights associated with designs
- rights related to databases
- other rights resulting from intellectual activity in the industrial, commercial, scientific, literary, and artistic fields

A number of public research institutes include their IP policy within a policy on partnership with the private sector. These research institutes will often concede that to ensure that developing countries have access to biotechnology-derived products and advanced biotechnologies, it may be necessary to enter into special agreements that stipulate some limitations on distributing derived and associated materials. Within the context of this policy, the institute may assemble a list of IP that it is willing to share with the private sector in exchange for access to its IP, under mutually acceptable terms.

4. IDENTIFICATION OF IP GENERATED BY A RESEARCH INSTITUTE

4.1 *Background*

An IP audit obviously has to identify all the IP generated by the research institute, whether existing in a registered or unregistered form. This requires analyzing questionnaires completed by management and research staff, as well as the examination of contracts, MTAs, licenses, collaboration agreements, memorandums of understanding, collaborative work plans, employment contracts and other legal arrangements. This will allow the auditor to: (1) clarify the terms under which IP is being accessed; (2) determine whether the terms of access impose restrictions on the institute's ability to distribute products and services produced with the help of this IP; (3) identify ownership of relevant IP; (4) identify the source of IP in order to identify areas in which IP access and ownership issues may have to be reexamined to ensure compliance with the institute's current IP policy; (5) assess the importance of the IP to the institute's activities; and (6) identify all new IP being developed at the institute (specifically, the IP opportunities perceived by the institute, for its own and third-party IP).

Typically, an audit will identify the following main types of IP:

- patents and know-how associated with the biological assets of the institute
- patents and industrial design rights
- IP associated with agricultural equipment developed by the institute
- copyright, database rights, and know-how associated with publications, computer programs, and databases generated by the institute
- copyright databases and know-how developed from the functional genomics research undertaken at the institute
- trademarks
- industrial designs

4.2 *Patentable biological assets*

The principal biological assets located at a scientific research institute will include:

- germplasm collection
- DNA collection
- biological tools for gene discovery
- enabling technologies (for example, marker genes and probes)
- advanced mapping populations
- near isogenic lines
- introgression lines: mutants (characterized/uncharacterized); BAC library
- introgression lines
- gene pyramids
- advanced lines from conventional breeding: conventional lines; new plant types
- inbred lines for hybrids: a, b, and restorer lines
- varieties/cultivars
- hybrids
- transgenic lines

These biological assets represent a considerable investment by the institute, its partners, and collaborators. Insofar as they contain potentially patentable or licensable information, they also represent various levels of added value, utility, and inventiveness.

4.3 *Patents, utility models, and industrial design rights*

A medical or agricultural research institute is likely to develop equipment and tools that need IP protection.

4.4 *Technological know-how*

Not all IP is protected through a system of registration. An important unregistered category of IP

in medical research is confidential information. It is often an adjunct to registered IP rights. For example, patent protection is conferred in exchange for the disclosure of enough information in a patent application to permit the invention, which is the subject of the application, to be used. To protect its competitive advantage, the applicant inevitably will withhold information about how to effectively commercialize an invention. This information, or know-how, may include plant design and setup, training, marketing plans, customer lists, and accounting and survey methods. Similarly, a protected trademark is of limited commercial utility without an associated scheme for advertising, licensing, franchising, and marketing the goods or services under that mark. Ensuring the quality control of the licensed goods will usually entail the application of trade secrets.

At the center of the attempt to protect confidential information are efforts to restrain the disclosure of trade secrets by former employees or researchers. A particular difficulty in these cases is distinguishing between information that can be regarded as the skilled employee's or researcher's own expertise and other information gained during employment, such as secret industrial formulae or processes, which may properly be regarded as the employer's. Generally speaking, if the information in question can fairly be regarded as a separate part of the employee or researcher's stock of knowledge that a person of ordinary honesty and intelligence would recognize, the information would be considered to be the property of the employee. In applying this objective test, the courts have tended to look, among other things, at the nature of the employment, the nature of the information, and whether the information was capable of being isolated from other unprotected information. Chemical formulas and recipes and engineering drawings and designs are usually considered to be discrete categories of undisclosed information that fall within the category of protectable confidential information.

National laws protecting confidential information differ. Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO) deals with the preservation of confidential test data submitted to government approval agencies. Given the long approval process, particularly for pharmaceutical products, the opportunities for wrongful appropriation of such data by competitors was self-evident. Accordingly, Article 39 (3) provides that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

4.5 *Biological assets protectable as plant varieties*

New plant varieties developed by agricultural research institutes may be protectable under plant breeders' rights legislation. Such varieties can also be patented in the United States but not in Europe.

4.6 *Rights associated with publications, computer programs, and databases*

Copyright arises in relation to publications, CD-ROMs, databases, online displays, and software. Governing the protection of works created within a country, copyright laws are territorial. But through international agreements a particular country's laws can be respected outside its territory. Most countries are signatories to the TRIPS Agreement, which affirms the Berne Copyright Convention and adds some additional protection.

Most copyright laws provide protection for printed works, such as books, conference proceedings, research reports, and journals. Copyright protection is also available for research notes, provided that these are in written form. Copyright protection is also available for films, photographs, sound recordings, and CDs. Under the Berne Convention and TRIPS Agreement, computer programs are treated as if they were literary works. Finally, copyright protection is available for online materials and

screen displays. The period of copyright protection is conventionally 50 years from the date of a work's publication.

4.6.1 *Publications*

Copyright will exist in the textual material, photographs, graphic designs, diagrams, charts, and the compilation or arrangement of a publication. A research institute will publish scientific books (including monographs, conference proceedings, manuals, and field guides); discussion papers; proceedings of conferences, meetings and workshops; technical bulletins; and scientific posters.

4.6.2 *CD-ROMs*

A number of different copyright interests may arise for material on a CD-ROM. Copyright may arise with respect to text, artistic works (such as photographs, drawings, diagrams), musical works, sound recordings, and films, as well as in relation to the compilation of material contained in the CD. An institute may produce CD-ROMS as part of its training materials. For example, the asynchronous Internet-based courses in Experimental Design and Data Analysis and in Agricultural English, created and administered by IRRI, are available on CD-ROM. When materials have not been generated at the institute, the audit should ascertain whether permission or clearance has been obtained from the author or original source prior to publication. The audit should also determine whether the author or original source is acknowledged. When material appearing on CD-ROM is generated at the institute, the CD-ROM should carry a copyright notification with respect to the compilation and the individual elements of the CD.

4.6.3 *Video materials*

Video materials produced for the purpose of training are copyright protectable. Thus video materials produced at the institute should acknowledge it as the source and carry a copyright notice. If desired, this could be accompanied by a notice authorizing reproduction or copying of the material provided the institute is acknowledged as the source. If videos are produced involving material generated from outside the institute, then procedures have to be put in place to obtain copyright authorization and copyright indemnities.

4.6.4 *Copyright databases and know-how*

The various research projects undertaken or underwritten by an institute generate considerable bodies of data. Under current copyright law, raw data or information is not protectable. But legislation is being considered in a number of countries that would allow databases and possibly raw data itself to become the subject of sui generis, or special, IP protection. However, while raw data contained in databases may not be copyright protected, the way in which information is expressed can offer some protection. For example, a passage of text, a diagram, or chart contained in a database may be protected by copyright. It is also possible that in certain circumstances, where sufficient originality or creativity in the arrangement of data is present, the database as a whole may be protected by copyright on the basis that it is a compilation. Because individual components of the database may be protected by copyright, there must be mechanisms and procedures to ensure that the database does not contain material that infringes the copyrights of others. IP rights are of particular concern when the creation of a database is collaborative. In this case, when copyright exists in individual entries it may be unclear whether the copyright belongs to one collaborator or to all the collaborators jointly. Moreover, when material is contributed from diverse sources, each collaborator may become liable as an infringer—even if only one of the collaborator infringes the copyright of a third party.

To deal with some of these copyright issues, the Document by Bioversity International recommends that the copyright notification page contain a general notification hyperlinked to a page of specific copyright notifications. These would identify which part, or center, of the institute owns copyright in the relevant material. The document suggests the following general notification:

This site is protected by international copyrights in the design of the site including the layout, typography, and graphics reproduced herein, and in the expression of the information contained herein,

whether as a compilation, literary or artistic work or otherwise.

The form of the specific copyright notifications recommended in the Bioversity International document is:

Copyright [*full name of copyright owner*] [*year of creation of work*] in [*describe*] as [*compilation/published edition/literary work/artistic work*] or otherwise.

4.6.5 *Online materials*

The copyright principles that apply to printed works and CD-ROMs apply equally to online materials. Thus an institute would have to secure permission and indemnities to use copyrighted material that it displays on its Web site.

IP approval for hypertext links to other World Wide Web sites has recently raised some copyright concerns. If the institute's home page links to a large number of Internet resources, it should be ensured that the proprietors of those online resources have no objections to those linkages.

Copyright issues are also raised by mirroring and framing. Mirroring occurs when a site is duplicated on another server. Framing occurs when one Web site imports material from another site and makes it part of its own site. When such framing or mirroring occurs, it is essential that copyright clearances and indemnities are obtained.

4.6.6 *Computer programs*

Copyright subsists in both source and object codes of computer programs. Where commercially available programs are used or are incorporated in larger programs developed by the institute, licenses are available from the suppliers of those programs. It should be noted that a license to use commercially available software will not necessarily authorize the development or improvement of that software. The development or improvement of commercially available software for the purposes of, for example, facilitating or improving the accessibility of information stored on a database will infringe the copyright unless a license to develop the program has been obtained. Where programs are written in-house by institute employees, copyright problems do not arise.

In order to provide evidence that computer programs have been generated in-house, it is recommended that when institute personnel generate such material they complete a declaration of originality. Such a declaration could be made in electronic form in order to facilitate and centralize collection and storage.

4.7 *Trademarks*

Research institutes commonly seek trademark protection for their names and key research products. The acronym and name of a research institute, for example, could be registered in Class 16 of the Nice Trademark Classification in relation to "research and educational materials." Registrations can be obtained in each country in which research is undertaken. When an institute makes products such as seeds, these could be registered in Class 30, in relation to "[plant] variety/breeding lines." Trademarks can also be sought for equipment and tools, for example in Class 7, which covers agricultural equipment.

4.8 *Confidential information*

Research data compiled in institute projects by institute researchers may be protectable as confidential information. To be protected, the institute has to impose confidentiality through confidentiality agreements with employees and researchers. These will inform them that the institute attaches the quality of confidence to its research data and to its research methods. For the most part, a public research institute will waive its rights to the confidential information that it generates in its research findings. However, for agreements according to which the institute undertakes to share unpublished research findings and data with its collaborators, some enforcement of confidentiality agreements will be necessary to ensure that the research findings are shared and not dissipated. As awareness of IP protocols becomes more widespread, research collaborators will begin to insist upon an enforceable confidentiality regime. It will be increasingly important, therefore, to put in place mechanisms and procedures that ensure that confidential material is not publicly disclosed.

4.9 *Biodiversity rights*

The Convention on Biological Diversity (CBD) seeks to establish an international program for the conservation and utilization of the world's biological resources, as well as for the "*fair and equitable sharing of the benefits arising from the utilization of genetic resources*." A similar policy animates the International Treaty on Plant Genetic Resources for Food and Agriculture. For example, the CBD contains provisions dealing with access to genetic resources. Article 15 requires contracting parties to "*endeavour to create conditions to facilitate access to genetic resources for environmentally sound purposes*" by other contracting parties according to mutually agreed terms and conditions on the basis of "*prior informed consent*." A detailed code of access to biotechnology is prescribed in Article 16. Access and transfer are to be "*provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights*." The Article provides that developing countries that provide genetic resources shall be granted "*access to and transfer of technology which makes use of those resources*." In addition, Article 19.2 provides for the grant of access on a fair and equitable basis and on mutually agreed terms to contracting parties, "*particularly developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those contracting parties*." Additionally, Article 8(j) of the CBD envisages that where the knowledge, innovations, and practices of indigenous and local communities are utilized, the benefits arising from their utilization should be shared equitably.

A number of developing countries have introduced legislation that seeks to enact the benefit sharing provisions of the CBD. Thus, when a patentable invention results from institute germplasm that is contributed by indigenous persons or local communities, or that is collected as a result of the utilization of the knowledge of those persons or communities, a compensation liability may arise. Indigenous groups and local communities have begun to insist upon the collection of samples under the terms of bioprospecting agreements, which invariably define the distribution of benefits from any royalties that may result from patents. In a number of developing countries, the use of bioprospecting agreements is becoming mandatory.

5. THIRD-PARTY IP

5.1 *Patents and know-how associated with biological technologies*

Most research institutes will have third-party proprietary technology licenses. The basis of the proprietary claims made by most of the licensors will be the confidentiality of the biological materials or know-how that is licensed to the research institute. Additionally, patented research technologies may be licensed.

The salient features of these licenses are:

- permissible use of the licensed material confined to scientific research
- confidentiality of licensed material to be preserved
- all information concerning improvements in the material or inventions associated with the material to be reported to the licensor
- research progress to be reported periodically
- use of material only by identified institute scientists
- advance copies of manuscripts of publications to be provided to licensor

The various obligations these agreements with third parties impose emphasize the importance of an IP management facility at a research institute.

5.2 *Genetic material*

Medical and agricultural research increasingly utilizes genetic material provided to an institute under an MTA or confidentiality agreement. The terms of that MTA may restrict how that material can be used. For example, it may be on the condition that IP rights are not sought in relation to that material, or that it is not used for commercial purposes. Sometimes the MTA will require that material derived from the supplied material should also be supplied under those conditions. In each of these cases, the responsibility

to observe those conditions will be imposed on the institute; it will be the purpose of the audit to identify these obligations and document how they are being managed.

On occasion, genetic material is made available informally by a scientist from a third party, acting without the authority of that third party. In this case, the unauthorized use could involve the research institute in liability. Consequently, the audit should identify the terms of all accessions of third-party genetic material.

5.3 *IP rights associated with equipment utilized by a research institute*

A number of items of research equipment obtained from commercial suppliers may generate IP obligations. For example the Bio-Rad Biolistic PDS-1000/He apparatus is often supplied to researchers at IRRI subject to an agreement that it be used "*for research purposes only*." The Hybaid PCR Express Thermal Cycler is also subject to a license "*to practise the PCR process for internal research and development*."

6. IP MANAGEMENT STRUCTURES

An IP audit should analyze the management of IP at a research institute from the perspective of the adequacy of the management structures and procedures. It should also consider IP management in terms of the staff's awareness of IP obligations. Finally, the institutional mechanisms for dealing with institute and third-party IP should be examined.

6.1 *IP management culture*

A critical feature of effective IP management is the existence of a research culture in which IP awareness is communicated to researchers. In order to ascertain the extent of IP knowledge and of IP management practices within an institute, questionnaires could be administered to administrative and research staff. To supplement the general IP consciousness-raising activities mentioned above, it would be very useful for staff to be provided with an IP handbook, containing a general primer on IP, as well as all relevant IP documents and procedures. This IP handbook could also be made available online and accessed from the institute's Web site.

6.2 *Office of IP coordination*

As IP becomes increasingly significant for scientific research, establishing an IP coordination office or officer for an institute becomes more important. This office, which may be within the research institute or located within the offices of a third-party subcontractor, would be responsible for coordinating both IP administration and procedures within the institute. The IP office would also be responsible for external IP liaison. The coordination of IP procedures would include securing the IP compliance of staff and visitors; ensuring the inclusion of IP provisions in relevant third-party agreements; ensuring the utilization of appropriate MTAs by the institute, both as a recipient and distributor of germplasm and biological tools; maintenance of a central repository of IP documents; maintenance of the institute's IP database; and raising awareness of about IP issues. Externally, an IP coordinator could provide an IP dimension to negotiations with research collaborators and act as a liaison with IP officials of other institutes.

The IP coordination office would ensure that:

- staff and visitors sign and adhere to IP and confidentiality agreements
- copyright permissions and indemnities are secured for various publications
- Copies of MTAs and other IP agreements are filed centrally and provided to appropriate staff members
- Proper research records are made, maintained, and filed
- the MTA granting procedure is coordinated
- the IP provisions of other agreements are supervised
- the institute's legal advisers are updated on IP matters

6.3 *Research records*

Establishing provenance for research is central to any policy of securing and exploiting the IP rights that might be generated from an institution's research. The practice of maintaining laboratory notebooks with consecutively numbered pages

that are signed at the end of each day by the supervising scientist is normal in private enterprise, but may be alien to the research culture at a public research institute. However, without this sort of management practice, it would be difficult to contest a *first to invent* dispute under patent law. Similarly, it would be difficult to identify the technological know-how brought by a scientist to the institute and to distinguish it from that which has been developed at the institute. This is important in delineating the respective confidential information of a staff member and the institute.

6.4 *Material transfer agreements (MTAs)*

Guidelines and procedures for the approval of material transfer agreements could efficiently direct the management of IP in a scientific research institute. For germplasm designated under the International Treaty on Plant Genetic Resources for Food and Agriculture, an established procedure already exists. Some of the Consultative Group on International Agricultural Research (CGIAR) genebanks distinguish between designated germplasm and germplasm that they themselves have developed, which is accordingly regarded as non-designated. Separate MTAs are being developed by research centers to deal with the distribution of this material.

7. CONCLUSIONS

Modern scientific research often requires expenditures to enable the generation of protectable IP. The institute will have to decide whether this IP will be placed into the public domain or registered, either to pursue commercial exploitation or to prevent its privatization by unauthorized third parties. Before any of these actions can be taken, however, the research institute must identify the IP that its researchers generate or utilize. An effective IP audit is therefore an important tool for supporting the research objectives of the institute. ■

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1 www.wsu.edu/~oipa/FacIP.html.

2 www.tamut.edu/SACS/3-2-1417-02-01.pdf.

3 www.utsystem.edu/OGC/Intellectualproperty/2xii.htm.

4 See, for example: www.irri.org/publications/chandler/pdfs/Appendices.pdf.

5 See, for example: www.irri.org/about/images/Memorandum%20of%20Understanding.pdf.

6 For an example of a standard research agreement along these lines, see Oklahoma State's template for a sponsored research agreement at: www.vpr.okstate.edu/Forms/Forms%202003/Spon%20Res%20Agmt.doc.

Conflict of Interest and Conflict of Commitment Management in Technology Transfer

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ABSTRACT

The potential for personal interests to influence institutional decisions in universities and public sector research institutions continues to grow. This is because of the increasing activity in intellectual property (IP) management and technology transfer undertaken by these institutions. The activities have the potential to generate both personal and institutional financial gain, making conflict of interest and conflict of commitment issues unavoidable. This chapter explains the nature of these conflicts and discusses the policies, regarding conflict of interest, of several universities, offering them as potential models for crafting these indispensable policies.

1. INTRODUCTION

Universities and public research institutions have been characterized historically by their selfless efforts to expand knowledge for the public good rather than for private gain. This has contributed to a high level of public trust in the integrity of these institutions, and they are seen as providers of unbiased information. This institutional integrity rests on the personal integrity of the people employed by or associated with that institution, which collectively represent the greatest asset of the institution. Indeed, any erosion of institutional integrity or of the public's trust can have devastating consequences in terms of public support for the institution.

One significant danger with regard to compromising the integrity of a university or public research institution is the potential for personal interests (often financial) to adversely affect an employee's professional judgment when exercising a university duty or responsibility, for example, the direction and conduct of research. The potential for a divergence between an individual's institutional obligations and his or her private or personal interests can become a conflict of interest: and a perceived conflict of interest can be as damaging as a real one.

The potential for personal interests to influence institutional decisions is greater today because every institution is doing more in the area of IP management and technology transfer, and because these activities have the potential to generate both personal and institutional financial gains, conflict of interest issues are a constant concern. Indeed, in today's modern research universities, the missions of which explicitly include the transfer of research to commercial partners, conflicts of interest are practically unavoidable. These conflicts need to be managed in ways that allow institutions to meet their technology transfer mission without compromising their integrity and the public's trust.

Another closely related pitfall is the pressure that technology transfer and commercialization activities place on employees' primary allegiance to their institution. In an era when researchers are encouraged to actively participate in technology

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transfer—and even in the development of new companies—it is necessary to ensure that the employee's primary professional loyalty is to the institution rather than to a private, extramural activity. When outside activities cross boundaries in ways that compromise, or appear to compromise, the employee's primary allegiance to the institution, a conflict of commitment exists. Because both conflicts of interest and conflicts of commitment are potential pitfalls in the technology transfer process, both are addressed in this chapter. Some universities address both conflicts in a single combined policy (for example, Stanford University), while most treat conflicts of interest and conflicts of commitment in separate policies.

2. CONFLICT OF INTEREST RELATED TO IP MANAGEMENT

Fundamentally, a conflict of interest is any situation in which there is a conflict between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are affected by his or her private interest.[1] It is important to note, a conflict of interest exists whether or not decisions are made that are influenced by personal interests. The conflict only indicates the potential for making biased decisions—not any likelihood of doing so or any a priori misconduct. One should also note that the precise definitions of conflict of interest are guided by national and local laws, research sponsor policies, and institutional policies; thus the definitions may vary widely depending on the geographic and institutional context.

The potential for financial conflicts of interest for individual researchers increases dramatically when an institution begins to actively support and promote the transfer of research results for commercial applications.[2] In many cases, the commercial development of early-stage research results can be carried out best by a start-up company. Typically, the university researcher is either a founder of or a consultant to the company and has substantial financial interests in the company. This gives rise to a personal conflict of interest, and any future decisions on research directions, assignment of research topics to students, the supervision of clinical trials, or any influence over institutional IP licensing decisions by the researcher/entrepreneur should be viewed through the lens of the institution's conflict of interest policies. Again, it is important to note that the existence of the personal financial interests should not, in themselves, but in general the conflict should be openly disclosed and any future activities and decisions by the conflicted individual reviewed and managed by the institution.

The potential for a researcher to have a significant financial interest in an outside potential licensee can be quite high, particularly if the licensee is a start-up company founded by the researcher/inventor. When the researcher participates in the licensing negotiations or even in discussions with the institutional licensing officer, the researcher is in a conflict of interest position: the researcher has the potential to influence an institutional licensing decision in which he or she has a direct financial interest. In California, such a position constitutes a criminal conflict of interest under the Political Reform Act of 1974. As a consequence of the Act, the University of California developed detailed guidelines and guidance on the disclosure and management of conflicts of interest in licensing. These guidelines permit participation in licensing negotiations by an inventor, even when he or she has a disqualifying personal financial interest. As the guidelines observe, such participation "*is appropriate and represents a useful contribution, because the transfer of University technology to industry is in the public interest and is consistent with the University's mission*."[3] Such participation, however, requires an appropriate intervening substantive review, called a Licensing Decision Review, which determines whether licensing decisions are inappropriately influenced (see Box 1). Although these guidelines for managing conflicts of interest in licensing are very specific to the laws of the State of California, they raise and consider a number of important issues that are both generic and specific to technology transfer.

An additional level of conflict of interest has also emerged as a result of universities taking an

Box 1: University of California Guidelines for a Licensing Decision Review

What is Licensing Decision Review?

Licensing Decision Review means there is a review by a noninterested person or persons before a proposed licensing decision goes to the final decision maker for approval. The review must be based on an independent consideration and assessment of the facts of the case. The Licensing Decision Review body, composed of qualified staff with appropriate expertise, knowledge, and professional judgment, must independently check the original data and analysis upon which the selection of licensees proposed by the licensing professional and other licensing decisions were made and make its independent recommendations concerning the decisions.

Who conducts the Licensing Decision Review?

Each University of California campus and laboratory was directed in a June 18, 2001, letter to chancellors and laboratory directors from Provost King and Senior Vice President Mullinix to establish a plan for conducting intervening substantive review of licensing decisions (in this case, called Licensing Decision Reviews), whether those licensing decisions are made in the systemwide Office of Technology Transfer (OTT) or at a campus or Laboratory Authorized Licensing Office. Each local Licensing Decision Review plan, including the processes, mechanisms, and bodies (individuals or committees) established to carry out Licensing Decision Reviews may accommodate local needs and circumstances, but must be responsive to the direction provided in that letter and, consistent with these Guidelines, must be filed with the OTT.

Source: University of California.[4]

active role in IP licensing, particularly to start-up companies. Typically, the university will accept equity in a company in lieu of upfront license issue fees, which gives the university itself a financial interest in the company. This leads to an institutional conflict of interest. Such institutional conflicts of interest have been particularly problematic in research involving human subjects, so institutional policies are being developed to ensure that the financial interests of the researcher and the institution do not create a conflict of interest in enrolling and ensuring the safety of human research subjects. Stanford University's Institutional Conflict of Interest Policy provides a concise approach to ensuring that all human-subject institutional reviews include a review of whether the university has any financial interests in drugs or devices under study or financial interests in the company that is sponsoring the research (See Box 2).[5]

3. CONFLICT OF COMMITMENT RELATED TO IP MANAGEMENT

Faculty and researchers working in educational and research institutions are expected to give primary allegiance and professional commitment to the institutions that employ them and devote primary energy to teaching and research. Even so, most institutions value their staff's contributions to professional and public service, including pro bono work and paid consulting. In addition, public institutions increasingly value the role of employees in technology transfer and its contribution to economic development. Effective technology transfer inevitably requires faculty and researchers to actively participate in the commercialization process, which often includes taking an active role in starting up new companies that are capable of developing and exploiting university inventions. These multiple institutional goals create the potential for a conflict of commitment between the institution's primary educational and research mission and the institution's interest in effectively supporting economic development and technology transfer through the external activities of its faculty and researchers.

Conflicts of commitment typically require determining the appropriate balance of time allocation between institutional and external activities—the critical test is that external activities

Box 2: Highlights of Stanford University's Institutional Conflict-of-Interest Policy

The goal of this policy is to preclude situations in which human-subjects research is carried out at Stanford or by Stanford researchers involving organizations in which the University holds ownership equity or rights to equity that is not publicly traded. The fundamental assumption underlying the policy is that such situations present a significant risk to the perceived objectivity of the research. The policy requires that the Office of the Dean of Research be informed of all such situations and provides that, after a review of the facts and circumstances, the Associate Dean of Research may either arrange the divestment of the University's holdings through the Office of Technology Licensing or, if that cannot be done, refuse to allow the research to proceed.

DISCUSSION AND DETAIL

1. **Review by the Office of Technology Licensing (OTL) of all human-subjects research protocols proposed by University Principal Investigators:**

   At the request of the Office of the Dean of Research, the Stanford Research Compliance Office has established a procedure that requires all new human subjects research protocols submitted for regular or expedited review to the IRBs to indicate (1) the nature and source(s) of all drugs, devices, or biologics (e.g., vaccine products, gene therapeutics) which will be used in the proposed research and (2) the source(s) of all funding to be used in supporting the research. Per this procedure, the information provided is then reviewed by the Director of OTL to identify situations in which the proposed research involves (1) the use of drugs, devices, or biologics that make use of Stanford-owned intellectual property or (2) funding from nonpublicly traded organizations in which Stanford owns equity or the right to acquire equity through a licensing agreement.

2. **Review by the Office of the Dean of Research of all protocols that might be subject to this policy:**

   Per the procedure described above, the Director of OTL flags for further review by the Office of the Dean of Research all proposed new human subjects research proposals involving the use of drugs, devices, or biologics that make use of Stanford-owned intellectual property or are funded in whole or in part by nonpublicly traded organizations in which Stanford holds equity or the right to acquire equity through a licensing agreement. Based on the facts and circumstances identified in this review, the Associate Dean of Research will (1) require OTL to divest that equity on behalf of the University or (2) prohibit or require modifications to the proposed human-subjects research which would remove any possibility for the University as an institution, or any University department, to benefit as a result of the conduct or outcomes of the proposed research. In the event the University's financial interest is in the form of royalties payable as a result of exclusive technology licensing rights, OTL will inform the Associate Dean of Research, who will determine on a case-by-case basis the significance and management, if appropriate, of the potential institutional conflict of interest.

3. **Monitoring compliance:**

   The University's Internal Audit Department will periodically review a sample of human subjects research protocols to ensure that all situations in which a potential exists for institutional conflict of interest have been properly identified and all risks to human subjects have been properly mitigated.

4. **Responsibilities of the Dean of Research:**

   The Vice Provost and Dean of Research is the University officer responsible for interpreting and overseeing implementation of and compliance with this Policy. Questions may be addressed to the Assistant Dean of Research.

Source: Stanford University.[6]

should not detract from their primary institutional responsibilities. Institutions vary widely regarding permissible external activities, which may reflect differing institutional priorities as well as whether the institution is public or private. Stanford University, for example, integrates both conflict of interest and conflict of commitment into a single policy that specifies the appropriate balance of time commitment to external activities to be approximately one day per week (see Box 3).

4. STRUCTURE OF A CONFLICT OF INTEREST/COMMITMENT POLICY

The development of institutional conflict of interest and conflict of commitment policies is a critical step in developing technology transfer capabilities and programs. Developing the policy will require identifying and articulating institutional priorities and determining the appropriate balance between institutional interests and the interests—both internal and external—of its researchers. In addition, the effort will require an in-depth analysis of the requirements placed on the institution by national or local laws and by the policies of agencies that sponsor research in the institution. The elements of a conflict of interest/commitment policy are outlined below; actual policies take many forms.

4.1 *The purpose of the policy and applicability*

The preamble of the policy should reiterate the primary mission of the institution and indicate in general terms how the institution views the balance between internal and external activities and the potential for developing conflicts. For example, the Washington University in St. Louis Conflict of Interest Policy is presented, in part, in Box 4.

The preamble should identify to whom the policy applies. In some cases, the policy may be broadly applicable to all institutional staff, while in other cases different policies may be required for teaching faculty, for clinical faculty, and for nonfaculty staff. Whatever the case, the applicability of the policy needs to be clearly stated early in the policy document.

4.2 *Definitions*

Definitions of key terms are typically provided to ensure the policy's clarity. For example, the definition of "significant financial interests" should be explicit with regard to applicable instruments of monetary value such as stocks and stock options. It should also explicitly state the extent to which such interests extend to the researcher's spouse, children, or domestic partner. Examples of terms that have been useful to define at our the University of California include:

- business entity
- clinical research
- compensation
- conflict of interest
- gift
- intellectual property
- investigator
- management plan
- research
- select officials
- significant financial or other interest

4.3 *Policy*

The policy statement should clearly describe acceptable and prohibited activities, requirements for reporting and disclosure, and processes for evaluating and managing specific situations that are not directly addressed by the policy.

4.4 *Process, roles, and responsibilities*

The policy should clearly describe the institutional processes for disclosing external activities, if there is a requirement to do so, as well as describing the processes for seeking a review and evaluation of conflict of interest disclosures. Most institutions have one authorized official with this responsibility and a committee that participates in evaluations. The policy should describe the processes for appointing the relevant committees and identify the institutional officials with responsibility for conflict of interest evaluations and management.

4.5 *References and links to source documents*

Finally, a conflict of interest/commitment policy does not exist in isolation but typically relies on the synthesis of a number of source documents,

Box 3: Summary of Stanford University's Faculty Policy on Conflict of Commitment and Interest

1. Faculty must maintain a significant physical presence on campus (main or overseas) throughout each quarter they are on active duty.
2. Faculty must not allow other professional activities to detract from their primary allegiance to Stanford. For example, a faculty member on full-time active duty must not have significant outside managerial responsibilities nor act as a principal investigator on sponsored projects that could be conducted at Stanford University but instead are submitted and managed through another institution.
3. Faculty must foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students and postdoctoral scholars is independent of personal commercial interests, and informing students and colleagues about outside obligations that might influence the free exchange of scholarly information between them and the faculty member.
4. Faculty may not use University resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way, as part of their outside consulting activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University.
5. Faculty must disclose on a timely basis the creation or discovery of all potentially patentable inventions created or discovered in the course of their University activities or with more than incidental use of University resources. Ownership of such inventions must be assigned to the University regardless of source of funding. The inventor will share in royalties earned.
6. Faculty must disclose to the University whether they (or members of the immediate family, as defined below) have consulting or employment relationships with, and/or significant financial interests (also defined below) in, an outside entity before the University will approve the following proposed arrangements involving them between such entities and Stanford: a) gifts; b) sponsored projects; c) technology licensing arrangements; and d) certain procurements. In such cases, approval by the school dean will be required prior to entering into each proposed arrangement.
7. In situations in which the objectivity of a faculty member could reasonably be questioned, the dean of a school may establish an independent oversight committee to take steps including (but not limited to) the following: to review the appropriateness of the proposed research to be conducted at Stanford, to oversee the conduct of the research, and to ensure open and timely dissemination of the research results. Such oversight committees will be required for all clinical trials raising questions of conflict of interest.
8. On an annual basis all faculty members must certify to their school deans their compliance with Stanford's policies related to conflict of interest and commitment. They must also disclose information about their (and their immediate family members', as described below) financial relationships with outside organizations that are sponsors of their teaching or research programs or are otherwise involved in current, proposed, or pending financial relationships with the University that involve the faculty member. In addition, faculty must disclose to their school dean on an ad hoc basis current, proposed or pending situations that may raise questions of conflict of commitment or interest, as soon as such situations become known to the faculty member.
9. School deans shall establish procedures to ensure timely review of their faculty's annual and ad hoc disclosures of potential or apparent conflicts, and to ensure (in consultation with the Dean of Research office) the appropriate management of such conflicts. Such procedures may involve representatives from the school's faculty as part of a reviewing body. School deans will file their own annual disclosures and certifications of compliance with the Dean of Research.
10. The Dean of Research shall approve each school dean's plans for implementing this policy, interpret policy provisions in consultation with school deans, respond to faculty wishing to appeal school deans' decisions, and report to the Committee on Research annually on the status of this policy and its implementation.
11. Should a faculty member wish to appeal a decision made by the Dean of Research, he or she may present the appeal to the Provost, who will consider the case in consultation with the Advisory Board.

Source: Stanford University.[7]

Box 4: Excerpt of Washington University's Conflict of Interest Policy

The faculty and administrators at Washington University recognize a shared responsibility to ensure that they conduct themselves in an unbiased manner and serve the goals of the University. It is thus the responsibility of the University and its employees to guard against conflicts of interest that might compromise the integrity and objectivity of the University community.

It is understood that the faculty, as developers of knowledge, have a unique opportunity and responsibility to disseminate that knowledge to the public. By adopting this Conflict of Interest Policy, the University reaffirms the value of collaboration with industry as a means of fostering public access to the practical benefits of University research. By adopting this Conflict of Interest Policy, the University also (i) demonstrates its commitment to the ethical principles that guide University research and (ii) establishes a mechanism to safeguard University and faculty integrity and objectivity so that University/industry interactions can optimally benefit society.

Source: Washington University. [8]

policies, and laws. These sources should be listed and hyperlinked from the policy.

5. CONCLUSIONS

In addition to the legal reasons to develop and enforce rigorous conflict of interest and conflict of commitment policies, the fundamental reputation of the institution rests on setting and maintaining high ethical standards. As Johns Hopkins University's policy states: "*public confidence in the University's integrity undoubtedly ranks among its greatest assets*."[9] Although technology transfer activities are only one of many areas in which the potential for conflict of interest exists, the interface between the mission of the university and the demands of industry and of private sector collaboration is a rich breeding ground for such potential conflicts. As an institution becomes engaged with the private sector and with technology transfer, the adoption of a thoughtful conflict of interest and conflict of commitment policy is essential. Not only is the policy itself an essential administrative tool, but the analytical process of developing the policy will reveal the institution's priorities. The process will also clarify what the university considers the appropriate balance of allowed and prohibited activities for achieving the university's mission(s). In the United States, there has been a convergence of norms in conflict of interest/commitment policies that is driven by our legal framework and by the policies of national research sponsors. It is likely, however, that other countries facing very different demands for research-based economic development may find that the U.S. approach does not conform to their regional and institutional needs. ■

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1 Chinn J and EC Kulakowski. 2006. Conflict of Interest in Research. In *Research Administration and Management* (eds. EC Kulakowski and LU Chronister). Jones and Bartlett Publishers: Sudbury, Mass. pp 511–21.

2 Garton JD. 2002. Conflicts of Interest and Technology Transfer. *AUTM Technology Transfer Practice Manual*, Part XIII, Chapter 2. AUTM: Northbrook, Ill.

3 University of California. 2001. Guidelines on Managing Potential Conflicts of Interest in Licensing. www.ucop.edu/ott/staff/ott00-05b.pdf. This and other conflict of interest and conflict of commitment policies are also available via the online edition of this *Handbook*.

4 Slightly edited and based on *supra* note 3.

5 An online tutorial on conflict of interest from Columbia University can be found at ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/index.

6 www.stanford.edu/dept/DoR//rph/4-7.html.

7 Ibid.

8 www.wustl.edu/policies/conflict.html.

9 jhuresearch.jhu.edu/Policy_onConflict_of_Interest.pdf

SECTION 6

Establishing and Operating Technology Transfer Offices

Ten Things Heads of Institutions Should Know about Setting Up a Technology Transfer Office

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ABSTRACT

Technology transfer is a rewarding process for the university, researchers, students, the business community, the public, and the professionals who make it all happen. Technology transfer brings new products, services, and jobs. But it is a complex process, one that requires sustained dedication at every level. This chapter offers advice about some of the most important policy and strategy issues: five are economic issues and five relate to implementation. The chapter concludes with a discussion of technology transfer pitfalls caused by unrealistic expectations. The chapter emphasizes the role of senior management in changing the IP (intellectual property) culture, the need for transparent conflict-of-interest policies, and the importance of sufficient autonomy and infrastructure support for technology transfer officers.

1. INTRODUCTION

The widely touted success of technology transfer from U.S. universities has attracted interest from universities and research institutes around the world. Such diverse countries as Germany, the Republic of China, South Africa, the United Kingdom, and many others have changed their laws and policies, modeling them after U.S. practices, to allow universities and faculty members to manage and transfer intellectual property (IP). In the United States, smaller universities and research institutes are looking to imitate the successes of their larger counterparts. Such changes are motivated primarily by two economic interests:

1. enhancing economic development by transferring new technologies to local industries
2. obtaining financial support from industry to support university programs

The advice offered in this chapter aims to provide to heads of a research institutes and universities perspective on what challenges to expect when setting up a technology transfer office. These "Ten Things" are based on almost 20 years of experience in the Technology Licensing Office of the Massachusetts Institute of Technology. The ideas expressed in this chapter reflect also my long-time experiences with the Association of University Technology Managers (AUTM), including a stint as president, during which I watched many North American technology transfer programs grow. The ideas expressed here have been influenced by my experiences visiting with universities in almost 20 different countries and learning about their technology transfer activities.

2. THE LIST OF TEN

Many items in the list of ten may surprise you (Box 1). The economic five may sound discouraging even, but that is not the intention. It is to encourage a realistic time frame and the sustained investments in time and money are needed to reap the substantial societal and

Nelsen L 2007. Ten Things Heads of Universities Should Know about Setting Up a Technology Transfer Office. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Box 1: Ten Things to Know about Setting up a Technology transfer Office

The economic five

1. **Technology transfer will not make your university rich.** A successful program will make a small profit but will not support the university. It will, however, provide many other benefits to the institution and the community.

2. **Building a robust technology transfer program takes sustained financial investment**. Investments are required to develop a patent portfolio, attract expert talent, and train office professionals.

3. **It will likely take eight to ten years before your program stops losing money—and it may never make your institution any substantial amount.** It takes time to build an IP portfolio, establish contacts, and develop skills in technology transfer. Following the set up, the TTO *may* begin to make money.

4. **It may take two decades or more before a university technology transfer program (including entrepreneurial spinouts) substantially affects the local economy**. Impact in regional economic development takes 20 to 30 years. Expecting substantial returns in a few years leads to underinvestment and disappointment.

5. **The ultimate impact may be very large—both economically and culturally—for the university, its graduates, and the community.**

The implementation five

6. **Sustained effort requires visible support—fiscal and otherwise—from senior administration**. Senior management must not only lead the way, but also sustain the effort to change the culture of research and investment.

7. **Only senior administration can set the mission, policies, and priorities for the program**. Clear mandates will help technology transfer professionals choose among competing priorities and the ever-present trade-offs between business and academic values. These policies will ultimately help to define the university. They need to be clearly stated, and supported from the top, so that technology transfer professionals can make the best decisions and withstand pressure from competing interests.

8. **Clear policies on IP ownership, the roles of researchers in interactions with industry, and other ground rules should be set up before the program begins.** Working out such policies in the middle of making deals leads to confusion and bureaucratic lethargy, slows down the learning process, and hurts a university's reputation for being able to consummate deals.

9. **Conflicts of interest, both real and perceived, are inevitable.** Clear policies and a well-understood review and appeal process need to be put in place early. Much can be learned from the experience of others in the technology transfer field. Again, support from senior administration is critical.

10. **Technology transfer is a talent-based business.** It is difficult to find people who can speak the two languages of academia and industry and who also have the creativity to craft agreements that meet the needs of both sides. One should not underestimate the combination and level of skills required. These skills and experiences are very different from those needed to conduct research.

economic benefits of a successful technology transfer program. A few TTOs have performed atypically and these provide exceptions to the principles described, especially with respect to the economic five. But these exceptions depend mostly on luck and planning—they cannot be counted on. The issues are discussed in more detail following the list.

The sections that follow discuss more fully the promise of technology transfer, the economic issues and expectations involved with technology transfer, and implementation matters.

2.1 *The promise of technology transfer*

There is little doubt about the ultimate potential of university technology transfer programs when it comes to accelerating the adoption of new technologies, enhancing entrepreneurship, creating new medicines and other products, creating jobs, and adding prosperity through economic development. The clustering of high technology and biotechnology companies around major universities has been well described, and AUTM and others have documented the creation of hundreds of thousands of jobs directly related to university licenses and startups.

Within universities, robust technology transfer programs also have many important benefits that are quite separate from royalty income (*royalty income* as used here includes royalties from licenses to university intellectual property and monetary return from equity holdings in spinout companies formed around university intellectual property). Among others, these include:

- productive interaction with the industrial community: ideas shuttling back and forth between the academy and the private sector, which often increases the quality of research
- increased industrial support of university research
- more willingness from central and local governments to support university research for economic development
- student exposure to the world of industry and to the commercial opportunities of research (including training in entrepreneurship), thus influencing their future career aspirations and ultimately impacting the country's economy
- financial support from grateful alumni and other entrepreneurs who have grown wealthy from companies started from university research

Such programs can have a major impact on the economy of the surrounding regions—and not only directly from entrepreneurial spinout companies from the university. The entrepreneurial ferment and capability resulting from university spinouts leads in turn to the formation of many other new companies. Larger companies also often move to the region to take advantage of relationships with entrepreneurial companies and the skilled employee base.

2.2 *Expectations in setting up a program*

Despite the promises of successful technology transfer programs, when communities and their universities try to start new technology transfer programs or to accelerate existing ones, the road is rocky. Unrealistic expectations are a major cause of failure and frustration. Universities often expect their programs not only to bring in industrial sponsorship for research but to provide royalty income and entrepreneurial spinouts that will support the entire university.

Unfortunately, government expectations are often equally unrealistic. Some governments, for example, have expected royalty income from technology transfer to replace government support of their universities. Too often, local and national governments believe that just a few years of financial support for technology transfer—coupled with pressures on universities to produce measurable impacts—will almost instantly create thriving clusters of biotechnology,[1] software, or telecom companies akin to those in Boston, Silicon Valley, or San Diego.

A more realistic picture, however, is provided by almost a quarter century of technology transfer experience in the United States under the Bayh-Dole Act of 1979, which allowed universities to own patents from federally funded research.

2.2.1 *Licensing income*

Income from royalties and equity in spinouts is measured most easily. Data from the AUTM survey of U.S. universities (not including hospitals and research institutions for fiscal year 2002 shows that total gross royalties (including income from equity) for 158 universities was US$959 million. This from a research expenditure base of over US $32 billion during that year!

Thus, even before subtracting expenses for patenting and staff costs, technology licensing and spinout equity income averages **less than 3%** of the amount universities spend on research. And the income distribution is skewed: ten universities in the United States (6.3% of the total) account for almost 60% of the total royalty income for all U.S. universities.

The income distribution is skewed because a good fraction of the total U.S. university income from technology licensing is from a few blockbusters: single inventions that yield very high royalties (millions or tens of millions of dollars per year, often for over ten years, until the patent expires). These blockbusters are few and far between—there are no more than two or three ones each year in the United States.

It is therefore unwise to look to technology licensing and income from spinouts (royalties or equity) to support the university.

2.2.2. *Program profitability*

Building a program to break-even profitability takes time and money. Again, the North American experience is instructive. Studies have shown that it can take a technology transfer program eight to ten years or more to reach profitability, although most programs become profitable if the effort to build them is sustained.[2]

If measured only by royalty income, universities with smaller research bases have a more difficult time breaking-even. Less research means fewer inventions, lowering the statistical probability of a blockbuster invention. Fewer opportunities for licensing also mean that the technology transfer staff gains less experience and learns the craft more slowly. Small technology transfer programs, therefore, may have to be sustained financially for a long period of time, with the revenue shortfall justified by their nonroyalty contributions to the university and community.

Finally, it should be noted that new technology transfer programs are too often starved—both for money to file patents and for staff. A university frequently expects its program to somehow bootstrap itself into profitability and expansion. An "anorexic" program, however, climbs the learning curve—and reaches profitability—much more slowly and has a much lower impact on the university and the community along the way.

Thus, the university must have a well-thought-out, long-term financial plan for building its technology transfer office. The plan should be based on expected benefits—both financial and especially, nonfinancial—and on what the university can afford during the decade or so it takes to build a mature program.

2.2.3 *Regional economic development*

Governments most frequently support technology transfer in universities directly because they hope that entrepreneurial spinout companies will revivify the regional economy surrounding the university. This is not an unfounded hope—a number of regions have demonstrated the success of such programs over time. But it takes time: more than ten years for more than a few spinouts to be formed, and as long as 20 to 30 years before a substantial cluster of technologically-based companies forms—and this only when such development has been purposefully planned and robustly supported financially. (The Research Triangle region in North Carolina, U.S.A., is one such success—after about a quarter century!)

Thus, government programs that support technology transfer for four to five years and then expect the programs to be self-supporting and surrounded by a flourishing cluster of companies are unrealistic. It will not happen that fast. Building a regional economy based on entrepreneurialism is a slow, gradual process.

3. IMPLEMENTATION

3.1 *The role of the upper administration: culture change*

Founding a successful technology transfer program means changing a culture. Researchers must become aware of how useful and rewarding it is to identify potentially commercializable inventions from their research. They also need to see the benefits of cooperating with industry to transfer such technology. For most researchers this will be a new way of thinking, and some will feel that it threatens the very purpose of the university.

This change in culture must start from above. The upper administration needs to clearly delineate the purpose and potential benefits of a technology transfer program—not only to the individual and the university but to the community at large. The administration of the university can thus allay mistrust by making it clear that technology transfer will not be allowed to distort traditional academic principles: investigator-initiated fundamental research, uncensored publication, and open exchange of information within the university.

3.2 *Defining the mission*

The upper administration and the faculty must define the mission and priorities of the technology transfer office: Is it primarily to produce licensing income? Or industrial support of research? Is the mission primarily to get technology developed for the public? Or is it primarily to generate startups and regional economic development?

There are inevitably trade-offs among these potential primary missions. Unless priorities are explicitly set, the practices of the technology transfer office may well diverge in time from the best interests of the university. Surprisingly, even in the United States, with a quarter century of experience in university technology transfer, discussions about mission and priorities rarely are held between university management and the technology transfer office.

3.3 *Setting the ground rules: policies and practices*

The technology transfer office—and the researchers, companies, and investors that it deals with on a daily basis—must all know the ground rules before work can begin. The growth and learning process of the office will by stymied if each new invention or license-in-negotiation must be run through a committee. Accordingly, policy guidelines concerning such issues as IP ownership; the rights, duties, and obligations of the faculty in regard to technology transfer; sharing of revenue and equity with inventors; use of university facilities by companies; and related issues should be clearly defined as early as possible.

New offices will find that there are many guides available from experienced universities to help them write their ground rules—but only the administration and faculty of the university can decide which rules make the most sense for their particular institution.

3.4 *Conflicts of interest*

Technology transfer inevitably brings conflicts of interest.[3] The challenge is to manage them.

For the university itself, conflicts may exist between the goals of maximizing royalty income and promoting publication, between commitments to fostering spinout companies (for example, by allowing the use of university facilities, staff, or even students) and preserving university resources or between strong IP ownership policies or indirect cost rates and attempts to bring in more research support from industry. One big conflict of interest arises when university administrations are called upon to make exceptions to long-standing policies in order to bring in a big program; the exception itself may be only marginally harmful to the university, but the willingness to make an exception for enough money or for a very senior person can be a dangerous precedent.

For faculty members, conflicts of interest may involve time commitments (often called *conflict of commitment*). For example, conflicts may arise between time spent in university teaching and research and time spent with the spinout company. Faculty may also be tempted to withhold research data from university research efforts because of potential usefulness to the company for the data to remain secret—or because of harm to the company publishing might cause. Using students on

company projects presents another potential conflict of interest, as does company use of university equipment. A conflict of interest also arises when a researcher has to decide whether his or her new patent belongs to the university, to him- or herself, or to the spinout company.

Even a national government can find itself with a conflict of interest: Does it want to support *basic* research in its university, keeping its scientific community at a world-class level in the pursuit of new frontier technology for the coming decades, or should it shift its support to practical research that is more likely to quickly usher in new transfer technologies, new spinout companies, and regional economic development?

For universities and their faculty members, written policies that are well thought out and consistently applied can avoid many conflicts of interest. There are, inevitably, gray areas or appeals for exceptions that will intensify with time as the technology transfer program matures. The university needs to define a clear chain of command for ruling on most of these issues. Only rare exceptions should find their way to oversight committees; otherwise the process bogs down in the interminable wait for committees to be assembled and convened. Twenty years of experience suggests that exceptions to policy should be granted very, very rarely. It is difficult in a university to make an exception for one researcher without soon being called upon to make a similar exception for the next one—and policies soon erode and become meaningless.

3.5 *Talent*

Technology transfer officers need an unusual combination of qualifications:

- an understanding of state-of-the-art research (though not necessarily as a practitioner), often over a fairly broad range of technologies in a multidisciplinary university. (This usually requires a solid background in science or engineering.)
- an understanding of the language of industry (Officers must be familiar with markets, how technology is developed into products, accounting and finance principles, and decision-making processes.)
- at least a minimal understanding of venture capital, spinout formation, and smallcompany operation
- more than a passing familiarity with patent law
- an understanding and sympathy with how academia operates, academic principles, and the career development paths and aspirations of students and professors
- outstanding written and verbal communications skills in both formal and informal situations
- good negotiation skills—or the innate talent, intelligence, emotional control, and "people skills" needed to learn them
- ability to deal with multiple constituencies with conflicting objectives, most of whom one has no authority over
- ability to deal with highly ambiguous, confusing situations
- both the drive and creativity to solve complex multidimensional problems and arrive at win-win solutions
- drive to get the job done, or follow through
- very high personal integrity and the wisdom to avoid situations that get *close to the line* on ethics—no matter how profitable the situation may be to the university, a faculty member, or the licensor. A university's reputation is priceless. It must not be endangered by unethical behavior—or naiveté.

And finally:

- the willingness to work at a university salary because of the inherent satisfactions of the technology transfer job: great technology, complex and always-interesting issues, the satisfaction of seeing new companies form and new technologies reach the market, and, above all, the opportunity to contribute to the university, its students, and the community

People who embody all of these qualifications are indeed difficult to find, but one should not underestimate the need for a very high level

of talent. My experience in hiring and supervising technology transfer professionals have taught me that it is a talent-based business—some can do it and some cannot. Those who can will perform many times better than those who cannot. They will also build much better relationships with researchers and the business community over time, thereby enhancing the office's effectiveness.

In choosing staff, some formal qualifications in technology and business are a sine qua non. These qualifications, unlike personal characteristics, can be easily be checked on a résumé. Whether the technical background is at a bachelor's or Ph.D. level is relatively unimportant, provided that the person is very bright and can understand how research is done and how universities operate. Unfortunately, until the candidate has taken the job, it is difficult to determine whether an individual has the creativity, interpersonal skills, ability to deal with ambiguity, and drive to completion that the job requires.

Staff should be given sufficient clerical and infrastructure support and sufficient autonomy so that they can do their jobs well. Clearly written policies help define the limits of that autonomy. Good training coupled with oversight supervision—but not micromanagement—allows the talented professional to learn and grow on the job while bringing his or her talents to bear on the tasks at hand. Plus, he or she can make decisions and get deals done quickly, without waiting for multiple levels of approval at each point along the way.

They must also be given *adequate clerical support*. Clerical support seems trivial: it is not. Regrettably, technology transfer is not only a *talent-based business* but also a *paperwork-intensive business*. If good computer systems and clerical help are not available, your very talented technology transfer professionals will spend far too much of their time on clerical work—which is both wasteful and demoralizing. ■

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1 See, also in this *Handbook*, chapter 3.11 by PWB Phillips and CD Ryan, and chapter 3.12 by K Viljamaa.

2 Brandt KD, EJ Stevenson, JB Anderson, CL Ives, MJ Pratt and AJ Stevens. 2005. Do Most Academic Institutions Lose Money on Technology Transfer? Boston University. Poster Session, AUTM Annual Meeting, 2005.

3 See, also in this *Handbook*, the chapter 5.7 by A Bennett.

Establishing a Technology Transfer Office

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ABSTRACT

Technology transfer does not just happen. Transferring knowledge and innovation from a public research organization to the private sector for commercial application and public benefit requires a formal mechanism—a technology transfer office (TTO)—to protect and license intellectual property. Establishing a new TTO is no trivial matter, and the decision to create one should be made within the context of a long-term plan that takes into consideration the following questions: (1) Does "research commercialization" align with the institution's mission? (2) Do the quality and quantity of research within the institution warrant the establishment of a TTO? (3) Is the institution willing to make a long-term commitment to required institutional changes and to adequately invest in resources and people? If the answer to all of these questions is yes, then it is time to develop a clear TTO business plan. In this effort, a strong dose of patience will help. An often-quoted rule of thumb in professional circles suggests that even under the very best circumstances, TTOs do not become successful for seven to ten years after they are established. This chapter provides practical advice for creating a proactive TTO and also offers historical examples from around the globe of TTO launches.

1. THREE FUNDAMENTAL QUESTIONS

Before initiating a planning process for a new TTO, a research organization must first address three fundamental questions.

1.1 *Does "research commercialization" align with the mission?*

If the institution's primary mission is education, or if its mission does not support research as a primary institutional focus, establishing a TTO may not be warranted. Without a strong research focus, the organization would do well to find alternatives for meeting the occasional need for technology transfer services.

With more than twenty years of experience, the international Association of University Technology Managers (AUTM)[1] has identified four key reasons for public research organizations to advance academic technology transfer:

- facilitate the commercialization of research results for the public good
- reward, retain, and recruit high-quality researchers
- build closer ties to industry
- generate income for further research and education, and, thus, promote economic growth

If these reasons make sense for your institution, then it may be time to set up a TTO.

1.2 *Do the* quality *and* quantity *of research warrant the establishment of a TTO?*

All technology transfer opportunities flow from research. The 2003 AUTM Annual Licensing Survey™ indicates that, on average, one formal disclosure of invention was made for every US$2 million in research activity at research universities in the United States. One U.S. patent application

Young TA. 2007. Establishing a Technology Transfer Office. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

was filed for every US$5 million in research expenditures, and one technology transfer or licensing agreement was executed for every US$8.5 million in research expenditures.[2] These statistics indicate that public research organizations review many more innovations (*disclosures of invention*) than are acted upon. Clearly, substantial research is required to generate technology transfer opportunities. Using the above averages, a TTO in a public research organization with a research budget of US$100 million might expect to record 50 disclosures of invention, 20 patent applications, and 11–12 license agreements per year. An institution must therefore determine whether its research volume is sufficient to warrant investing in a new TTO.

The quality of research accomplished within an institution is another critical variable. This may be affected by an institution's ability to recruit and retain world-class researchers who are at the cutting edge of science and engineering advancements. Furthermore, pursuing basic research may generate fewer opportunities than would applied research. If the estimated quantity and quality of research are below the AUTM averages cited above, the institution should use alternative means to address its occasional need for technology transfer services.

1.3 *Is the institution willing to make a long-term commitment to the TTO?*

Time may be the greatest predictor of success for a TTO. In other words, the longer a TTO operates, the better will be its cumulative results and performance measures. This makes sense intuitively: as innovations, patent applications, and license agreements are added cumulatively each year to the institution's portfolio, there is a greater chance that a fraction of these will eventually generate returns. Technology transfer practitioners suggest that it typically takes five or more years for technology that is licensed to an industry partner to result in a marketable product. Thus, according to these practitioners, TTOs require seven to ten years to be successful, regardless of how one chooses to measure success. Institutions should expect similar experiences and be prepared to subsidize the office for many years to come. A commitment to support a TTO is more than a two- or three-year financial obligation.

1.4 *If the institution does not meet the four criteria, then what?*

If the research organization does not, in its initial planning processes, answer yes to the fundamental questions, the following alternative models, which have proven successful globally, can be used:

- An external organization, which can be not for profit or for profit, contracts with the institution to manage the occasional disclosure of invention on an ad hoc basis. There are many examples of these organizations utilized in smaller research organizations globally.
- An individual or small internal office could review, filter, and rank disclosed innovations and an external for-profit company could implement commercialization of the most promising opportunities. Consider the model offered by Baylor College of Medicine Office of Technology Administration and BCMT Technologies in Houston, Texas, both in the United States.[3]
- One TTO could serve a consortium of several public research organizations in a region. The Chinese Northern Technology Exchange Market offers a good example of this approach.[4]
- One office, funded by the national government or a philanthropic institution, could serve as a TTO for several public research institutes. Examples include the U.S. National Institutes of Health Office of Technology Transfer[5] and the Innovation Fund Commercialisation Office in South Africa.[6]

2. ALL GO? DEVELOP A TTO BUSINESS PLAN

When the four fundamental questions have been satisfactorily explored and a TTO has been decided upon, both short- and long-range plans should be developed, much as a for-profit organization would develop its business plan. At the very least, an executive-summary plan addressing the essential elements should be crafted.

2.1. *Developing a mission statement*

First, the TTO should establish a transparent mission statement developed in concert with its constituents (including but not limited to its administration, inventors, and external clients, including potential industry partners). TTO missions may focus upon three primary objectives or combinations thereof: (1) service, (2) economic development, or (3) income.[7]

2.1.1 *Service mission*

The TTO can be considered a service unit to the researcher, similar to an institution's human resources office or a contracts and grants office. In this model, the institution may not share with the office a percentage of the income from successful commercialization. Instead, it fully subsidizes the office—just like any other internal department. Researcher satisfaction typically is high because all innovations receive TTO attention and work.

2.1.2 *Economic development mission*

Institutions inspired by the goal of economic development see their primary mission in terms of creating jobs and economic growth in the local community—and perhaps the region, state, or nation—through spinout companies and through licensing to local companies. A cluster of companies (*centers of excellence*) may be created around a core area of technology. Significantly, a recent Milken Institute study on the high-tech economy concludes that "*research centers and institutions are indisputably the most important factor in incubating high-tech industries.*" The same study found that 29 of the top 30 high-tech clusters in the United States were home to a comprehensive research university.[8]

2.1.3 *Income mission*

As expected, earning income from the transfer of innovations to commercial concerns is nearly always the primary focus of the operation with income as its main objective. Such institutions are very selective, identifying innovations with the highest potential and quickly abandoning others. Not surprisingly, this can lead to overall researcher dissatisfaction; this is not usually the case with institutions that have a strong researcher-service orientation. Institutions with higher income levels from licensing are typically teaching/research hospitals at which the possibility of an outstanding commercial success is more realistic.

Of course, TTOs do not focus on a single mission but combine their vision in ways that best satisfy their own constituents. The mission statement serves as a guide for implementing these goals and sets forth the activities expected from the new TTO. A short and simple mission statement might be: *The TTO serves to assist researchers in the transfer of the institution's research results to industry for commercial application, economic development, and public benefit.* TTOs must be careful to avoid "mission creep." This can occur when TTOs are charged with managing activities not directly related to commercializing innovations (research administration, institutional export regulation requirements, conflict of interest compliance, and other tasks not within its stated mission).

Finally, while TTOs are business offices within academic institutions, the mission statements of these offices increasingly announce a societal role. As the managers of institutional innovations for commercial use, do TTOs also have a social responsibility to improve the well-being of humanity? The answer is a resounding YES! Social responsibility and a contribution to societal wellbeing must fit within the TTO's mission. These can easily be incorporated into the service mission of the office and the institution. Indeed, public research agencies should be in full support of the United Nations' Millennium Development Goals.[9] Furthermore, given that the current debate opposes corporate profit flowing to a range of important social goals—sustainable development, the health of the environment, the indigenous farmer, and free or low-cost treatment of AIDS, malaria, and other diseases in developing countries of the world—public research institutions must make sure to align themselves with societal welfare. The TTO mission statement is a powerful place to announce these aims.

There are many ways to balance these goals with commercialization. One relatively simple way would be to carefully craft license agreements

to ensure that social benefits for developing countries are incorporated into the grant section. For example, a grant for an improved agricultural variety could require the corporate licensee to sell seed for commercial production with royalty or added-value premium pricing but to indigenous farmers in developing countries at cost (or at least without requiring them to pay royalty to the university or the added-value premium charged by the company to commercial producers).

2.2 *Policies and procedures*

The system for managing innovations should be easily understood, and transparent policies should guide the implementation of the institution's mission statement. Defining the *ownership* of intellectual property (IP) resulting from institutional research must be at the very heart of the institution's policy. A disposition of ownership can take many forms, but the disposition must be defined clearly without question or ambiguity. In some countries, ownership is defined by national law. In other countries, each institution holds the prerogative to determine the ownership of research results: the government, the inventor, the institution, or two or more of these parties. In the United States, for example, each research institution is free to determine how ownership is allocated, with the exception (under the U.S. Patent and Trademark Law) that if the innovation is developed with government sponsorship, ownership lies with the institution. Regardless of the approach the institution chooses or is compelled to adopt, technology transfer is impossible without a clearly defined, written policy concerning ownership (including written assignment of title, when required).

Even after more than 20 years of proactive technology transfer practice in North America and throughout the globe, debate continues about the best model of IP ownership for academic institutions and other public research organizations. The inventor-owned model and the institution-owned model both have positive and negative attributes, as seen in the examples of success in both the United States (institution-owned, except for the University of Wisconsin) and Canada (inventor-owned in many institutions). Several countries in various parts of the world have moved recently to the institution-owned model (Japan, Germany, and the United Kingdom, for example). It seems clear that either approach can work well.

However, a disturbing trend has been seen in the recent laws of various countries just entering the technology transfer arena. In some cases, the new national laws require that the ownership of IP arising from sponsored research be *shared* between the research sponsor and the institution. Ownership is shared equally to begin with, but later becomes negotiable (such a provision is stated in Brazil's new technology transfer law of 2005). Such an arrangement is not viable, as these countries will find as they seek to implement a national technology transfer regime. In seeking to be politically correct and not offend the country's corporate sector, the governments have created a situation in which neither party wins: the transfer of research results will be blocked by the inability of either party to maintain exclusivity. This will create an impenetrable barrier that will prevent any corporate partner from investing the energy and money necessary to take an embryonic technology to market. The result will be impasse; the transfer of technology will by stymied.

Obviously, policies should address a multitude of other issues that are critical to the success of technology transfer programs, such as royalty-income distribution, the disclosure process, assignment of responsibility for seeking patent protection, researcher and institutional conflict of interest, dispute resolution, management of licensees' contractual performance, management of equity interests in spinout companies, and many more requirements. As examples, the policies for most research-intensive universities in the United States and in many other countries are found on the AUTM Web site.[10]

2.3 *Financing the TTO*

As previously established, an institution's new TTO will require subsidies for years under the very best of circumstances. However, as different countries have discovered, there are many different funding models.

2.3.1 *Australia's models*

In Australia, public research organizations, within a relatively unregulated environment, are responsible for financing their own technology transfer operations. Two primary models have emerged: (1) the formation of an external company, and (2) the establishment of an internal institutional department or office. Using the company model, the corporation generates cash flow through a variety of related business activities such as consulting, conference management, and professional development courses. The proceeds enable the company to support the organization's technology transfer function. In some cases, a university has provided seed funding to initiate the company's operations.

In the internal-office model, the organization provides funding directly to the TTO, which is then considered one of the organization's central administrative functions. The amount and adequacy of TTO funding depends upon how important innovation management is to the central administration and upon the TTO's ability to demonstrate the benefits it brings to the institution.[11]

2.3.2 *India's model*

No formal legislation for organizing and financing TTOs exists in India. However, during the last ten years, most technical universities and research institutes independently established organizations to interface with industry. Such organizations perform many of the technology transfer activities typically assigned to TTOs in other countries. Some of these autonomous entities were initiated with seed funding provided from state governments or the central government. For example, the Indian Institute of Technology in Delhi established the Foundation for Innovation and Technology Transfer (FITT) with a corpus grant equivalent to US$400,000 from the Indian Ministry of Human Resource Development. In other cases, TTOs were formed by funds appropriated by a governing board of the autonomous university or research institute.

In all cases, such support is provided only for a limited time. These organizations are expected to attain self-sufficiency, working as "profit centers" with a well-managed business plan. As in Australia, income may be derived from service charges levied for business-development activities that may have little to do with managing the innovations from the research institute (for example, industrial consultancies and other business services provided to small and medium enterprises). In addition, each center typically receives a percentage of the royalty income for the technology transfer transactions it manages for the public research organization.[12] In April 2005, the Society for Technology Management (STEM) was formally launched as India's professional technology transfer society, including institutional and individual members.[13]

2.3.3 *Japan's model*

In 1998, the Japanese government enacted legislation to create government-approved university TTOs. Once a TTO was approved, the government would provide two-thirds of its operating cost, up to the equivalent of US$300,000 per year for five years; the universities or other university-related organizations were expected to match government support by contributing one-third of the funding. At the end of the five-year period, the TTOs were expected to be able to sustain themselves without the income streams resulting from commercialization. However, when the Japanese government realized that such expectations could not be achieved, it extended its direct subsidy of a portion of the cost of TTO operations, including the direct allocation of funds to secure patent applications for selected top-tier or so called Super TTOs. Furthermore, in 2004, Japanese law gave all national universities independent legal status, allowing them to participate in these TTO initiatives.

Finally, a number of Japanese TTOs quickly discerned that the funding from the government was insufficient to support their operations. They therefore created associated for-profit companies that facilitated the creation of spinout companies. Faculty members were asked to invest in these companies, which commercialized university R&D. Now, several faculty-owned companies associated with university TTOs exist to assist the commercialization of R&D through spinout companies. This provides incentives for faculty

members to disclose their inventions, because they have a personal stake in the commercialization company. The government and universities realize, however, that this expanding strategy will require new support systems, such as incubators and risk capital, in order for these Japanese institutions to become entrepreneurial universities.[14]

2.3.4 *People's Republic of China*

In 1998, inside China, only Tsinghua University and Peking University in Beijing operated TTOs. Today, most public research organizations in China have a TTO. These were originally supported by the Chinese government, but as China moves from a state-planned economy to one that is more market based, this TTO funding model is changing. Most of the TTOs today operate as associated private companies, solely owned by the corresponding university and initially supported with university funds. As private companies, these TTOs are very active in business-development services, such as setting up incubators, assisting small- and medium-sized enterprises to prepare business plans, helping develop spinout company requirements, investing in new spinout companies with university-based venture funds, and so on. Most often, the TTOs negotiate for significant equity shares in new university spinout companies and may wholly own some spinout companies. Eventually, the TTOs—often called technomarts—are expected to become self-sufficient from their equity holdings and the income received from licensing and other related business-development activities.[15]

2.3.5 *South Africa*

South Africa has made government support for research and innovation a key part of the national economic-development strategy. In August 2002, South Africa's government approved a new national R&D strategy, and discussions continue for implementing the new strategy, including national funding for technology transfer. Funding for commercialization activities and patents is critical, but a major capacity-building and development effort is under way. This effort will build upon capabilities that exist in a few universities and public research councils.

South Africa is seeking to build strong links between its emerging technology transfer system and its research system. This means building a new culture of innovation inside the research community and ensuring that all benefits of research (including noncommercial and social benefits) are understood and exploited. To support this integrated approach, the Southern African Research and Innovation Management Association (SARIMA) was formed in 2002 to assume the lead role in national efforts to build capability in research and innovation. SARIMA is supported by the government, participating academic institutions, and U.S. and European philanthropic donors.[16]

As part of its national strategy, the South African government established its Innovation Fund to promote technology innovation, which has increased networking and cross-sectoral collaboration. The fund has invested South African Rand ZAR650 million in more than 100 projects. Many of these have produced patents and in some cases spinout companies. Most recently, the government established the Innovation Fund Commercialisation Office (IFCO), a centralized office to provide one-stop support for protecting and commercializing intellectual property rights for all of the nation's public research organizations. IFCO complements existing technology transfer offices in South African public research organizations.[17]

2.3.6 *United Kingdom*

Shortly after the 1998 report White Paper on the United Kingdom's Competitiveness, issued by the government of the United Kingdom, many policy initiatives and government funding streams were established to stimulate cooperation between the researchers at universities and the country's industrial entrepreneurs. This cooperation significantly changed the way universities in the United Kingdom organize their technology transfer activities. Several prominent universities created separate companies to commercialize IP, especially innovations that were thought to have potential to serve as foundations for spinout companies (university companies or UNICOs[18]). Nonetheless, the majority of universities also have

internal TTOs that collaborate closely with the sponsored-research office and with the UNICOs to develop industry relationships. The growth and development of TTOs have been stimulated more recently by direct government funding to universities for this *third stream* activity via the Higher Education Innovation Fund in England and Wales (HEIF)[19] and the Scottish Executive Expertise, Knowledge, and Innovation Transfer Programme (SEEKIT).[20]

Initially, HEIF financial support was awarded to institutions through competitive solicitation. Today, the government distributes HEIF funds directly to universities through a *formula funding* process that is based upon numerous criteria, including but not limited to institutional research capacity (quantity and quality) and TTO performance measures.[21]

2.3.7 *Russian Federation*

A major initiative began in 2002 to establish TTOs in leading universities in the Russian Federation. This was led by the U.S. Civilian Research and Development Foundation (CRDF) of Arlington, Virginia, in cooperation with the Russian Ministry of Education. The 19 universities participating in the so-called Basic Research in Higher Education (BRHE) program were identified for R&D development and technology transfer focus. Funding was provided primarily by the John D. and Catherine T. MacArthur Foundation through CRDF and the Russian Federation Ministry of Education. In 2003, CRDF and the Ministry held a joint competition in which BRHE universities submitted proposals to establish TTOs with dedicated funding. Four universities were selected by CRDF to receive funding for TTO establishment, which provides a good example of financing TTOs through a third-party philanthropic source. The awards ranged from US$75,000 to US$150,000 and were paid out over three years. Most recently, the U.S. Department of Commerce and the Russian Ministry of Education and Science executed a bilateral agreement that included establishing the U.S.-Russian Innovation Council on High Technologies. The first meeting of the council was convened in Moscow in June 2005. One of the four focused working groups established by the council will address the role of universities and research organizations in the process of innovations and commercialization. This will include considering how to establish and finance TTO operations in the Russian Federation. Finally, most research in the Russian Federation is conducted by the research centers of the Russian Academy of Science. Many of these centers have extensive technology transfer operations funded internally and directly by government allocations made to research centers at the academy.[22]

2.3.9 *The United States*

No government funding for TTOs is provided to universities inside the United States, and there are no national universities. However, the Bayh-Dole Act of 1980, enacted as PL 96-817 and codified in the U.S. Code of Federal Regulations[23] provides a legal basis for TTO funding. The act states that income recorded from commercializing government-funded-research results can be utilized for *only* three purposes: (1) to fund the administration of the technology transfer function (TTO), (2) to provide a share of income to the inventor as an incentive to participate in technology transfer, and (3) to support education and further R&D at the institution.

The act does not specify the percentages of income to be allocated for these three purposes. Universities are free to determine how to allocate commercialization income as they see fit. Most institutions have set aside a portion of the income stream to fund the TTO: allocations for TTO operations usually range from 10% to 25%. Typically, after allocating a portion of commercialization income to support the TTO, the university directly subsidizes the TTO from internal sources during the first years of its operation. Then, as income is realized from license agreements, the subsidy required from the university for the TTO operations is reduced over time. Eventually, the institution expects that the income stream generated by the TTO will eventually eliminate the need for direct university subsidy. As mentioned above, several years are required for a TTO to become entirely self-supporting from the allocated income. In a few rare cases, a TTO has become

self-sufficient early in its growth from a successful project that immediately generated a large stream of royalty income. Finally, it should be mentioned that other public research organizations in the United States (such as federal laboratories) are funded directly through a *set-aside* of the annual appropriation provided to departments of the executive branch of government, such as the U.S. departments of defense, energy, and commerce (see Federal Laboratory Consortium for Technology Transfer[24]).

2.3.10 *Assessing the options*

The previous examples demonstrate how TTO funding models vary around the globe. Each model has developed to fit the cultural, political, and economic conditions of the corresponding country. Two themes are found in most international models:

1. The TTO typically is allocated a percentage of the income stream from the commercialization of innovations.
2. The TTO is expected to eventually become self-supporting from this allocation of income and perhaps other related income-generating services.

Despite a new axiom (discussed in section 2.5), many countries or regions may have no choice but to establish a regional or inter-institutional model, for the reasons presented, with regard to the costs of establishing a TTO and the quantity and quality of an institution's research results. The greater the distance from the regional office to the institutions the office serves, however, the greater are the challenges for identifying research results with commercial potential, protecting such results, and finding corporate partners for commercialization. Here are a few recommendations that, when followed, can diminish the negative impact of physical distance:

- Within each institution served by a regional office, an individual must be identified to act as the institution's liaison with the regional TTO. (This individual would have other responsibilities as well.) Having a specific point of contact is necessary for coordinating even the simplest administrative tasks. Ideally, this individual should not be a rector, vice president, provost, or dean, but rather a second-tier administrator who reports to such institutional authorities.
- The best communication infrastructure possible must be in place between the regional TTO and the institutions it serves, including, but not limited to, video-conferencing capabilities when possible.
- Key staff of the regional TTO must make regular, frequent visits to each of the institutions it serves in order to have adequate face-to-face contact.
- Transparency in the operations of the regional TTO is essential. Transparency requires: (1) sharing costs between served institutions on a negotiated and equitable basis (if the regional office is not fully government supported), and (2) equal treatment and consideration toward all institutions served by the TTO (that is, no favoritism shown to any one institution).

For 13 years I directed a TTO that served ten academic institutions within the Texas A&M University system. At one time during those years, the TTO sought to serve smaller Texas universities outside the A&M system. The greatest challenge I found in seeking to manage such a broad program was that despite all efforts on the part of the TTO against it, favoritism was perceived by the institutions served. Such perceptions are likely unavoidable and simply must be managed. Once one of the served institutions records a significant success, the other institutions want to know and understand why they have not achieved, or are not achieving, similar success. Individuals who perceive that their institutions have been slighted will frequently blame the "failure" on the TTO and its staff. Over the years, I spent many hours addressing this issue in high-level meetings with institutional officers and system-level officials, even though the TTO office and staff sought to be impartial. Thus, a regional TTO must be prepared to address this critical issue, or the collective approach is likely to fail.

2.4 *Staffing the TTO*

Staffing a new TTO is a major challenge. Engaging the right individual or individuals to operate the office often is the factor that determines failure or success. In the United States, the number of TTOs began to increase in the 1980s, and selected to direct the new TTOs were individuals from various backgrounds including high-level administrators, staff from other departments (contracts and grants staff, for example), clerical staff, scientists, attorneys, businesspeople, and so on. Significant debate went on in the 1980s and 1990s as to which combination of skills was most desirable for directors and licensing associates to possess: scientific skills, legal skills, or business skills? At the same time, many offices evolved from simple one- or two-person operations to complex operations with many different positions to address specific job tasks, such as general administrative management, clerical support, accounting support, paralegal services, and project management (evaluation, marketing, licensing, and so forth).

For the university contemplating a new office, two would be the fewest number of positions to start with:

- **a director/licensing associate.** In an ideal world, a person charged with setting-up a new office should have significant business experience (marketing, management, and business development), combined with a science or engineering education. Generally, neither scientists nor attorneys have the business acumen necessary to establish, organize, and manage a TTO. The director/licensing associate should have excellent communication skills to effectively market innovations and to work successfully with both internal constituents (researchers and administration) and external constituents (potential corporate licensees).

  Unless the new TTO recruits an experienced technology transfer professional, the new director/licensing associate should be trained before operations begin. There are many opportunities for workshops and other training events internationally, through such organizations as AUTM and the Licensing Executives Society International.[25] Additionally, internships are available in numerous countries, for instance, in the United States, the Special American Business Internship Program (SABIT) is offered by the Department of Commerce.[26] AUTM offers scholarships for training, such as the Howard Bremer Scholarship and the Developing Economies Scholarships (five awards). Each of these scholarships is offered annually through a competitive solicitation process.
- **clerical support.** TTO operations require significant clerical and administrative support. TTO activities generate tremendous volumes of paper in the form of patent application drafts, license agreements, project summaries, and marketing materials, as well as daily correspondence with attorneys, potential licensees, and researchers. Project files and docketing systems must be prepared to manage the progress of ongoing work on each innovation, which not only requires clerical support but also appropriate computer and electronic database resources. The telephone rings constantly with calls from inventors and potential corporate partners. Additionally, Web sites must be created and maintained, and incoming e-mails can be overwhelming. Excellent clerical/administrative assistance for the director is essential when establishing a new TTO.

When helping countries and institutions to establish TTOs, I have frequently heard this question: "Should we hire an in-house attorney to file patent applications for the institution?" Generally, in-house counsel retained for the drafting and filing of patent applications is not recommended for the following reasons:

- By and large, the breadth of an institution's research is too wide to be within the technical expertise and knowledge of any one patent attorney. Furthermore, the cost of hiring several attorneys with the relevant technical skills to address this breadth is not cost effective. Exceptions to these conclusions may be Centers of the Consultative Group

on International Agricultural Research (CGIAR) or similarly focused research institutions with narrower institutional research results.

- The claims of a patent application form the basis for products and companies. Especially in human-health research, tens and even hundreds of millions of dollars are spent to bring an embryonic technology to market. Such investments depend upon and are protected by the strength and enforceability of the patent rights to the subject technology. An institution would be extremely shortsighted to cut its patent application costs by using an in-house attorney made to be responsible for too many fields of technology. Given the high stakes, it is far better to secure the best possible patent counsel available to draft the strongest claims possible for the subject invention.
- Corporate licensees prefer to use the best counsel available to back their investments, and they may not have full confidence in the capabilities of an in-house attorney.
- In today's litigious world, use of outside counsel creates a third-party buffer, an entity that must take responsibility for conducting thorough prior art claims, meeting filing deadlines, drafting the best claims possible, and managing the patent prosecution process from start to finish in the most professional manner. If problems arise along the way, as they often do, the institution is best served by having the attorney's firm, and not the institution, be responsible for all of the constituents: the inventor, the institution, and the licensee. It is not advisable, when things go wrong, for the university to be in the position of defending the patent prosecution with in-house counsel.
- Finally, many institutions have legal counsel in an *office of the general counsel* (or similar name) that can offer assistance to the TTO, from time to time, for contractual questions, contract enforcement, and other legal issues.

Many TTOs in the United States—including the TTO of the Texas A&M University system—have hired an in-house *paralegal specialist*, rather than in-house counsel, to manage the interface between the institution and its patent attorneys engaged under contract. The paralegal is responsible for ensuring that all documents are properly executed and filed with the attorney firm, for maintaining "suspense files" or tickler files to provide a backup system to ensure that no filing deadlines are missed at domestic and international patent offices, for filing copyright applications for software and other works on behalf of the institution and its faculty, and for maintaining a relational database of all official project documentation.

2.5 *Organizing the TTO*

During the initial growth of the technology transfer industry in the United States in the 1980s and 1990s, TTOs were located in a variety of administrative units within public research organizations, including (1) offices of general counsel, (2) business administration offices, (3) offices of the vice president for research, and (4) contracts and grants offices. Over time, however, TTOs typically were placed within the research administrative unit of the institution, which usually reports to the vice president for research. In many cases, an individual serves as the organization's officer for research and technology transfer, combining the functions within one administrative unit.

Additionally, as TTO offices grew in the United States and other industrialized countries, the offices diversified to create individual operating divisions to manage focused tasks:

- general administrative office management
- clerical support
- project management services through a licensing associate (responsible for evaluating inventions, marketing, coordinating industry relations, and negotiating license agreements)
- accounting services (responsible for managing general fiscal operations, as well as accounts receivable from licensees, and accounts payable to consultants, patent attorney firms, and other service agents)

- paralegal services (responsible for managing the volumes of correspondence and carrying out discussions with patent attorney firms, executing and notarizing legal documents, and docketing critical dates to ensure filing deadlines are met)
- marketing/public relations (responsible for managing Web sites and producing brochures, press releases, and other marketing materials, as well as organizing frequent promotional events for researchers and industry)

More entrepreneurial offices may even create divisions to establish new spinout ventures, incubators, university venture funds, and the like. Obviously, new TTOs may utilize existing units outside the office to manage some of these activities—such as working with a university communications office to produce marketing materials—until such time as the growth of the office warrants a dedicated person inside the TTO.

As has been suggested, TTOs have taken various organizational forms, in addition to the traditional stand-alone unit or department within the public research organization. These include (1) an external company owned by or closely affiliated with the institution to manage its technology transfer activities, (2) a service or consulting contract with a third-party company to manage occasional innovations disclosed by researchers, (3) one office serving multiple institutions in a region under collaboration agreements, and (4) a government agency serving as a TTO for universities and other research organizations in a region, state, or nation.

How to choose? This chapter suggests a new "TTO axiom" to help guide planners toward the most effective organizational form: *The closer the TTO is physically to the scientists and researchers it serves, the more effective it will be.* The reverse is also true: *TTO effectiveness diminishes the further it moves physically from its customer base.* This latter holds true even in our age of e-mail, instant text messaging, and other video, voice, and digital communication techniques. None of these techniques can replace frequent face-to-face communication needed between the TTO staff and its inventors, or the ability to call, on short notice, meetings between project stakeholders—inventors, TTO staff, academic administrators, potential licensees, and so forth. At times potential corporate partners arrive at the TTO with little or no advance notice, and getting the inventor to join the group for a meeting, lunch, or dinner obviously is not possible if the individual is in a faraway city. Moreover, simple administrative and logistical requirements in managing innovation suggest that physical proximity is important. Consider the example of an inventor receiving a call from the attorney-of-record on a patent application saying that the inventor's signature is needed on an affidavit before the end of the day. Such a situation could only be addressed if the TTO were on-site.

3. OPERATIONS

The degree to which TTOs participate broadly in research, technology transfer, and industry relations varies widely from institution to institution and from country to country. The degree of participation depends upon many factors, the most important being the entrepreneurial culture of the institution and of the region or nation. Institutional culture is determined most often by the attitude and degree of support from the president or chancellor of the institution. Some entrepreneurial chief executive officers have expanded their initial TTO operations to include activities in support of their industry partners. This can create closer connections to the corporate sector, such as the development of spinout-company business plans by a university's college of business administration; the creation of university-based technology business incubators, and/or research and science parks; organizational venture funds, and so on. Constituents of a new TTO, however, expect the following minimal activities:

- **Assist faculty and researchers in identifying research results that have commercial value and document the discoveries through a disclosure process.** The disclosure-of-invention form should be simple and make it easy for the inventor to document the discovery; more detailed information can be obtained through interviews and subsequent

interactions with the inventor. The complexity of the disclosure form should never be a deterrent to faculty participation in the technology transfer process.

- **Evaluate commercial potential of disclosed innovations.** A TTO exists to find commercial applications for technology and partners to realize the commercial potential, not to judge the value of the science. Such evaluations may be the most difficult of all tasks for a TTO. There are many approaches to invention evaluation.[27] The evaluation process lays the foundation for future decisions about IP protection and marketing.
- **Determine whether or not to protect IP rights in the innovation; secure funding for filing patent, trademark, or copyright applications; and manage the protection process.** The challenge of securing funding for protection of intellectual property internationally—especially when seeking protection in highly industrialized countries where the primary markets for the expected products lie—is often overwhelming and perhaps even impossible in many developing economies because of the tremendous expense. Yet, there may be very small or nonexistent commercial markets for the innovation in the country of origin, which can present a serious dilemma. The only solution in many cases is to first secure protection in the country of origin, thereby "buying time" under the requirements of the Patent Cooperation Treaty (PCT)[28] to find a corporate partner to pay the patent costs internationally as a business expense in the license agreement.
- **Conduct market research to identify potential industry partners, and then market the innovations.** Research has shown that in the United States, the primary source for identification of licensees is the inventor. In industrialized countries, inventors typically are familiar with the marketplace[29] in their area of scientific expertise; they may even know their counterparts in industry (potential licensees) on a personal basis through their professional networking activities.
- **Once one or more industry partners are identified for an innovation, negotiate legal contracts (license agreements) with these industry partners to transfer IP rights in the innovation in exchange for royalties or other consideration.** The goal is to negotiate a fair arrangement that facilitates and assists the commercial partner in successfully developing and marketing the product, rather than simply seeking to negotiate the absolute highest fees and royalties in the agreement. Developing industry partnerships can lead to many unexpected benefits, such as sponsored research, student employment opportunities, consulting opportunities, and even philanthropic donations to the institution.
- **Maintain and manage administrative functions in support of the primary functions of IP protection and technology transfer.** These functions can include accounting, royalty distributions, licensee performance management, and patent application management.
- **If the TTO decides not to pursue IP protection and commercialization of an innovation, implement a process to ensure that others have an opportunity to pursue protection and commercialization, if they chose to do so.** The "others" will most often be inventors.

4. EXEMPLARY TTOS AND CONCLUSION

In 2000, Dr. Louis Tornatsky conducted a study for the National Governors Association in the United States to identify the common practices of the most exemplary TTOs in the country. The study highlighted seven characteristics that were common to most exemplary offices:

1. A clearly stated TTO mission
2. Transparent TTO policies and procedures
3. Entrepreneurial staffing and an entrepreneurial environment
4. Customer-friendly relations with both internal and external constituents by TTO staff

5. A highly supportive university administration and community (local, regional, and national)
6. Strong TTO links to potential industry partners
7. TTO access to risk, or venture, capital[30]

TTOs exist in all shapes and sizes around the world, ranging from a part-time individual at a small research organization, to offices with several hundred professionals (such as the University of California system), to a contracted third-party organization that manages an occasional innovation with commercial potential. Furthermore, sources of TTO funding, the organizational structure of the office, the scope of activities, and many other operational factors vary from office to office and from country to country.

The most compelling forces that determine a TTO's characteristics and performance have been a primary focus of this chapter: the volume of research activity within the institution and the quality of the research results. Research is the source from which all innovations and opportunities for TTO management originate. Public research organizations contemplating the creation of a TTO should always first consider whether the research quantity and quality of their institutions justify the endeavor. ■

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1 www.autm.net.

2 The survey is published online at www.autm.net/surveys/dsp.surveyDetail.cfm?pid=16. The survey can be accessed by members of AUTM at no cost. Nonmembers may purchase the survey on the AUTM Marketplace at www.autm.net/shopping_cart/.

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4 www.ntem.com.cn/.

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23 Another source of the Bayh-Dole act: (i) AUTM offers a description of the Act, with a link to the actual legislation: http://www.autm.net/aboutTT/aboutTT_bayhDoleAct.cfm. (ii) When you click on the AUTM link, it takes you to the actual legislation at: www4.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html.

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25 www.lesi.org.

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How to Set Up a Technology Transfer Office: Experiences from Europe

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ABSTRACT

Technology transfer has an important role to play in the today's world, where access to know-how and knowledge are valuable economic commodities. A technology transfer office (TTO) can be set up in many different ways. The TTO should be tightly aligned with its supporting institution's missions and goals. Available external resources will affect the TTO's strategy and its operational structures, so it is important to consider the TTO's external environment. Income generation is typically one of the main objectives for the TTO, but technology transfer is valuable also because of its capacity to facilitate innovation and broker the exchange of knowledge for society's benefit. This chapter discusses the key elements involved in building a TTO—from structure and staffing to external engagement—and how to lay the foundations for success. A number of European models and trends are described to provide greater context.

1. INTRODUCTION

There is no "right" way to set up a technology transfer office (TTO), but success does require considering some key issues. This chapter discusses how to establish and run a TTO, and, drawing on experiences from a number of such offices, the chapter provides case studies to illuminate these issues. Emerging trends in funding TTOs are also discussed.

2. FOUNDATIONS

Any technology transfer office should be aligned with and supported by the institution it serves. The TTO's mission should be consistent with the institutional mission, and the TTO's approach and activities should support and add value to the institution. The TTO and the institution should agree upon what adds value, because financial returns alone are an insufficient measure of value for universities viewing their commercial activities strategically and contextually. Long-term returns, such as sustained partnerships, cultural change, job creation, and societal well-being should be part of the value provided by TTOs. These long-term returns supplement shorter-term, more tangible returns such as income, access to resources and expertise, and program delivery. This point has been emphasized by the U.S. technology transfer association, the Association of University Technology Managers (AUTM) and the U.K. association for technology transfer (UNICO[1]), which have disseminated data and case studies of how technology and knowledge transfer can benefit society.[2]

Deciding whether the TTO should undertake pure commercialization or broader knowledge transfer is important for developing an operational strategy. In a knowledge-based economy, access to know-how and use of knowledge (outside of the environment in which the knowledge was gained) is a valuable commodity.[3] The U.K. Research Councils define such knowledge transfer as:

Campbell AF. 2007. How to Set Up a Technology Transfer Office: Experiences from Europe. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

[T]he two-way flow of people and ideas between the research environment and wider economy, [which] thereby contribute[s] to national prosperity, the quality of life of U.K. citizens, and cultural enrichment of our society. Knowledge Transfer encompasses the systems and processes by which knowledge, expertise and skilled people transfer between the research environment (universities, centers and institutes) and its user communities in industry, commerce, public and service sectors.[4]

While the public good is always a part of a TTO's agenda, some have made income generation the prime objective. Others base their agenda on public benefit or economic development. Deciding upon the TTO's objectives will determine how the office should be configured, resourced, and operated. (Examples are presented at the end of this chapter.)

The senior management of the host institution must actively support establishing these foundations. To do so, managers will need to understand the relevance of technology transfer to the institution. Understanding the TTO life cycle is essential for helping the TTO office to encourage academics to participate in technology transfer and will help maintain support when returns seem slow or when a partnering decision appears unappealing on the surface. Such an understanding involves vision from both partners in the transfer and an ongoing dialogue between principals. In particular, it should be clear to all parties that, while technology transfer may be an extra income stream, it should not be relied upon to generate significant revenue for institutional planning. At Isis Innovation (Oxford University), perhaps one of the best-known European examples of technology transfer success, the gross income from technology transfer is about 0.005% of annual turnover. This is based upon annual turnover for the University of UK£530 million, gross income from technology transfer activity of UK£2.7 million, and net income from technology transfer (after the costs of undertaking the business), UK£260,000 (2005–2006 figures).

National and regional policies and objectives also should serve as a framework for shaping the office and directing priorities. When TTOs benefit from funding for local development, for example, they have been able to secure partnerships and fund specific activities of interest to the local region. In the Aachen region of Germany, for example, regional imperatives have engineered local economic development to ensure that an exhausted traditional coal mining region transitions into a high-technology center for innovation. Special initiatives and funding have encouraged the development of new businesses within the region. The scientific institute in Julich (Fachhochschule Aachen[5]) has been central to this redevelopment, having been built up to offer a variety of supporting technology-transfer services, including consultancy, provision of facilities, and the brokering of business advice.

An early step in setting up the TTO—and an essential ongoing activity—is identifying and fostering relationships with stakeholders. This group will include academics, representatives of the business and user community, and regional and governmental offices. The most important group at the outset is the internal community. Successful and meaningful technology transfer is demand driven, so it is important to understand the external partner's needs. If the internal academic community does not support the technology transfer process, there will be scope for failure at various stages of the process. Although time consuming for the technology transfer manager, he or she should be seen in the academic departments being served. This visibility will accelerate culture change and help integrate the TTO into the fabric of the university. The institutional message must be one of support and encouragement for engaging in technology transfer. TTO staff must work with academics at all levels to educate them in entrepreneurial behaviors at the macro and micro scales. This work could include training in how to engage with business and respond to its needs, how to act as consultants, and how to identify partnership or licensing opportunities. All academics will need to be aware of the intellectual property (IP) rights process, including disclosure, confidentiality, types of protection, and so forth. Such awareness training may be delivered by the TTO itself or in partnership with external providers. For example, IP specialists,

lawyers, and research sponsors are often willing to provide limited training. In the United Kingdom, government funding of universities consortia has established a number of enterprise centers for such training.

Incentive schemes for academic staff need to be carefully considered; policies should be implemented early. Experience has shown that acknowledging an employee's participation in technology transfer and sharing some of the financial reward are clear incentives to encouraging engagement in technology transfer. Siegel and colleagues[6] highlight the importance of faculty reward systems—along with removing cultural barriers and staffing the TTO, the reward system is one of the three key factors for success in technology transfer.

3. STRUCTURING THE TECHNOLOGY TRANSFER OFFICE

3.1 *Personnel*

The core element for successful technology transfer is people. Technology transfer is a "contact sport," so managers must have the ability to engage with people at all levels and across national boundaries. Managers need to understand the potential of their offerings and be highly flexible. Technology transfer managers need to be capable of engaging equally well with academics and business; they must be both inward and outward facing. Business skills are important but hiring an MBA graduate is not essential. The office should be led, however, by an individual who understands the details of running a business. Staff with work experience in the relevant business/user sector who can appreciate its requirements and tailor opportunities accordingly are also very useful. To build up an understanding of the potential for new opportunities, the technology transfer manager needs to win the confidence of academics, which is why it is helpful for the TTO to be embedded in the institution and for the office to be perceived as part of the institution. Staff should be able to spend time with academics to better understand what they can offer to the business and user community—as well as how these opportunities can best be developed for mutual gain by the institution and the community. Similarly, staff must actively engage with businesses to better understand market needs and gain agility in matching proposals with the institution.

An effective TTO is a team with complementary abilities. There is no one rule for the type of background that TTO staff need; much can be learned on the job and through specific training. However, if the office will be brokering opportunities in particular technical areas, then it is wise to recruit technical specialists. They will need to be able to use technical language with academics and customers, understand an opportunity and its applications, research areas of interest to a partner, and translate their ideas into an offering that business professionals will understand. Not all TTOs need to be large. A core viable unit at the outset may have three staff members, two of whom have business and technical skills and have or can develop expertise in IP rights and commercialization. The third staff member would provide administrative support. Often it is hard to resist the seduction of employing specialist staff in preference to administrative staff. However, an office that does not have access to appropriate administrative support will always be inefficient.

Specialist advice can be outsourced (for example patent and legal counsel). A growing number of legal firms have experience with the academic technology transfer sector, and they can provide a service that responds to the needs of this sector—both in terms of the type and level of advice and in the cost of counsel. When options have not been identified, a discussion within technology transfer networks will often reveal a number of suitable choices. While most offices use external legal advisors, a growing number of TTOs now employ in-house advisors, which may be desirable but naturally depends on whether the volume and complexity of work make such an appointment financially sensible.

Free business advice—which can be useful—is abundantly available to TTOs. Peer advice, including participation in technology transfer networks, can be invaluable. Other sources include funders of research (for example, Wellcome Trust, the Centre for the Management of Intellectual Property in Health Research and Development

(MIHR), and the Bill and Melinda Gates Foundation) and government and regional bodies. Business itself is an eager ally of the academic institution and the TTO. Often, experienced people will give their time to advise on specific issues or to become part of an advisory group. Many are delighted to be asked, and few refuse to help.

3.2 *Building skill sets*

As technology transfer has become a recognized profession within many countries, an inventory of best practices has accrued. There are many opportunities to build core skills in the team through networking, training, and literature. Some ways to improve the skills of the office will be free, through personal networks and mentors, for example. Secondments, where a member of one organization spends time in another, and internships with business and other TTOs are an attractive way to bolster skills, gain understanding, and share best practices. Such arrangements always work two ways, and both parties in the arrangement will normally be keen to participate. For the most part, however, specific training is needed for a team to acquire core skills and—as business needs and the landscape evolve—attain new ones. In Europe, the most prominent networking forum is the Association of European Science and Technology Transfer Professionals (ASTP)[7], a professional membership organization for technology transfer managers that hosts conferences across Europe. For technology transfer training, Praxis (a not-for-profit organization) offers a full range of courses that are delivered by practitioners.[8] Emphasizing experiential learning and networking, Praxis offers training both for new entrants and for more experienced professionals. Its courses are open to international delegates. In the United Kingdom, UNICO has published a series titled *UNICO Practical Guides* in a handy, readable format that provides in-depth advice on the range of technology transfer activities, from student IP rights to legal agreements and company formation.[9] There are also numerous guides available both for purchase and free of charge. The *MIHR Handbook of Best Practices for Management of Intellectual Property in Health*[10] is a good example of the latter.

3.3 *Managing information*

When setting up an office, adequate attention must be paid to information management. It is crucial to establish business processes at the outset. Technology transfer is naturally a long-term prospect, and key information on IP rights and legal agreements must be captured, organized, and maintained for a long time. The life of a patent, for example, may last for up to 20 years. Naturally, so will the license obligations. Moreover, most litigation requiring access to initial documents comes after a successful product is on the market, often several years after patent filing and licensing. Without adequate access to records, patent positions may not be sustainable and income may be lost. To develop business, project and contact information must be captured and shared across the organization, so a CRM (customer relationship management) style of database is desirable. It can be purchased off the shelf or developed internally. Each approach has its own strengths and weaknesses. A number of producers and many TTOs who have tried different systems are happy to share their expertise.

3.4 *Budget*

An office without an appropriate budget will struggle. As described above, technology transfer requires a complex combination of activities and skills. All technology transfer outcomes involve a transaction based on hard or soft IP rights (that is, patent or know-how). Invariably, the transaction will be by way of a legal agreement, which requires legal drafting (or use of template agreements) and negotiation skills. The transaction will have a financial component that must be clearly understood, and it will be based upon IP rights and/or access to resources that will need to be valued and protected. This means that someone must understand what elements can and need to be protected. The drafting and filing of a patent application are best done in conjunction with a patent agent, and there is a requirement for ongoing patent prosecution. All of these activities require funding; however, some costs may be recovered through a business deal or by passing them onto a partner.

3.5 *Business model*

Offices tend to be departments within institutions or subsidiary companies. As a department, the TTO is embedded in the institution and has its interests clearly aligned with institutional objectives. TTO staff will be on par with academic colleagues. Running technology transfer through a subsidiary company, however, may encourage a positive perception of technology transfer and demonstrate the seriousness with which it is viewed by the institution. A subsidiary company gives more operational flexibility and the ability to structure staff remuneration packages. Debates over TTO staff pay and incentives are frequent, and it is increasingly common to award performance-related pay and bonuses for meeting targets. This works well when the targets can be easily defined and measured and when reward is against outcomes rather than activities. However, this reward system skews behavior in favor of reaching those targets, so care needs to be taken to ensure that reward systems are properly cast to promote core business objectives. This is another reason why the TTO should have clear objectives that can be easily communicated to its staff—regardless of whether they are employed by the company or by the university. As a final twist on the internal/external TTO, staff do not necessarily need to be employed by the company; they may be employed by the university (and subjected to the university pay and pension scheme structure) and then seconded to the company.

Chain of command and accountability must be clear. A departmental TTO should report to a senior university staff member. A company will be responsible to a board, which may be chaired by a university senior staff member. In either case, the TTO will be accountable to the university governing body and will be expected to produce at least annual reports of activity. For both types of organizational structure, it will be helpful to have a group of advisors inside and outside of the institution. The advisors can bring new experience to the organization and act as internal and external champions. Advice on the most tax-efficient structures for establishing and running the TTO, for example, may help to determine whether it should be treated as a department or as a separate business. Governance should be considered where a company is formed and may be accomplished by forming a board with nonexecutive directors and/or an advisory board.

A final option is to outsource technology transfer to an independent third party. Outsourcing minimizes investments and the risks for the institution but also reduces the returns to the institution since the partner will take the lion's share of them. Such models are usually predicated upon income, and so the partner will likely pursue activities directed towards high-value, income-generating opportunities rather than technology transfer for the broader public good.

4. TRENDS IN TECHNOLOGY TRANSFER OFFICES

The landscape of technology transfer activity is changing. As Campbell[11] discusses, the United Kingdom is particularly progressive. Universities are creating innovative partnerships and developing expertise in technology transfer to secure financial investment and build future returns. Research funders are looking for initiatives to fill gaps in the technology transfer process.

Sheffield University is an interesting model. It lacked the funding needed to fulfill its technology transfer ambitions, so the director of the TTO set about developing a relationship with external experts, an initiative that led to establishing a separate company: BioFusion PLC (Sheffield, U.K.).[12] With a ten-year exclusive agreement with Sheffield University to commercialize all University-owned medical IP rights, BioFusion is run independently of the University and its TTO. In 2005, BioFusion listed on the Alternative Investment Market (AIM) of the London Stock Exchange, raising UK£8.23 million. The University is one of the shareholders. This funding allows the company to manage and fund both existing and new portfolio companies within the life sciences area. BioFusion has made clear its intention to develop similar relationships within the sector. With the increasing interest in technology transfer as an area for external investment, academic technology transfer companies have been able to secure funding when there is a clear income-generation

model. The most prominent example is Imperial Innovations of Imperial College, London. With a solid track record in commercialization and a robust pipeline of spinout companies, Innovations (and in turn Imperial College) has benefited from private institutional investment and intends to become a publicly listed company. Of course, this model of external funding does not work for all TTOs because it applies only to those organizations with potentially high investment returns. This will not be the case for most technology or knowledge transfer activities because most offices are brokering partnership deals to bring cash to a university for specific research rather than to generate unencumbered income. At Imperial, knowledge transfer and research partnership development has remained within the institution; Innovations concentrates on the cash-generating activities of licensing and spinouts.

5. EXAMPLES OF TECHNOLOGY TRANSFER OFFICE MODELS

At King's College London (KCL), technology and knowledge transfer is managed within one organization, KCL Enterprises Ltd., a wholly owned subsidiary of the university. KCL Enterprises is responsible for new opportunities and research support, which bring all the external business facing and research funding activities together. This combining of functions weaves the activities of the organization together and creates an extended, integrated team. Established 12 years ago, the initial team was a small technology transfer unit of staff specializing in the protection and commercialization of college IP rights. Over time, the research grants and contracts office of the university was incorporated into the organization. The company has since grown to 50 people and now encompasses business development, consultancy, work placement, marketing, technology transfer, spinout company incubation, and research support. The mission of the organization is to leverage the intellectual capital of the university to generate income and benefit society. The business development team underpins the activities of the company; specialist functions take on the leads appropriate to them. Eight business development managers specialize in different sectors and are co-located in both Enterprises and their relevant academic departments. Their objectives include developing collaborative research with business and promoting enterprise within King's and externally. The technology transfer team focuses on the identification, management, and exploitation of IP. They are skilled in patent prosecution, due diligence, and drafting and negotiating license agreements, and are supported by a team dedicated to mentoring and incubating new company spinouts from the university. The expansion of the team has been possible through funding from the university and from government, both of which recognize the increasing importance of the knowledge economy and applied research. Particularly active in promoting knowledge transfer, the U.K. government has established a specific stream of funding, the Higher Education Innovation Fund, which is available to universities within England. This has allowed many universities to develop knowledge transfer capabilities and capacity. It also allows them to take some risks in finding mechanisms to encourage and capture new opportunities at the institutional level.

The government has been keen to encourage development of knowledge transfer through the public sector research establishments within the United Kingdom. An early leader in this sector is Medical Research Council Technology (MRCT), a wholly owned subsidiary of the Medical Research Council (MRC). This technology transfer company grew from a team of four MRC staff in 1990 to a company that currently employs more than 60 people and that this year saw a windfall of over UK£140 million in income from royalty sales. MRCT in many ways is a unique example of technology transfer, but in other ways it points the way for others to follow. MRCT became a separate entity by merging with another applied-research activity of the MRC, thus gaining staff and expanding its technology transfer offerings to include applied-development laboratories. Its expansion was enabled through a record of good work and the vision and support of its parent institution. While the amount of income it generates is unusual, the sources of the income are typical: a suite of related technologies and their various,

carefully crafted exploitation. (This case still supports the general notion—discussed by Scherer and Harhoff[13]—that big wins in commercialization come from only a few deals.) Continuing its expansion into applied research, MRCT has developed new activities to add value and speed the uptake of academic IP. One approach has been to create a drug discovery team that identifies academic IP and develops licensing leads in industry. U.K. funders and international initiatives have also tried to expedite the process. For example, Cancer Research Technology (CRT) has a drug development laboratory, and the Wellcome Trust offers Translational Awards for developing early-stage opportunities into more commercially attractive offerings. International approaches include Medicines for Malaria Ventures, which brings public, private, and philanthropic sector partners together to fund and manage the discovery, development, and registration of new medicines to treat and prevent malaria in disease-endemic countries.

A push for technology transfer in the past ten years has created more than 20 technology transfer offices across Switzerland. To build critical mass, the two universities of Bern and Zürich jointly own a subsidiary nonprofit technology transfer company that they established in1999: Unitechtra. With a staff of seven and serving two other research institutes, Unitechtra has a clear mission to contribute to the economy, facilitate research uptake for the public good, develop mutual beneficial close ties with industry, motivate and retain academic staff, and, ultimately to increase income to the institutes. These objectives are pursued through activities that include the commercialization of research results, the negotiation of research agreements, support for the creation of new spinout companies, and training and education for scientists in the field of technology transfer. As a natural next step in the evolution of Swiss technology transfer, in 2003 the Swiss Technology Transfer Association (swiTT[14]) was formed. A network organization, it aims to bring together TTOs and specialists in the field to improve the provision of services and to share information and resources. The Swiss Network for Innovation (SNI) and the Swiss federal government provide funding to swiTT.

6. CONCLUSION

TTOs can be set up in a variety of ways, but in all cases it is helpful to draw on external skill resources where possible. Possessing clarity of purpose and building the right foundations is essential for planning the operations of the TTO. Making money will always be a consideration when setting objectives, but technology transfer adds value in other important ways: as a resource to facilitate innovation for the public good and as a way to broker the exchange of knowledge between the business and public sectors for society's benefit. Transferring knowledge across such disciplines as the humanities, law, and social sciences is as important as transferring knowledge and technology across the applied sciences, and TTOs should be set up to have the flexibility to accomplish this broader knowledge-transfer objective. ■

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How to Set Up a Technology Transfer System in a Developing Country

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ABSTRACT

This chapter reports the results of a recent study of the current state of technology transfer in Chile, including recommendations for the development of a new technology transfer system. Currently in Chile, few commercially viable technologies are transferred from research institutions to the private sector. This means that many universities should review their role and implement innovative ways of contributing to society.

1. INTRODUCTION

In emerging economies, existing R&D capabilities tend to be highly concentrated within universities and public research institutes. In Chile, about 85% of scientists are formally linked to universities, and the Chilean government contributes an estimated 80% of funds spent on R&D.

In early 2004, the Ministry of the Economy entrusted Fundación Chile, a private, independent, nonprofit research organization located in Santiago, with studying the technology transfer units at Chile's universities.[1] The ministry's aim was to find ways to improve the mechanisms for transferring the results of R&D performed at Chile's universities and research institutes to the private sector. In order to carry out this study, Fundación Chile assembled a team of six local specialists and three foreign experts.[2]

First, Fundación Chile set out to assess the current state of university technology transfer in Chile. Interviews and surveys were conducted at seven universities that together currently conduct 51% of all university research projects in Chile. Surveys were also conducted at four technology transfer offices (TTOs) located within business incubators associated with these universities.

Second, a workshop was held involving specialists from the Ministry of the Economy, CORFO (Corporación de Fomento de la Producción),[3] CONICYT (Comisión Nacional de Investigación Científica y Tecnológica),[4] and the team of experts assembled by Fundación Chile. The first day, the workshop focused on the current condition of technology transfer at universities and research institutes in Chile (see Section 2 in this chapter). The second day, the participants discussed their experiences of technology transfer in other countries. The participants then created guidelines for technology transfer from Chile's universities and research institutes to its commercial sector.

The assessment of Chile's current conditions and the guidelines created by the workshop participants were used to develop a proposal for the creation of a new national technology transfer system (described in Section 3).

Fernandez C. 2007. How to Set Up a Technology Transfer System in a Developing Country. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2. THE CURRENT STATUS OF TECHNOLOGY TRANSFER IN CHILE

2.1 *The role of universities within the national R&D context*

Traditionally, universities have fulfilled two primary societal functions: educating students and conducting research. In recent years, however, universities have had to fulfill an additional function: promoting the commercialization of the results of their research. This expansion has required changes, not only in policy and allocation of resources, but also in academic culture itself.

In an ideal environment, many mechanisms link the academic and business worlds. Researchers exchange information through seminars and publications, and there are informal and formal ties between researchers in various types of institutions. Additionally, academics work as consultants and as company board members and are involved in professional training, contract research, and the spinout and incubation of new businesses. And, of course, universities educate the researchers of the future.

In Chile, however, the lack of systematic policies for technology transfer has hindered productive interaction between the academic and business worlds. This, in turn, has led to other challenges:

- There are few incentives for academic researchers to participate in technology transfer and commercialization.
- Academic culture does not see technology transfer and commercialization as "legitimate" activities.
- The academic and business worlds have different ideas about technology transfer: different short- and long-term visions, different expectations about how resources should be used, and different priorities when it comes to meeting shared targets.

For the past 20 years, Chile's growth has been sustained by industries exploiting the country's rich natural resources. Technology transfer during this period mostly occurred by importing capital and by receiving foreign investment, virtually excluding the local innovation system of Chile. As a result, both the formation of innovative companies and the development of an entrepreneurial culture in Chile were inhibited.

In Chile, around US$480 million is spent annually in R&D; only about one-fifth of this money comes from private sources. Universities carry out some 58% of ongoing R&D projects in Chile; 4,800 specialists—or three out of every five scientists and engineers in Chile—work on such projects. Only 6% of those working in R&D do so in a private company.

Furthermore, no more than 13% of the national budget for R&D goes toward commercial development activities. The rest goes to basic and applied research projects. In contrast, about 60% of the R&D expenditure in developed countries supports development activities, and only 40% goes to basic and applied research.

In a recent study, Benavente[5] suggests that joint activities between universities and the private sector should receive more financing from government and that TTOs should to be established in order to promote the commercial application of university research results.

2.2 *A survey of technology transfer units at universities in Chile*

The results of the surveys conducted by Fundación Chile of seven universities and four technology transfer offices are summarized in the following nine items:

1. **IP-protection activities in universities.** The concept of intellectual property embodies the right of ownership protected by law to intangible (that is, intellectual) works or information, or representations of information such as literary works, trademarks, logos, data, and know-how. In Chile, intellectual property can be protected by patents, copyrights, trademarks, industrial designs, or rights for plant varieties. Like any other goods or assets, intellectual property can be bought, sold, or licensed.

   The surveyed universities were asked what specific IP protection activities (such as signing confidentiality agreements or applying for IP protections) they engaged in each year. Most of these activities involved

agricultural, health, and energy technologies. The total number of such activities for all eleven institutions was fewer than 100. Signing confidentiality agreements accounted for almost half of the activities; filing applications for patents accounted for another quarter. The remaining quarter primarily involved copyright and plant-variety registrations. Only about four confidentiality agreements were signed per institution per year.

2. **Communications between universities and the private sector.** At 73% of the institutions surveyed reported that their technology transfer offices (TTOs) and/or investigators contacted private companies. Other methods of contacting companies included publications and the Internet (55%), fairs and exhibitions (36%), and technology brokers (27%).
3. **Procedures for evaluating potential technologies.** Formal evaluations (those that do not rely solely on the opinions of the research team) are the best way for universities to determine which technologies should be transferred to private companies. However, only one of the seven universities surveyed claimed to have a formal procedure for evaluating technologies. Three of the four TTOs associated with the incubators did have such a procedure.
4. **Policies regarding ownership of research results.** It is important to clearly define who owns the rights to research results. Only three of the seven universities surveyed had a formal institutional policy regarding the ownership of research results. None of the TTOs associated with the incubators had such a policy.
5. **Policies regarding conflicts of interest.** TTOs need to have the resources to manage potential conflicts of interest. Only two of the eleven offices surveyed had a specific policy regarding conflicts of interest.
6. **Distribution of income generated by technology transfers.** On average, the universities distributed revenues from technology transfers as follows:
   - 38% to the researchers
   - 15% to the research units (departments)
   - 18% to the central administration
   - 8% to the technology transfer office
   - 21% to other actors

   The offices associated with incubators distributed revenues as follows:
   - 37% to the research units and to the researchers
   - 12% to the central administration
   - 10% to its own transfer office
   - 41% to other actors
7. **Networks for collaboration.** The surveys reveal that institutions do not collaborate with each other to any appreciable extent. For example, of the universities surveyed only half of them belong to networks with other universities, and only two of them are part of networks with business organizations. Of the offices associated with incubators, only one participates in a network of research centers.
8. **The influence of technology transfer on university researchers' careers.** Four of the seven universities stated that technology transfer has no influence on their researchers' academic careers. Two of the seven noted that successful technology transfer may raise researchers' salaries, and one of the seven reported that it influences promotion decisions. The technology transfer experience of potential candidates for academic jobs has no influence on hiring at any of the seven universities surveyed. Therefore, it is not surprising that 78% of the university investigators participating in Fondef projects consider this fund only as a source of financing for their own projects and Institutions.[6]
9. **Spinouts and startups.** Over the last 19 years, the 11 surveyed technology transfer units have created a total of 28 companies using the results of their institutions' R&D. Of these new companies, two-thirds are spinouts and the rest are start-ups.

   Over 13 years, from 1991 to 2003, Fondef. has financed a total of 159 R&D projects:

- Agriculture 37 projects
- Fisheries and Aquaculture 35 projects
- Forestry 34 projects
- Mining 17 projects
- Education 13 projects
- Other 23 projects

A total of US$126 million was invested in these projects, of which only 28% was contributed, in money or in kind, by companies or other institutions interested in using the technologies produced by these projects.

These 159 projects led to the creation of 33 companies, 13 business units, and 12 new lines of business in existing companies. Two-thirds of these institutions are still operating today. By the end of 2002, these projects had generated an accumulated sales total of US$8.9 million.

These results show that technologies developed by Chilean universities lead to very few start-ups or spinouts.

2.3 *The current state of university technology transfer in Chile*

The existence of TTOs in Chilean universities is a recent phenomenon. The capabilities of these offices are still limited. Generally, they have small staffs. Many have yet to establish essential policies regarding the formal disclosure and evaluation of technologies, the ownership of intellectual property, and conflicts of interest. Most have little experience in such areas as technology management, IP protection, and commercial agreement negotiation.

Academics are not encouraged to engage in or initiate technology transfer to the productive sector. Moreover, very few university projects result in commercially viable innovations, so few technologies leave the universities, and few spinouts or startups are created. Therefore, many universities see little reason to set up technology transfer offices.

3. A PROPOSAL FOR A NATIONAL SYSTEM OF TTOS

The participants in the cross-disciplinary workshop proposed the creation of an institutional consortium, the members of which would share a central TTO. Each institution in the consortium would also have a local TTO to assist in relationships between researchers and private companies, as well as with technology marketing. The consortium would represent the interests of the member institutions and operate with the double aim of improving Chile's technological capabilities and developing a national entrepreneurial culture.

The consortium would be a private, nonprofit organization, governed by a board of directors made up of representatives from the member institutions. These offices would be established using public funds; once they are operational, they would support themselves with fees they earn for the services they provide.

3.1 *A business model for the TTO system*

The central TTO would need to have the capacity to manage 20 to 30 technology transfer projects annually. The TTO system would be involved in these projects from gestation to final commercialization. The system would also be required to participate in the analysis of about a dozen completed Fondef and FDI projects, in order to identify opportunities for the commercialization of the technologies they have developed.

The central TTO system would require an annual budget of approximately US$650,000. The member institutions would make annual contributions based on the volume of research that each has conducted. The TTO would also charge member institutions an *ex ante* fee for each project based on its size and complexity. Furthermore, the TTO system would receive fees from companies that it assists, as well as from other users of its professional services. The institutions belonging to the consortium also would be expected to pay annual dues for the right to participate in the consortium. During the system's first three to five years of operation, any additional financing needed would come from public sources; however, this public subsidy would be granted only if the TTO system continued to receive positive annual performance evaluations. The consortium's board of directors would be responsible for securing outside financing for the TTO system.

The TTO system's financial management would be based on annual accounting (an

examination of the system's total income and expenses) and separate accounting (an examination of the income and expenses relating to each individual project). The following formula for the distribution of royalties is recommended: the university distributes one third of net income to the inventor and another third to the inventor's department or research unit; this formula is aligned with international practices. The remaining third typically goes to the university's general fund, but may go to other specified funds, including the TTO system's own fund. Royalties would be distributed after the end of each fiscal year. General expenses such as salaries, rent, office equipment, and general travel would be paid for by the TTO system's fund. Any project-specific expenses (such as the legal fees involved in a patent prosecution) would be paid for by royalties that accrue from the licensing of the corresponding technology. The board of directors would review this distribution of funds annually and modify it as necessary.

3.2 *Central and Local TTOs*

3.2.1 *Contracts between central and local TTOs*

The central TTO would supervise and work together with each of the local TTOs to protect and market the technologies resulting from R&D conducted at member universities and institutes. The contracts between the central and local TTOs would need to include the following information:

- Policies outlining:
  - the legal supervision of the consortium by consortium members
  - the ownership of intellectual property
  - the distribution of income from the development of intellectual property
  - conflict of interest resolution and what obligations each party has to the others
- terms and conditions for the formal evaluation of inventions with commercial potential
- plans for marketing and licensing the inventions, both domestically and internationally
- plans for a follow-up system to track the success of inventions
- plans to disseminate and communicate the results of the TTO system
- plans to establish national and international strategic alliances in technology development and commercialization

3.2.2 *Function of the central and local TTOs*

The main functions of the *central TTO* would be to:

- evaluate the results of R&D projects expected to have commercial potential
- apply for patents and other forms of IP protection
- market technologies
- provide expertise and technical assistance to the local TTOs
- establish national and international strategic alliances in areas important for successful technology transfer

The main functions of the *local TTOs* would be to:

- facilitate interactions between their institutions and industry (duties would include developing research contracts, identifying collaborative research projects, and consulting)
- educate academic investigators about opportunities and techniques for marketing research results
- stay abreast of new technologies developed at their institutions and identify marketing opportunities for these technologies
- serve as a contact point between the central TTO and the institution
- help researchers gain funding for R&D projects

As the local TTO gains experience and becomes more effective, it may take on other functions, such as offering its services to other institutions (for example, local business incubators) that are not part of the national consortium.

3.3 *Human resources and infrastructure*

A fully functioning TTO system would have the following personnel needs, some of which could be fulfilled by outsourcing, either for the long

term (as would be appropriate for the office's legal experts) or on a short-term basis (as would be appropriate for consultants hired to conduct market studies, for example).

3.3.1 *Central TTO personnel*

The central TTO would need to employ skilled individuals to fill key roles:

Director. The director would need proven leadership skills; excellent ability to create networks and establish alliances; business vision; experience in technology management; knowledge about national and local laws and regulations; and an understanding of the national university system, the national innovation system, and the status of local industry. In addition, the director would need a minimum of ten years' experience in a relevant field, and good written and spoken English.

Program managers. International experts recommend that the central TTO initially be staffed by program managers. This encourages specialization and focused searching. It also takes advantage of the synergies that can be generated via networks. Program managers would need to have within their ranks:

- a Ph.D. in biological sciences and/or biotechnology with both laboratory experience and experience in product development, a minimum of ten years of professional experience, and good written and spoken English
- a Ph.D. in the engineering sciences with broad knowledge of the product development process, at least ten years of professional experience, and good written and spoken English

Project analysts. The central TTO would need at least two economists and/or engineers. They would need to have completed at least some graduate studies, with a minimum of five years of experience in the profession, and good written and spoken English.

3.3.2 *Local TTO personnel*

The local TTOs would need a staff composed of:

- a director or manager
- two or three professionals with graduate degrees, preferably Ph.D.s, with at least five years of professional experience in either biological sciences/biotechnology or engineering
- project analysts

The volume and type of R&D being carried out at each university or institute would determine the size of the office and the discipline(s) in which its staff members would need to specialize.

3.3.3 *Office support staff and infrastructure*

The central and local TTOs would need an administrative and support staff. At minimum, each office would need a computer for each professional, a printer, local and international communications networks, filing space for documents, and the space and equipment to make formal presentations.

3.4 *Policies*

The TTO consortium would design collectively the key policies regarding the technology transfer process, and these policies would form an integral part of the consortium's charter or proposal. They should clearly establish the terms of IP ownership, the distribution of income, and the resolving of conflicts of interest:

Ownership of IP rights. The universities or institutes participating in the technology transfer consortium would need to have uniform guidelines for assigning IP ownership. Uniform practices help to reduce transaction costs, increase transparency, and facilitate utilization of intellectual property protected by third parties. Government agencies could encourage members to agree on common guidelines through "codes of practice" or by making adherence to certain guidelines a requirement for receiving funds from the state.

Distribution of income. Fair distribution of income generated from technology commercialization is common practice around the world, and it is a powerful incentive for the various players in the technology transfer process. There are many options for how to distribute such income, and the options taken would have to depend on institutional and national context.

Resolving conflicts of interest. The consortium members would need to include clear policies and procedures for resolving potential conflicts of interest in the initial proposal for the creation of the technology transfer system.

3.5 *Early phase*

Planners/developers of the TTO consortium would need to consider a few issues early on in the creation of the national system:

- Skills at different levels would need to be developed.
- The concept of the national TTO system would need public support so that the central TTO could assume a leading role by establishing its own trademark.
- Initially, the TTOs could help address their institutions' weakness through training and educational efforts that would provide them with the necessary skills.

4. CONCLUSION

A foundation of innovative technology companies and the development of an entrepreneurial culture will drive the development of new industry and enhance the global competitiveness of Chile's economy. The author believes these goals can be best achieved through a TTO system such as the one proposed in this chapter. Such a system could provide a full range of technology transfer functions for the main universities and research institutes in Chile in the most economically efficient manner. ■

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1 Fundación Chile. 2004. Design of a Model for Technology Transfer Applicable to Chile. The Ministry of Economy sponsored this study.

2 The selection of foreign experts began with a request to the Association of University Technology Managers (AUTM) of which Fundación Chile is a member. AUTM is the leading professional association in technology transfer, with about 3,200 members worldwide. The foreign experts who were chosen have been actively involved in the design and implementation of different transfer offices—in their home countries and abroad: Alan Bennett, Executive Director of the University of California system's Office of Technology Transfer; Niels Reimers, an international consultant and formerly the Director of Stanford University's Office of Technology Licensing; and Pedro Palominos, Director of Spain's Consultoría Tecnológica de Instituto Robotiker. The local team consisted of Eduardo Bitrán, Director General of Fundación Chile; Sergio Burdiles, Project Head in Information Technologies at Fundación Chile; Joaquín Cordua, Manager of Fundación Chile's Human Capital and Information Technologies Area; Carlos Fernández, Head of Regulations for Fundación Chile's Agribusiness Area; Michael Moynihan, Director of Research for Biogenetic S.A.; and Gabriela Paiva, from the law firm Paiva Associates.

3 CORFO is a government organization that promotes the productivity and competitiveness of the Chilean economy. www.corfo.cl/.

4 CONICYT is a government organization that promotes science and technology development. www.conicyt.cl/.

5 www.expansiva.cl.

6 Santibáñez E. 2003. *Intellectual Property, University and Business*. Presentation at the WIPO-ECLAC Regional Expert Meeting on the National System of Innovation: Intellectual Property, Universities and Enterprises. Santiago: Chile.

Practical Considerations for the Establishment of a Technology Transfer Office

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ABSTRACT

The establishment of a technology transfer office (TTO) is a complex undertaking, so it is important to decide—before the office is established—about its operational scope, how the office will be funded, how it will be managed, and for what kind of issues the office should develop a policy. This chapter provides basic information that is indispensable for running effective TTOs. The chapter explains what physical and human infrastructures are needed, outlines the responsibilities and powers of TTOs, emphasizes the importance of technology evaluation, and stresses the centrality of good communication and negotiation skills.

1. INTRODUCTION

The last decade has seen tremendous growth in the use of IP (intellectual property) protection in business ventures, particularly those concerning biotechnology. As a result, more and more institutions are establishing technology transfer offices (TTOs) to assist in the legal transfer of technology. These offices serve a variety of functions, such as evaluating research results in regard to potential commercialization, advising on IP protection, filing and prosecuting patent applications, assisting in funding issues, conducting feasibility studies, and so on.

Starting a TTO is a complex and costly endeavor. The project must receive the support of administrators and scientists, and it must get off to a dynamic, effective start and focus on those who will use it. First impressions count.

It is important to define the TTO's scope of operations—as well as how it will be funded and managed—from the outset. Because several years can pass before any revenues or royalties would be collected from IP transfers, the office has to operate with the highest possible efficiency. Success or failure will depend mostly on the human resources and physical infrastructure available to the office.

2. PHYSICAL INFRASTRUCTURE

The location of the TTO is critical. An office that is located close to the scientists' workplace is most efficient and the proximity will help to establish cooperation and trust between the scientist/researchers and the TTO staff. Most TTOs start in either a research office or an administration building.

Elements of physical infrastructure that might be required include but are not limited to:

- **office space** (presumably either leased or rented). In cases of universities, locating the office on campus may make it easier for scientists to contact the TTO; on the other hand, an off-campus location might better serve potential licensees. Such factors as the need for confidentiality, meeting rooms, and so on, should be take into consideration.

Dodds J and S Somersalo. 2007. Practical Considerations for the Establishment of a Technology Transfer Office. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

- **office furniture**, including desks, chairs, filing cabinets, conference tables, decoration, carpets, and so on. If budgets are very tight, acquiring salvaged or second-hand furniture can save money.
- **computer systems**, including PCs, printers, cameras, speakers, and so on. A high-speed modem or DSL line is critical.
- **phone equipment** able to handle conference calls, call transfers, and voice mail.
- **a photocopier**. If budgets are tight, selecting a small copier or a second-hand machine can save money. Remember that photocopiers are notorious for frequent and inconvenient breakdowns.
- **general office supplies**, including pencils, pens, paper and staples. Keep a good office-supplies catalog handy. Every office needs a good coffee and tea service; guests appreciate this simple, yet thoughtful, form of hospitality.
- **a library** of limited scope. It is useful to have a few key handbooks, such as *Black's Law Dictionary*[1] and *McCarthy's Desk Encyclopedia of IP*.[2] CD-based IP manuals can be handy references as well as being easy to use and to store; a computer could be dedicated for utilizing this resource.
- **online legal databases**, both paid-service (such as LexisNexis®[3] and WestLaw®[4]) and others that are free of charge.[5]
- **various software packages**. A standard office package should be adequate, at least at first. It must contain anti-virus, firewall protection, and disk-maintenance software.

3. HUMAN INFRASTRUCTURE AND TALENTS

Human infrastructure is even more important than physical infrastructure. A TTO needs to have employees with expertise in intellectual property, business, law, contracting, and negotiation. People will be needed to fill the following positions to operate a typical TTO:

- office director (usually a scientist with extensive business experience rather than a lawyer)
- administrative assistant
- licensing specialist
- attorney (either in-house or contracted from outside)
- students (often local law students)

A TTO's daily operations touch on a number of different fields. An office should therefore have access to external specialists for advice: an advisory panel, hired consultants, or colleagues. The types of specialists that are needed usually include, but are not limited to:

- patent attorneys or patent agents (depending on the field of invention)
- general legal counsel
- licensing specialists
- marketing specialists
- database specialists
- drawing and design specialists

One of the most important skills relates to communication and negotiation. An office director should possess these communication and negotiation skills:

- good interpersonal skills (especially important when interacting with inventors)
- good interaction skills for dealing with entrepreneurs in the private sector, the public sector, and small and large businesses
- good spoken and written language skills
- formal experience in negotiation

4. THE SCOPE OF THE OFFICE

With the goal of providing comprehensive IP services as effectively as possible, the responsibilities and powers of the TTO should be established at the outset.

4.1 *Patenting and other protections*

Patenting work may involve searching, freedom to operate, filing, maintenance, and so on. If patenting is a key duty of your office, it may be worthwhile to consider hiring a patent agent. Either way, it is essential to have a clear understanding of the various protection options including:

- utility or design patents
- filing a national patent application

- filing in foreign countries
- filing provisional patent applications to get initial protection and later filing non-provisional, national or even international applications under the Patent Cooperation Treaty (PCT).

Offices may need to consider the options case by case with each invention or the office may have a default process for most invention disclosures. Some offices, for example, file a relatively cheap provisional patent application in the United States, in each case, and then market the technology for the year that the provisional patent is valid, before spending more money on patent prosecution. If it seems that there are interested licensees, you may then file national or international applications. This is, of course, only one strategy among many.

The TTO should also consider the role of *trademarks* and *service marks* in its operation. Product branding is a very important element of global marketing, but trademark protection is often underused. It may be wise even to protect the mark of the TTO itself. Copyrights are a very simple and cheap form of protection for books, papers, and databases; the latter is becoming common in genomics as a cost-effective form of IP coverage. Trade secrets are the cheapest form of coverage: they are free! Of course, relying on only trade secret protections, a TTO runs the risk that someone will reverse-engineer and IP-protect the invention so the TTO cannot use it!

4.2 *Policy development*

It is important to have an internal office policy that addresses the following questions:

- How will licensing revenues be shared?
- Can the office accept equity in a company as part of licensing-related transactions?
- Should the office represent competing technologies?

A TTO must develop a system for identifying and dealing with possible conflicts of interest and questions of ethics. For example, it will need to anticipate such questions as should a staff member be allowed to license an invention to a company for whom he or she works as a consultant? TTOs should consider assembling an ethics and conflicts panel to regularly review office actions.

A policy development document should guide the institution in developing its own IP policies.

4.3 *Licensing*

Licensing is the heart, the essence, indeed the very bread and butter of a TTO. Remember that the flow of information and materials is two-way: some staff will access the IP of others through license agreements, and the TTO will be licensing its technologies through license agreements.

4.4 *Invention marketing*

Great technologies do not sell themselves. TTOs need good marketers and should pay them on a contingency basis. Do not underestimate the role of the inventors in identifying potential licensees.

4.5 *Negotiations support*

Negotiation is an art form that takes skill, practice, patience, and sharp wits. TTO personnel should consider taking courses to improve their negotiating skills. Alternatively, the TTO can hire negotiating experts. Whatever is done, TTOs should watch out for legal loopholes.

4.6 *Technology evaluation and assessment*

One of the challenges facing any TTO, especially at the beginning, is deciding which inventions to protect, and to what extent. No office has the resources to patent all inventions, especially if they are not likely to generate revenue for some time. As a rule of thumb, ten invention disclosures may lead to one patent, and one license might come from ten patents. In other words, only 10% of patents provide royalties. It is critical, therefore, that the TTO invest in only those inventions that are both truly innovative and appear to have commercial value. Remember that some great scientific advances cannot be marketed. At the same time, some simple inventions have huge commercial value.

TTOs usually have an internal committee that reviews invention disclosures for commercial viability and gives feedback to inventors. If the TTO manager needs to tell a scientist that

his or her invention will not be patented, good communication skills are critical. Obviously, the manager does not want to discourage an inventor from coming forward again in the future with another idea that may be commercially viable.

As a result, TTO staff should be prepared to spend time, effort, and money when deciding what to protect. The decisions should be influenced by a product's market potential—not by the excellence of the science behind it nor the desires of the inventor. Remember, the goal is not simply to patent inventions but to strategically patent inventions with commercial potential.

The TTO director must make sure he or she is fully aware of the TTOs legal rights before starting the negotiating process. It would be unfortunate to invest in a technology and later find out it cannot be licensed.

4.7 *Monitoring royalty incomes and potential licensing infringements*

Once a technology has been licensed, the TTO has to make sure that the licensee pays the royalties it has agreed to. The licensing agreement should give the licensor (the TTO) the right to audit the licensee, and this right should be exercised.[6]

The office must also monitor potential licensing infringements. This is not an easy task: the office may have to monitor companies that are using competing technologies, as well as minor distributors who might sell patented products out of ignorance.

4.8 *A note on confidentiality*

The nature of the IP business means that all employees of a TTO must observe strict confidentiality and always adhere to office policy on such matters as conflict of interest. These considerations should be taken into account during the hiring process, and the office's operations should always be fully documented.

5. EXPENSES

The costs of evaluating, protecting, and maintaining IP coverage are substantial and might include the following:

- patent and trademark search fees
- patent and trademark filing fees
- PVP fees
- maintenance fees
- copyright filing fees
- issue fees
- attorneys' fees
- drafting fees

In the United States, the cost of a trademark (including attorneys' fees) is approximately US$1,200–2,000. A provisional patent application costs US$2,500–8,000, and a nonprovisional application costs US$6,000–30,000. The cost of filing and maintaining a patent globally is approximately US$500,000. The TTO director must keep in mind that the filing of an international patent will make it necessary to use the services of a translator and that translation fees add up fast.

6. KEEPING UP TO DATE

It is important for the TTO to keep a close eye on developments in technology and markets. In order to stay informed, TTO employees should be active members of professional associations, such as the Association of University Technology Managers (AUTM) and the Biotechnology Industry Organization (BIO).

Another aspect of keeping up to date relates to obligations with contracts and agreements. Producing and reviewing contracts and agreements is a large part of the work of the TTO manager. Therefore, it is important to establish a portfolio of standard contract and agreement templates that can be customized as needed.

It is often tempting to cut costs by using standardized forms and agreements. However, it is important to note that such standardized documents are rarely drafted in favor of the person initiating the deal. If standard forms and agreements are used, a lawyer should review the final versions and point out any specific clauses that need to be further negotiated.

7. OFFICE ORGANIZATION

A number of organizational matters need to be addressed in the early stages of the establishment

of the TTO. These include creating a staffing plan and an employment handbook, incorporating (if necessary), and establishing procedures for handling federal and state filing requirements, taxes, and payroll.

- **staffing plan**. A coordinated and coherent staffing plan should provide details of lines of authority, job descriptions, and work plans for each day. Early planning will prevent future headaches.
- **employment handbook**. The staff employment handbook must state the company's policies regarding confidentiality, ethics, and conflicts of interest, among other topics.
- **procedures for federal and state filing requirements**. The local representative of the Secretary of State may be able to provide assistance with filing such documents as work permits, pension plans, occupancy permits, fire inspection permits, and so on.
- **plan for incorporation**. The office may wish to (or need to) become an independent legal entity. In the United States, such independent offices (often called research corporations) have charitable, or "501(c)(3)," tax status.
- **tax strategy**. It is money well spent for a TTO to hire a good accountant and a good audit firm.
- **payroll plan**. The TTO director must remain aware of federal and state tax policies. It is wise to hire a good accountant and a good audit firm to oversee such matters.

12. CONCLUSIONS

A TTO serves many masters and has a range of different functions. An effective and efficient office needs employees with good business, legal, technical, and contracting skills. And it is important to establish the office's scope and to develop a comprehensive office policy as soon as possible.

This chapter provides only a basic template for a TTO. Naturally, each office will have unique needs that will need to be addressed—creativity and a good team spirit will make it much easier to do so. ■

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1 Gardner BA, ed. 1999. *Black's Law Dictionary*. West Group, St. Paul, MN.

2 McCarthy JT, RE Schechter and DJ Franklyn. 2004. *McCarthy's Desk Encyclopedia of Intellectual Property*, 3rd edition. The Bureau of National Affairs: Washington, DC.

3 www.lexis.com.

4 www.westlaw.com.

5 See also, in this *Handbook*, chapter 14.3 by H Thangaraj, RH Potter and A Krattiger.

6 See also in this *Handbook*, chapter 15.1 by HH Feindt.

Administration of a Large Technology Transfer Office

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ABSTRACT

This chapter describes the organizational management of a technology transfer and licensing office based on the experience of Stanford University's Office of Technology Licensing (OTL). It consists of a director, seven licensing associates, eight licensing liaisons, one copyright licensing specialist, and an administration staff. The administrative staff comprises an assistant to the director, an administrative services manager, a manager of information systems, receptionist(s), a manager of compliance and assistant, and an accountant and assistant. The industrial contracts office is part of OTL and consists of a manager and three associates.

1. BACKGROUND

The mission of the Stanford University Office of Technology Licensing (OTL) is to promote the transfer of Stanford University's technology for society's use and benefit, while generating unrestricted income to support research and education. Thus, the primary focus of OTL has not been to maximize income generation, but to facilitate putting into use for society's benefit the innovations developed at Stanford University.

In the early years, staffing levels were kept very low to control total expenses. There were only two people on staff for the first five years of operation. A third person was added in FY 1974–75 and total staffing was three people for the next six years. Today, the OTL has the following employee composition:[1]

- director (1)
- assistant to the director (1)
- licensing associate I (0)
- licensing associate II (1)
- licensing associate III (6)
- marketing, software and copyright specialist (1)
- licensing liaison I (0)
- licensing liaison II (8)
- administrative services manager (1)
- administrative support personnel (7)

The benefits to Stanford resulting from the formation and operation of the OTL have been many. Although it took many years for substantial net revenues to be obtained, at the end of FY 2005–06, the OTL had received total revenues of US$1 billion and had total operating expenses of US$45 million. In its 36 years of operation, the OTL has contributed US$591 million to Stanford and its inventors

2. PERSONNEL ISSUES

Reporting to the director are the licensing associates, administrative services manager, marketing,

Hines S. 2007. Administration of a Large Technology Transfer Office. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Second Edition, Part II: Chapter 3).

software and copyright specialist, manager of compliance, accountant, manager of the industrial contracts office, and the director's assistant. Each of the licensing liaisons supports one licensing associate; the liaisons report directly to the associates. The manager of information systems reports to a senior licensing associate. The receptionists report to the administrative services manager.

Professional staff are divided into licensing liaison and licensing associate positions (Table 1), whereas Figure 1 shows the organigramm. Complete job descriptions are provided in Box 1, at the end of this chapter.

2.1 *Licensing associates*

Each licensing associate has a specific area of expertise (see OTL Web site[2]). Many of the Stanford licensing associates have been recommended to OTL by other universities or individuals in the field. There are no lawyers in the licensing associate category.

- *The technology licensing associate I* handles routine cases (with supervision) and participates in the negotiation and preparation of more complex cases. Some experience in at least one of the following is necessary: licensing, negotiation/contracts, marketing, or patents.
- *The technology licensing associate II* handles a variety of complex cases and requires a high degree of technical and business expertise, a familiarity with the legal issues involved, and at least four years of applicable experience.

Table 1: Main Professional Licensing Positions

Position	Job Description (corresponding appendix)
Licensing liaison I	Direction from supervisor, assist with marketing, routine amendments, patent prosecution, database management; position is 75% clerical
Licensing liaison II	With some supervision, market new inventions, including carrying out market research and preparing abstracts; docket administration; coordinate and monitor patent activities; inventor meeting scheduling; handle administrative/clerical responsibilities in support of licensing associate
Licensing associate I	Evaluate and handle licensing with respect to standard and nonstandard cases with some guidance
Licensing associate II	Evaluate and handle licensing with respect to nonstandard cases with independence; take appropriate, independent action in a majority of situations
Licensing associate III	Evaluate and handle independently the licensing of complex cases; appropriately handle a variety of IP

Note: Standard cases involve nonexclusive licenses and template-type agreements. Nonstandard cases require creativity in resolving issues. Complex cases require unusual creativity in resolving new issues.

See also Box 1 at the end of this chapter for job descriptions.

- *The technology licensing associate III* is reserved for individuals handling major cases where licensing potential is estimated to be in the millions of dollars. Because of the magnitude of the cases, the work has a significant impact on the university and involves much coordination and complex decision making. Eleven or more years of applicable experience and/or two years of experience at the OTL are required. After an individual has been with the office for five years (and has reached the associate III level), he/she has the privilege of using the title senior associate.

2.2 *Licensing liaisons*

Stanford OTL has two levels of licensing liaisons. The licensing liaison I level requires more direction from the licensing associate than the licensing liaison II level. There are many ways to find good people. Probably the best ways are referrals, ads on various Web sites, and through licensing organizations such as the Association of University Technology Managers and the Licensing Executives Society.

3. CONCLUSIONS AND THE NEED FOR SOPS

Running and administering a technology transfer and licensing office is a challenging task from many perspectives, ranging from policy to strategy. As Nelsen[3] describes them, one of the key aspects are rigorous, consistent, and authoritative administrative approaches and procedures. This chapter described the approach of one entity, Stanford University's OTL.

It is important to keep yearly statistics about the office and collect them in a database for analyzing the progress of the office and for use by other entities. Such data for Stanford University's OTL are published annually and are available on the OTL Web site.[4]

Finally, in order to ensure smooth operations, each member of the staff of the office is trained in and has access to the Standard Operating Procedures (SOP's) through the OTL Intranet. These SOP's consist of step-by-step instructions about procedures for handling various documents. Two sample SOPs are included in Box 2. It is important to note, however, that the SOPs are evolving, and each tech transfer office should develop its own operating procedures, adjusted to institutional policies and the prevailing administrative procedures. ■

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1 The information provided here is current as of the publication date. As with any technology transfer office, structure, job descriptions and responsibilities, and the number of persons employed change over time.

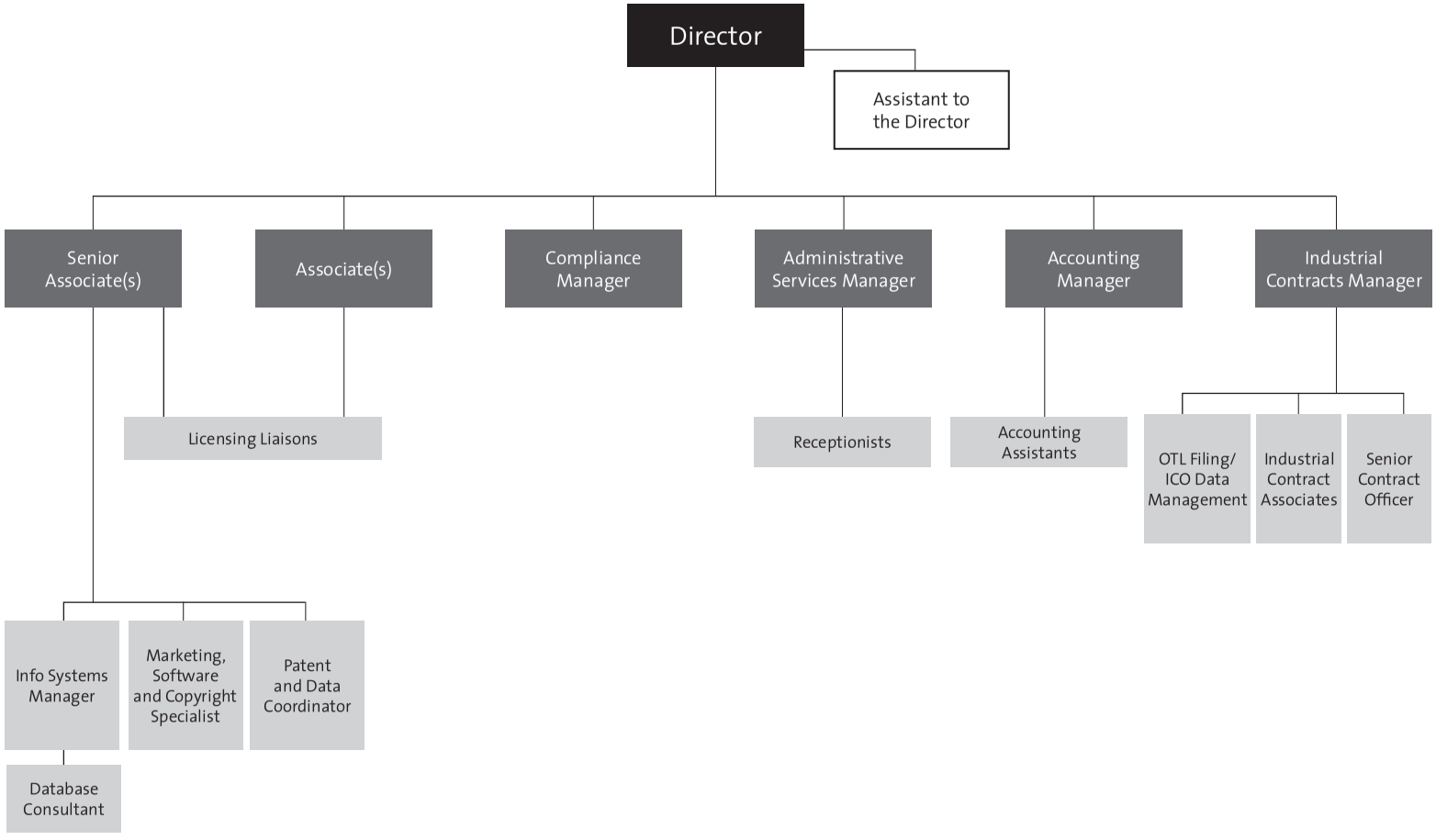
2 otl.stanford.edu.

3 See, also in this *Handbook*, chapter 6.1 by L Nelsen, which provides relevant information for heads of research institutes and research hospitals, whether private or government supported.

4 otl.stanford.edu/about/resources.html.

5 Note that SOPs are rarely shared with third parties because they are highly specific for the particular institution and environment in which an office operates.

Figure 1: Oranigramm of Stanford University's Office of Technology Licensing



Box 1: OTL Licensing Job Descriptions

Technology licensing associate I

The Licensing Associate works with the inventors (Stanford professors, graduate students, and research staff) and with prospective licensees. The Licensing Associate evaluates, obtains proprietary protection, markets, and negotiates the terms and conditions of the licensing agreement with industry.

The Licensing Associate I typically performs the following functions:

- Evaluation and analysis of new invention disclosures (initial review; meeting with inventor(s); identify industry reviewers; make contact, send materials, follow-up; collect and evaluate information; and make decisions and provide necessary notifications)
- Licensing (Develop licensing strategy; identify potential licensees; negotiate terms; prepare draft agreements; and close the deal)
- Patent-related activities (selection of attorney; make decisions regarding when and where to file patent applications; and manage inventory of unlicensed cases from a financial perspective)
- License Agreement Monitoring/Relations with Licensees (ensure compliance with diligence terms; prepare and execute amendments; process terminations; and hold meetings with licensees to monitor progress in Licensed Product(s) development)
- Professional Development (participate in professional associations; attend association conferences; and take training classes)

The Licensing Associate I level handles (with supervision) standard and nonstandard cases, where agreements tend to be modifications of established patterns. The Licensing Associate also participates in the negotiation and preparation of more complex cases.

Some experience is necessary in at least one of the following: licensing, negotiation/contracts, marketing, and patents. Approximately four years of work experience is preferable. A minimum of a BS/BA degree in a science or engineering field—or equivalent applicable experience—is required.

Technology licensing associate II

The Licensing Associate works with the inventors (Stanford professors, graduate students, and research staff) and with prospective licensees. The Licensing Associate evaluates, obtains proprietary protection, markets and negotiates the terms and conditions of the licensing agreement with industry.

The Licensing Associate II typically performs the following functions:

- Evaluation and analysis of new invention disclosures (initial review; meeting with inventor(s); identify industry reviewers; make contact, send materials, follow-up; collect and evaluate information; and make decisions and provide necessary notifications).
- Licensing (develop licensing strategy, identify potential licensees, negotiate terms, prepare draft agreements, and close the deal.

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Box 1 (continued)

- Patent related activities (selection of attorney; make decisions regarding when and where to file patent applications; and manage inventory of unlicensed cases from a financial perspective)

- License Agreement Monitoring/Relations with Licensees (ensure compliance with diligence terms; prepare and execute amendments; process terminations; and hold meetings with licensees to monitor progress in Licensed Product(s) development)

- Professional Development (participate in professional associations; attend association conferences; and take training classes)

The Licensing Associate II independently handles a variety of nonstandard cases and would be considered an experienced professional. These positions require a high degree of technical and business expertise, a familiarity with the legal issues involved, and approximately four years of applicable experience (for example, scientific, research, marketing, business development, patents, and licensing). A minimum of a BS/BA degree in a science or engineering field is required.

The Licensing Associate II is a position in which qualified professionals may enhance their career experience and move up the OTL career development ladder to a Licensing Associate III. The Licensing Associate II must be able to participate as a member of the OTL team, while continually assuming increased responsibility and independence.

Technology licensing associate III

The Licensing Associate works with the inventors (Stanford professors, graduate students, and research staff) and with prospective licensees. The Licensing Associate evaluates, obtains proprietary protection, markets and, negotiates the terms and conditions of the licensing agreement with industry.

The Licensing Associate III typically performs the following functions:

- Evaluation and analysis of new invention disclosures (initial review; meeting with inventor(s); identify industry reviewers; make contact, send materials, follow-up; collect and evaluate information; and make decisions and provide necessary notifications)

- Licensing (Develop licensing strategy; identify potential licensees; negotiate terms; prepare draft agreements; and close the deal)

- Patent-related activities (selection of attorney; make decisions regarding when and where to file patent applications; and manage inventory of unlicensed cases from a financial perspective)

- License Agreement Monitoring/Relations with Licensees (ensure compliance with diligence terms; prepare and execute amendments; process terminations; and hold meetings with licensees to monitor progress in Licensed Product(s) development)

- Professional Development (participate in professional associations; attend association conferences; and take training classes)

The Licensing Associate III level would be reserved for individuals handling major cases (for example, Cohen/Boyer or FM Sound) where licensing potential is estimated to be in the millions

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Box 1 (continued)

of dollars. Because of the magnitude of these cases, the work has significant impact on the University and involves much coordination and complex decision making (for example, participating in decisions on whether to pursue major litigation).

In order to qualify for the level of Licensing Associate III, an individual is required to have 11 or more years of applicable experience and/or two years of experience at the Office of Technology Licensing.

A Complex Case has one or more of the following attributes:

- Requires exceptional good judgment and special attention because of the following: exceptional number of patent applications/patents involved; the level of royalty revenue (potential or actual); and/or the number of licensees involved
- Involved in litigation in which Stanford is either responsible or intimately involved and where Stanford's involvement presents a significant liability or revenue opportunity for Stanford
- New and complex intellectual property issues are involved in the licensing such that creative solutions must be developed
- The case has either the potential to generate $3–5 million or costs $1 million (in litigation costs or claims against Stanford) or has a major impact to OTL's licensing program

Examples of complex cases include:

- Sondius Program: the technology consists of a portfolio of patents, trademarks, copyrighted works; licensees include a start-up, major corporation, and other companies, and the licensed fields of use are varied; the revenue potential is considered significant; Stanford invested significant resources into the development of the technology; the potential of litigation is relatively high.
- ARIM Portfolio: involves 20 patents and copyrighted technologies licensed exclusively and nonexclusively to many companies; licensing strategy is to make the technology broadly available while encouraging investment in the technology.
- Phycobiliprotein: Complicated license strategy (exclusive license to two companies, converting one of these two licenses to a nonexclusive); sued one licensee; generating over $3 million/year in royalties with the extensive management and monitoring of the licensees because the chain of distribution is often unclear; auditing; each license is separately and individually negotiated.

The Licensing Associate must have demonstrated exceptional good judgment, breadth of knowledge of patents, copyrights, and trademarks, and the ability to independently resolve complex issues and deal with unusually difficult situations. The Associate must use exceptional creativity in structuring win-win licenses in difficult and complex cases. Typically, complex cases present issues that have not been dealt with in the past and, therefore, require particularly creative solutions.

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Box 1 (continued)

Licensing liaison I

With close supervision from Licensing Associate:

- Assist in the marketing of inventions to industry, including identifying potential licensees, initiating contact, preparing and distributing promotional materials
- Research library and computer database resources to identify potential licensees in the invention field of use
- Help monitor performance of licensees to ensure diligence provisions are met
- Prepare routine amendments to agreements, give notice and process termination of agreements when required
- Assist in the coordination and monitoring of patent filing and prosecution
- Prepare financial and status reports and complete other tasks in the analysis and marketing of inventions as assigned and designated by Licensing Associate
- Keep highly organized and indexed files (both paper and computer database) to track evaluation, patenting, marketing, and maintenance functions for inventions
- Extensive database management including entry of information on new inventions, keeping people, company records, and patent information up to date, and entry of license agreement data
- Prepare and sign own correspondence whenever possible, and prepare correspondence for associate's signature

General:
Assist with general office-support tasks as needed for the efficient operation of the office. It would be expected that 75% time would be devoted to clerical duties.

Qualifications:
College level training highly desirable, preferably in science or engineering. Demonstrated strong oral and written communication skills. Ability to take initiative, to prioritize workload, and to work independently. Exceptional organizational and analytical skills. Attention to detail. Interest/experience desirable in technical marketing. Ability to use PCs, familiarity with databases (preferably 4th Dimension) and software programs Microsoft Word and Microsoft Excel.

Licensing liaison II

With some supervision from Associate, Licensing Liaison is responsible for marketing and invention management assistance. The Licensing Liaison will work with the Licensing Associate (with some supervision and good judgment on the part of the Licensing Liaison):

- Marketing, including identifying potential licensees through market research, initiating contact, preparing and distributing promotional materials

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Box 1 (continued)

- Market research using library and computer database resources
- Preparation of invention abstracts for database
- License Agreement monitoring ensuring compliance with diligence provisions and financial terms of the agreement
- Patent-related activities including coordinating and monitoring patent filings and prosecution. Coordination of inventor signatures on documents and licensee input
- Responsible for all sponsor compliance ensuring that all regulations and obligations are fulfilled
- Prepare financial and status reports and complete other tasks in the analysis and marketing of inventions as assigned and designated by Licensing Associate
- Preparation and execution of royalty sharing and nondisclosure agreements
- Processing of dropped cases and follow through
- Secondary administrative support and database entry for Associate
- Keep highly organized and indexed files (both paper and computer database) to track evaluation, patenting, marketing, and maintenance functions for inventions.
- Schedule inventor meetings
- Assist with general support tasks, including reception, as needed for the efficient operation of the office. This position will have administrative/clerical responsibilities in support of licensing associate

Qualifications:
No licensing experience is required, but at least three years of experience as a paralegal or other relevant experience is preferred. BS/BA strongly preferred. Experience with intellectual property preferred. Ability to take initiative, to prioritize workload, follow-up consistently, and work independently. Good communication skills (oral and written) important. Exceptional organizational skills and attention to detail required. Experience with databases, word processing, and spreadsheet software required.

Box 2: Standard Operating procedures[5]

List of SOPs

Invention Disclosures
Conceptual Disclosures
Preliminary Disclosure Information Entered into Database
Disclosure Notification of Government and Other Sponsors
Associate Docket Review

Royalty-Sharing Agreements (RSA)
Prepare Royalty-Sharing Agreement
Copy Distribution
Enter RSA Data into Database

Compliance—Government and Other Sponsors
Government Sponsors
Disclosure Notification of Government Sponsors
Transmit Compliance Information to the Government
Copy Distribution
Corporate and Other Sponsors
Disclosure Notification of Corporate and Other Sponsors
Transmit Compliance Information to Corporate and Other Sponsors
Copy Distribution

Processing Patents
Patent Application
Patent Prosecution
Newly Issued Patents
Patent Maintenance
Patent Abandonment/Expiration

Marketing
Decision to Market
Develop Non-Confidential Abstract
Develop List of Companies
Marketing Letter—Have Inventors Review/Comment

Confidential Disclosure Agreements (CDA)
Send Two Original CDAs to Potential Licensee(s) for Signature
File Stanford's Original Agreement

License Agreements
Negotiate the Terms of the Agreement with Potential Licensee(s)
Agreement Signature Procedure
Enter License and License Terms into Database
Copy Distribution
License Agreement Process
Amendments
Terminated-Agreements Process

Equity
Receiving Stock Certificates from Company

(Continued on Next Page)

BOX 2 (CONTINUED)

Tabled Dockets
Assess whether Invention Belongs in "The Pound"
Steps for Sending Invention to "The Pound"
Consider Re-Marketing While in "The Pound"
To Remove from "The Pound"

Terminated Agreements
Letter to Terminate Received/Issued
Update "Terminated" Safe Documents
Termination-Letter Distribution

Dropped Dockets
Decision to Drop a Docket

Off-Site Storage
Files to Be Archived for First Time
Files to Be Re-filed at Off-Site Storage
Miscellaneous Documents to Be Archived

General Administrative Filing
Outgoing Correspondence
General Filing

SAMPLE SOPS FOR LICENSE AGREEMENTS[4]

1 **Negotiate the terms of the agreement with potential licensee** ..... Associate

A Royalty-Sharing Agreement should be completed when a patent is filed or when a license negotiation is initiated.

(See also Exhibit L, titled 1st Licensee Meeting Checklist and Exhibit M, titled Parameters of an Exclusive License Agreement [not included in the *Handbook*].)

1.1 Term Sheet ..... Associate/Team

Associate and Team determine the desired:
- financial terms
- BATNA (Best Alternative to No Agreement)
- walk-away conditions for the agreement
- type of license (non-exclusive, field exclusive, or exclusive)

Associate either generates a term sheet (See Terms Sheet example [not included in the *Handbook*]) or requests a proposal from a licensee. For all field and fully exclusive licenses, Associate receives a development plan from licensee.

Associate and company representative agree on financial terms.

(CONTINUED ON NEXT PAGE)

Box 2 (continued)

1.2 License Agreement ..... Associate

Once term sheet is agreed upon, enter financial terms, and docket-specific information, into standard License Agreement (see standard document license agreements on OTL Intranet; not included here). Utilize clauses library and input from Team as needed. Keep Director informed, particularly if the license contains nonstandard provisions.

1.3 Conflict of Interest Review ..... Associate

Prepare Conflict of Interest Memo if inventor has a financial stake in the company or other relationships with the company, including:

- has equity
- is or will be a consultant
- is or will be on the Scientific Advisory Board
- is or will have sponsored research or collaboration with company

a. Ask inventor to send their COI memo to Deans describing relationship with company and how any potential conflict of interest would be managed. Suggest inventor check out the COI Web site of their respective institution (for Stanford University, see www.stanford.edu/dept/DoR/ad_hoc.html). ..... Associate

b. Obtain approval required by School Dean and Dean of Research before signing the Agreement. ..... Associate Tracks

2. **Agreement Signature Procedure**

Signature order not critical; if OTL signs first, include a deadline for the agreement to be returned.

2.1 Director reviews and approves final draft of agreement. ..... Director

2.2 Prepare two original agreements for execution. ..... Liaison

2.3 Licensee signs (preferably first). ..... Licensee

2.4 Director signs for OTL. ..... Director

2.5 Return one original to Licensee. .....Associate/Liaison

3. **Enter license and license terms into the database .....** Liaison/Associate
Be sure to add all necessary information, including:

- To License record
  - All standard fields
  - Equity (if applicable)
  - Office of Scientific Research funds (if applicable)
  - Corporate contact
  - Entity size
  - License-specific notes

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Box 2 (continued)

- To License Terms:
  - All royalty terms
  - Progress report terms and
  - Diligence terms or reminders to self

4. **Copy Distribution .....Receptionist**
   - Original to SAFE file
   - Routing copy, which is routed to:
     1. OTL Accounting; then
     2. OTL staff; then
     3. Receptionist for scanning
   - Personal copy to Associate (Associate should notify receptionist if he/she already has a personal copy).

5. **Processing and filing Stanford's original agreement**

   5.1 After license terms entered: ..... Associate

   - If license issue fee was received, forward check to OTL Accounting for processing.
   - If license issue fee was not yet received, have OTL Accounting send invoice to Licensee.

   5.2 Notify inventors of license agreement, verify their address and update 4D. ..... Associate/Liaison

   5.3 If inventor requests a copy of the license agreement and there are no confidentiality provisions in the agreement that prevent this: ..... Associate/Liaison

   - The inventor must sign and return an Inventor Confidential Disclosure Agreement.
   - File original inventor CDA in SAFE and stamp "CONFIDENTIAL" on the copy of the agreement before sending it to the inventor.

   5.4 When licensed, notify patent attorney to: ..... Liaison
   - Pay large entity fees.
   - cc licensee on correspondence with the patent office (for exclusive licensees only).

6. **Amendments**
   Amend for "minor" changes; rewrite agreement if major changes.

   6.1 Prepare up to two amendments per agreement, rewrite agreement thereafter. .....Associate/Liaison

   6.2 Associate and team determine desired terms and conditions. .....Associate/Liaison

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Box 2 (continued)

6.3 Follow same signature procedures for original agreements (see Section 2, above) .....Associate/Liaison

6.4 Update 4D license and license terms, if necessary. .....Associate/Liaison

6.5 Original Amendment filed in SAFE; Associate keeps a personal copy. .....Associate/Liaison

7. **Terminated-agreements process** ..... Associate

(See SOP section "Terminated Agreements" for further instructions [not included in the *Handbook*].)

Sample SOPs for Invention Disclosures

1. OTL/Associate receives new paper disclosure..... Associate/Liaison
(for online disclosures, go to 3)

Give disclosure to Director.
(See http://otl.stanford.edu/inventors/resources/disclosure.pdf)

2. Preliminary disclosure information entered in database .....Director

2.1 Assign docket number, associate initials and title.....Director

2.2 Give copy of disclosure to Front Desk. ..... Assistant to the Director

2.3 Create correspondence folder and give folder to Associate. ..... Front Desk
Give copy of disclosure to Compliance Manager.
(See SOP section "General Administrative Filing" [not included in the *Handbook*].)

2.4 Review, sign and witness disclosure, then give it to Liaison for processing.....Associate

2.5 Enter all remaining information from invention disclosure form into database, including each inventor's:
- Name
- Addresses
- E-mail address
- Phone number
- Fax number
- Department (please verify using Stanford Directory) .....Liaison

Also check each Database box that corresponds to a special affiliation or situation (e.g., HHMI or SRC).

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Box 2 (continued)

2.6 If invention is sponsored, and sponsor is already listed in the database: enter sponsor name and contract number in the sponsor portion of the docket screen. ..... Liaison

If no sponsor or "None" listed: double check with the inventor.

If an inventor is an HHMI employee: HHMI should be included as a sponsor.

If an inventor is a VA employee: VA should be included as a sponsor. (See SOP section "Compliance: Government & Other Sponsors" [not included in the *Handbook*].)

2.7 If sponsor not already in database, obtain copy of any nonfederal sponsored agreement from Industrial Contracts Office, Office of Sponsored Research, or inventor and put agreement in file. Then enter sponsor information/terms into database. Verify sponsor requirements and communicate them to Compliance Manager as needed. (See SOP section "Compliance: Government & Other Sponsors" [not included in the *Handbook*].) ..... Liaison

3. **OTL receives new online disclosure, and Database notifies Director** ..... Director

3.1 Director assigns docket to Associate and generates database e-mail to Associate/Liaison team. ..... Director

3.2 Print out attachment(s) included with Director's e-mail, if any, for correspondence file ..... Liaison

3.3 Review disclosure (found in the Database Disclosures view):
- Add/update inventor and sponsor information in Database, as needed
- If no sponsor or "None" listed: double check with inventor
- If inventor is a Howard Hughes Medical Institute employee: HHMI should be listed as a sponsor
- If inventor is a Veteran's Administration employee: VA should be listed as a sponsor
- Approve docket and generate database e-mail to director
- Print out disclosure

3.4 Director creates docket and sends 4D e-mail to Associate/Liaison team. ..... Director

3.5 Once docket number has been assigned by Director, write docket number in upper right-hand corner of printed disclosure and give original disclosure (with printouts of attachment(s), if any) to Front Desk to create correspondence folder. ..... Liaison

3.6 Database notifies Compliance Manager of new disclosure ..... Database

4. **OTL notifies government and other sponsors of Stanford's action on the disclosure** (See SOP section "Compliance: Government & Other Sponsors" [not included in the *Handbook*].) ..... Compliance Manager

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Box 2 (continued)

5. Associate docket review

5.1 Read disclosure and arrange to meet with Inventor(s) within 1 month. .....Associate

Have the disclosure signed by inventor(s), witness, and Associate.

If there was a material transfer agreement (MTA): copy the MTA from Industrial Contracts Office files and review for any IP requirements.

Confirm whether inventor(s) plan to publish or present, including online.

Enter status note (in Database Notes view) that describes inventor meeting and docket evaluation.

(See also Exhibit B: 1st Inventor Meeting Checklist; [not included in the *Handbook*].)

5.2 Evaluate disclosure for patentability and commercial potential. Evaluation may include input from:
- Biological or Physical Sciences Team
- Patent attorneys
- Industry contacts
- Technical Experts (for example other faculty, Niodesign Network)
- Full marketing ..... Associate/Team

5.3 If not provided with disclosure, obtain marketing abstract information from inventor or create marketing abstract..... Associate/Liaison
(See Exhibit D: Marketing Abstract [not included in the *Handbook*].)

5.4 Enter following information into database (these should be updated if there was an online disclosure):
- Abstract
- Applications
- Advantages
- Publications
- Stage of Development
- Continuing Research
- Links to lab Web site
- Status
- Action
- Categories
- Bio/PhySci
- EPIC if applicable
- Patent Bar date..... Associate/Liaison

5.5 Make preliminary domestic/foreign filing decision—defer if more research required ..... Associate/Team

5.6 Send out standard royalty sharing agreement (RSA) memo if:
- Invention is being marketed
- Patent application is filed
- RSA not needed if invention is being dropped prior to marketing.....Liaison

(See SOP Section "Royalty Sharing Agreements" [not included in the *Handbook*].)

Training Staff in IP Management

SIBONGILE PEFILE, *Group Manager, R&D Outcomes, Council for Scientific and Industrial Research (CSIR), South Africa*
ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University, Chair, bioDevelopments-International Institute, and Adjunct Professor, Cornell University, U.S.A.*

ABSTRACT

This chapter provides an overview of training opportunities that developing country institutions can explore to start to address problems related to a smooth implementation and execution of all intellectual property-related aspects (policy, management, procedures, and so forth). The chapter offers to institutions guidelines for evaluating training needs and reviews different kinds of training programs, identifying the pros and cons of each. IP management training is a long-term investment, but a cost-effective one, leading to better utilization of third-party IP resources, more effective internal IP management policies and procedures, and higher efficiency in regard to out-licensing and partnership development. The chapter emphasizes the importance of strategic and practical training programs related to participants' responsibilities within an organization. Finally, multidimensional case studies are provided to illustrate the myriad issues that may arise with respect to the management of intellectual property.

1. INTRODUCTION

Whether technology comprises new products and services, or improvements of existing ones, and whether it is simple or sophisticated, technology is an important contributor to socio-economic development. The processes by which knowledge and technology are transferred ensure that technologies can be applied in virtually all industry sectors. But technology and knowledge transfer capabilities in developing countries are not meeting local needs for socio-economic development and for driving progress in such critical industry sectors as health and agriculture. Despite an active research environment, developing countries have been less effective in exploiting research outputs, especially intellectual property. Institutions in developing countries face numerous problems in managing their own intellectual property.[1] These include a limited understanding of the IP system and how it can be applied in the public sector research environment, a low appreciation of the benefits that can be derived from managing institutional intellectual property, and inadequate human and financial resource capacity to invest in institutional IP management policies and resources.

In IP management, the importance of practical training events cannot be overemphasized. For this reason, we have included, at the end of this chapter, a few brief case studies that can be used for training purposes (Box 1 at the end of this chapter). These case studies will allow the participants to play roles (that is, role-play situations that arise in the day-to-day management of intellectual property) and, most importantly, will allow participants to see how their specific roles in real life affect (directly or indirectly) deal-making activities. Even for those who are not involved in deal-making, this practical approach is especially useful as it enables participants to view their respective tasks in broader contexts and thus better understand their roles and responsibilities, as well as their importance in the process.

Pefile S and A Krattiger. 2007. Training Staff in IP Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2. A STRATEGY FOR IP MANAGEMENT CAPACITY BUILDING

2.1 *Analyze institutional goals*

Deciding upon a program to build IP management capacity begins with a thorough analysis of institutional goals, recent policy changes, and required adjustments in the institutional strategy, with respect to IP management. Institutional capacity in IP management means a range of things: including clear and transparent policies (conflict of interest, licensing, patent, and so forth); established procedures (for example, for incoming and outgoing materials, laboratory notebooks); and people at nearly every level of the organization being well informed on how the procedures work, and why. It is essential to identify weaknesses and strengths of the IP management system within an institution in order to take better advantage of existing organizational structures. This means identifying where the weakest links are. A training program then will assist staff in better understanding and helping the institution to achieve its goals.

2.2 *Identify training needs*

The next step is to identify the competencies required to accomplish the overall goals. This requires an analysis of the required proficiencies, existing deficiencies, and the causes of the deficiencies. In general, the training requirements of staff members are summarized in Table 1. In order to ascertain specific needs, the following question should be answered:

- What knowledge and skills are required for optimal operation of the IP office and therefore required among IP management staff?
- What IP-related knowledge and skills are required for the research staff?
- What are the communication gaps with respect to intellectual property both within the institution and with third parties?
- What are the particular elements of the IP policy that seem least well understood and implemented?
- What resources are required to bring knowledge and skills to the required levels?

Information on training needs can be gathered in various ways:

- **interviews.** one-on-one or group format; face-to-face or by phone; formal interviews and off-the-record discussions
- **focus groups.** conversations among teams of workers from across the organization
- **questionnaires and surveys.** anonymous or not
- **document analysis.** a study of policies, strategies, and management procedures (for example, employment agreements, grant documents, and other contracts)
- **observation**.

2.3 *Develop strategies to achieve training goals*

Ranking the training goals and determining how to meet the highest-priority training needs is difficult. A well-developed plan should have specific and realistic objectives, include measurable and achievable outcomes, schedule clear time frames for all activities, and should undergo regular monitoring and evaluation.[2] Of course, different people have different understandings, vested interests, and preferences, so a lot of soft negotiation will be required. It may be helpful to work with a third-party training provider who, if they understand the organization, can take a more objective view and assist in better designing the training program to meet institutional goals.

3. IP TRAINING PROGRAMS

Initially, individuals interested in IP training were limited to a small collection of course offerings available through staff members of organizations that, due to their practical experience in the field, were able to share their know-how. But intellectual property as a field of study is growing in importance as institutions value it more and more. In addition to the essential practical training offered by institutions such as the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), formal training in IP management is also available from

Table 1: Generalized Training Needs of Different Staff Groups

Group	Training requirement (minimum)
Researchers	• maintaining good laboratory records • a basic understanding of the types of IP agreements, especially in the context of exchanging research material and information • the importance of confidentiality, especially with respect to publishing and delivering academic presentations • when to disclose intellectual property to the relevant office • institutional IP policy guidelines and procedures
Research managers and institution directors	• the importance of IP management and management functions • IP protection processes and procedures; the investments required to manage intellectual property effectively (include key decisions required at different stages of intellectual property and research development) • implementing IP policies, processes, and procedures • an appreciation of the role of technology in addressing socio-economic needs
IP managers	• overview of IP management from the generation of intellectual property to its exploitation and application • awareness building • understanding of science (some domain understanding of certain fields of science an added benefit)
Operations	finance • understanding of IP policy guidelines, namely, systems and processes to handle IP payments and receipts, for example, royalties; the administration of benefits to researchers and the institution human resources • IP policy guidelines and interface with other institutional policies such as, conditions of service, recruitment, conflicts of interest and commitment, contracting with clients, and so on legal services • IP policy guidelines • IP contracts and agreements • What is intellectual property; and the different forms of IP protection • IP negotiation grant and contract research • IP contracts and agreements, especially clauses regarding IP ownership • IP policy guidelines

MIHR.[3] The online version of this *Handbook* will list many other such programs and places.

IP training opportunities can be divided into two distinct disciplines: law and IP management, which includes deal making as the central focus.

3.1 *IP law*

Although most training programs begin by covering IP law, it is more appropriate to present this topic at the end of the course. A brief overview at the beginning might be appropriate, but placing emphasis on it at the beginning diverts attention from the more important issues, namely what an institution is doing with its intellectual property and with the intellectual property of third parties. Therefore, a training program really ought to begin with the central issue, which is deal making for most institutions.

IP law is concerned with statutory regimes for the legal protection of IP rights. IP law studies normally include:

- **patent law**. the study of patents for inventions, including international and regional treaties that form part of an international legal framework in patent law
- **copyright law**. the study of principles and standards of protection under national and international copyright and related rights treaties
- **trademark law**. the study of legal provisions relating to trademarks in national, international, and regional IP treaties
- **industrial design law**. the study of laws pertaining to the registration and protection of original and innovative designs. (In some countries, design patents go under different names, such as "utility model" in France and the law for "minor inventions" in Australia.)

Other training opportunities exist in areas such as:

- legal aspects of traditional knowledge and biodiversity
- legal aspects of electronic commerce

Many law faculties offer training for becoming a patent lawyer. Typically, patent lawyers are responsible primarily for preparing and prosecuting patent applications, conducting patent searches, patent infringement and litigation, and preparing and filing applications for patent and other IP protection. During the course of performing these duties, patent lawyers are required to communicate with counsel and guide clients on legal issues in this field.

3.2 *IP management*

On the other hand, IP management courses train individuals to become IP practitioners. An IP practitioner may not necessarily have formal education or training related to intellectual property but would have work experience and some informal training in the field. IP management is the convergence of basic IP law, business and research management, and institutional policy administration. IP practitioners need to know the IP field well enough to make appropriate strategic and management decisions about the protection and exploitation of institutional intellectual property. Furthermore, IP practitioners are expected to: develop institutional IP policy, advise on when, where, what, why, and how to protect intellectual property; identify useful intellectual property from their institutions; establish institutional systems and processes to manage intellectual property; assess the value of intellectual property; report on IP activities; and build awareness of the importance of intellectual property within the research community. Essentially, the IP practitioner serves as a bridge between science and the outside world. Such an individual should know, therefore, how to articulate issues effectively to different stakeholders and when to seek professional counsel for highly technical matters.

3.3 *IP law vs. IP management training*

Important issues to consider when deciding on which type of IP training program would be appropriate for staff members include:

- **training costs.** It is important that the institution receive value for its training investment.
- **duration of training.** Legal training in IP law takes several years; short courses in IP management take weeks or months.

- **institutional needs.** While it is not unheard of for IP lawyers to be involved in IP management activities, normally, these lawyers are focused on legal issues. Institutions can outsource legal functions to local law firms. Depending on the type and volume of work, institutions need to determine whether their IP managers require a legal qualification in addition to the scientific and research management background that most IP practitioners possess.
- **access to and availability of training opportunities.** Unless an institution organizes an internal IP training program, the institution often relies on the training schedules of other programs. Some training opportunities may take place at awkward times in the organization's business cycle. Furthermore, it can be exceedingly costly for developing country institutions to fund individuals to attend a one- or two-day training course overseas as is often the case with such IP training programs.
- **size of institution and volume of IP activity.** Large institutions with a significant, growing IP portfolio may need an IP lawyer in addition to an IP manager. For most institutions, however, an IP practitioner may be adequate.

3.4 *Training locations*

A growing number of IP training programs are available on the market. The list of programs below is by no means exhaustive; an Internet search of the topic will certainly yield many more results.

3.4.1 *IP law*

Degree programs or courses in IP law are offered by numerous universities in both developing and developed countries. The World Intellectual Property Organization (WIPO), along with the University of South Africa (UNISA) offer a distance-learning course in IP law.

3.4.2 *IP management*

Highly regarded IP management courses are offered by:

- MIHR[4]
- AUTM (The Association of University Technology Transfer Managers)[5]
- NTTC (National Technology Transfer Center)[6]
- WIPO Worldwide Academy[7]
- NIH (United States National Institutes of Health) Office of Technology Transfer[8]
- PIIPA (Public Interest Intellectual Property Advisors, Inc.)[9]

3.5 *Designing training programs*

A training strategy should begin with a clear mission and provide measurable training objectives through which progress can be monitored. The training program should facilitate the achievement of the institution's goals for promoting and commercializing products that emerge from research.

Training-program development can be broken down into ten essential steps as illustrated in Figure 1. Note that training is a continuous and iterative process.

3.6 *Elements of a good training program*

Given the many different types of training programs available, how does one distinguish good training opportunities from those with little value? Key considerations to bear in mind when planning an IP training program include:

- **relevance to practical issues.** For example, whereas for lawyers, the course may well center around the law, in most cases emphasis on legal aspects, especially patent law, for IP management practitioners is too strong. Rather, equal emphasis should be placed on deal making, which should run like a thread through training programs for technology transfer managers.
- **reputation of trainers and programs.** Over the years, certain programs have built a good track record and are often recommended by former course participants. It is useful to seek the views of past trainees and trainers about courses attended and the value derived from those course.
- **qualifications and experience of trainers.** Some training programs provide a biogra-

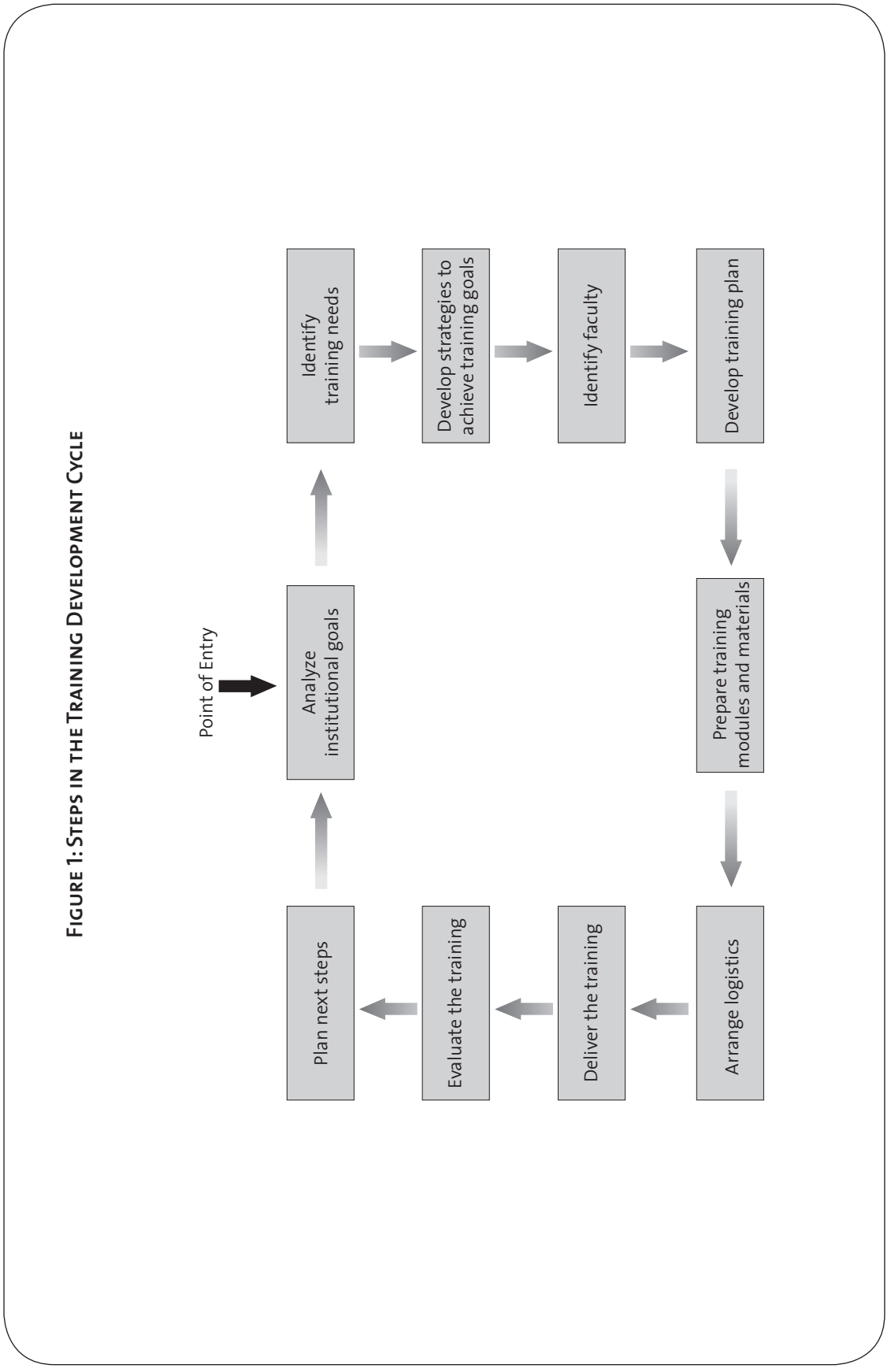

Figure 1: Steps in the Training Development Cycle

phy of trainers and presenters. The biographies provide useful information about the trainer's knowledge and expertise in the field, as well as experience in providing training to a given audience.

- **training topics and relevance.** It is possible to rapidly appraise the usefulness of the training opportunity by carefully examining the training subject matter. To maximize the benefit of the training opportunity, course content should be current, provide new knowledge, and show relevance to the training needs of the selected audience.
- **method of instruction.** To ensure effective learning, training should incorporate different methods of instruction. Lecturing is the most common form of instruction (although this may not be the most effective). Demonstrations, group discussions, role-playing, and simulations are other methods of instruction that can be used to maximize the training opportunity and maintain the audience's interest. Programs that use different instruction methods and a mix of student-teacher interactions tend to be the most effective and offer the greatest benefit to the trainee.
- **training environment.** The location and environment of the training site is of major importance to the trainee and the trainer. The training environment should not interfere negatively with the learning process. Venues and facilities need to be easily accessible and conducive to learning. Without a suitable setting, the training will be compromised.
- **training schedule and session plans.** A well-designed session plan will focus on topics that the audience needs to know. Session objectives should be clearly stated, the target audience identified, and the schedule should communicate the method and content of presentations and the time available for questions and discussion. A detailed analysis of the training schedule ahead of time will reveal whether or not the program is well planned and inform choices about which training programs to invest time and money in.
- **training material.** The merit of a course can be evaluated based on the quality and relevance of training material offered prior, during, and after the event. Pre-training material is important for introducing the topic and preparing the trainee. Post-training material should reinforce the training and provide trainees with reference material that will be useful for applying the new knowledge.
- **post-training support.** Support after the training event is important. In most cases, the real training takes place in the work environment, which is where the learning can be applied and utilized. Trainees may not always be certain of themselves; when it is possible for trainees to ask questions and reaffirm learning, the chances of applying the new learning successfully are greater.

Different forms of training programs exist, and some programs will be more valuable than others; if possible, trainees should experience a range of opportunities. Post-training reports should not only detail the outcomes of a given training program but also explain how the training experience will change work practice. The measures that management can use to monitor development should be clear. The institution paying for the training should be able to measure the outcomes of the training experience. Long-term outcomes should address the competency gaps identified in the needs analysis and should be evaluated using measurable indicators. Long-term outcome measures would include:

- increased research outputs
- more efficient resources utilized for IP management activities
- improved financial performance of the organization
- portfolio performance

Short-term outcome measures include:[10]

- improvements in skills performance
- improvements in the efficiency of conducting procedures and tasks

- showing an understanding and appreciation of performing tasks in a prescribed way

Table 2 introduces the different types of training and examines the pros and cons of each form. Box 2 presents an outline of a workshop plan.

4. CONCLUSIONS

The chapter provided an overview of training opportunities that can enable developing-country institutions—or indeed institutions anywhere in the world—to strengthen staff competencies and thus build internal IP management capacity. The chapter offers to institutions guidelines for evaluating training needs and reviews different kinds of training programs, identifying the pros and cons of each.

The adage "reading is learning, seeing is believing, and doing is knowing" is particularly appropriate in the context of training and capacity building. Accompanying this chapter are several case studies for short courses, each presenting a different challenging IP management scenario. Case studies give trainees opportunities to envision how a technology transfer project might be carried out.

Finally, a detailed workshop plan that provides comprehensive steps is important. Such an IP management training course so that it can then be successfully implemented, while engaging, educating, and motivating participants. ■

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1 CIPR. 2002. *Integrating Intellectual Property Rights and Development Policy*. DFiD: London. www.iprcommission.org/papers/pdfs/final_report/Ch7final.pdf.

2 OPM. 2006. *Guidelines for Conducting Diversity Training*. Office of Personnel Management: Washington, DC. www.opm.gov/hrd/lead/Policy/divers97.asp.

3 www.mihr.org.

4 *Ibid.*

5 www.autm.net.

6 www.nttc.edu/services/training.asp.

7 www.wipo.int/academy/en/index.html.

8 tttraining.od.nih.gov/.

9 www.piipa.org.

10 Boydell T and M Leary. 2001. *Identifying Training Needs*. Chartered Institute of Personnel and Development: London. pp. 8–10.

11 Although the case studies are based on real occurrences, the scenario has been adapted to protect the privacy of all organizations and individuals involved.

Table 2: Pros and Cons of Different Types of Training Programs

Type of training	Pros	Cons
Short courses	• trainee not absent from work for extended periods • training opportunity focused and aimed at professional development • can be inexpensive • teaching specifically targeted to adult learners • possible to be selective and choose only the most relevant training courses	• no formally recognized qualification • course content shallow • course coverage possibly unfocused • value of learning experience dependent on the extent to which the trainee can apply the new knowledge
Full-time courses	• often leads to a formal qualification • course content detailed and the learning intense • direct access to training material, lecturers, and other resources • better opportunity for trainee to build lasting networks • greater chances that trainee will complete course within the stipulated period	• trainee absent for a longer period • training might be costly • not all of the course content relevant to the institution's current needs
Part-time courses	• trainee not away for extended periods • learning in segmented modules enabling trainee to apply new knowledge in a more structured manner	• overall training period possibly longer than full-time course • overall cost of releasing trainee from work not necessarily cheaper • possibility that trainee may take longer to complete course due to flexibilities built into the course
Distance learning	• flexible learning schedule • trainee can be situated anywhere • training material is normally in a form that makes it readily available for future reference • trainee may not necessarily need time off work	• need for good time-management skills and the discipline to study • trainers and training resources less accessible • coursework coincident with full-time employment

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Table 2 (continued)

Type of training	Pros	Cons
Internship	• can be customized for the individual • practical experience • greater exposure for trainees through secondments to different organizations • training in depth and teacher/trainee exchange better, resulting in a potentially better cost benefit to the institution supporting the training • overall training experience typically varied with broader exposure	• may necessitate extended absence • can be costly • no formal qualification obtained
Internal training	• training customized and contextualized • greater control over course content • training intense and in depth • can be structured to cater to the different needs of different groupings within the research community • greater number of individuals can be exposed to a single training episode • assists with creating an internal culture of learning and understanding intellectual property • helps to develop institutional IP networks and systems • post-training assistance is normally available	• the institution must pay unless training is funded • for the duration of the course, productivity may be lower • institutions need to be involved in the planning and implementation of the event; in some cases, institution may need to assign staff member to assist with training arrangements

Box 1 : Case Studies for Use in Training

EYEBORN™ ORBITAL IMPLANT

Your local research and technology institute (RTI), in collaboration with a clinical research organization (CRO), a group of surgeons and the local university, have developed an orbital implant to replace eyes lost due to disease or injury. The Eyeborn™ implant is to be launched as a commercial product at the next International Ophthalmology Conference. The central aim of the project, supported by an angel investor, is to develop an improved and more cost-effective orbital implant. The hydroxyapatite material from which the implant is made, allows tissue and blood vessels to grow into the porous ceramic. Since the eye muscles are attached to the orbital implant, mobility of the implant is synchronized with that of the normal eye. Once a polymer prosthesis, or cap, with artwork of an iris and a pupil is placed over the implant, it is often difficult to discern a difference in the eyes in appearance and movement. This means patients who receive an implant appear to have normal ocular function. Presently, your product offers a more affordable, high-quality alternative to existing implants. It will benefit a larger percentage of the poor population, and, because of the lower cost, will be more accessible to government hospitals and clinics. Presently at government hospitals, patients that have lost an eye are given either a silicon eyeball or nothing at all.

Background

- A local patent has been granted for the eye orbital.
- There is a patent application for the orbital eye inserter.
- RTI owns the intellectual property.
- You have approached a local company to do the manufacturing.
- You would like to sell the product nationally and internationally.
- You would like to ensure that the product is available at an affordable price at all local public health facilities.
- You have a three-year window of opportunity to get your product on the market and to secure a sustainable market position.

Tasks

- Determine whether or not you will file international patents, stating where, how and why.
- Determine how benefits will be shared with the consortium of researchers.
- Identify any other forms of IP you may consider protecting.
- Summarize what commercialization vehicle you will use and why.
- Identify your key partners to help you get the product on the market.
- List agreements you require with your partners.
- Describe your business model for supplying private *and* public sector health facilities.

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Box 1 (continued)

THE SMART-LOCK SAFETY SYRINGE

The Smart-Lock Safety Syringe provides improved protection against needle stick injury and contamination. The device has an added benefit of being easier to use and providing more accurate measuring.

Background

- The Smart-lock Safety Syringe technology is a new disclosure by your institution's researchers.
- A prototype has been developed.
- The market for syringes in your country is highly competitive and saturated. While there are no Smart-Lock Safety Syringes on the market, there are many different other types of syringes available.
- You have been promised significant distribution opportunities for your product in francophone Africa, provided you establish a factory in one of the countries. Most countries in this region have weak IP protection systems.
- To manufacture the Smart-Lock Safety Syringe is a highly technical process; the know-how or the process resides with the small group of researchers at your institution.

Tasks

- Develop an IP protection strategy for the Smart-Lock Safety Syringe detailing:
  - whether or not you wish to protect your intellectual property (if not, go to the next task); if so:
    - where to protect the intellectual property (taking into consideration national, regional, and international patent systems)
    - when to start applying for IP protection

- Given your answers to the questions above, develop a business plan that details how you intend to exploit your intellectual property . In the summary of the plan, address the following issues:
  - partnerships and partnership agreement conditions
  - other agreements required
  - technology and knowledge transfer arrangements
  - your business model

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Box 1 (continued)

AVENGING MONTEZUMA'S REVENGE!

The purpose of this case study is to consider basic strategies related to the building of public–private partnerships, the pooling of resources, building on comparative advantages, and achieving the dual goals of social needs and commercial objectives. Specifically, trainees will be addressing the issues of licensing across public and private sectors that are attempting to meet needs in developed and developing countries.

In this case study, trainees are encouraged to develop creative ways in which public and private sectors can combine their resources, segment markets, and address the specific needs of different constituencies (developed and developing countries).

Background

Viajes BioTech Inc.[11] is a small biopharmaceutical company in North America, founded by Jose (Pepe) Herrera, a Mexican immigrant to the U.S. Prior to establishing the company, Pepe worked for his mother's travel agency while he was studying for his doctorate degree at the Autonomous University of Cancun, Mexico, and visited all corners of the world. During these times, he often had intestinal discomfort and returned with diarrheal diseases. His doctoral thesis focused on such diseases, and he collected many *Escherichia coli* specimens from around the world. After making good money during the dot-com boom, he set up Viajes BioTech Inc. in San Diego, United States, to build on his Ph.D. research with the primary purpose of alleviating the suffering of the many millions of travelers to the developing world.

The Research To-Date

E. coli heat-labile enterotoxin (LT) is composed of catalytic A and noncatalytic homo-pentameric B subunits and causes diarrheal disease in humans and animals. In order to produce a nontoxic LT for vaccine and adjuvant development, two novel derivatives of LT were constructed by a site-directed mutagenesis of A subunit; Ser63 to Tyr63 in LTS63Y and Glu110, Glu112 were deleted in LT delta 110/112. Mice immunized with the purified mutant LTs (mLTs) either intragastrically or intranasally elicited high titers of LT-specific serum and mucosal antibodies. These results indicate that substitution of Ser63 to Tyr63 or deletion of Glu110 and Glu112 eliminate the toxicity of LT and both mutants are immunogenic to LT itself. Therefore, both mLTs may be used to develop novel antidiarrheal vaccines against enterotoxigenic *E. coli*.

Note that the particular strain used in this research originated from a sample collected from a *campesino* at a clinic in Pepe's grandparents' hometown, Chulula, outside San Cristobal de las Casas in the State of Chiapas. Whenever he visited his family at Christmas and Easter, Pepe would spend a few days helping in a clinic in that village. Campesinos are generally poor farm laborers.

Business Model of Viajes BioTech Inc.

The company focuses on the development and commercialization of a vaccine for diarrheal diseases that occur predominantly in developing countries but that have a significant market in developed countries among travelers for both business and leisure.

Viajes Biotech Inc. counts some 50 highly trained staff and has laboratories able to produce nonGMP pilot lots of the vaccine but has no clinics or production facilities.

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Box 1 (continued)

The company owns the key intellectual property for the vaccine in the form of a single dominating patent (but a series of *continuations in part* are still at the patent office in the United States). Pepe still has another two months to file for (PCT Patent Cooperation Treaty) applications in foreign jurisdictions, having marked all possible boxes in the application. Money, however, is relatively tight, and it is not clear whether the expense is warranted.

Because the infections are extremely rare in most developed countries, it is difficult to test the vaccine in those countries. Thus Viajes BioTech Inc. is seeking a partner in the developing world to assist in the clinical trials. Pepe, having lived the first 25 years of his life in Mexico, also wants to find a way to extend the benefits of the vaccine to people in the developing world.

During his recent vacation trip over Christmas to the South African vineyards, Pepe visited a former fellow student of his, Koreen Ramessar, who works on muscular dystrophy at the Department of Human Genetics at the University of Cape Town medical school. Koreen heard of the advances her classmate had made with his vaccine and introduced him to the director of IIMR, the International Institute of Medical Research in Colombo, Sri Lanka. The current director, D.C. Mokhobo, is originally from Cape Town and was visiting her family over the festive season.

Pepe and Dr. Mokhobo of IIMR had dinner just before New Year's Eve and agreed, in principle, on a joint effort to develop the vaccine further whereby Viajes BioTech would focus on introducing the vaccine into developed countries, and IIMR, through appropriate partnerships, would focus on developing countries.

The International Institute of Medical Research, IIMR

IIMR is an autonomous international nonprofit organization headquartered in Colombo, Sri Lanka. It maintains a network of laboratories and research centers hosted by a series of leading research institutions across the developing world. The institute also carries out research, teaching and training in its facilities. The entity does not have its own clinics but arranges for clinical studies through collaborating centers in developing countries.

Tasks

General

To develop a framework agreement between a public (IIMR) and a private entity (Viajes BioTech Inc), sketching the outline of a business plan, with particular focus on the IP strategy, incorporating all the available tools, as appropriate.

The Teams

Pepe and Dr. Mokhobo each requested the relevant people in their institutions to work out the details on how the scheme could be made to work to benefit both parties. Two teams were created:

- One team represents the business development and marketing side of Viajes BioTech Inc.
- Another team represents the R&D program of IIMR and also includes the deputy director for International Cooperation.

The Specifics

First, meet in your own team for 60 minutes to determine the issues that need to be addressed. Specifically, think of the ***needs*** of your entity to ensure that the primary policy of the entity is

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Box 1 (continued)

respected in the deal. Also think of the needs of the other party. For example, Viajes BioTech must find a way of making a return on its investment. IIMD, on the other hand, does not sell things and will need to think of marketing alliances and licensing, as well as obtaining the funding to conduct the work.

Second, the teams meet together and compare ideas, issues, and approaches. Note that this is *not* primarily a negotiating exercise. Begin by developing the overall business plan for how the vaccine would be tested and commercialized, both in the developing and developed worlds. Then develop a coherent IP strategy that reinforces the business plan.

Remember that your bosses have made the policy decision, in principle, to get this venture going. Your task is to flesh out the framework for how it could work in practice. Hence the other party is not a hostile team but, essentially, in the same boat as you are. Also, you are not required to develop a detailed investment plan with cash flow and royalty rates; rather, the principles of the deal are to be developed.

The Assumptions

- The time required to develop the vaccine for clinical trials is 9 months.
- Clinical trials will take two years to complete if all goes well.
- The cost for clinical trials across five countries is estimated to be US$20 million.
- The cost of production for 1 million units is US$10 million. That cost could be reduced to US$5 million if produced in a high quality laboratory in India. Note that these costs do not include marketing and distribution costs, commissions, advertising, and so forth.
- The total market in the United States, Europe, and Japan for business and leisure travelers is estimated by Viajes BioTech Inc. to be approx. five million units per year in the first five years, increasing to 15 million units per year thereafter. Viajes BioTech Inc. estimates that travelers are willing to pay up to US$25 per shot/unit.
- The total market in the major cities in Asia, Africa, and Latin America is estimated to be at least 100 million units per year.
- Viajes BioTech Inc. already invested US$7.5 million in the vaccine. The next round of financing will be launched in three months and the company needs to show a sound business plan and potential for significant profits, if it is to convince its current and prospective new investors of putting up an additional US$30 million or so over the next three years.

The Report to Your Bosses

Specific issues you should address in your report (in the form of a slide presentation lasting no more than 10 minutes), should include:

- Who supplies the vaccine for clinical trials?
- In which countries outside the U.S.A. should Viajes BioTech Inc. file for patent protection? Remember that each such filing will cost some US$25,000 including translation and filing fees.
- What other form of IP protection should be sought? When, where, and why?
- Who is liable for untoward events with the vaccine in clinical trials?
- Who should own potential new intellectual property generated from the clinical trials conducted by IIMR?
- Means by which the vaccine could be (1) produced, (2) marketed, and (3) sold in the developing world.
- How will you deal with third-party technologies that may have to be licensed-in for the production of the vaccine?

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Box 1 (continued)

- Are there any issues of compensating Mexico for use of the *E. coli* strain that led to the vaccine? If so, what might they be and how could they be resolved?
- Prior review of the labeling of the vaccine for sale in any market. Include an explanation of why there should be review.

Additional Considerations

- Should your group require specific technical, strategic, and legal advice, it can be made available for a limited time. However, the external advisors will only respond to well-formulated and relatively specific questions.
- Invent whatever additional information you feel you may need, but be sure to specify such assumptions (amount of capital needed, types of IP protection sought and obtained, terms of the commercial licenses required, the way that regulatory issues are addressed, and so on). Make reasonable assumptions, given the milieu of your activities.

Box 2: Sample Workshop Plan

Objectives

- To provide quality training for sustainable knowledge and skills transfer in intellectual property management.
- To develop appropriate skills for identifying, protecting, developing, valuing, and commercializing research resources.
- To develop knowledge and skills in strategic IP management, focusing on the fundamentals of IP rights: licensing issues and negotiating joint venture agreements that seek to enhance the availability of research results for health products.

Workshop emphasis

The workshop will focus on providing participants basic/intermediate/ advanced [indicate which] level training in IP management.

Background

Many developing country institutions lack the human capital and capacity required to design and implement IP management systems that serve the IP management needs of academic institutions. Without meeting the need to provide training to personnel in IP management, the execution of IP management practices is less likely to succeed. The proposed capacity-building initiative will focus on developing learning experiences that have immediate relevance to the participant's occupation and experience, thus providing the basis for activities that lead to institutional IP management development.

Partners

Acknowledge the organizations collaborating on or sponsoring the training.

Workshop format

- Tutorial work and presentations
- Case studies and role-play
- Materials for reading and future reference

Training topics

- The fundamentals of intellectual property management. This component will provide the basic principles of intellectual property protection processes and an overview of IP regimes.
- IP strategies and methodologies. The purpose is to teach participants the approaches to negotiation, establishing agreements, licensing, technology transfer processes, and business development.
- Technology transfer management. An overview of technology management functions and strategies is provided.
- Commercialization. Provide instruction on how to develop a commercialization plan, include discussion of the key components of such a plan and guidance on aspects such as negotiation, deal structuring, and venture fund sourcing.

(Continued on Next Page)

Box 2 (continued)

Teaching and learning methods

The teaching techniques selected are designed to enable trainees to gain knowledge through traditional tutoring methods and from each other's experiences.

- *lectures*. knowledge transfer using conventional teaching techniques (direct instruction)
- *presentations*. "guest speakers" including IP professionals representing private and public sector industries
- *case studies*. interactive practical exercises that encourage participants to apply the knowledge they have acquired to solve complex intellectual property issues
- *role play*. exercises that expose trainees to strategies and approaches in operation in various IP management disciplines

Workshop content and curriculum

The teaching content of the workshop will be developed in consultation with key partners. The suggested agenda for a four-day workshop is presented below.

Day 1. Refresher on IP processes and regimes: An overview of IP processes

Day 2. IP management practices

- current practices and issues in IP management
- licensing fundamentals

Day 3. IP management strategies: Managing an IP portfolio

Day 4. Technology transfer strategies and commercialization

- fundamentals of technology transfer
- fundamentals of commercializing intellectual property

Training materials

- slide presentations
- case studies
- role-play supplies
- reading material
- CD of reference material and Web-based links

Accreditation

Participants will receive acknowledgement for full attendance of the training program.

Tutors

Tutors will include:

- three to four keynote speakers
- lecturers and presenters
- facilitators of interactive activities

(Continued on Next Page)

Box 2 (continued)

Who should attend

This training program is directed at professionals in health R&D interested in acquiring skills in IP management. The target audience includes:

- technology transfer office staff
- research managers and scientists
- senior management

Venue

Accommodation will be provided at preferential rates. Refreshments and meals will also be provided.

Costs

Participants will be required to pay their own travel costs. Participants will be required to make a single payment [or other payment plan] when registering for the workshop.

Entry limitations

Entrance will be granted to the first 20 applicants who complete registration.

Subsequent training and support

Post-workshop activities will include issues identified during the training-needs analysis and also take into account responses received following a workshop survey among participants.

Workshop evaluation

The assessment measures will be determined first by the specific objective of the workshop, and second, by the expectations of participants. Evaluation measures will include:

- relevance of the workshop to participants
- choice of tutors
- professional diversity of trainees
- duration of workshop
- balance between theory and application
- training techniques
- discussion and exchange
- documentation

Suggestions for further improvement will be sought from trainers, trainees, and observers.

Building Networks: The National and International Experiences of AUTM

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ABSTRACT

Developing and implementing best practices in intellectual property (IP) management requires several critical inputs, and building networks is among the most important. The experience of the Association of University Technology Managers (AUTM) serves as an excellent example of how to build and maintain such networks. The important lessons learned as AUTM grew and expanded its networks are broadly applicable to building dynamic, productive, and sustainable networks anywhere in the world. Furthermore, since AUTM is an association of individual, rather than institutional or organizational members, it functions all the more as a catalyst for networking. Networking provides two important benefits. First, it facilitates relationships between individuals with varied experience, expertise, and skill sets, encouraging individuals to contribute to each other's professional expertise. Second, the network itself contributes to the overall quality of group performance. Working through networks, practitioners exchange ideas and experiences to form best practices that become performance standards for individuals and their institutions. Networks thereby contribute to building IP management capacity at both the individual and institutional levels, and this capacity building then feeds back to further support and expand the network. This chapter considers the networking practices established by AUTM. It charts the organization's growth over a period of 30 years from a small group of U.S. and Canadian patent managers to an association of more than 3,400 members from countries on every continent.[1] As the story of AUTM demonstrates, networks can begin locally and gradually expand to operate on a national, regional, and even international scale. However, as AUTM has shown, the organization itself must begin with—and steadfastly maintain—a clear and focused central mission.

1. INTRODUCTION

Networking among peers in any profession generally provides two important benefits. It encourages relationships between individual practitioners, some of whom may be highly skilled while others are less so. Regardless of the proficiency levels of individuals, each one contributes to the experience of every other. Whether individuals function as mentors or apprentices, the one-on-one interactions raise the level of each person's expertise and professionalism. Moreover, networking contributes to the overall quality of group performance. By working through networks, practitioners exchange ideas and experiences, developing best practices that become standards for performance. The Association of University Technology Managers (AUTM) provides a shining example of how this process can benefit an organization. The history of the AUTM provides a solid case study of the usefulness and power of networking.

2. FORMING A NETWORK TO SOLVE PROBLEMS

AUTM began its journey as a direct result of networking. Coming together as a small group to solve a set of common problems in the mid-1970s, a handful of individuals formed a network that would eventually grow into AUTM. Midway through 2006, the total membership

Hersey K. 2007. Building Networks: The National and International Experiences of AUTM. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

stood at 3,494. The organization plays a global role in developing academic technology transfer as a unique profession.

AUTM, or more accurately its antecedent, the Society of University Patent Administrators (SUPA), did not start out to establish a new profession. Rather, it started as a loose organization of individuals, notably *not* institutions, who saw a need to work together to solve problems. The problems of the day were specific to the then-current university patenting situation in the United States. A jumbled array of inconsistent patent policies among U.S. government agencies funding research at U.S. universities made for a difficult landscape for early practitioners of university technology transfer. At the same time, a few experienced individuals recognized that other issues involving patenting and licensing periodically emerged in their daily activities as university licensing professionals. Patenting and licensing concerns were not commonly understood by the colleagues of these individuals. Although there were relatively few U.S. universities engaged in technology transfer in the mid-1970s, there was enough activity to suggest a need for an association of individuals who could help each other. In the beginning, AUTM (SUPA, at the time) was chartered to create networks of individuals who would find solutions to problems arising from the complex legislative landscape in the United States and who could provide useful interpersonal linkages to help understand and deal with the complexities of patent licensing.

3. EARLY DAYS: DEVELOPING THE MISSION

Early efforts to draw new members into the fledgling organization could succeed only if organizing filled a need. Articulating a mission was then, as now, indispensable to creating sustainable networks. While the word *networking* was not commonly used in those days, the enumerated purposes for establishing the organization included, among others, "*generating self-help programs to enable universities to establish an in-house patent technology and licensing capability*" and "*effecting interchange of views amongst university patent administrators.*" These goals certainly match the modern concept of *networking*. These early efforts to articulate a useful mission were successful: at its first annual meeting in 1976, some 51 individuals paid a $30 fee to join SUPA.

No two networks are alike, nor is the process by which they are formed. Each network is a unique creation formed by different people for different purposes. Each grows according to the activities its members choose to focus on. Often, the role a network takes on is influenced by external factors that simply *happen*. Such was the case with SUPA. Its unexpected ability to wield influence through its networking capacity became apparent early on, as its members were rallied to gather support for the most significant piece of legislation to affect university technology transfer in the United States: the Bayh-Dole Act.[2] By using the organization as a pulpit from which information about the Bayh-Dole bill could be broadcast, SUPA was able to give members the information they needed to urge their own congressional representatives to support the bill. The organization gained public recognition from this early experience of energizing its member network. It continues to play a role in virtually all U.S. federal policy efforts that involve technology transfer at universities.

4. EXPANDING GEOGRAPHIC BOUNDARIES

Today, AUTM's membership is an ethnically and culturally diverse group with individuals from around the globe. This diversity is due, in part, to another external factor that played an unanticipated role in expanding the AUTM network. While there was no overt intention to reach beyond U.S. boundaries during SUPA's formation in 1974 and 1975, the organization embraced Canadian institutions nearly from the start. It happened quite naturally that Canadian members were included because of their personal connections and relationships to SUPA's organizers and also, perhaps, because a mailing list was used that reached across the United States/Canadian border. The outreach encouraged a contingent of six Canadians to attend SUPA's first annual meeting in 1976. By 1978, SUPA had its first Canadian trustee, and a concerted effort was made to extend information about

SUPA to licensing practitioners in Canadian universities. Another reason for AUTM's international membership had to do, no doubt, with the omission of any geographical or national limitations in early membership requirements. Membership was open to "*any individual who has some responsibility for the administration of inventions and/or intellectual property at an institution of higher learning….*" Although not part of the early planning, the fact of early Canadian involvement paved the way for AUTM to grow as an *inclusive*, rather than *exclusive*, global network. By not limiting its membership, SUPA was providing avenues along which global networking could begin to develop.

5. DEVELOPING A NETWORKING STRUCTURE

Early decisions to structure AUTM as an association of individual, rather than institutional or organizational members, laid the foundation for the organization as a catalyst for networking. The first step in developing its networking capacity was to use *regionalization* as the best mode for organizing subgroups, rather than using public/private, big/small or other classification schemes. Organizing by U.S. geographical regions (East, Central, West), and then forming a Canadian region, promoted networking in several important ways. It helped individuals in the same geographical region to become acquainted with one another and provided opportunities for discussing issues that were common to their region. Closer regional associations also promoted faster and more-satisfactory resolutions of ownership and licensing issues where faculty and students in neighboring institutions actively partnered in research. Organizing in regional cohorts also laid the groundwork for local summer meetings that AUTM introduced in 1992. The purpose of the new format of regional summer meetings was expressly to provide small, informal meeting venues that were more conducive to forming personal relationships than were general meetings attended by the membership at large.

In 1978, the organization took a second step to expand opportunities for member networking by adopting a category of affiliate membership. Individuals can be admitted as affiliate members if they are, "*engaged either directly or indirectly in activities relating to the administration of intellectual property… and [their] organization interacts with institutions of higher education or teaching hospitals.*"[3] An important reason for introducing the affiliate-member category was to provide an opportunity for regular members to make contacts with prospective licensees, as well as with service providers such as patent counsel. Through these opportunities, members could begin to develop personal networks among companies considered to be customers. AUTM recognized that networking could be used as a marketing tool to build relationships with potential customers. The decision to do so had a tremendous impact on the growth of the organization.

Through trial and error, AUTM adopted an internal structure to support its networking goals. Initially, the management structure did not include any position dedicated to enriching networking activities. But as the organization's membership grew and its educational activities expanded, it became clear that AUTM had to pay closer attention to specific member needs. Over a period of two years, between 1993 and 1995, AUTM reorganized and made networking a fundamental focus of its organization. This was accomplished by adding two new positions to the board of trustees: a vice president for membership and a vice president for communications. Further strengthening its commitment to the networking needs of its members, the organization added a vice president for affiliate members to the AUTM board in 1997, and in 2000, the organization created a vice president for international relations position. AUTM has made other recent changes at the trustee level to support and bring greater emphasis to its network. A vice president for public policy supports the efforts of AUTM's members to speak in a collective voice on relevant policy matters. In addition, because the organizing of the annual meeting and the data gathering function, overseen by the Metrics and Survey Committee, have emerged as the primary interests of the organization's membership, these two functions (formerly under a single vice

president) are now represented on the AUTM board by two separate vice presidents.

6. MEMBER NETWORKING

While supporting networking through the organizational structure is an indispensable activity, more than structure is needed to instill networking as a seamless part of a member's experience. Over the past 30 years, AUTM has pursued different avenues to reach this goal:

- The AUTM Web site went online in 1995. It provides members with online access to shared information. Networking is specifically addressed through a MEMBER CONNECT capability that allows members to find and communicate directly with one another through email.[4]
- The *AUTM Newsletter* provides information and articles of current interest. The newsletter is now delivered six times a year electronically, and members receive weekly updates by email.
- Educational courses are held throughout the year to provide professional education to both new and more experienced members. These courses directly contribute to the overall quality and influence of the AUTM member network.
- Special interest groups (SIGs) encourage members with particular interests to meet together to discuss issues and solve problems. Each SIG meets in conjunction with AUTM's annual meeting.
- Summer meetings are held in each AUTM region, with networking opportunities forming a major element of program planning. Special workshops promoting networking have been included in both summer and annual meeting programs.
- Activities at AUTM's annual meeting that support its networking goals include:
  - logistical and space planning to facilitate *networking breaks,* which serve to support prearranged and impromptu meetings
  - social events specifically arranged to promote relationship building, such as sporting events, receptions, group dinners, and a special reception for new members to facilitate their first AUTM networking opportunity
  - specific time set aside for each AUTM region to meet
  - one afternoon dedicated to SIG meetings
  - the Networking Fair, first held in conjunction with the 2000 annual meeting, providing a forum for members to meet with affiliate members looking for new licensing opportunities (The fair enables members to build their own marketing networks and has become a major annual meeting event.)
  - the Innovation Showcase, introduced at the 2006 annual meeting, gives AUTM members an opportunity to formally present new and promising technologies to AUTM's network of affiliate members (The 2006 showcase produced several relationships with potential licensees. As another successful example of promoting networking among AUTM's members and their customers, the showcase will be repeated at the 2007 annual meeting and after, as interest warrants.)

Forming an integral part of the AUTM structure, most of these efforts continue today.

Metrics are one way to measure the importance of organizational activities to members and to gauge the success of the organizational efforts to support those activities. An AUTM survey conducted in 2005 was especially instructive, as it measured the importance of networking to AUTM members. The survey results indicated that networking with colleagues was cited as a primary reason for *joining* AUTM by 22% of respondents; and 51% of respondents cited networking with colleagues as the reason for *remaining* an AUTM member. Networking was by far the most important reason for retained memberships. Thirty-eight percent of respondents selected networking as the second most important reason for joining AUTM. It is clear from the survey that working to build successful member

networks should remain a primary focus for the association.

7. BUILDING AUTM'S INTERNATIONAL NETWORKS

7.1 *Options*

AUTM has long debated how to extend its member network beyond the United States and Canada to include relationships with technology transfer professionals in other countries. The importance of learning from counterparts in Europe, Asia, South America, and elsewhere was always regarded as an important goal. Memberships were routinely accepted from individuals from any country who fit the regular-member or affiliate-member definitions. However, member surveys and questionnaires through the 1980s up until the mid-1990s showed that most Canadian and U.S. members were not engaged in enough global activities to warrant placing the question of how to "internationalize" on the AUTM agenda.

As globalization increased during the 1990s, the situation changed. More institutions were doing business abroad, and there were more and more requests for memberships from foreign countries (although foreign members still account for only a small fraction of all AUTM memberships). It is probably fair to say that a major factor in AUTM's thrust onto the global stage was the publication of two important works by the organization in 1994: the *AUTM Technology Transfer Practice Manual* and the first annual AUTM Licensing Survey™. These enhanced the organization's reputation for leadership in technology transfer, both at home and abroad. Requests for translation rights to the practice manual made it clear that AUTM had provided a practical resource for technology transfer professionals regardless of nationality, and the AUTM licensing survey provided a model that other countries and geopolitical units could look to in measuring their own technology transfer activities.

Despite growing international interest, AUTM responded slowly. This hesitation was due not to any lack of interest in networking with international colleagues, but rather to cautiousness about selecting the structure for the interaction. Any networking organization that begins regionally but wishes to expand must consider how the expansion fits in with the its mission. The organization must decide whether it can expand without compromising that mission and whether, in the case of AUTM, it should attempt, as a wider organization, to extend beyond its borders, or leave it to disparate national regions to do so individually. AUTM wrestled with these questions throughout the 1990s. It considered proposals for international growth that ranged from marketing materials worldwide, under the AUTM brand, to franchising. The organization weighed the options of establishing an "international region," that would mirror the United States and Canadian regions, with establishing a looser type of structure where networking, sharing of educational materials, and joint meetings would form the basis for AUTM's international relationships.

The path toward finding an appropriate international role for AUTM formally began with its agreement in 1997 to partner with Science Alliance in sponsoring a conference in Amsterdam aimed at European participation. The success of this conference resulted in similar conferences sponsored jointly by AUTM and Science Alliance in 1998 and 1999. Partly as a result of networking at these conferences, Europe formed its own organization, the Association of European Science and Technology Transfer Professionals (ASTP) while UNICO, among others, was formed in Britain. In a sense, then, AUTM's approach to internationalizing was determined not by AUTM, but by the *individuals* who would people the new international organizations. Those individuals answered the question for themselves. They would have most to gain, in terms of networking and education, by forming their own independent organizations to focus on regional issues. And as these organizations now begin to grow their own networking capacities, they may find AUTM's experience useful.

This is not the end of the story, however. Although AUTM had decided neither to franchise itself nor to form an international region, international interest in AUTM's educational and

networking activities was growing. Without compromising its initial mission of education, networking, and influencing academic technology transfer directions in the United States, AUTM added a vice president for international relations to its board of trustees in 2000. In the same year, AUTM hosted its first independent international conference in Edinburgh, Scotland, attracting 182 participants from 18 countries.

7.2 *Networking for a global impact*

AUTM's current challenge is to meet the networking and educational needs of colleagues in developing countries. A first major step in this effort has been to offer very low-cost electronic memberships (US$10 per year) to colleagues in developing countries. Electronic memberships give these members electronic access to AUTM's publications and news updates and provide these members with opportunities to participate directly in AUTM activities—all without paying the higher costs associated with regular memberships. In an effort to build a global network of partnerships, AUTM is seeking to form sustainable relationships with organizations such as MIHR (Centre for the Management of Intellectual Property in Health Research and Development) and WIPO (World Intellectual Property Organization).

7.3 *Networking as part of strategic planning*

While network building has been central to AUTM's organizational efforts from its inception, in many respects networking among members has naturally *happened* without robust or direct planning. Nonetheless, as a result of recent changes in AUTM's strategic planning, *networking* will command a center stage with two strategic goals: (1) to specifically identify and gather a number of essential skills and best practices that have been learned through AUTM's networking activities, and (2) to add a new networking component that will establish networks with other organizations that have related interests. The latter goal is explained as an effort "*[to] develop a networking map of key organizations, both for-profit and not-for-profit, and individuals with whom AUTM wishes to collaborate.*"[5]

8. CONCLUSIONS

Network building by any professional organization or association comes from a unique combination of individual member preferences, goals adopted by the organization, and factors that happen randomly. Thus, the experience of AUTM is unique simply because there is only one AUTM. It is not unique, however, in terms of adopting networking practices and activities that are driven by the fundamental interests of its members and that seek to encourage both learning and mentorship based on shared experiences. This goal represents a universal maxim of network building that can be applied across the world, in both developed and developing countries. Strong member networks build quality and integrity by adopting best practices that have been tested and found to be successful. Building networks both among its members and with aligned organizations provides the credibility an organization needs if it aspires to a leadership position in its sphere of operation. The AUTM experience may be helpful for others seeking to reach those goals.

Networks, as groups of like-minded, mission-driven professionals, can be formed at different geographical levels in order to serve various functions. This multilevel approach allows organizations to address different aspects of their respective missions:

- Local networking creates opportunities to work with colleagues who are in the immediate vicinity. They might be working on similar problems, and so such networks can build synergistic collaborations.
- National networking can be a useful mechanism for working with colleagues to encourage national legislation that addresses IP and technology transfer. National networking can also be useful for designing and implementing systems for appropriate IP management, training, and education.
- Regional networking provides opportunities to work with neighboring countries in coordinated research and development endeavors and related IP management and technology transfer initiatives and includes building AUTM-like organizations.

- International networking will become increasingly important as globalization advances. Building networks with colleagues from around the world will provide opportunities for many forms of technology transfer and for building IP management capacity. ■

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1 The author gratefully acknowledges the contribution to this chapter by Jon Sandelin. (Sandelin J. 2004. *Association of University Technology Managers: 30 Years of Innovation*. Association of University Technology Managers: Northbrook, Ill.) While the work is not quoted herein except as noted, it provided a history of AUTM that would not have been otherwise available.

2 35 U.S.C. § 200–212 (1980, 1984).

3 See AUTM Bylaws, Article IV: Categories of Membership: Affiliate Members. www.autm.net.

4 www.autm.net.

5 AUTM Strategic Plan, adopted by the board of trustees, 1 March 2006. www.autm.net.

How to Select and Work with Patent Counsel

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ABSTRACT

Public sector technology transfer offices (TTOs) are in the business of "moving" technology from research and development to eventual commercialization in order to advance their missions of serving the greater public good. Intellectual property (IP) management is integral to this process, and integral to IP management is patenting. Maximal captured value for public sector technologies will be greatly affected by the quality and scope of the patent coverage and this, in turn, is greatly influenced by the quality of work done by patent counsel. It is therefore essential for a TTO to select a patent attorney whose work will enhance the institution's prospects for obtaining optimal licensing arrangements. From selection to hiring to ongoing interactions, it is important for the TTO and the patent counsel to develop and maintain a good working relationship. Central to this relationship is ensuring that patent counsel can prepare and prosecute patent applications in a manner that achieves positive results cost effectively. This is a complex process, and there are many responsibilities that both counsel and the TTO must assume. In addition, patent attorneys can provide general counseling: resolving inventorship issues, providing licensing and agreement support, and settling disputes. The TTO will be the patent attorney's actual client and function as the interface between counsel and the institution. By selecting qualified patent counsel and then developing a good relationship, a TTO can ease its workload and facilitate its mission. Therefore, retaining a skilled patent attorney and one that is well suited to the particular needs of the TTO is an essential element for operating a viable technology transfer program. The search for such an attorney must be approached thoughtfully.

1. INTRODUCTION

Technology transfer offices (TTOs) at a university or other academic institution have only one product to sell—technology. The value attributed to such technology is influenced heavily by the quality and scope of the patent coverage. If a patent is drafted poorly or does not provide adequate coverage for the technology and reasonable extensions thereof, licensing opportunities may either be lost or greatly devalued. Unlike manufactured goods, patents are not made by machines—they are prepared by people, in other words patent attorneys or patent agents. As a result, patents will vary in style and quality as a function of who prepares them. Due to the possibility of such variability, it is important to select carefully a patent attorney whose patent work will enhance the institution's prospects for obtaining profitable licensing arrangements. Guidelines on making this selection are suggested in this chapter.

Once suitable patent counsel is selected, it is important to develop a good working relationship between the patent counsel, the technology transfer manager, and any other individuals involved in these processes. One aspect of this developing relationship involves ensuring that patent counsel can prepare and prosecute patent applications in

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Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Part IV: Chapter 1).

a manner that achieves good results in a cost-effective fashion. Beyond that, however, it is important to recognize that patent attorneys can provide general counseling, resolve inventorship issues, provide licensing and agreement support, and resolve disputes. Suggestions on how TTOs can work effectively with patent counsel in all these areas are also provided.

By selecting qualified patent counsel and developing a smooth working relationship with him or her, TTOs can develop a resource that will ease their workload and facilitate their ability to handle difficult situations. Inevitably, when patents are well prepared and prosecuted, they become more valuable, and licensing income may be enhanced. Making an appropriate selection of patent counsel and developing a good working relationship with him or her is one of the essential elements to operating a viable technology transfer operation.

2. SELECTING PATENT COUNSEL

2.1 *The patent attorney*

Patent attorneys must be registered with the U.S. Patent and Trademark Office (PTO) in order to practice before that governmental agency. Obtaining such registration is not like registering to vote. Patent attorneys must pass a written examination given by the PTO. In addition, patent attorneys must have a degree in science or engineering or a sizable amount of course work in those areas.

The PTO registers both patent attorneys and patent agents. Those with law degrees and admission to a state bar are registered as *patent attorneys*, while individuals who are not lawyers are registered as *patent agents*. In a law firm (as opposed to in a university setting) the practice of a patent agent is usually limited to preparing and prosecuting patent applications before the PTO. Patent attorneys also handle these responsibilities and, additionally, may litigate patent disputes, prepare and negotiate license agreements, and provide legal advice. Because patent agents usually handle only a limited scope of work within a law firm, a TTO is best served by selecting a patent attorney as its primary contact.

Names of patent attorneys can be obtained from a variety of sources. Like most professionals, patent attorneys are best located by seeking references and by "word-of-mouth." Listings in a telephone book and the PTO's register of patent attorneys are potential sources; however, they provide no basis for distinguishing between the listed individuals. The local bar association or intellectual property (IP) law association may be somewhat better resources, because these organizations would have some knowledge about individuals' reputations in the community and, presumably, would recommend someone with a solid reputation.

As members of the Association of the University of Technology Managers (AUTM), technology transfer managers are an excellent source of counsel who have experience with academic institutions and have provided quality assistance to peers in other TTOs. A few calls to the TTOs of other institutions should result in names of recommended individuals.

Local companies are another source of patent counsel recommendations. Companies with their own in-house patent attorneys are likely to use attorneys in private practice for some projects, so in-house patent attorneys are likely to be a very good resource. In companies with no in-house patent attorney capability, the individual in charge of research, development, or engineering or the company's general counsel are likely to be working with outside patent counsel and should be able to provide recommendations.

2.2 *Evaluating the Patent Attorneys*

Once the names of some patent attorneys have been obtained, the technology transfer manager is ready to begin the evaluation of those recommended. The following items are offered as criteria to be considered when determining which attorney will best meet the needs of the institution:

- size of the attorney's firm
- scope of the attorney's legal experience
- the attorney's experience with academic institutions
- the attorney's technological background
- the firm's location

2.2.1 *Size of the firm*

One consideration is the size of the firm with which the attorney is affiliated. Large firms will have a critical mass of patent attorneys and the resources to handle whatever problems the institution might encounter. These resources include large libraries, access to databases, staff to maintain and utilize the resources, and so on. The staff of patent attorneys at a large law firm is likely to include individuals with biotechnology, chemical, mechanical engineering, software, and electrical engineering backgrounds, so that the firm can handle work in virtually any technology. In addition, these attorneys will collectively have experience in patent prosecution, litigation, IP counseling, interferences, and licensing. As a result, a large law firm is generally able to handle most any legal problem that confronts a technology transfer manager. On the other hand, smaller firms might have the advantage of lower cost while having individuals with the skills needed to service the institution. Although firm size is a consideration, its significance should not be overstated. The technology transfer manager will be working with individual attorneys, and, therefore, the attorney's capabilities should receive the bulk of the manager's attention during this evaluation process.

2.2.2 *Scope of legal experience*

A manager should know the patent counsel's scope of legal experience. Because a significant portion of the work required by TTOs involves preparation and prosecution of patent applications, the attorney selected should have a solid patent prosecution background. Careful scrutiny of an individual's capabilities in prosecuting patent applications is appropriate. Ask how long the attorney has been doing such work, how many applications he or she has prepared and prosecuted, and so on. Make sure the attorney does a significant amount of original patent-application drafting as opposed to prosecuting cases that originated overseas. Ask to review patents that the attorney prepared and the files of issued patents he or she prosecuted (these are publicly available after the patent issues or the patent application publishes). The technology transfer manager should also examine whether the attorney being considered has experience in other areas, such as litigation, interferences, licensing, and counseling. There will inevitably be times when a TTO will need such skills.

2.2.3 *Experience with academic institutions*

It is also beneficial for the patent attorney selected to have experience representing academic institutions. Attorneys with such a background are comfortable working with TTOs as clients and in dealing with faculty. Unfortunately, such experience includes the ability to prepare patent applications under the seemingly constant pressure of filing a case prior to publication. Another facet of expertise in handling patent matters for academic institutions is the ability to work with faculty who have little knowledge about IP and have a variety of undertakings competing for their time and attention. Lastly, the attorney needs to be acquainted with procedures commonly used by TTOs to delay or minimize costs. For example, patent counsel should be familiar with the Patent Cooperation Treaty procedure for foreign filing in order to delay payment of national filing fees in the selected foreign countries. Further, patent counsel without experience working with universities may not know that a reference to government rights should be inserted in the specification. Rapport and mutual respect between patent counsel and faculty inventors are also crucial to cost-effective, strong patent protection.

2.2.4 *Technological background*

Another selection criterion is the extent that patent counsel's technological background matches the needs of an academic institution. Larger institutions may have work in myriad technologies from electrical engineering to biotechnology. As a result, such institutions must retain different attorneys with these backgrounds (or a firm with such attorneys). On the other hand, a smaller institution, such as a medical center, may only need an attorney with a biotechnology or medical background. In selecting patent counsel, TTOs should evaluate their needs technologically and find someone with a matching background.

2.2.5 *The firm's location*

How close are patent counsel's offices to the institution? Generally, it is preferable to use a local attorney if he or she is otherwise satisfactory. If there is no local attorney with the necessary legal and technical expertise, however, proximity must give way to quality. If a manager needs to go outside the local vicinity to find a patent attorney with suitable credentials, the manager should try to structure the relationship so that the attorney has maximal opportunities to visit the institution. For example, if possible, the technology transfer manager should give the attorney more than one project to work on at a time so that he or she can come to campus, talk to the inventors, and handle the matters in a cost-effective fashion. Personal meetings between TTO personnel and patent counsel are important for fostering a good working relationship, and making it easier for the technology transfer manager and office staff to receive advice. When personal meetings are not possible or cost effective, a patent attorney outside the local area should be able to work effectively with the technology manager and the institution's faculty by telephone, fax, e-mail, and overnight courier.

2.3 *Selecting one firm vs. many*

Another criterion to consider in retaining patent counsel is how many individuals or firms the technology transfer manager should select. This depends on the volume of work generated at the institution. The technology transfer manager must, of course, select enough individuals or firms to handle the institution's work volume. On the other hand, it is preferable to use as few firms as possible to ease administrative requirements on the TTO. It is also easier to establish a good working relationship and to ensure that the institution's procedures are followed when only a few firms are used. Nevertheless, it may not be a good idea to use only one firm, because that firm may not be able to handle certain projects for any of a variety of reasons. For example, the legal profession has rigorous conflict of interest standards that prevent attorneys from representing one client in an action against another client. In patent matters, conflict of interest issues are complicated by the need to avoid representing clients with technologically similar inventions. It is difficult to anticipate conflict of interest issues; they may never arise or may arise years after patent counsel is first retained. Another potential problem is that the counsel or the firm selected may not, at some distant time in the future, have the capacity to handle a particular project. This may occur because the attorney or the firm are otherwise engaged or lack the required technical expertise. Rather than dealing with a conflict of interest or a lack of capacity situation on a crisis basis, it may be better to select and work with a back-up firm that can handle such projects.

2.4 *Conditions of representation*

Once the technology transfer manager has selected patent counsel, the conditions of representation should be established. In many jurisdictions, lawyers are required to establish such a relationship in writing through a retainer letter.

One purpose of the retainer letter is to establish contact people on both sides to handle administrative matters, particularly billing issues. The TTO should select the person from its staff who is most likely to interact with patent counsel as counsel's contact person. The retained attorney or law firm will designate the attorney who will prepare and send out bills. It may also be appropriate to use one attorney as the point of contact between the institution and the law firm. That person can act as ombudsman within the law firm to ensure that the institution's special needs or requirements are met. It is still a good idea, however, to know which attorney will be taking primary responsibility for particular projects and to ensure that the individual is qualified.

The retainer letter should also establish billing procedures. Because most law firms work on an hourly rate basis, the retainer letter should specify billing rates for the attorneys likely to be handling the institution's work. There is an occasional desire to utilize alternative billing procedures, such as fixed fees or fee and equity combinations. Further, some TTOs

choose to pay their counsel a monthly retainer fee to cover routine counseling and advice. This makes TTO personnel and faculty less reluctant to contact counsel with small but important questions. The terms of any special fee arrangement should be stated in the retainer letter. The retainer letter will also specify billing cycles. Generally, bills are rendered by most law firms every month.

Another feature of the retainer letter will be a specification of the bill content. An acceptable bill will include, on a daily basis, an indication of which attorney worked on a particular project, the amount of time spent daily on that project, and what that work involved. This will make clear the services for which the TTO is being charged. Block bills containing a narrative of all work done on a particular project without specifying which attorney did that work, how much time the attorney spent on a particular task, and when that task was done should not be accepted.

TTOs should also prepare their own retainer letter for newly selected patent counsel. In the institution's retainer letter, the TTO should state what it expects from counsel. One important point that this letter should stress is that the TTO—not the faculty—is counsel's client. This is a seemingly simple concept, because the TTO is receiving and paying the attorney's bills. Nevertheless, things can become confusing in academic settings where patent counsel is working heavily with faculty members who generally operate as "free agents" with respect to the institution. It is easy for such faculty members to regard patent counsel as their attorney and to begin asking the attorney to handle their other projects without approval from the TTO. In such situations, patent counsel should refer such requests back to the TTO. The TTO's retainer letter should emphasize this point and inform counsel that charges for unauthorized work will not be paid. To diminish further the possibility of such a problem, the TTO should emphasize to faculty that patent counsel represents the TTO—not the individual faculty member—and that any patent work the faculty member wants carried out should be channeled through the TTO.

3. WORKING WITH OUTSIDE PATENT COUNSEL

3.1 *Allocation of work*

Having selected patent counsel, the TTO should begin to establish a working relationship with that attorney. Determining how work is to be allocated between patent counsel and the TTO is an important starting point in establishing such a relationship. Generally, the less work that is sent to the attorney, the lower the TTO's legal fees. On the other hand, the more work the TTO retains for itself, the less time its staff will have for other matters. It is, therefore, important for the TTO to assess how its resources are to be utilized and then to distribute its workload accordingly.

3.2 *Evaluating the invention disclosure*

Quite often, a TTO will receive an invention disclosure from a faculty member while the underlying research is ongoing. An evaluation must then be made to determine whether the matter is ripe for filing a patent application.[11] The TTO should consider:

- the invention's commercial value
- whether there will soon be a public disclosure regarding the invention
- whether that publication will enable those skilled in the art to practice the invention
- whether meaningful protection can be obtained at this stage of the invention's development

Generally, the TTO should make an initial effort to decide whether (and when) a patent application should be applied for on a particular technology. However, where resolution of this issue becomes legally and technically complex, patent counsel should be consulted.

Another important consideration with respect to a newly submitted invention is *whether that invention warrants an investment* in patent protection. This decision should be made by the

TTO that has experience in marketing and valuing technology.

3.3 *Pre-filing patentability evaluation*

Once the TTO makes a preliminary decision to proceed with obtaining patent protection, it is advisable to make a *pre-filing patentability evaluation*. An initial evaluation of this type can be conducted by the TTO if it has access to computer-search databases or is willing to work directly with an outside search firm. Generally, computer searching is appropriate for biotechnology and chemical inventions. On the other hand, devices are best searched by manually reviewing the U.S. Patent and Trademark Office's collection of patents in the relevant area. The TTO, of course, must have the staff to conduct and/or evaluate such searches.

One possibility to increase staff assistance in a TTO is to use engineering, science, or law students on a part-time basis for such work. When utilizing such part-timers, however, it is recommended that their role be restricted to gathering information for evaluation by patent counsel or a staff person who has experience in evaluating patentability. Staff persons making initial patentability evaluations need to acquire a working knowledge of patentability standards and what is considered prior art (in other words, subject matter capable of preventing issuance of a patent). An ideal way to gain such an understanding is to attend AUTM programs on the subject. Other organizations also have basic courses about patents and patentability. Ultimately, however, knowledge is best obtained over time by working with (and learning from) patent counsel.

A TTO that does not have the staff to make an initial patentability evaluation should send disclosures out to patent counsel who can then arrange for a patentability search and make an evaluation. This, of course, is the most expensive route, because patent counsel is taking responsibility for obtaining a patent search, evaluating that search, and providing a recommendation. Many TTOs, however, utilize this approach because their staffing resources are committed to marketing and technology transfer.

3.4 *Preparation and prosecution of a patent application*

Once a patentability search has been obtained and a decision is made to proceed with preparation and prosecution of a patent application, patent counsel will bear the bulk of work responsibility. Nevertheless, the TTO should act to facilitate the process (to minimize costs and to ensure that there is valuable IP to license). This can be achieved in a number of ways.

3.4.1 *Inventor participation*

The TTO should make introductions between patent counsel and the inventor(s), personally or by mail. The TTO should insist that the number of meetings between counsel and the inventor(s) be held to a minimum. In most cases, one meeting to discuss the invention and one meeting to discuss a draft application is sufficient. Brief telephone conferences can be used to fill in gaps left by such meetings.

It is important to impress upon the inventor(s) the need to cooperate with counsel's requests for information. The inventor should furnish any draft journal article to facilitate preparation of written examples for the patent application. If the article does not provide sufficient information for examples, the inventor will be requested to provide additional experimental write-ups. This often requires a fair bit of work, but the inventors are much better able to do this than patent counsel. Moreover, having the inventors undertake this task (as opposed to patent counsel) will reduce cost.

For biotechnology and chemical inventions, patent applications will frequently be faced with a rejection (35 U.S.C. §112, 1st paragraph: failure to disclose and explain the invention in detail) because the application's disclosure does not support the broad scope of protection being sought. To overcome this problem, the scope of protection may have to be narrowed to an often unacceptable extent. Applications based on little more than draft publications are particularly susceptible to such problems, because publications generally report only the work actually carried out by the researcher; it does not usually discuss alternatives or way in which the invention can

be expanded. To obtain a broad scope of protection, the inventor(s) will be requested to assist patent counsel by providing information about how the invention can be utilized. The TTO should impress upon the inventor(s) the importance of their cooperation in this regard so that commercially valuable patent rights are obtained in a timely manner.

3.4.2 *Duty of disclosure*

It is important for the TTO to understand the duty of disclosure to the PTO. Under this duty, patent applicants must disclose all information that a reasonable examiner would consider important in deciding whether a patent should issue. Inventors must not submit inaccurate data and must disclose all patents, publications, and other disclosures (such as prior art) which would be relevant to patentability. This includes the inventor's own efforts to disseminate information as well as those of others. Published abstracts and information disseminated at poster sessions must also be disclosed. This duty is not extinguished upon filing of the application. If the inventor discovers prior art after his application for patent has been filed, he has a continuing duty to submit such information to the PTO.

The TTO will need to advise patent counsel which aspects of an invention it considers to be valuable. The attorney can then frame the patent claims in a way that will provide the desired protection and enhance licensing opportunities. It would be prudent for the TTO to monitor what is being claimed initially and throughout prosecution to ensure claim scope expectations are met.

3.4.3 *Office Actions*

After the application has been filed, the PTO will eventually issue an "Office Action" that must be responded to by patent counsel. Generally, counsel will need input from the inventors when preparing this response. The technology transfer manager can assist in this process by stressing to the inventors that a prompt response to the attorney's request for information or additional experimental data is imperative. If a response to the PTO Office Action is filed without all the information requested by counsel, it is likely that the PTO will mail another Office Action; thus requiring the TTO to incur the expense of filing another response, which includes the information that should have been put into the prior response.

In responding to Office Actions, extensions of time can be obtained by payment of additional fees. To minimize costs, there should be limited use of such extensions.

3.4.4 *Foreign filing*

After an application is on file in the United States, counsel will eventually inquire whether the case needs to be filed overseas. Decisions on foreign filing require consideration of whether:

- the return on foreign filing justifies the expense
- such filing is going to be considered valuable by domestic licensees
- the invention has sufficient value to attract a licensee in a particular foreign country

There are, of course, other factors that must be considered in deciding whether to foreign file, but they are beyond the scope of this chapter. A technology transfer manager should provide the attorney with plenty of advance notice about foreign-filing plans. This will enable the necessary papers to be prepared without a last-minute rush.

3.4.5 *Further research and new data*

After an application is filed, inventors often breathe a sigh of relief and assume that they are done with patent applications. They then continue their research without informing the TTO or patent counsel of any developments. This is unfortunate, because such later work can be the basis for further (and, indeed, often more valuable) patent protection. The technology transfer manager should impress upon the inventors the need to keep either patent counsel or the TTO apprised of future developments.

3.5 *Maintenance fees and annuities*

Once patent protection is obtained in the United States or overseas, it is necessary to decide who

will be responsible for paying maintenance fees and annuities. The TTO can undertake this task itself or work directly with an annuity service. On the other hand, it can rely upon patent counsel and counsel's docketing system to handle this task.

4. WORKING WITH PATENT COUNSEL ON OTHER MATTERS

Working with patent counsel should not be thought of only in terms of preparing and prosecuting patent applications. There are a number of other areas where counsel can provide valuable assistance.

4.1 *Dispute resolution*

Quite frequently, inventorship disputes arise in academic settings. These issues are best resolved before any patent application is filed.

Inventorship disputes may arise between faculty members and their graduate students. Sometimes, graduate students are merely "a pair of hands" who simply follow instructions from the faculty member. In other situations, the student conceived or helped conceive the invention. To make a proper inventorship determination, it is necessary to interview the parties and to review their documents to ascertain each inventors' contribution. Patent counsel should have a level of expertise in resolving inventorship disputes that will make all parties involved feel that their views have been properly considered.

Faculty often collaborate with scientists at other institutions or companies. Such collaboration is rarely undertaken with an eye toward patents. However, once a decision is made to go forward with a patent application, disputes can arise regarding who will be named as inventors. Again, patent counsel can be useful in investigating the situation and providing an opinion on how to resolve the matter. This is particularly important when dealing with a collaborating institution or company, because, in order to maintain what has been up to that point a good working relationship with the collaborating institution, the technology transfer manager may choose to use patent counsel as an advocate to resolve conflicts. Moreover, early involvement of patent counsel in any such dispute will enable the attorney to position the dispute to the advantage of the client—the TTO.

4.2 *Preparation and negotiation of agreements*

Patent counsel can also provide TTOs with support in the preparation and negotiation of licenses and other agreements. Some TTOs have a great deal of experience in these efforts and do not need to use patent counsel for such services. On the other hand, other TTOs lack this experience and should strongly consider involving patent counsel in these activities. For instance, counsel can prepare agreements, review draft agreements from potential licensees or the TTO, provide selected clauses for inclusion in any agreement, and negotiate with potential licensees. Involving patent counsel in such negotiations is particularly critical where discussions are centered around substantive patent issues, such as the scope of patent protection available, and whether the potential licensee has rights in the subject technology due to a dispute over inventorship or over who was first to invent. Patent counsel should be involved in such negotiations to help persuade potential licensees that the client has a meritorious position. At the very least, patent counsel should be kept apprised of the substance of any license negotiations so that any changes needed to enhance the quality of the application can be promptly made.

4.3 *Interference proceedings*

Issues of *priority of invention* (who was first to invent) are resolved in the PTO through proceedings known as *interferences*. Often, these issues become apparent during license negotiations as discussed above. Alternatively, the inventors may become aware of similar work by others when they attend conferences. No matter how this information becomes known, it is important that patent counsel be kept apprised. This enables the attorney to undertake a strategy that will put the TTO in the most advantageous position possible in any interference proceeding. The attorney should be involved in such situations at a very early stage and should meet with the inventors to discuss strategy. In the event that an interference is declared, such a proceeding is like a mini-patent

litigation. This is a complex proceeding, and patent counsel will need to be involved. Indeed, the attorney should be the institution's representative in any such proceeding.

4.4 *Getting questions answered*

Lastly (and most importantly), patent counsel can serve a TTO by being available to answer simple questions on IP matters. Most patent counsel are willing, without charge, to help a technology transfer manager in patent awareness efforts by giving seminars to groups of institution faculty or participating in special events such as invention fairs relating to the technology transfer program. By providing such advice to that office and faculty, patent counsel can help ensure that protection for valuable technology is not lost but, instead, enhanced.

5. CONCLUSIONS

The mission of public sector research institutions is research and development of technological advances that will eventually provide benefits to the public, especially in terms of health and nutrition. IP management (of which patenting is integral) advances this mission by facilitating the development and commercialization of public sector innovations. Therefore, for public sector TTOs, the products that they will want to disseminate will be their technology and the patents covering this technology. To ensure that the greatest value is realized from the fruits of the institutions' research scientists, it is essential that good patents are drafted, prosecuted and maintained. Therefore, it is of the utmost importance to select the institution's patent counsel carefully. This will involve evaluating several key factors, such as size of the attorney's firm, scope of the attorney's legal experience and capabilities, the attorney's experience with academic institutions and technological background, and the firm's geographic location. Once counsel is selected, a good working relationship with him or her should be actively pursued. This will require defining the conditions of representation, the allocation of work, and the dynamics and management of patent counsel's relationship with its client (the TTO) and also with the institution's administration, staff and scientists. By carefully taking all of these steps, the TTO can ensure that quality patents are obtained and managed in a cost effective and timely manner. ■

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1 See also in this *Handbook*, chapter 9.1 by L Nelsen and chapter 9.3 by R Razgaitis

How to Hire an IP Attorney and Not Go Bankrupt

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ABSTRACT

As a result of the growth in intellectual property (IP) protection, more and more institutions are establishing technology transfer offices (TTOs) to spearhead or support the effective transfer of technology. These offices serve a variety of functions, all of which must be integrated in order to transfer the technology cost effectively and to benefit the institution. One responsibility of a TTO is to provide services: from strategy development to contracts and agreements; from patenting to trademark protection; and from conflict-of-interest analysis to negotiation support. In all of these areas, legal inputs are important, and few offices will have the necessary range of in-house expertise. Gaining access to and developing relationships with attorneys are important elements in any strategy to set up effective TTOs. This chapter provides important information for deciding how to select and work with an attorney (or attorneys) who will provide IP backstopping to the TTO.

1. INTRODUCTION

The process of hiring an attorney to represent your IP interests can be complex and costly. It is therefore important that your office finds dynamic, effective, and user-oriented representation from the beginning—first impressions really do count. The support of administrators and scientists to the technology transfer office is critical, especially in the first few months and years of its operation. Hiring the right lawyer can really help you achieve your IP goals.

The technology transfer office (TTO) serves many masters and has a range of functions; this makes it very important at the outset to clearly define the scope of the office and the ways in which work will be analyzed and implemented.

2. THE ATTORNEY-CLIENT RELATIONSHIP

The legal relationship between a lawyer and a client is protected under a special set of legal rules that encompass the concepts of "client confidentiality" and "legal privilege." This umbrella of confidentiality and legal protection from disclosure is an important part of the relationship, that allows attorneys and clients to deal with sensitive issues without compromising a client's privacy. This confidentiality can be particularly important when a staff member of a client company wishes to discuss a matter that involves disclosing potential wrongdoing but does not want to risk having the disclosure made public. It is important early on in the relationship for the client to understand the nature of this special relationship and use it effectively for the benefit of the TTO.

3. THE SCOPE OF THE TTO AND ITS LEGAL-REPRESENTATION NEEDS

Establishing the scope of the work for the TTO is an important initial step. The TTO should be able to provide a comprehensive IP service without being overwhelmed with work and

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obligations. The types of issues that need to be debated and resolved will affect the type of legal representation required and should include the ten items discussed below (see also Box 1).

3.1 *Strategy development*

A critical initial role of the lawyer should be to work closely with the TTO to develop an IP strategy that delivers benefits most effectively to the institution or company (more about this will be explained below). Early decisions on the goals and strategies of the institution or company will save funds later (for example, money can be saved by not filing applications deemed frivolous to the goals of the TTO). Helping the client to decide goals and strategies may be one of the most critical jobs for the lawyer, whose assistance in devising the new strategy is crucial to the long-term success of the IP office. Ensuring that expenses are incurred only in those areas that fit the strategy is also crucial.

3.2 *Patenting*

The area of patenting includes patent searches, work related to freedom-to-operate, prior art searches, patent filing, patent maintenance, and so forth.

In your discussions you need to think about whether the type of patenting done by the TTO will involve utility or design patents, or utility patents on plant. When should provisional applications rather than nonprovisional applications be used? If in doubt, use a provisional application to buy yourself a year to seek partners and develop interest in the concept. (You also need to be aware of the Patent Cooperation Treaty provisions and when to apply them in order to file for multicountry coverage.) It is vital to involve a patent attorney in these steps of the process and to be guided by him or her as to the nature of the subject matter. Try to develop a portfolio of experts that can be called upon to advise you when patents are being sought in their particular areas of expertise.

3.3 *Trademarks and copyright work*

The trademark area is often significantly underused. Product branding is an important marketing element in a global environment. Think of the brand value of names such as Coca-Cola® and Kodak®. Again, use the guidance of the lawyer when choosing for inventions, their names, logos, slogans, and so forth, so as to minimize costs later when dealing with potential infringement actions.

Copyright is a simple and cheap form of protection; it is useful for books, papers and databases. In the genomics area, more attention is being given to using database protection as a cost-effective form of IP coverage. The use of this type of IP in the overall strategy development of an office is critical. As an example, companies such as Celera Genomics and Human Genome Systems have used highly effective copyright and contract law provisions to protect and exploit their databases on sequence data.

3.4 *Trade secrets*

Protecting innovative ideas from becoming public knowledge is the cheapest form of coverage—it is free! And not very popular with IP lawyers! The downside of this IP approach is that you *must* keep your secret a secret. If you do not, you risk having someone reverse engineer your invention and patenting it. Then you could be precluded from using your own invention! Protecting a secret in a commercial environment is really not as simple as one might imagine, and substantial effort is required to maintain secrecy, or to license it.[1]

3.5 *Plant variety protection*

An important area of IP specifically applied to sexually propagated plant species is plant variety protection. Separate chapters in this *Handbook* deal with the topic in detail.[2]

3.6 *Contract and agreement development*

Develop a good portfolio of standard agreements and templates that can then be customized as needed and as appropriate. But take care to fully customize the required content. Use a lawyer to review them and ensure that your interests are covered. It is tempting to think that once you have used one agreement you can just use the same for others without consultation—this is a mistake!

3.7 *Policy development*

You will need to create an internal office policy document, which may well assist the institution in developing its IP policy and guidelines. Obtain a lawyer to review and comment on progress during the initial strategy development stage. Remember, it is hard to go against something that is included in the policy document. Again, this is a crucial area since the policy of the TTO can be used as a tool in both negotiations and litigation.

3.8 *Conflict analysis*

Consider using a lawyer and an ethics-and-conflicts panel to regularly review the TTO's actions regarding potential conflicts. Conflicts are a surprisingly common problem, especially where staffs develop consulting contracts, serve on boards, and so forth. Having a review panel is also valuable when faculty or staff develop competing technologies. Effective rules must be established so that support of one patent does not affect a competing patent, a situation that would breach a fiduciary relationship.

Box 1: Scope of TTO Activities—The Easily Forgotten Items

Legal Documentation:	One of the key outputs from your lawyer should be legal documentation. Do not measure the volume of paper as an indication of output. Instead, focus on a limited amount of high-value text such as opinion letters, contracts crafted, and so forth.
Keeping Up to Date:	It is very important for the TTO to maintain an active surveillance of keeping abreast of changes. The lawyer can be used to "police" agreements and technologies. This can be an important way to identify infringers and potential licensees.
Legal Matters Linked to Office Organization:	A wide range of legal matters needs to be addressed early on in the establishment of the TTO. These include, but are not limited to, the following: ■ **Staffing contract**: This should lay out a staff line-of-authority plan and work definitions. The employment contract needs to be reviewed by a lawyer. ■ **Staff employment handbook**: This must include matters related to confidentiality, ethics, and conflict of interest. The lawyer should review and give input on this. ■ **Governmental and state filing requirements**: Your local equivalent of the Secretary of State can help on this. Requirements include work permits, pension plan provisions, occupancy permits, fire inspection permits, and other documents. ■ **Possible incorporation of the entity**: The TTO may wish or may need to form a separate legal entity. In the U.S., many of these offices are known as research corporations and have charitable, so-called 501(c)(3) status. This is the domain of the lawyer. Seek his or her counsel before you proceed. ■ **Tax matters**: Be aware of all U.S. federal and state tax matters if you are in the U.S. (Other countries have local, regional, and/or national laws) Hire a good accountant and audit company. They are as important as your lawyer.

3.9 *Licensing*

The bread and butter of a TTO is licensing. The flow of information, ideas and materials is two-way. Some staff members will be accessing the IP of others through license agreements, and the TTO will be licensing technologies through license agreements. Be careful, you will be bound to abide by any agreements that you sign! Make sure a lawyer reviews all major-deal documents. You may also wish to seek advice from a lawyer on creative arrangements for licensing your technology. Such arrangements may involve using your IP as an investment by contributing to a joint venture. Consider hiring a lawyer or technology transfer company to do this on a contingency or partial-contingency basis.

3.10 *Negotiations support*

Successful negotiating is an art that takes skill, practice, and sharp wits. Lawyers are trained in the skills and use them each day. Moreover, the representational responsibility of a lawyer can make him or her an excellent advocate for the TTO. Under certain circumstances, you may wish to use a lawyer as your negotiator.

3.11 *Strategy development and technology assessment*

The area of strategy development and technology assessment is one of great importance. It is perhaps the area to which money spent on lawyer fees can be applied most effectively. If your TTO strategy is ill conceived, all efforts in the other aspects of your office are redundant.

One of the key challenges facing any TTO, especially in the early stages, is trying to decide which inventions to protect and to what extent the protections should apply (that is, in which countries or fields of use). Costs and fees are such that no individual entity has the resources to patent all inventions. Typically, ten invention disclosures will lead to one patent, one license will come from ten patents, and royalties will come from 10% of the patents. That is why the lawyers' input here is so vital. Use patent attorneys to help you evaluate the potential market for an invention.

It is critical to spend your money wisely and try to evaluate only those inventions that are truly innovative *and* that appear to have commercial value. Remember that some great science has no market, and some simple inventions have huge commercial value.

Most often, TTOs set up an internal committee, or panel, to review invention disclosures and give feedback to inventors. Use the lawyer as a part of this evaluation process.

4. THINKING OUTSIDE THE BOX

The lawyer can be used highly effectively to think of innovative ways of capturing value from an IP portfolio. Patenting may not be a viable option in some areas, and the use of creative instruments of copyright, trademark, and contract law may be viable, and even preferable, alternatives to consider.

4.1 *Outsourcing services*

An effective technology transfer office should consider building access to a set of contracting agents, who can provide external skills that can be counted on for needed advice or service. This might be achieved through the maintenance of an advisory panel, through a series of consulting contracts, or through a well-functioning personal (business) network. The lawyer can play a critical role in setting up such outsourcing arrangements. Before outsourcing services, consider the following:

- **Hiring patent attorneys**: Choose an attorney with a range of qualifications and specializations tailored to the nature of the invention portfolio. A chemical engineering background might be helpful for advising on a natural products patent, for example, whereas a background in biological engineering might prove better for handling a patent on a biolistic gun.
- **Retaining general legal counsel**: Find someone who knows the big picture but who understands the science of the invention and the client as well. Be guided by the attorney as to the big-picture issues.

4.2 *Costs and fees*

The cost of evaluating, protecting, and maintaining IP coverage is not insubstantial. A wide range of

fees is payable in relation to IP protection. The types of fees a TTO may face include the following:

- patent and trademark search fees
- patent and trademark filing fees
- plant variety protection fees
- maintenance fees
- copyright filing fees
- issue fees
- attorney fees
- drafting fees

These fees can be substantial. In the United States you would pay US$1,200–$2,000 for a trademark, US$2,500–$8,000 for a provisional patent application, and US$6,000–$30,000 for a nonprovisional application. A patent filed and maintained worldwide over its entire life will cost about US$500,000 in fees. When retaining a lawyer to negotiate for you, don't neglect to negotiate your legal fees!

4.3 *Use of form agreements and contracts*

Lawyers often do not like the use of standard forms. The forms are designed to be party neutral. The obligation of a lawyer is to act on the client's behalf, which is why lawyers react adversely to such forms.

At times, it is tempting to use standard forms and agreements to keep costs low. The situation can be resolved by using standard forms and agreements where appropriate, and then having a lawyer review the final version to comment on any specific clauses that need to be negotiated and agreed upon.

5. CONCLUSIONS–AND A NOTE ABOUT CONFIDENTIALITY

The importance of confidentiality and trust cannot be underestimated. The inventions of the clients, the nature of the business, and so forth, requires that all TTO employees observe the strictest rules in relation to confidentiality and conflict-of-interest matters. The hiring of personnel should take this into account. Moreover, full and adequate documentation about confidentiality and conflict-of-interest issues, in relation to the TTO's operations, should be used to further strengthen compliance with the rules. The lawyer has a special relationship to the TTO and can be used as a valuable resource to deal with difficult and delicate matters. Attorney privilege is a legal strength to be used to your advantage. ■

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1 See also in this *Handbook*, chapter 11.5 by K Jorda.

2 See also in this *Handbook*, chapter 4.7 by M Blakeney and chapter 10.11 by W Pardee.

Technology Transfer Data Management

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ABSTRACT

A technology transfer office must be able to manage enormous amounts of dynamic data. This chapter examines how electronic file systems can meet this need, focusing on the importance of shared communication links and the benefits of using advanced spreadsheet applications developed by the private sector. It considers the relative merits of spreadsheets, flat file databases, and relational databases, and highlights the numerous benefits of a network solution. The chapter explains how to ensure data integrity and manage "analysis paralysis" in such systems, and it offers a self-questionnaire to guide decisions about adopting a software management solution.

1. INTRODUCTION

Managing a technology transfer office (TTO) requires strong administrative, technical, and communication skills. To make informed decisions, a tremendous diversity of information needs to be captured and analyzed. A TTO's ability to handle this information is complicated by how rapidly new information becomes available. Moreover, the average academic TTO usually has limited funds and staff with which to create such a sophisticated data management system.

Meeting these challenges and making timely, informed decisions can be very rewarding. However, as workflow increases, the ability to maintain a high standard of decision making can be compromised. If the TTO is a *closed system*, and no additional professional or support resources can be acquired to deal with the additional workflow, other solutions must be found. These solutions will very likely involve fundamentally changing how the office uses its available tools.

Fortunately, being one or more generations behind in implementing data management and decision support software systems does not translate into years of catch-up for the TTO. TTOs can reap the rewards of corporate investment in these areas. For more than a decade, companies have collectively spent many millions of dollars experimenting with executive decision-support software and management information systems that were designed to get information to organizations quickly and thus increase efficiency and facilitate rapid response. These objectives apply equally well to TTOs.

Airline-booking applications are good examples of large, end-user friendly, real-time information systems. Much has been learned about software design since the first implementation of such systems, resulting in more accessible applications that conform to the workflow logic of the end user. While early linear programming efforts proved

Sloman RG. 2007. Technology Transfer Data Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at www.ipHandbook.org.

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inaccessible to end users, modern software application design is event driven and object oriented.

As computer prices have plummeted, the power and sophistication of hardware computing have increased dramatically. Decommissioning exotic mainframe computers because of their exceptional maintenance and professional support costs, companies are now implementing enterprise computing models on local area networks (LAN) of workstations, sharing resources from a file server.[1] The computing advances pioneered in the corporate realm—specifically, improved efficiency, reliability and work throughput—are now available to TTO managers.

2. PHYSICAL OR ELECTRONIC FILES?

2.1 *Considerations*

A resource for shared information should be accessible to those who need the information in order to make decisions. Often, technology transfer and intellectual property (IP) management decisions depend on a mix of variables, including information about the inventors, their ongoing research programs, the companies interested in the technology, the relevant patent applications and their status, and the amount of money invested in each technology transfer case. In this complex environment, electronic data management systems provide the most rapidly adaptable support tool.

Physical files suffer from some fundamental limitations. In a TTO, records (or documents) are generally filed by case or technology according to the manager's guidelines. The technology transfer manager will probably find physical files limited and difficult to maintain because there will be only a single physical copy—unless staff members make multiple copies of files and place them in related areas. The person doing the filing makes a judgment about where best to file each document. This is why a manager may routinely find information in the "wrong place"—or not find it at all. A manager may apply certain rules for filing documents, but the rules are generally complex and loose, and therefore are frequently bent or misapplied. Often, a technology transfer manager must review an entire file to find the information in question. Another problem with physical files is the time it takes for information to be processed and correctly filed. If files are not up-to-date, a technology transfer manager may be forced to wade through stacks of paperwork to find a needed piece of information.

With an electronic system, however, a job packet can be quickly delegated to an officemate. All case-related data and activities can be transferred easily, with instructions, to another manager or to support staff. This is the electronic equivalent of handing a physical file to a person with the necessary instructions and briefing information. With a physical file, the recipient may miss relevant action items. However, with an electronic file, the previous manager can easily transfer a variety of action items associated with that case to the new manager.

Of course, one of the most compelling reasons to use a state-of-the-art data management system is the unprecedented ability to interrogate enterprise-wide data creatively. A manager can now rapidly formulate questions that in a physical file environment would be unthinkable due to the time required to assemble and analyze the information sets.

2.2 *Connectivity*

The key to achieving connectivity through networked computing environments is to create shared communications links, including e-mail facilities and a shared information pool. No alternative method achieves the degree of connectivity offered by a networked environment. Indeed, networked computing environments can develop connectivity between the files themselves in a way that is not possible with physical files. For example, a technology transfer manager can check to see if contact has been made with a particular company or individual, regardless of what case that contact is associated with. The labor required to accomplish this task with physical files would be prohibitive.

3. FINDING THE BEST TOOL FOR THE JOB

3.1 *Computer applications*

3.1.1 *Spreadsheets*

Financial modeling tools, called spreadsheets, were the first applications developed for the PC.

Since the release of Visicalc™,the first widely used spreadsheet, many generations of powerful analytical tools have been developed. (A secondary market has developed for templates. These add utility by providing spreadsheet layouts and built-in algorithms, enabling plug-and-play simplicity. Unfortunately, few of these templates are useful for the technology transfer professional.)

When a technology transfer manager is seeking to generate graphs from data for reports, the spreadsheet has no equal. Users can create relationships between different spreadsheets, allowing data to be shared and linked from one sheet to another. However, users who have tried to create complex links between several layers of spreadsheets know that this can be a complex task, tantamount to programming. Unfortunately, because of the soft nature of the links, they can become corrupted. One corrupt spreadsheet cell, or one with a pilot error,[2] can be copied into other spreadsheets with catastrophic results. Such errors, moreover, are difficult to trace.

Of course, spreadsheets are useful for budgeting and license revenue forecasting. They are well understood and provide dramatic visual outputs, such as graphs. The modern spreadsheet is capable of conducting "what if?" scenarios that can be particularly useful when attempting to forecast patent maintenance fees, for example. Some of these packages also contain rudimentary database-like functions that create screens for data entry. However, the sheer size and complexity of spreadsheets make them difficult to program. In addition, they do not compare favorably in this area to purpose-built database products.

Some very sophisticated, complex systems using Microsoft's Excel® and other software products have been developed by TTOs. Sharing these systems is encouraged, since the time required for designing linked spreadsheets suitable for managing the forecasting and budget processes is daunting.

3.1.2 *Flat file databases*

Flat file databases create an environment where the user can create records with data about a particular class of event or package of information. For example, records on a technology and the data elements directly related to it may be contained in a single record. Patents, however, would be in a separate database file. In a flat file database, therefore, a user would need to consult first one database and then the others in order to connect the data in meaningful ways. Because a programmer or user can change the data structure of a particular table, these databases are quite flexible. Moreover, they can also be changed without upsetting relations with other databases. In short, flat file databases have the benefits of design simplicity, ready recognition by end-users, and flexibility.

Though navigation is straightforward in a flat file database, the burden is on the user to look in the right place. There are other disadvantages. Generally, the end user must purchase a flat file database engine and then design his or her own system. Experienced users of flat file databases work out routines and patterns of interrogation at which they become adept; new users, however, may have a problem navigating around these systems with sure-footedness.

In addition, reporting from a flat file database is difficult because the links required to bring information together can be as complex as those used to link cells in spreadsheets. If a technology transfer manager is contemplating a flat file database structure, she or he should consider preferred report design and useful templates, which will reduce some of the complexity.

3.1.3 *Relational databases*

Relational databases contain a group of tables with various aspects of the information base coded together or hard-linked to other tables. A data-input screen may draw on a number of tables to show information in a pseudorelational mode. In a truly relational database design, however, there must be one or more linking fields between tables.

Technology transfer managers require access to data on finances, faculty, patent prosecution, and marketing contacts, among other things. Each functional data element might be contained in a separate data management resource, but this would be inefficient. In programming parlance, access to *backroom* (detail) data is important, but technology transfer managers increasingly value data that can be easily navigated without any knowledge of

the underlying data structure. A relational database system can accommodate this need.

Relational database systems permit the manipulation of larger sets, such as the technology portfolios for each manager and each department, among myriad other selectable criteria. Transferring sets of physical files would require a review of the file and, probably, a briefing from a previous manager. With a relational database, one can transfer the entire project from one manager to another, enabling a more efficient transfer of action items and information than is possible with physical files. This maximizes the use of professional management talent, for example, if one manager needed to focus attention on other urgent projects, such as infringement support, cases could easily be temporarily redeployed with a relational database tool.

The inherently rigid structure and connectivity of data in a relational database gives unprecedented power to look at the data and business models in different and creative ways. Exception reports, run with some frequency, can rapidly show where data gaps exist, which can drive administrative projects. Managers can forecast expenses and revenues to isolate a variety of parameters and determine if divisions are real. The ability to conduct nearly instantaneous audits can help managers plan office activities, and this connectivity also enables a supervising manager to evaluate the performance of technology transfer managers using data management systems.

Some argue that a disadvantage of a relational database is that it uses a rigorous data structure that does not allow variability. However, a rigid data structure is essential if a technology transfer manager wants to get reliable results from an electronic interrogation. To accommodate the real need for free-form annotations, it is possible to provide note or memo fields in which special details can be recorded. Indeed, a technology transfer manager should look for a balance between rules and flexibility when selecting or designing a relational data management system.

In some relational database models, connectivity is enhanced by regularly downloading recent data that can be read and interpreted by all office members. This works best when the office eschews a hierarchical structure. If the office director, managers, and support staff are electronically briefed about cases and contacts, then meetings can proceed more efficiently, and briefing sessions can be shortened or eliminated. When meetings do occur, it is more likely that decisions can be made with confidence; those who are not directly involved in the case may still have sufficient information to contribute useful ideas. Also, when support staff is kept current they can plan their workflow more efficiently.

In relational database design, there are rules that describe how data should be "normalized."[3] Rigid rules dictate elegance and resource efficiency. For *transaction-based* databases, the design can be optimized to increase the speed of recording a sales transaction or stock movement. Alternatively, the design can be optimized for ready access to a large pool of *related data*. This latter version most conforms to the needs of a technology transfer management information system. The reason is simple: technology transfer decisions are based on complex, variable information. A technology transfer manager requires access to a range of information, including IP status, commercial contacts, expenses, and other information. The transaction- and related-data design paradigms, however, need not be mutually exclusive. In other words, even if the demand for data interconnectedness dominates, the goal of high-speed response need not be abandoned.

When thinking about the complexity of technology transfer data management requirements, the relational database is the engine of choice because it requires less data entry and can be easier to maintain and audit. With expert programming code, a relational database can quickly present the information a technology transfer manager needs. Because the complexity of the data sets requires these powerful and capable computing tools, the commercial databases used by the technology transfer community are all relational or pseudo-relational database engines.

One perceived disadvantage of licensing an independent vendor's technology transfer management system is that the vendor controls the structural design. That is, during the next generation of offerings, additions will invariably arise, and the end user is not able to modify the data structures as needed. Viewed from the perspectives of the vendor and licensee, there are excellent reasons

for this limitation. The cost of developing the code generated for such applications frequently involves many thousands of dollars, as well as years of careful thought and programming. The investment in programming code of this type can cost in excess of US$200,000!

3.2 *Network solutions*

All of the above database tools can be shared over a local area network (LAN). However, only relational databases can function reliably in multiuser mode, with a number of users accessing the same data pool simultaneously, without fear of data corruption. For example, on a LAN, if a technology transfer manager were to open a spreadsheet file that someone else had on his or her screen, the manager would either receive an error message indicating that the file was in use or be advised that it was available in read-only mode. In the later scenario, any changes made would be lost. More accurately, they would be saved but then overwritten by the person who had the file open first and saved it. Flat file databases may be problematic in the same way.

Relational databases have built-in record locking and transaction-tracking features that control the access to shared files and the procedures used to update data. Many TTOs associate networks with the Internet. This chapter, however, is addressing LANs, a computing environment where one computer acts as the file server for client workstations. LAN technology has advanced dramatically in the last several years, with a number of well-supported systems available. Even for small TTOs, the advantages of using a LAN in combination with a relational database are remarkable.

3.3 *Data portability*

Most software applications are able to export and import data. The advantages of data portability are evident. If a technology transfer manager can enter data in one application and transport it in an organized fashion to a different application, data doesn't have to be entered twice. Rekeying data not only wastes time but also increases the likelihood of data integrity problems if data is recorded differently in two places (for example, if the date of receipt of funds from a licensee or the response due date for a patent application office action is wrongly entered).

It is important to use the most appropriate tool for a given job. Relational databases are the best all-around data management tool. Spreadsheets are a good tool for financial analysis and graphics. A technology transfer manager may choose to use a relational database engine to store data and then export data to a spreadsheet for manipulation and graphing.

Relational database engines are at the core of all commercially available accounting packages. An increasing number of commercially available accounting packages are designing their database file structure to be compatible with DBase®. DBase data file structures, in turn, are an example of so-called XBase data structures. When the data structures between two applications are equivalent or compatible, fewer steps are required to translate data between them. So, if an accounting package with DBase-compatible data structure is used, it would be advantageous to choose a management information system with a compatible data file structure. DBase data file structure is currently supported and promoted by two of the leading proprietary relational-database engine suppliers. Accordingly, a technology transfer manager should be aware that not all relational database engines are compatible with DBase.

3.4 *Data distribution*

Data distribution means providing rapid access to current information to precisely those people who require it to make informed decisions. The ease with which data can be queried will determine how often the database is used by the technology transfer staff. With the power of relational database engines and the connectivity of a LAN, designs that can be easily interrogated by end users are now possible.

The technology transfer manager should view the investment in the acquisition of a system and the time spent in data entry as an asset in production. This system data should be fully utilized by the technology transfer manager to coordinate office activities and generate reports sequentially or on an ad hoc basis.

3.5 *Paradigms for data management*

The main design paradigms for technology transfer management information systems are driven either by (1) committee and administration or (2) end-user functionality. System designs that are driven by the former usually prioritize the design of report outputs. Administration, for example, may announce, "We want a monthly report showing which patent applications are due for a maintenance fee, sorted by the technology licensing manager." As a result, a table structure may be defined and a report written to support this management objective. But while defining objectives is important, this approach may create conflicts in terms of data structure. To create a design of this type requires the consideration of all the ways the data may be interrogated, while at the same time avoiding massive data duplication, rekeying, or excessive look-up requirements that slow a system down.

If the system is designed around the very specific interrogatory output paradigm, the administrative objectives will be supported, but the ease of use for end users will be diminished. When a management information system provides little end-user functionality, it will not be kept as current as one that does. With daily functionality, end users more easily navigate around other parts of the system. Even though most users will spend 80% or more of their time in a single module, they will be familiar enough with navigation techniques to find their way to other relevant sections when the need arises.

A technology transfer manager may want to opt for a system designed first for the end user, but with powerful and flexible administrative report functions. The design goal should be to create a system that acts as a partner in real time, so that data is entered as the workday unfolds. If users enter the data as they move along during their day, data entry is more current and accurate. In addition, the time burden decreases and the sense of accomplishment is enhanced.

4. DATA INTEGRITY

4.1 *Assigning data-entry tasks*

For day-to-day contact functions, users should have the flexibility to use the system in a way that supports their work habits. Relying on technology transfer managers to complete data entry on their patents and licenses may not be the most effective use of their time. Rather, this task could more efficiently be delegated to the individual responsible for administering the contracts or to an experienced administrative staff person. It is desirable that a single individual be delegated the responsibility of entering specific sections of the data (for example, the data on patent prosecution and revenues and expenses for each technology or case). This approach reduces the likelihood of errors and data duplication. In general, a management information system should allow an administrative support staff member to easily complete such data entry.

4.2 *Auditing*

It is preferable to conduct audits of the information in all environments. Reports can accomplish this function and can be set up to run at certain intervals or to run on an as-needed basis. In addition, for truly mission-critical information, reports should be created and submitted to outside professional service providers for periodic review. An example might be generating reports from the database with current information about a particular patent prosecution and presenting that report, or portfolio of reports, to the patent attorney. Staff could then request that the attorney update the report.

One direct and immediate benefit of this approach is improved data integrity. Another benefit is that service providers may come to understand how much information about a university's technology transfer assets, patent applications in this case, is valued.

If a technology transfer manager is interested in implementing such a review, doing so on a rotating basis, rather than as a direct audit of all records, may be sufficient and would reduce incremental costs.

5. ANALYSIS PARALYSIS

The term *analysis paralysis* is being used here to describe a period of time when an office shuts down operations, virtually stopping all services, to allow the staff time to update, analyze, modify, and

discuss the technology data. This process can be an excellent educational experience for an entire office staff. Generally, teams should be planned in advance and assigned a batch of technology or case files to find answers to predefined questions. This process can help define the office's future mode of operations and may uncover areas in need of attention. If the entire staff is engaged in the process, a sense of team building may be achieved.

Through this process, a technology transfer manager may be able to anticipate questions from the university's administration. Moreover, if all technology staff are involved in the production and interpretation of the data, experts among the staff may emerge in different fields. And finally, periodic analysis of data results allows for a faster response when a quick, unexpected analysis is needed. This "time out" might seem an impossible goal, but the rewards can far outweigh the cost.

6. EVALUATING SOFTWARE SOLUTIONS

If a technology transfer manager is going to adopt a software management set of solutions, this author suggests taking the process to its most advanced state possible. In determining suitability, a number of questions should be asked (see Box 1).

The decision to design a system or acquire a commercially available software package to manage technology transfer data should be based on the TTO's needs. Like all computer solutions, the system will be only as good as the people

Box 1: Key Questions for Decision Makers in Evaluating Software Solutions

1. **How suitable to the task is the software solution?**

   The solution recommended in this chapter is not cheap, especially when a technology transfer manager considers the cost of a LAN, a commercially available package, and training.

2. **Is adopting the software solution worth the investment of both money and staff time?**

   Only the technology transfer manager can answer that question, taking into consideration all variables of the university and the TTO. A technology manager may want to consider the following advantages of incorporating a software solution:

   a) Managers with ready access to current data can work faster and with greater accuracy and can make decisions with increased confidence.

   b) Staff will be more likely to bring important issues to the attention of the supervising technology transfer manager, and necessary interventions will more likely occur.

   c) As a training tool for new technology licensing managers, the software tools described in this chapter can create an environment where staff can work more efficiently, with fewer work projects falling behind schedule.

   d) Software solutions can increase responsiveness to clients and the ability to analyze workflow and make appropriate resource allocations.

3. **Why is time being spent in entering the data (as opposed to completing the day-to-day functions)?**

   One possible response to this question is that data entry creates a work environment where relevant data can be readily accessed when needed by users, managers, and support staff so informed decisions can be made in a timely fashion.

using it. Therefore, a final consideration when purchasing or developing any system is the likelihood that staff will actually use the software. It is not necessarily true that staff who collectively design a system will be more likely to use it. This may sound counterintuitive, but it is based on our real-world experience.

7. CONCLUSIONS

A key element in developing a data management system is setting clear goals of effective data management. The technology transfer manager should have information to support the essential tasks of the office staff in both tactical and strategic modes. Tactical support means ensuring ready and current access to information about all aspects of a particular case. The strategic mode demands the presentation of information that can illuminate trends and assist in office organization, workflow distribution, and planning. Other examples of such data use include revenue forecasting and cash-flow planning. While cash flow may not be a prominent issue yet in all academic TTOs, the cost of doing business in the field of technology transfer is increasing rapidly, and cash-flow planing may soon become imperative.

Data management tools should act in concert with the goals of managers and adapt to the way managers work, instead of requiring users to adopt a certain pattern of processing information. Regimentation of data is important, but this need not create a barrier to end users.

It also is important to think ahead and ***design an application for the future***. As programming tools and desktop computers have become more powerful, workgroup software with event-driven, rather than programming-driven, applications have emerged in full graphical user interface presentation formats. The industrial relational-database literature reveals that the focus of applications development is moving away from the exotic hardware of the mainframe and minicomputer and toward the client-server model of distributed computing environments such as LANs.

The TTO management experience is relatively fresh, and the cost of failing to professionally manage data is not yet widely recognized. Examples of such costs include large, unpaid obligations that persist because of inefficient methods for collecting revenues, or poor management of a technologies portfolio. Both of these situations could result in real costs to the TTO, although it may take several years for this to become evident.

With a properly designed and implemented software solution, a manager can decide with greater confidence that the data needed to support a decision are at hand. Allowing managers and staff to be more responsive to clients, data management systems solutions can also dramatically enhance the general professionalism of an office. ■

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1 A file server is a high-powered personal computer linked by communication cables to computer workstations. The file server provides storage of shared data files and software applications, as well as printer sharing capabilities.

2 A spreadsheet "pilot error" is a data entry error made in an algorithm or data cell that causes erroneous results.

3 "Normalized" data has been organized into relationships in a way that seeks to minimize duplication of data and maintain data integrity.

WIIPS™: Whitehead Institute Intellectual Property System (A Relational Database for IP Management and Technology Transfer)

AMINA HAMZAOUI, *Associate Director, Intellectual Property, The Whitehead Institute for Biomedical Research, U.S.A.*

We are pleased to announce that the Whitehead Institute for Biomedical Research in Cambridge, Massachusetts, U.S.A., has kindly allowed MIHR and PIPRA to distribute the Institute's proprietary *WIIPS*™ Database. This database offers tangible benefits to improve the function and efficiency of any technology transfer office (TTO). In accordance with the non-profit missions of MIHR, PIPRA, and the Whitehead Institute, the sharing of *WIIPS*™ will be free of charge and is primarily aimed at assisting developing country TTOs.

WIIPS™ is a relational database designed to automate essential intellectual property management and technology transfer functions. It simplifies recordkeeping and generates useful reports for technology disclosures, patent applications, joint invention agreements, licenses, and material transfer agreements. In addition, the system stores essential information on every inventor, owner, and licensee who has interacted with a given TTO. Thus, the system effectively automates all recordkeeping, and offers immediate and accurate information on the status of every case, including documentation, patenting and licensing information. Not only will it allow TTOs to better manage volumes of IP data, it will also increase productivity and accuracy, since *WIIPS*™ allows for easy communication among staff members. The system is easy to learn and use and comes with detailed system documentation. In addition, *WIIPS*™ provides complete financial control, with financial audit trails and automation to meet the compliance requirements that are often required of TTOs. *WIIPS*™ can be used to manage all the financial aspects of the TTO, allowing better control of patent-filing costs. The system permits effective monitoring of expenses and legal bills, thus helping to ensure timely expense reimbursement and accounts receivable management, and it facilitates faster royalty calculation and distribution.

In order to better adapt *WIIPS*™to the needs of TTOs, users will be authorized to copy and modify the software, and/or to re-write the accompanying user guide, as long as any modified products mention that the product is based on *WIIPS*™ and has been modified by the user. Users may also make and use as many copies of *WIIPS*™ as are required.

The relational database and the user guide can be downloaded for free, subject to the terms of a license, from the online version of the *Handbook* at www.ipHandbook.org as of August 2007. The database requires that users are running Microsoft® Access® on a Windows XP or higher system.

Hamzaoui A. 2007. WIIPS: Whitehead Institute Intellectual Property System: A Relational Database of IP Management and Technology Transfer. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

As a non-profit, research and educational organization with focus on research in the biomedical field, the Whitehead Institute is pleased to further MIHR and PIPRA's missions of disseminating information and tools of best practices in technology transfer and intellectual property management, and we are keen to contribute to these commendable efforts. ■

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Organizing and Managing Agreements and Contracts

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ABSTRACT

Agreements and contracts are not just pieces of paper to be signed before money changes hands; they are vitally important documents. If an organization hopes to properly fulfill the terms of its contracts, to say nothing of negotiating future contracts, it must have a system for organizing and managing its contracts. Such a system must make data accessible as well as keep it secure. Resources and tools should be incorporated wherever possible to design and implement a system within the available budget. After it is implemented, the effectiveness of the contract management system should be continuously monitored and evaluated.

1. INTRODUCTION

Social and cultural differences can cause people, even good friends, to misunderstand each other. Written agreements and contracts are therefore critical in that they formalize the details of a deal and ensure that all parties concerned understand their rights and obligations. For these reasons, a contract is not just a piece of paper that must be signed before money changes hands, but a vital document throughout the life span of the relationship between the parties to a deal.

It is important for a company or institution to be able to organize and manage contracts to know what its existing contractual obligations are. After all, there is no use negotiating a wonderful deal for a piece of technology if your organization does not have the rights to the technology (or has already licensed rights to certain parts of the technology). Even worse, you will not be able to sign a deal at all if you cannot find out whether you have the rights to use a technology. Both of these situations require that your organization can quickly determine where you stand with existing contractual obligations related to the technology that is being developed.

This chapter will consider the life span of a contract from the point of view of what is required to manage the rights and obligations under that contract. Life span is defined as the entire process (or the stages) from the initial idea of a deal to the expiration of the contract or of its obligations (Figure 1).

2. REQUIREMENTS OF A CONTRACT-MANAGEMENT SYSTEM

Agreements and contracts have a life span and the needs for contract management will change over time: during negotiations, for active contracts, and after a contract has expired or been terminated.

2.1 *Requirements during negotiations*

Contracts begin as a potential relationship between two or more parties. Ideally, the parties negotiate an agreement that ends in a signed contract, but the agreement may be put on hold, or

Potter R and H Rygnestad. 2007. Organizing and Managing Agreements and Contracts. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

even dropped completely, if the parties cannot agree or if the agreement process is somehow derailed. The level to which pre-signing activity needs to be captured in a contract-management system depends on the parties involved and the way the deal was initiated and brought to a close. The following questions need to be considered: Would it be valuable (for the parties involved or for future negotiators) to have the history of the negotiation on record? Did communications during the negotiations have any bearing on the final deal? Will the negotiations (especially if they do not lead to an agreement) affect potential future deals?[1] The staff that were a part of the negotiations will likely be able to answer these questions. Generally speaking, in a small organization, it may not be critical to formally record such information. However, in larger organizations a high staff turnover and a larger number of contracts often translates into a shorter "institutional memory" and a greater need for formally recording the information.

2.2 *Requirements for active contracts*

It is important to store a signed contract securely; however, it is also critical that the staff responsible for implementing the terms of the contract have access to the documents, so that they can ensure that all rights are enforced and obligations honored. For example, licenses fees must be paid and reporting dates must be met. In addition, a contract may oblige one of the parties to disperse funds, to follow up diligently on product development, to grant rights to derived materials to third parties, or to obtain such rights from third parties. The methods of storing and accessing contracts will largely depend on the size and resources of the organization, and is discussed in detail in a later section.

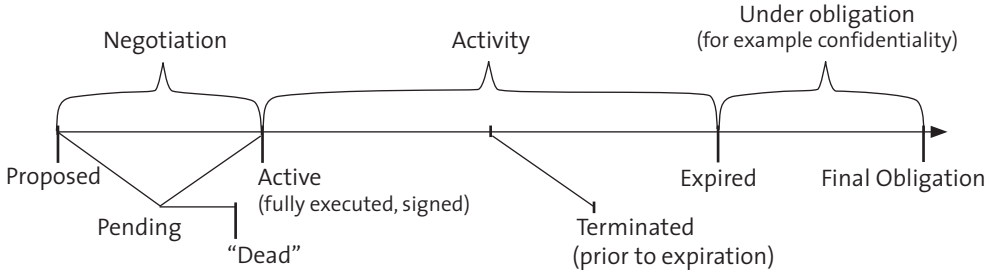
2.3 *Requirements after contract expiration*

When a contract expires or is terminated before its due date, the parties involved often still have various legally binding obligations toward each other. For example, all parties are typically bound by confidentiality clauses that last longer than the contract period. There may be other obligations, as well, such as the obligation for one party to give up the rights to original or derived materials. The extent to which each party fulfills its obligations may directly affect the success of future deals, so both administrative and management staff must be familiar with the obligations of all parties. To facilitate this information sharing, the requirements of a contract-management system are as much about enabling access as they are about secure storage.

3. DESIGNING A CONTRACT-MANAGEMENT SYSTEM

A contract-management system can be based on many components such as institutional memory, hard-copy filing, electronic filing, or a computerized database. However, a system composed of a combination of these components is more robust. Moreover, since it is not entirely dependent on any one technology, the reassignment of staff, a flood in the archive room, a fire in the computer

Figure 1: The "Life Span" of a Typical Deal



room, or a failure of the database tool will not cause a catastrophic loss of information.

Determining the right blend of components requires input from all levels of the organization. The staff knows how the current system works, or why it does not work, and can offer suggestions for improving the management system. All users of the management system should be involved during system design to ensure successful implementation: when users are involved in the design and take ownership of the system, it becomes a useful tool rather than a resource-costly burden.

Designing a contract-management system is more than picking a software tool and its starts by finding the balance between accessibility and data security that meets your organization's requirements. The desired design is subsequently guided by available resources such as existing tools, personnel, and information technology infrastructure. In the end the desired design is adapted to meet the available budget.

3.1 *Requirements: Accessibility versus data security*

When designing a contract-management system it is important to find the balance between making the system accessible and maintaining data security.

3.1.1 *Accessibility*

One of the main purposes of implementing a contract-management system is to minimize reliance on one or a few persons to manage the organization's contracts and associated obligations. This requires a certain level of accessibility to contract documents as well as any other related information.

Hard-copy filing systems. Maintaining and using hard-copy systems do not require users to have specialized technology skills, but hard-copy systems may be difficult to organize and update. If several people are involved in the management of contracts and storage of documents, there may be no central point allowing timely access to required information including original documents. No matter what other storage techniques are used, hard-copy originals must always be stored in a secure manner and kept on hand.

Electronic filing systems. With electronic filing systems documents can be made easily accessible, especially if they are stored on network-accessible media. Documents are transferred to electronic media such as scanned computer files and can be copied and updated much more easily than for hard-copy files. An electronic filing system can be stored centrally and accessed directly from a storage location or viewed remotely over a computer network.

Database. An electronic filing system makes it easier to retrieve documents when these need to be reviewed. However, it still remains time-consuming to search for specific information and to get an overview of all contracts and agreements. Computer-based databases, including simple ones kept as spreadsheets and text documents, are useful because they are more easily searchable than hard-copy files. Databases should record the following information for each contract and related documents:

- Name and address of contract parties
- Dates of execution and expiration
- Length of the confidentiality term
- Deadlines by which products or information must be delivered
- Deadlines by which funds must be transferred
- Keywords or a brief summary describing the scope of the contract
- Electronic links to the document(s)

Searchable databases have several fundamental advantages. They can:

- Reduce the time and resources needed to find physical or electronic documents
- Incorporate searches of electronic document texts provided these have been made searchable through a process of Optical Character Recognition (OCR)
- Produce automatic reminders of expiring contracts and upcoming deadlines
- Help identify potential conflicts of interest before new contracts are signed

When properly designed, searchable databases can help staff find the proverbial needle in a haystack. Not only can databases retrieve any

and all documents that contain a particular term, but they can be designed to automate searches of such information as outstanding payments, overdue reports, or upcoming deadlines.

System access. All employees will need a different level of access to the system, depending on their job duties. An employee who scans documents and inputs data will probably require a lower level of access than one who needs to access specific records or information. For example, a system can be designed so that it only displays the details of selected contracts to authorized users. Staff can generate statistics on overall performance (such as the number of contracts finalized, payments made, or reports overdue) without being granted access to sensitive material. In a Web-enabled application external parties can even have direct access to information related to their own obligations, thereby reducing the number of requests handled by the contracts-management office.

A contract-management system that combines electronic filing of documents with a searchable database can also be designed such that it is accessible by users at a central point or from a workstation on an internal network (Intranet) in one location or over a Virtual Private Network (VPN) linking different geographical locations. Access over a network is a benefit as long as the connections are secure and reliable with minimal downtime. This is particularly important if the whole system is stored off-site with no central access point on-site if the network is down.

3.1.2 *Data security*

Regardless of the measures put in place, a contract-management system will be labored with security problems related to both loss of data and access by unauthorized users.

Data loss. Regardless of how you store your data, it can be lost due to fire, flood, theft, or a number of other catastrophes, so it is important to take steps to guard against data loss. Preventative measures include safes, fire alarms, sprinkler systems, burglar systems, and fire- and waterproof filing cabinets. The chances of data loss are minimized further if hard-copy and electronic systems are maintained in separate locations. It is also a good idea to keep a backup electronic copy in an off-site location. Off-site storage and backup services can be purchased and/or managed commercially or by other departments in your organization. These service providers should guarantee that they have appropriate measures in place to prevent unauthorized access and accidental data loss.

Unauthorized access. Lockable storage facilities, filing cabinets, and safes generally prevent unauthorized access to hard-copy material. Electronic material and databases may be at greater risk of unauthorized access than hard-copy materials, especially if they are stored off site. Network traffic should be encrypted and usernames and passwords should be used to make sure only authorized persons can input, view, or alter data.

Information technology support. In-house computer support is essential because of increased reliance on information technology. If an organization lacks the resources to employ full-time computer support personnel, it must train some staff members to deal with common computer problems. More complex technical problems will need to be addressed by a reliable and responsive external party.

3.2 *Available resources*

The next step after having determined your organization's requirements for accessibility and data security is to determine how available resources will affect the system design and implementation. When taking available resources into account the original plan often needs revising to include issues such as: newly discovered needs, change in staff expertise, new technologies, and declining available funds.

3.2.1 *Identify existing tools and procedures*

The first step is to identify all–if any–tools that already exist and are used currently for contract management within the organization. Such tools could be filing systems, procedures, spreadsheets, or more-advanced databases and reminder systems. These tools can be used as models for designing components of the new system. As noted before, current contract managers can shed useful

light on tools and procedures that work, but also those that do not work, as this information is often more useful.

3.2.2 *Select new tool*

Low-technology solutions. A contract-management system is more than a software tool such as a database, and, with some limitations on accessibility and security, low-technology solutions can still be viable solutions if resources are particularly limiting. Some organizations use hard-copy filing systems with continuously updated hard-copy summary sheets for each contract. The summary sheet is good for quick-reference but may lack accessibility. As noted before, a backup system is important to avoid data loss.

Simple databases. Other organizations design and maintain computer-based databases in their simplest forms, for example in spreadsheets or text documents. This improves accessibility, enables a quicker overview, and can be supplemented with some form of reminder system for upcoming deadlines and obligations.

Database software packages. Some organizations decide to use internal or external expertise to design a more complex database tool in software packages such as Microsoft® Access or FileMaker® Pro. These software packages provide a user-friendly front-end for designing and maintaining databases. More advanced approaches could involve other software such as Oracle®, MySQL™, Microsoft® SQL Server, and DB2®. Using these packages allows for tools to be designed more to order and is a good option if an organization has some level of internal expertise with the software of choice.

Off-the-shelf tools. There are software packages designed for contract management that are more or less ready for use off-the-shelf. It is important to make sure that the software has the necessary features. Although off-the-shelf tools can usually be customized to some extent, it may make more sense for an organization to redesign its procedures than to try to make an off-the-shelf tool perform tasks that the system was not designed to handle.

Custom built tools. Another option is to have tools custom built. A provider tailors an application to the client's needs. The more complex the tool, the more time and resources will be required for its design and implementation—and the higher the cost. The implementation of customized software should be expected to cost roughly twice as much as the software tool itself. It is important to remember that more advanced (and more expensive) tools are not always the best or most cost-effective solution.

Numerous companies provide software systems for managing intellectual property assets—including filing patents (mostly U. S. patents) and licensing inventions. A number of these systems are customizable, including software packages that either the clients or the company must modify to fit their own needs. All of the systems are quite expensive to purchase. They are likely to be most useful to larger research institutions and research-based companies. You can find a list of providers and links to their Web sites in the endnotes following this chapter.[2]

Finally, there are many other options for less- specialized, less-expensive document management system. A simple search will turn up 20 or 30 companies that provide such software. It is quite possible that future versions of common operating systems or office productivity suites will include such applications. However, as discussed in this chapter, contract management is much more than just storage and retrieval of documents.

3.2.3 *Personnel considerations*

When transferring information from the old system to the new, considerable time will be needed to locate existing documents, convert them to electronic files, and enter the corresponding data into a database. At the same time, new contracts must be entered into the system. After the initial transfer is completed, keeping the filing system and database up to date must be considered as a time-consuming task. If a system design change becomes necessary, time will also have to be allotted for accomplishing this task.

The amount of staff training that is required by a change in management system will depend on the complexity of the system and on existing staff skills. Staff may be trained in such skills as filing, data entry, reporting, and day-to-day problem solving. Providers of commercially purchased management systems usually offer employee training sessions for an additional fee.

3.2.4 *Select information technology infrastructure*

The choice of Information Technology (IT) infrastructure is largely guided by the balance between accessibility and security discussed above. A contract-management system might include some or all of the following items:

- **Physical storage facilities**. Fire- and flood-proof filing cabinets that can store hard-copy originals, or system-backup media, that do not require frequent access
- **Computer/server**. A computer or server with the necessary software that stores all electronic documents and the database tools —in other words, the central collection point. The organization should obtain professional IT advice and continued IT support to ensure data security.
- **Backup system**. A system in the form of another computer or storage medium that automatically backs up the information in the contract-management system on an hourly, daily, or weekly basis, depending on how frequently data is updated. If automatic backups are impossible, manual backups should be performed, for example, on backup drives or other storage media, and the copies stored safely away from the central collection point.
- **Scanning capability**. Scanning hardware and software, with or without optical character recognition capabilities that can convert documents into searchable electronic media.
- **Network**. Computers connected to the central collection point also with professional IT support that can ensure stable accessibility as well as data security over the network.
- **IT and system support**. Support both for maintaining network infrastructure and for running the system. If the system is designed in-house, details of operations should be extensively documented in order to make future maintenance and development easier. If the system is purchased off the shelf or designed by an external developer, the service provider should provide on-site or telephone support

3.2.5 *Budget considerations*

Finally, the desired system requirements, such as accessibility, data security, existing tools, personnel resources, choice of system tool, and information technology infrastructure must be compared to the available budget. Trade-offs will be necessary and each organization must determine which needs are absolute requirements and which are only desirable. While it is often tempting to cut back on such expenditures as training and support for users, it is important to note that the system investment will be a waste of money and resources if it is not used to its capacity.

Some organizations have the resources to think big and to implement systems with more capability than is needed at the outset, thereby delaying the cost of frequent upgrades. Where possible, an organization should plan for success and institute a system that seems too big now, as it will likely appear too small in a few years time. An organization with tighter budget restrictions should aim for a system that will serve its current needs and implement a smaller or cheaper system, but try to ensure that there is room to expand it later.

3.3 *Monitoring benefits of the new system*

Because it is costly to implement a new contract-management system, and because the cost must be justified to senior management, it is important to be able to measure the benefits of the new system. Many, if not all, of the benefits can be tracked and monitored automatically by the most advanced systems. Table 1 outlines the baseline data that should be established and against which benefits can be measured.

Table 1, below, provides only examples; each organization will want to monitor itself according to its own criteria. Monitoring the benefits of a new system not only helps to justify its expense but also helps to identify aspects of the system that need revising.

4. CONCLUSIONS

Managing contracts and agreements is not glamorous, but it is vital—especially if the organization is involved in complicated technology transfer deals with many rights and obligations. Ideally, a contract-management system should be

Table 1: Examples of Criteria that Can Be Used to Measure Benefits of a New Contract-Management System

Baseline Data	Measurable Benefits
Time and resources spent searching and managing contracts	Additional staff time available for performing other tasks due to more-efficient contract management
The value of successful proposals, less the value of unsuccessful proposals	Increase in the value and number of successful proposals, due to less time spent researching potential conflicts with existing contracts
The value of invitations to submit proposals Grounds for successful and unsuccessful proposals	Improved reputation with collaborators, funding bodies, boards, and contractors
Resources spent or committed without contract	Minimized exposure due to nonexistent or expired contracts
Number of deliverables that are not submitted according to contract	Fewer deliverables not submitted according to contract
Number of delayed reports. Resources committed to preparing reports	Time and resources saved because reports (whether scheduled or ad hoc) are processed timely and with minimal effort
Penalties for delayed payments	Money saved because payments are processed on schedule.
Number of times that confidentiality terms are broken	Confidentiality terms are adhered to

established before any contracts are negotiated. The sooner a functional system is implemented, the easier it will be to keep it updated.

Identifying the system requirements starts with balancing accessibility against data security throughout the life span of a contract. This is followed by considerations for the available resources, including personnel and budget. The contract-management system should be planned and implemented with the full involvement of all levels of the organization to make sure that it becomes a useful tool and not another administrative burden.

Smooth contract management is almost invisible, but the marks of poor management are all too evident: lost deals, a poor corporate reputation, and, in the worst case, lawsuits. Investing resources in management is like any preventive measure: you will really never know how much time and money it has saved you. ■

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1 If negotiations are aborted, there may still be certain obligations that affect future deals. These include confidentiality agreements. Being aware of other types of information about the party with which negotiations were aborted, for example reasons for failure or specific problems encountered, may also be useful when future deals are being contemplated.

2 Knowligent has developed IP-Portfolio (an IP management system) and many lab-management software modules. www.knowligent.com/.

Computer Packages provides customized solutions for managing IP portfolios and collecting royalties. www.computerpackages.com/.

Inteum LLC is the maker of Inteum C/S® (the successor to a widely used system called DEALS), a program that manages the entire technology life cycle from negotiations to final obligations. www.inteum.com/.

InfoEd supplies module-based software for managing sponsored research programs, including technology transfer modules. www.infoed.org/.

O P Solutions Inc. provides software to the IP legal industry, including software for patent and trademark filing and prosecution management. www.opsolutions.com/.

Master Data Center provides IP management software, including installation of software systems and maintenance services. www.masdata.com/.

Knowledge Sharing Systems LLC makes TechTracs, a complete management system covering sponsored research, patent filing, and compliance with licenses and agreements. www.knowledgesharing.com/.

Monitoring, Evaluating, and Assessing Impact

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ABSTRACT

Much has been written about the socio-economic benefits and competitive advantage achieved by developed countries as a result of investing in scientific research and technological innovation. For developing and emerging economies, sustainable development is dependent on establishing and supporting R&D institutions that not only perform good science, but also effectively share their knowledge and technology outputs. Both the extent to which a return on an investment is realized from R&D activities and the magnitude of the resulting impact on intended beneficiaries are important to funders, policy-makers, taxpayers, government officials, development agencies, and the research institutions themselves. This chapter provides guidance on building organizational capacity to plan, monitor, evaluate, and assess the impact of R&D investments. It should be noted that the chapter does not address measuring the performance of a Technology Transfer Office to manage intellectual property, but rather focuses on determining the socio-economic impact of transferred knowledge and technology.

1. INTRODUCTION

Much has been written about the socio-economic benefits and competitive advantage that developed countries achieved by investing in scientific research and technological innovation.[1] For developing and emerging economies, it is recognized that sustainable development depends on establishing and supporting R&D institutions that both perform good science and share their knowledge and technology outputs.[2] A return on R&D investment, and the magnitude of that return, is important to policy-makers, tax payers, government officials, development agencies and, of course, those funding the research and the research institutions themselves. This chapter provides guidance on building organizational capacity to plan, monitor, evaluate, and assess the impact of R&D investment on society and in the market. It should be noted that the chapter does not evaluate the performance of Technology Transfer Offices in managing intellectual property, but rather focuses on determining the socio-economic impact of transferred knowledge and technology.

R&D institutions in developing countries operate with limited financial resources for R&D and even less funding for technology and knowledge transfer. The socio-economic challenges experienced by developing countries put more pressure on R&D institutions, requiring them to effectively and efficiently address local social and economic development needs through the transfer and adoption of innovative science. To this end, a key responsibility of research institutions in developing countries is to make research outputs available for use by society and local industry. It is therefore critical that research institutions not only generate relevant research, but also transfer and diffuse research results in a way that maximizes impact. A well-developed

Pefile S. 2007. Monitoring, Evaluating, and Assessing Impact. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

and comprehensive monitoring, evaluation, and impact assessment framework is necessary to measure efforts by institutions to meet R&D objectives. Such a framework can assist research institutions in:

- improving the efficiency of research resource allocation
- improving the standard and effectiveness of project decision-making
- directing future research plans more effectively
- obtaining evidence of resource mobilization
- prioritizing research based on the level of economic returns and positive social impact

Technological innovation transforms an idea generated during research into a new or improved product that can be introduced into a market, a new or improved operational process used in industry and commerce, or a new approach to a social service.[3] Monitoring, evaluation, and impact assessment should be conducted throughout the R&D continuum described below:

- **research and technology generation.** Basic research, applied research, and experimental development are included.
- **technology development.** During this stage, knowledge from research is combined with practical experience to direct the production of a new product.
- **technology adaptation.** This entails piloting technology and simulating real-life conditions for the production of the technology are typically involved.
- **technology transfer.** An important component of technology transfer is IP (intellectual property) management. Typically, institutions manage IP protection, routes to commercialization or transfer, and contractual arrangements that facilitate the transfer of intellectual property from the lab to the market.
- **technology adoption and diffusion.** This stage of the process is key, for it signifies the point that products, transferred to the market, achieve depth and spread widely. Technology *adoption* is measured at one point in time and is associated with the use of transferred technology; technology *diffusion* is the spread of a technology across a population over time.

A robust monitoring, evaluation, and impact assessment framework should demonstrate transparency and confer accountability. It is therefore important that systems enable institutions to document, analyze, and report on research and technology transfer performance effectively.

2. THE FRAMEWORK

There are different methodologies and processes for monitoring, evaluation, and impact assessment. An impact assessment study can be customized and structured to suit the information and reporting requirements of an institution and its stakeholders. Figure 1 illustrates a comprehensive monitoring, evaluation, and impact assessment framework. (The components of the diagram are described in greater detail in subsequent sections of this chapter.)

2.1 *Diagnosis*

For many developing country institutions, the public expects the research to provide solutions to health, food security, sanitation, water, poverty, and environmental challenges. As institutions invest their limited resources in these important areas, their research efforts must be focused so that the resulting impact on society and the economy is optimal. Institutions, therefore, must be able to articulate the problem that the science sets out to address. The needs assessment conducted at the start of a project defines the problem and provides baseline data for the *ex ante* evaluation. At the diagnosis stage of the process, questions should include:

- Who is responsible for collecting performance information?
- What information is being collected?
- When and how often is the performance measure reported?
- How is the information reported?
- To whom is the performance measure reported?

The needs assessment should also seek to determine:

- What is the nature and scope of the problem requiring action?
- What intervention may be made to ameliorate the problem?
- Who is the appropriate target population for the intervention?

The outcome of the diagnosis should be a document that:

- defines baseline information
- sets project targets
- states assumptions
- specifies measurement indicators
- could be tied with *ex post* evaluation, that is, evalulation after the project has ended

2.2 *Planning*

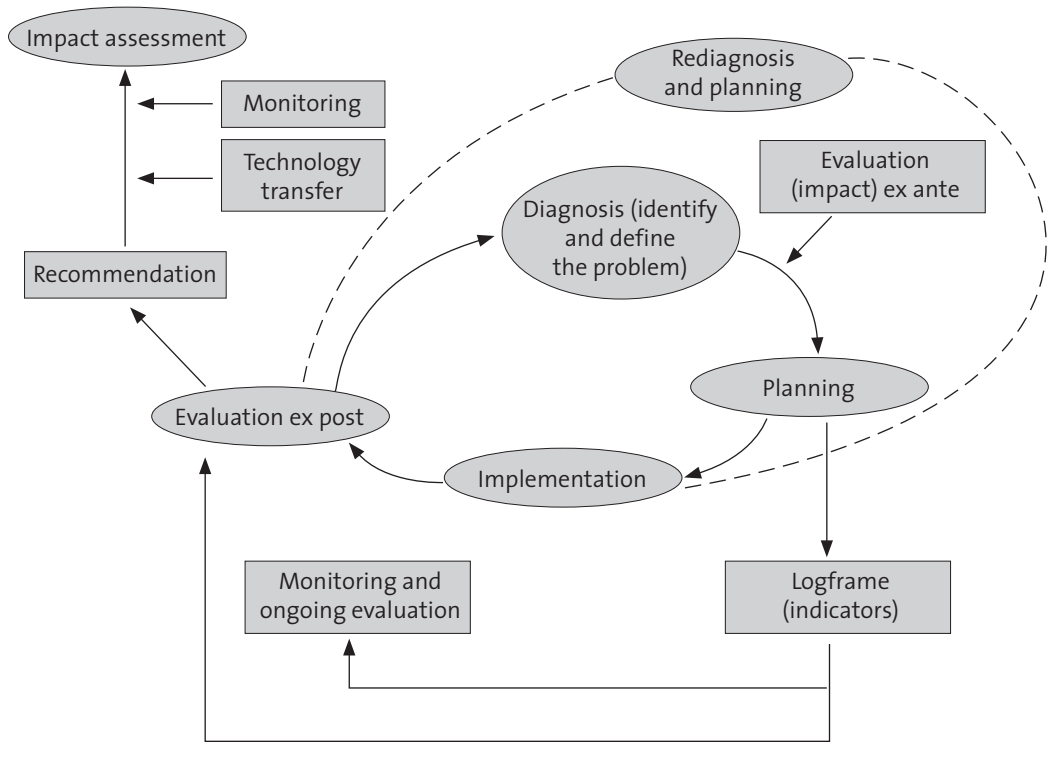
Once the problem has been identified, a plan should be drawn up to explain how the research will address the challenges. A logical framework can be used to structure the various activities and specify means and ends. Information in a logical framework should include:

- why a project is being conducted
- what a project is expected to achieve
- how the project is going to achieve these results
- what external factors are crucial for the success of the project
- how the success of the project can be assessed
- where the data required to assess the success of the project can be found
- what the project will cost

This information is then used to complete the matrix summarizing information, which is required both to design and evaluate the activity. Table 1 illustrates such a matrix.

A logical framework (logframe) is a useful tool for the assessor and has the following advantages:

Figure 1: The Planning, Monitoring, and Evaluation Cycle



- It makes the project appraisal transparent by explicitly stating the assumptions underlying the analysis and by allowing a check on the proposed hypotheses and expected results in an *ex post* analysis.
- It deals explicitly with a multitude of social goals and does not require reducing the benefits into one figure.
- It is understandable to nonscientists. It can therefore be used as a tool to clarify the trade-off among objectives and, thus, specify the decision-making process.
- It is flexible with regard to information and skill requirements. It can incorporate social cost, benefit analysis, use input, output tables, and partial models. It can also be used with rudimentary information skills, albeit at the cost of more hypotheses and uncertainties.

2.3 *Implementation*

Implementation is the actual evaluation; it entails data collection, analysis, and reporting. Evaluation is systematically assessing a situation at a given point in time, whether that point is in the past, the present, or the future. Put another way, an evaluation is the periodic and systematic assessment of the relevance, performance, efficiency, quality, and impact of a project, in relation to set objectives and goals. Evaluation seeks to investigate and determine whether:

- the intervention is reaching the intended target audience
- the intervention is being implemented as envisioned
- the intervention is effective
- the costs of the intervention, relative to effectiveness and benefits, is lower than the benefits

Different monitoring and evaluation systems can be used. The method chosen mainly depends on the following considerations:

- **What should be measured?** The evaluation should be based on the project design. Stakeholders should agree about how the crucial project issues should be measured.

Table 1: Logical Framework Structure

Narrative summary	Objectively verifiable indicators (OVI)	Means of verification (MOV)	Important assumptions
Inputs	• Nature and level of resources • Necessary cost • Planned starting date	• Sources of information	• Initial project assumptions
Outputs	• Magnitudes of outputs • Planned completion data	• Sources of information • Methods used	• Assumptions affecting the input-output linkage
Purpose	• End-of-project status	• Sources of information • Methods used	• Assumptions affecting the output-purpose linkage
Goal	• Measures of goal achievement	• Sources of information • Methods used	• Assumptions affecting the purpose-goal linkage

- **For whom should it be measured?** The users of the evaluation results should be identified and the results should correspond to their expectations.
- **For what purpose should it be measured?** This determines the sensitivity of the measures and the degree of accuracy needed.
- **How should it be measured?** Consensus is needed between the evaluator and program/project managers on whether a proposed measure truly indicates a change in the desired direction.
- **How should the data be collected?** The design of the evaluation system should be determined and the desired level of accuracy in the information agreed upon.
- **When and in what form is the information needed?** It should be available when needed in a usable format.
- **Who collects, analyzes, and presents the information?** This is necessary to adapt the monitoring and evaluation system to the management realities of a program/project. Managers should not underestimate the time needed to analyze and present the information.

The specific questions that an effective evaluation should answer are:

- Is the program effective in achieving its intended goals?
- Can the results of the program be explained by alternative explanations that do not include the program?
- Does the program have effects that were not intended?
- What are the costs of delivering services and benefits to program participants?
- Is the program an efficient use of resources?

Deciding which evaluation process to use depends on numerous factors, such as set objectives, available time, skills, and resources. To guide your choice, Table 2 summarizes data collection designs and their different characteristics.

Typically, data collection methods include checklists, scoring models, cost-benefit analyses, surveys, and case studies. The best approach is to use several different methods in combination, balancing quantitative and qualitative information.

Ongoing monitoring and evaluation processes measure:

- technical aspects: physical input-output of goods and services
- institutional aspects: organizational and managerial aspects, including customs, tenure, local organizations, and cultural setting
- socio-cultural aspects: broader social implications, resource and income distribution, and employment opportunities
- commercial aspects: business and financial, securing supplies, and market demand
- economic aspects: economic efficiency, costs and benefits
- environmental aspects: biological and physical effects

2.4 *Rediagnosis and replanning*

Should the results of a monitoring and evaluation exercise indicate that a project is not going according to plan, then rediagnosis and replanning is required. Rediagnosis and replanning require the measurement process to be continually improved, and changes in the measurement process should be aligned with changing needs and priorities.[4] Program replanning and rediagnosis may also require going back to prior steps in the planning process to review whether:

- the problem is well defined and described
- the objectives are adequately implemented
- a revised-impact model has been developed
- the target population has been redefined
- the delivery system has been redesigned
- there are revised plans for monitoring impact and efficiency

Research programs are dynamic, and evaluations should take this into consideration. Naturally, the longer the research project lasts, the greater the likelihood that a given project will require modification and adjustment. Table 3 summarizes the design, implementation, and assessment requirements of research projects at different stages of maturation.

Table 2: Data Collection Designs and Their Characteristics

Characteristics evaluation design	Cost	Reliability	Technical expertise	Types of evaluation (primarily adoptive to the design)	Ability to measure what is happening	Ability to exclude rival hypothesis
Case study: one measurement (actual vs. planned)	low	very low	low	reporting	very low	nonexistent
Case study: two measurements (before and after)	medium	low	low	process evaluation	good	low
Time series design (prior trend vs. actual)	relatively low, if feasible	medium	medium	impact evaluation	very good	medium
Case study with one measurement and a control group (with and without)	medium	low	low	formative evaluation	low	low
Quasi-experimental design	relatively high (variable)	relatively high (variable)	relatively high	impact evaluation	very good	good (variable)
Experimental design	expensive			evaluation research	very good	very good

2.5 Ex post *evaluations*

These take place at the end of a research project, when the effects and results of the project can be tracked and used in adoption studies. At this stage, the evaluation:

- assesses the project's performance, quality, and relevance, immediately after its completion
- works best when a pre-project baseline had been defined, targets projected, and data collected on important indicators
- is often done by professional and external evaluators
- requires that classical criteria be broadened to include user satisfaction
- should be an integral part of project implementation
- demands advanced preparation
- uses a blend of interviews, field visits, observations, and available reports
- provides lessons that can be systematically incorporated into future activities, for example *ex ante* evaluation, as well as project planning
- is usually only done for more important, innovative, or controversial projects

Essentially, *ex post* evaluations determine impact and are used to demonstrate accountability. The evaluations sum up the lessons learned from the project. They provide a firm foundation for future planning and for establishing the credibility of public sector research. They can also be used to justify an increased allocation of resources.

2.6 *Recommendations*

The recommendations that arise from evaluation studies should assess the information collected. Evaluations should also review:

- what turned out differently than expected
- which part of the strategy produced the desired results and which did not
- whether a cross-section of views were sought and accommodated

Table 3: An Assessment Planning Guide

	Innovative programs	Established programs	Fine-tuning
Conceptualizing	• problem description • operationalizing objectives • developing intervention models • defining extent and distribution of target population • specifying delivery system	• determining capacity for evaluation • developing evaluation model • identifying potential modification opportunities • determining accountability requirements	• identifying needed program changes • redefining objectives • designing program modifications
Implementing	• formative research and development • implementation monitoring	• program monitoring and accountability studies	• R&D program refinements • monitoring program changes
Assessing	• impact studies • efficiency analyses	• impact studies • efficiency analyses	• impact studies • efficiency analyses

- with whom the findings need to be shared
- in what form the results should be presented

There are various uses for evaluation findings. The outcomes of an evaluation can be categorized into three basic types: direct, indirect, and symbolic.[5] Evaluation outcomes are direct when information or findings are applied directly to alter decisions and results in an operational application. Indirect use refers to a more intellectual, gradual process, in which the decision maker gleans a broader sense of the problems addressed by a project or program. Indirect use of study results produces a strategic or structural application of outcomes. Symbolic use refers to situations where the evaluation results are accepted on paper, but go no further. Unfortunately, many evaluation studies end up as symbolic initiatives. It is imperative that technology transfer assessments do not end up simply as academic exercises. When an assessment is not practically applied or used, not only is the effort wasted, but future programs may continue to repeat mistakes and waste money.

2.7 *Impact assessment*

An impact-assessment study aims to determine causality and to establish the extent of improvement for the intended beneficiaries. Impact assessments are time sensitive and, therefore, studies should be conducted periodically throughout the duration of a project. An impact study should measure the rate of adoption for technologies that have been made available for social or industry use. Such studies should assess the technology's level of use by targeted beneficiaries and estimate the benefits of R&D investments. By following these guidelines, impact studies should be able to determine the impact of technology generation and transfer. Impact assessments should also seek to measure both intended and unintended outcomes, taking into account behavioral change among potential users and beneficiaries. The resulting effect on productivity and quality of life should be measurable and, therefore, evaluated and reported.

When conducting an impact study, the impact is assessed by gathering information on the number of users, degree of adoption, and the effect of the technology on production costs and outputs. Studies should be conducted at different levels (for example, household; target population; regional and national; and at primary, secondary, or economy-wide sector levels.)

There are different types of impacts. Production and economic impact measure the extent to which the project addresses:

- risk reduction
- yield increases
- cost reduction
- reduction in necessary inputs
- employment creation
- implication for other sectors of the economy

Socio-cultural impact measures the extent to which the project contributes to:

- food security
- poverty reduction
- status of women
- increases in knowledge and skill level
- number and types of jobs
- distribution of benefits across gender and geographical locations
- changes in resource allocation
- changes in cash requirement
- changes in labor distribution
- nutritional implications

Environmental impact measures the project's effects on:

- soil erosion and degradation
- silting
- compact soil
- soil contamination
- water contamination
- changes in hydrological regimes
- effects on biodiversity
- air pollution
- greenhouse gases

Institutional impact measure effects on:

- changes in organizational structure
- change in the number of scientists

- change in the composition of the research team
- multidisciplinary approaches and improvements
- changes in funding allocated to the program
- changes in public and private sector participation
- new techniques or methods

2.8 *Tools*

Different tools are used to measure performance over time. These include (1) secondary analysis of data, (2) the screening of projects and research orientations by peers and experts in the field, (3) qualitative descriptions of case studies and anecdotal accounts, and (4) matrix approaches, which provide rich information and help to rationalize and simplify choices.

Examples of the matrix approach include:

- **systemic methods.** can be used to implement an evaluation (This method is not really suitable for evaluating and can be very difficult to implement.)
- **financial methods.** namely, cost-benefit measures that take into account marketable outputs and commercial resources (It is often difficult to collect the information, and some factors cannot be financially assessed.)
- **technological forecasting methods.** entail the use of scenario methods and allow for the causality chain to be reversed (This method also allows for forecasting and takes into account social transformations.)
- **quantitative indicators.** for example, science and technology indicators and measurement, pure descriptiveness, and selection integration (Indicators provide fundamental scientific output measures.)

To help select the most appropriate study method, Table 4 maps the desired impact of a study against the assessment method and technique.

2.9 *Indicators*

Developing indicators is a critical step in the evaluation process. Ultimately, indicators drive impact assessment and influence how the assessment is conducted. In summary, there are three evaluation methods used to assess impact. These can be (1) qualitative, such as peer review, (2) semiquantitative, such as tracking scientific evidence, or (3) quantitative, such as econometric measures. The evaluation method selected should depend on the evaluation objectives of the study and the needs of each stakeholder (Table 5). The strengths and drawbacks of each tool are presented in more detail in Table 6 (at the end of this chapter).

3. CHALLENGES AND KEY SUCCESS FACTORS

Monitoring, evaluation, and impact assessment is a complex field. The conditions, methodologies, and projects described here present various challenges that need to be factored into the evaluation and impact study. These challenges include the relatively unpredictable nature of research and technology transfer events. Certain research outcomes are discrete and are thus difficult to measure, track, and document. Moreover, there is no single, accurate method to objectively evaluate R&D performance. There are also institutional challenges. Effective communication between stakeholders can be a problem, partly because of the difficulty of maintaining data quality. And because assessments tend to focus on measuring more immediate, short-term benefits, there is the risk of overlooking some of the longer-term benefits of R&D. This issue is also related to determining the frequency of assessment studies. For example, the European Union has adopted a system that calls for three impact assessment studies: an *ex ante* study at the start of the project, a project-end assessment, and an *ex post* study three years after the completion of the project.[6] The frequency of the study may affect its temporal focus. Of course, without establishing the commitment and resources to collect, process, store, and make accessible key performance data, nothing can be accomplished. Technology transfer managers need to develop the infrastructure necessary to have valid and reliable performance information and use this data for decision-making. They should take the time to develop a shared understanding with funders about the role

Table 4: Impact Assessment Methods and Techniques

Impact Type	Method	Technique
Intermediate impact • Institutional changes • Changes in the enabling environment	Survey, monitoring	Simple comparison/trend analysis
Direct product of research	Effectiveness analysis using logical framework	Simple comparison: target vs. actual
Economic impact (micro, macro, spillovers)	Econometric approach, surplus approach	Production function, total factor productivity, index number methods, and derivatives
Socio-cultural impact	Socioeconomic survey/ adoption survey	Comparison over time
Environmental impact	Environmental impact assessment	Various • Qualitative • Quantitative

Table 5: A Summary of the Evaluation Needs of Different Stakeholders[7]

Evaluation activity	Policy-makers	Donors	Research managers/ program leaders	Researchers
Review of entire system	X	X	X	X
In-depth review of component		X	X	X
Ex ante evaluation of program/ project		X	X	X
Ongoing evaluation/ monitoring of research activities		X	X	X
Ex post evaluation of a research program/project		X	X	X
Impact assessment	X	X	X	X

of public R&D within the national innovation system. Such efforts may make it possible to alleviate shortages of essential financial, human, and knowledge resources.

It is essential to identify the key factors that, if in place, will improve the effectiveness of an assessment framework. Managers must strive to have in place as many of the following key success factors as possible:

- leadership commitment
- a desire for accountability
- a conceptual framework
- strategic alignment
- knowledgeable and trained staff members
- effective internal and external communication
- a positive and not punitive culture
- rewards linked to performance
- effective data processing systems
- a commitment to and plan for using performance information
- adequate resources and the authority to deploy them effectively.

4. CONCLUSION

An effective evaluation system should strengthen an institution's ability to maintain leadership across the frontiers of scientific knowledge. The system should enhance connections between fundamental research and national goals, such as improved health, environmental protection, prosperity, national security, and quality of life. Such an evaluation system also will stimulate partnerships that promote investments in fundamental science and engineering, as well as the overall more effective use of physical, human, and financial resources for social and economic benefit.

As a way of benchmarking progress, it is helpful to examine how other organizations measure impact. Impact measures are a sure way of knowing that science is delivering on its objectives and that R&D projects are having their intended effect. Without a measurement process, institutions cannot justify their efforts in R&D, IP management, commercialization, and technology transfer in relation to their economic and social goals.

Finally, it is essential to take the time to digest, reflect upon, and learn from an impact-assessment process. Lessons can be learned from both successes and mistakes, and these lessons should not only be used to take corrective action but also to improve future performance. ■

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7 Interest depends on the activity and the role of the stakeholder concerned.

Table 6: Comparison of Assessment Tools

Methods	R&D time frame	R&D type	Strengths	Weaknesses
Modified peer review	past, ongoing, and future	all	• relatively easy to organize • can provide valuable information on potential impacts • probably the best method for basic/ strategic R&D • low to medium cost	• relies on the opinions of a small number of people • qualitative information only
User surveys	past and on-going	applied R&D	• overcomes the problem of a small number of respondents • possible to develop quantitative indices • medium cost	• structuring the survey and analyzing the results can be tricky • often requires considerable time to identify users, develop survey methodology, and analyze results
Benefit-cost methods	past, can be used for ongoing and future R&D in certain circumstances	applied R&D	• can provide reasonable defensible estimates of potential benefits • provides a structure and a framework for assessing R&D projects that forces the right questions to be asked	• can be very time consuming and labor intensive • results are critically dependent on assumptions that can be highly uncertain • because of cost and time requirements, can only be used for a limited number of projects • relative cost is high • data collection requirements are demanding
Cost-effectiveness analysis	future, past (to a certain extent)	applied R&D	• simplest • does not require benefit information • medium cost	• there is nothing to prove that any of the alternatives can yield benefits over and above costs • if one of the alternatives costs less, but produces a low quality product or has a different impact, then the assessment becomes more complicated

(Continued on Next Page)

Table 6 (continued)

Methods	R&D time frame	R&D type	Strengths	Weaknesses
Case studies	past	applied R&D	• can provide good illustrations of the relationship between R&D and its impacts • probably the best method for basic/strategic R&D • medium cost	• generally there is no way to add up the results of a group of case studies to obtain a measure of the total impact of the group • the results cannot be extrapolated to other R&D projects that are not in the group
Partial indicators	past, ongoing, and future	all	• the information required to specify the indicators relatively easy to collect • probably the best method for ongoing monitoring • low relative cost	• the individual indicators can generally only be added up on a subjective basis, making overall impact assessment more difficult • provides only a very partial picture of impacts
Integrated partial indicators	future	applied R&D	• an easy but structured way to identify research priorities • forces decision makers to explicitly consider the key determinants of impacts • low relative cost	• relies heavily on the judgment of a few individuals • there is a potential for bias in assigning weights to different criteria
Mathematical programming	past, ongoing, and future	applied R&D	• more powerful and sophisticated • enables one to select optimal portfolio • can handle simultaneous change in many variables	• demanding in terms of data requirements • high relative cost • not particularly useful for evaluating too diverse a set of R&D projects • if either the criteria or constraints are not well defined, there is a risk of arriving at a nonsensical "optimal" solution

(Continued on Next Page)

Table 6 (continued)

Methods	R&D time frame	R&D type	Strengths	Weaknesses
Simulation method	past and future	applied R&D	• flexible • can be used to estimate optimal level of research at national, commodity, or program level • can estimate the effect of research on prices, income, employment, or other parameters • can handle simultaneous change in many variables	• to be useful, it must accurately reflect the relationship between technological advancement and economic development • requires an extensive amount of time to construct and validate data • medium to high relative cost
Production function approach	past	applied R&D	• offers a more rigorous analysis of the impact • estimates marginal rates of return • statistically isolates the effects of R&D from other complementary inputs and services	• uncertainty in projecting past rates of returns to future • demanding in terms of data • selection of suitable functional form can be difficult • serious econometric problems may be involved • relative cost is high

SECTION 7

Contracts and Agreements to Support Partnerships

Agreements: A Review of Essential Tools of IP Management

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ABSTRACT

Public-sector research institutions can use a variety of agreements to protect and manage intellectual property. These agreements are powerful tools to foster competition in the private sector and reduce prices for consumers in developing countries. This chapter provides an overview of the following types of major agreements—confidentiality, material transfer, development (in which the licensee is responsible for further development), co-development (in which two parties collaborate on continued development), and distribution—explains the functions of those agreements, and suggests strategies for their effective use. The chapter also discusses the meaning and usefulness of the standard elements and formulas found in such agreements. It explains the meaning and significance of the terms and language used and discusses such key issues as product liability, fees and royalties, and arbitration. The chapter emphasizes the importance of establishing and maintaining trust when negotiating and implementing agreements.

1. INTRODUCTION

One important goal of public sector licensing should be to promote competition between private companies. Monopolies and high prices are not caused by patents themselves but by how patents are managed, so the goals of the public sector can be served by using licensing strategies that foster competition and reduce prices.

Many kinds of agreements are used to protect and manage intellectual property (IP). These include agreements for confidentiality, material transfer, development (in which the licensee is responsible for further development), co-development (in which two parties collaborate on continued development), and distribution.

Most agreements are between two parties, but some may involve three or more parties. The public sector agency or the negotiating party may provide the first draft of an agreement for negotiation. Whoever writes the first draft often has the advantage, so public sector agencies should, whenever possible, take the initiative to prepare the agreement. Regardless of who provides the first draft, the proposal should adhere to the principle of good negotiations: offer an agreement that you would be willing to sign, if you were the other party. A good agreement benefits both parties. For an agreement to work, the two parties must trust each other and maintain this trust throughout the implementation of the agreement. With a high level of trust, moreover, a request to renegotiate by either party may be better received should circumstances change. Finally, since enforcing international agreements through legal remedies may be difficult, such agreements should be considered solemn commitments that must be observed.

2. THE USE AND LIMITATIONS OF TEMPLATE AGREEMENTS

The chapter provides a number of template or sample agreements for each major type of contact.

Mahoney RT and A Krattiger. Agreements: A Review of Essential Tools of IP Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

The online version of this *Handbook* also provides many agreements from different institutions from countries around the world. Each of these agreements can be downloaded in Microsoft Word or Adobe PDF formats.

Evidently, no template agreement can be nor should be considered as the "correct" or "best" agreement. Any agreement must embody, specifically, the deal that has been struck between the parties, and a good deal for all parties will depend on the purpose of the deal and the context in which the deal takes place. The template agreements are merely intended as illustrations and possibly become a starting point for discussions and negotiations. In the discussion of the agreements in the Section 3, special reference is made to humanitarian-use clauses where appropriate and relevant.

It should be noted that template agreements are useful when used judiciously and as a starting point in the total process that ends in a final agreement between or among the parties. A template agreement may be more or less complete, but clauses will always have to be changed, deleted, or added. It is useful, however, for any organization to develop its own template agreements that include the major elements that are regularly used. The final draft agreement should be reviewed by the institution's counsel before signature (and in some cases even before sending it to the other party for review).

The online version of this *Handbook*[1] will include a section with several hundred actual downloadable agreements from many different institutions.

3. MAJOR TYPES OF AGREEMENTS

Two parties establishing a long-term working relationship could sign a series of agreements, or they could sign one or two agreements that combine several agreements within them. The following list appears roughly in the order that agreements would be signed when two parties are engaged in the development and distribution of a new or improved product.

3.1 *Confidentiality agreements*

Confidential information will probably be part of discussions to establish business relationships involving proprietary health products. Such confidential information could concern laboratory data and other research data, sources of materials, methods of production, the nature of licensing agreements, detailed design of specialized equipment, staff-training requirements, countries in which the developer would like to sell the product, and so on. It is wise to conclude a confidentiality agreement before entering into serious discussions about a relationship with another party. Aside from the obvious aim of protecting confidential information, such an agreement ensures that both parties are treating the discussions seriously. An agreement to convey and protect confidential information is a measure of the willingness of both parties to proceed. This is especially important for the party receiving confidential information. They should be able to ask any reasonable question and expect a fairly detailed response. Without a confidentiality agreement, the other party can refuse to provide information that they consider sensitive. It is more difficult to negotiate a confidentiality agreement after negotiations have begun, especially if trust has been damaged.[2]

3.2 *Materials transfer agreement*

Before agreeing to sign a license for further product development, a potential licensee may wish to evaluate the new material(s) or products to see if it works well in his or her hands. Although licensors should be willing to provide samples, they have an interest in assuring that the prospective licensee does not misuse the samples. Misuse might involve passing on a portion of the sample to a third party or using the sample to generate additional material for future use without concluding a license. It is generally recommended that public-sector research organizations use either a Simple Letter Agreement[3] or the Uniform Biological Materials Transfer Agreement and the Implementing Letter format developed by the National Institutes of Health.[4] In cases where large numbers of materials need to be transferred on a regular basis, such as by plant breeders, a simple material transfer agreement, such as that developed by with the International Network for Genetic Evaluation of Rice (INGER),[5] various national agricultural research and extension

systems in Asia and the International Rice Research Institute (IRRI) might be most appropriate (Box 1: see also Appendix of this *Handbook* at the end of Volume 2, page 1853).

3.3 *Invitations to collaborate*

To achieve its product-development goals, a research institute will often need to collaborate with another organization. This need may arise at any point, from laboratory studies through licensure and distribution. For example, when a public-sector research program requires prototype products for clinical trials, it will probably need to find a partner because most public-sector research centers lack high-quality production facilities. Likewise, for many neglected diseases in developing countries, highly specific, highly sensitive, affordable diagnostics are unavailable, and so collaboration might be needed when diagnostics are required for surveillance or clinical trials. Collaborators are such an important part of successful development that public-sector research institutions should have a thorough process for identifying them. Collaborators may be sought through Invitations to Collaboration, which should be widely distributed in international journals or other media, including the Internet and an organization's Internet home page. Summaries of the goals of the collaboration might also be included in the invitation. Responses to an invitation should be reviewed according to well-defined criteria, and all applicants should receive a report on the outcome of the process. An open and transparent process (with appropriate protection of confidential information) will establish a reputation for fairness. Sometimes, sole sourcing for one of the collaborating entities may be appropriate because of the undisputed capability of one organization to undertake the work rapidly, effectively, and inexpensively. Cases of sole sourcing, however, should be clearly documented, and management should be able to explain clearly why the sole-source route was chosen (see Box 2). Once a collaborator has been identified, it will be timely to negotiate a co-development agreement.[6]

3.4 *Co-development agreements*

If research and development have reached a stage at which further extending the work requires additional capabilities that a public-sector research institution either lacks or does not wish to allocate, then the institution will want to enter into a co-development agreement with a partner identified through the Invitation to Collaboration process.

Co-development agreements vary widely with regard to the extent to which the original owner or product developer retains control over the product. A lone inventor with no development capability may have very little control over what happens to the product once a co-developer is brought into the picture. On the other hand, a large firm that has completed virtually all of a product's development, and only needs, for example, to clinically test the product at a new dosage, may retain almost complete control (in such cases, the firm may simply execute a subcontract with the clinical-testing organization). A co-development agreement will define the nature of the final product or other output sought, the role of each party in the development process, the resources (financial, personnel, and institutional) each party will invest, the process by which the project will be managed, the interim goals (milestones) and timetable, and provisions for sharing in the success or failure of the effort. Of particular importance is the project-management system. It is common to establish a project-management committee comprising staff from each party. The number of members from each party, the authority of the committee, the frequency of meetings, and the requirements for written reports will be specified in the agreement (see the Appendix of this *Handbook* for a sample co-development agreement).[7]

3.5 *Technology licensing agreement*

These are the most common types of agreements negotiated by universities. It allows one party to use, make, or sell products involving the intellectual property of the other party. The agreement has terms defining the length of time the license is valid; the markets (territory) in which the licensee can make, use, or sell the product; whether or not sublicenses are permitted; the nature and amount of up-front fees and royalties; and whether or not the licensor has rights to any improvements developed by the licensee. Many other terms can appear in a licensing agreement. See Appendix for a

sample technology-license agreement, and Sections 11 and 12 in this Handbook contain many chapters dealing with specific elements of licenses.

3.6 *Distributorship agreement*

Distributorship agreements permit the licensee to receive a product from a licensor or to purchase a product from a third party for distribution in a defined market under a number of conditions involving price, quantities, quality, labeling, royalties, and so on. The agreement often allows the distributor to arrange for clinical trials, submit required documentation to the national licensing authority, and prepare and carry-out product promotion. A public-sector research institute, for example, may arrange for a diagnostic to be manufactured by a commercial company that may not be interested in marketing the diagnostic in any or all territories.

Because they place a valued product in the hands of a second party, distributorship agreements are treated very carefully, especially the negotiation and implementation phases of such agreements. In cases of drugs, vaccines, and diagnostics, a license grants the licensee the right to obtain a regulatory permit to sell the product in a given market. If the license should be terminated because the licensee does not perform or loses interest in the product, the licensor and a new licensee may find it difficult to get a new permit from the regulatory authority. They may have to repeat many expensive activities with the attendant delays. One way to address this potential problem, if local law permits, is to require the regulatory license to be transferable to a third party selected by the licensor. A distributorship agreement can also be the first step in building a long-term relationship that can lead to technology-licensing agreements and additional co-development agreements. The Appendix of this *Handbook* contains a sample distributorship agreement.

4. STANDARD ELEMENTS OF AGREEMENTS

4.1 *Recitals, preamble, and whereas clauses*

Laying out the broad motivations and goals of the parties, this opening section is important, particularly in agreements between public and private sector agencies. It documents that the parties believe their motivations and goals are complementary, and because the objective of an agreement is to have a win-win outcome, this section should set the right tone and clearly state the parties' reasons for entering into the agreement. If a dispute ever arises between the parties, the information in this introductory section could be invaluable should the dispute end up in arbitration or litigation.

4.2 *The parties*

The parties are those persons, companies, or institutions that willingly enter into an agreement. Most often, there are two parties, but the number may be more than two. The agreement may be between two institutions or two individuals, or an institution and an individual. It is important to note that if one of the parties is an institution, then the entire institution is bound by the agreement.

Note that the incorporated names of the institutions involved, as well as their headquarters, are included in the parties' names and addresses list. Some organizations have regional offices or subsidiaries with authority to enter into agreements. The addresses here may be different from the addresses to which notifications or data must be sent.

4.3 *Definitions*

Any agreement is built around the meaning of the written words. Many words or phrases are legal "terms of art" that do not require definitions if the usage is standard within the corresponding field. Including a definition section enables a lawyer, in drawing up an agreement, to use the language of the agreement precisely, clearly, and consistently without deviation in either the forms of terms or their meanings. For example, as a legal term of art, the term *infant* refers to any child up to the age of adulthood—not just a baby—and a "foreign corporation" is one incorporated in any jurisdiction, not necessarily another country. If there is any doubt whether a term will be understood, it is advisable to define it, in order to avoid any confusion later.

4.4 *Confidentiality*

Confidential information disclosed in tangible form is managed very carefully. The information is placed in a secure, locked filing cabinet or in a password-protected computer and marked "CONFIDENTIAL." Only those staff covered by the confidentiality agreement have access to the material. Either they should complete a check-out form when they remove the material, or, with digital materials, a record should be made of the materials being accessed. Orally transmitted information should be put in writing soon after it is provided and the written form checked in and out as appropriate. Scientists commonly discuss research findings freely and seek to publish them early. However, if the generation of intellectual property is an important goal, scientists will have to consider how they can disseminate their findings while helping to produce the intellectual property. One way to overcome this difficulty is for IP management offices to swiftly evaluate whether to patent a new discovery. Some technology transfer offices can complete such an assessment in 30 days, which does not unreasonably delay the presentation or publication of the work. It should always be remembered that confidential information has commercial value and its improper release can cause substantial damage. The original owner of the confidential information could seek financial damages for the unauthorized release of confidential information. Divulging confidential information might also be grounds for terminating the agreement.

4.5 *Territory and exclusivity*

In a licensing agreement, the territory is the geographic region in which the licensee is permitted to make, use, or sell the product. Applying mainly to distribution agreements, a territory can be a part of a country, a whole country, several countries, or the whole world. Exclusivity determines whether the licensee will have to share the territory with one or more other licensees of the same products. Licensors grant nonexclusive licenses to stimulate competition among licensees and to provide alternate distributors in case one licensee fails. For health products, a licensor rarely grants anything but an exclusive license when the license is for the limited territory of a single country. One reason for this is the cost and time required to obtain the approval of the national licensing authority. Few licensees would be willing to take on this burden if others could freely take advantage of their costs for obtaining regulatory approval.

In general, licensees want the most territory and the highest level of exclusivity. This gives them the greatest opportunity to exploit markets, seek profits, and keep competitors away. Moreover, it generally lowers the licensee's risk. With an unproven licensee, it is prudent to limit both territory and exclusivity to the minimum necessary for the project to succeed (at least initially). It is a licensor's nightmare to spend several years working with a licensee only to have that licensee fail to develop the product's market. A compromise middle ground is for the licensor to grant increasing levels of territory and exclusivity as the licensee achieves various performance milestones. For example, the licensee could receive a license to a new territory after successfully completing a marketing plan for that territory and investing some base levels of funds to implement the plan. Or a licensee could be required to pay a separate license fee for each additional territory granted. The amount should be large enough to ensure that the licensee will want to protect the amount paid by actually developing the market in the new territory. A good rule of thumb is that a license should be granted only when it is probable that the licensee will be able to develop that market. A key consideration for the licensor is to calculate the minimum market size necessary to reach its financial goals with the product. One issue with exclusive licenses is that they de facto form monopolies, which can make it difficult for the public sector to obtain the product at an affordable price.

4.6 *Product liability*

Product liability is increasingly important. Once an issue primarily of concern in the United States, product liability is becoming a problem in Europe as well as the rest of the world. It affects many aspects of the health product business, from the conduct of clinical trials to product

prices, which are increased to cover the cost of liability self-insurance.

All health-product manufacturers and distributors should be concerned about the safety of their products. There is a chance that a product will harm an individual. Preventive products (for example, vaccines) are the cause of greater concern than therapeutics, since the former are given to healthy individuals. When a health product harms an individual, it is reasonable for that person to be compensated for the injury. The form of compensation, however, will vary depending on the country. Unfortunately, in developed countries, "product liability" has, to some extent, become a kind of lottery: individuals seek huge awards based more on the ability of the company to pay than on the actual losses. Sometimes the awards are so large that the very survival of the company is threatened. This situation has made companies quite defensive regarding liability, affecting their willingness to enter new markets and to develop new health products.

When negotiating a license, the key question with respect to liability is: who should accept product liability and for what? For some matters the answer is clear. A manufacturer, for example, should be responsible for adhering to good manufacturing practices and should be responsible for any injury caused by errors in the production process. A public sector licensor will usually expect the licensee to assume most of the liability because the licensee sells the product. A licensor may, as a condition for granting the license, make acceptance of liability by the potential licensee, which places a special burden on the licensee to assess carefully the product's potential liability implications. It is extremely rare for a licensor to be brought into a liability suit. If accused, it is even rarer for a licensor to be found liable.

Even if a licensee holds the licensor harmless, doing so would not prevent the licensor from being named in a suit. The costs of defending a suit, especially in the United States and Europe, can be very large—sometimes almost as damaging as a liability judgment itself. The licensor should therefore request, and have this specified in the agreement, that the licensee meet all costs incurred, within reasonable limits, by the licensor in defending a liability case. Insurance is available to cover just the legal costs of defense. The licensor should ask for proof that the licensee has obtained liability insurance and that the insurance is kept in force. Liability is an extraordinarily important issue, and public sector research groups are well advised to obtain high-quality professional advice.

4.7 *Up-front fees and royalties*

A license transfers value. The up-front fees and royalties, therefore, are the agreed price representing that value. Since licenses are not traded in open markets, where the price can be set through supply and demand, each negotiation is unique and reflects the evaluations of each party. A licensor will have several considerations. First, the licensor will want, at a minimum, to recover the expense, or some reasonable portion of the costs, already invested in the product. Second, the licensor will want to generate a steady flow of income.

Up-front fees have to balance two issues. First, they should be high enough, if possible, to meet the licensor's need for short-term income and to assure that the licensee is seriously seeking to develop the product. Second, they should not be so high that they limit the ability of the licensee to invest in the product and make it a success. Other factors to consider are the expected life of the product and the lifetime of the IP rights being granted. The shorter the life of a product (because other, better products are expected to emerge quickly), the less the licensor can ask for up-front fees and, to a lesser extent, royalties. If the license is based on a patent, at the end of the patent's life the level of royalties may decrease or the license may even expire. The term of the license is more complicated when the license is for know-how. A reasonable but complicated approach for such licenses is to have the royalty diminish with time and eventually reach zero when both parties agree that the know-how is no longer valuable. Such an event might occur when the licensor stops using the know-how. But if the know-how is essential for successfully manufacturing and selling the product throughout its lifetime, there is no reason for the royalty

to change. Also, a licensor may make continual changes in the know-how and pass those on to the licensee. In this situation, royalties may be collected for a very long time.[8]

Having said all this, it is important to remember that the goal of the licensing strategies discussed here is to maximize benefits for the public sector. Possible up-front fees and royalties should be seen simply as two ways to extract value for the public sector—and perhaps not the most desirable ways.

4.8 *Arbitration*

Successful agreements are based on trusting relationships, and both parties in an agreement should work to maintain trust in implementing the agreement. Some agreements, usually those negotiated between two parties in the same country, can allow for disputes to be settled in court. The more common practice, however, is to use arbitration. The issues for consideration here are the number of arbitrators, how they are chosen, their operating rules, the location where the arbitration shall take place, which party shall bear the costs of the arbitration process (or what share each party will bear), and whether the arbitration should or should not be administered by an arbitration institution.

In one formulation, three arbitrators are used. Each party chooses one, and the two arbitrators, so chosen, choose the third. The third arbitrator serves as the chairperson of the panel. The arbitrators may operate according to various rules. An international set of rules is a common reference, and many arbitration institutions have their own arbitration rules. In addition, most countries have laws that govern arbitral proceedings conducted within their territory. These laws should be carefully considered when choosing the arbitral locale. Location is also important because of costs. If arbitration occurs at the offices of one party, the other party will have to incur costs to be present for the proceedings. Cost allocation can be specified in the agreement, or the arbitrators can allocate the costs. Arbitration can be very costly, which further emphasizes the need to ensure that the initial negotiations are as thorough and specific as possible.[9]

4.9 *Term and termination*

Term and termination clauses specify the term over which an agreement is to last. The beginning date can be either a specified calendar date or, more usually, the date on which the last signature is applied. A specified date might apply when certain calendar-specific tax matters are important or when it is essential to ensure that one party does not delay initiation of the agreement.

Termination is a much more complex issue. A standard termination provision should include cases in which one party breaches a part of the agreement. The party that feels there has been a breach by the other party will be required to send a notice of breach. Usually, a period of time is provided during which the supposedly breaching party can correct the breach or prove that a breach has not occurred. Also, since circumstances can change, it may be desirable to allow one or both parties to terminate the agreement following the expiration of a defined notice period (for example, 60 days). It may be desirable to define the circumstances under which such termination is allowed.

4.10 *Jurisdiction, warranties, notices*

The agreement will specify that, in the case of a dispute, laws will apply in a particular country, state, or province. The jurisdiction will usually be that of the licensor, although there may be reasons to have a neutral third location.

Each party to the agreement should warrant that it has the authority to do what is contained in the agreement. For example, if the agreement is a patent license, the licensor will warrant that it owns the patent and that it is not aware of any infringement of the patent. Conversely, this warrant may include that the licensee cannot hold the licensor liable for any unknowing infringement that may be discovered. Warrants are often symmetrical (that is, each party warrants the same things).

An agreement will specify the name, address, and other contact information of the individuals or positions within each party to which official communications should be directed. The notice clause may also specify whether fax and electronic documents are acceptable.

4.11 *Other potentially important clauses*

In certain types of agreements or jurisdictions, the following clauses may be of particular importance:

4.11.1 *Illegal/unenforceable provisions*

In some jurisdictions, it might be advisable to include certain limitations:

Should any court of competent jurisdiction later consider any provisions of this Agreement to be invalid, illegal, or unenforceable, such provisions shall be considered severed from this Agreement. All other provisions, rights, and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intentions of the Parties.

4.11.2 *Statement of completeness*

Many organizations have more than one agreement with a specific third party in place. If that is the case, then the formerly existing agreements should be cited whenever possible and reviewed for consistency with any new agreement. Alternatively, the agreement may be limited to the purpose that has previously been defined. Typical language could read:

The above constitutes the full and complete Agreement on this Purpose by and between the Parties.

4.11.3 *Subject law*

In the subject-law section, the Parties clarify where they wish to have an agreement interpreted and adjudicated. Such a determination is not always necessary but can make future interpretation less difficult, particularly if the Parties are located in different countries. Typical language is:

This Agreement shall be interpreted, construed and adjudicated under the laws of _____ province [or state, canton, etc.] _____ within the nation of _____.

4.12 *Signatories*

Representatives with authority to bind their respective institutions are the persons who should sign agreements. It is advisable to include the person's title to make clear that the person is representing the Party and not signing the agreement as an independent entity.

In some cases, more than one representative from each party should sign an agreement. For example, when materials are transferred to a laboratory of a specific scientist, it is important to ensure that the scientist is fully aware of the obligations so the scientist may be included as a signatory.

Further, in a university setting, different departments or even legal entities may have certain responsibilities over in-licensing and out-licensing. For example, an office of sponsored programs may be responsible for incoming materials, whereas a foundation that commercializes university inventions may also have a stake in the agreement. In such cases, there may be signatories representing at least three entities, one of which may include the chief scientist.

5. CONCLUSIONS

No agreement will ever be perfect. Evidently, there are good and not-so-good agreements (and even poorly written ones or highly ineffectual agreements). The better ones may take longer to negotiate, but the good news is that each time an agreement has been successfully developed by two parties, the process gets easier. Taking time to think through and discuss the terms of an agreement helps foster communication between the partners. Such an activity, especially if carried out early on, sets the project on a path for success. In any case, the critical aspect of any agreement is what the parties do after the agreement has been signed; an agreement should always be seen as just the beginning of a long and mutually beneficial relationship. ■

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1 www.ipHandbook.org. Included there are many actual agreements including confidentiality, material transfer (for germplasm, biological resources, materials for testing, research tools, and experimental animals), IP licenses for copyright, software, trademarks, trade secrets, and various forms of exclusive, coexclusive and nonexclusive licenses, as well as the Model Provisions for an Equitable Access and Neglected Disease License developed by the working group, based at Yale University, convened by Universities Allied for Essential Medicines. Other chapters in this *Handbook* also contain sample agreements including nonasserts, invention disclosure, licensing checklist, and more. Please refer to the index for a list of agreements.

2 See, also in this *Handbook*, chapter 7.2 by SP Kowalski and A Krattiger.

3 See, also in this *Handbook*, Box 3 in chapter 5.7 by AB Bennett.

4 See http://ott.od.nih.gov/policy/rt_guide_final.html and http://ott.od.nih.gov/NewPages/UBMTA.pdf.

5 The swift program at Cornell University and IRRI collaborated at the time for the INGER Training-Workshop on IPR, 17-18 July, 2001, Maruay Garden Hotel, Bangkok, Thailand.

6 See, also in this *Handbook*, chapter 17.10 by KR Schubert.

7 Ibid. and chapter 7.4 by MB Steinbock.

8 See, also in this *Handbook*, chapter 5.4 by BJ Weidemier.

9 See also, in this *Handbook*, chapter 15.3 by E-J Min.

10 Mahoney RT (ed.). 2004. Handbook of Best Practices for Management of Intellectual Property in Health Research and Development. MIHR: Oxford, U.K.

Box 1: Material Transfer Agreement for the Genetic Evaluation of Rice to and from INGER Collaborators

The International Rice Research Institute, MCPO Box 3127, Makati City 1271, Philippines ("IRRI"), provides the "Material" _____

_____

under the following terms and conditions:

1. The Material provided is not intended for the exclusive use of any single organization.
2. IRRI requires written notification if the recipient distributes the Material to a third party.
3. Recipients may not seek any form of intellectual property rights protection on the Material without prior written consultation with IRRI. IRRI reserves the right to refuse to grant such permission.
4. Use of the Material will be publicly recognized when and where appropriate, and recipient will provide IRRI with reports on its use of the Material on a reasonably frequent basis.
5. IRRI does not warrant or guarantee the title, quality or correctness of the Material being supplied and will not be held liable for the Material or its use.
6. IRRI provides the Material on acceptance of the terms and conditions of this MTA. Recipient's retention of the Material shall be deemed to constitute acceptance.

Name of Recipient _____

Title _____

Institution _____

Address _____

E-mail _____

Date _____

Box 2: Invitation to Collaboration

Development of a Health Product A

Objective
The Public Sector Research Centre (PSRC) is seeking collaborative relationships with one or more organizations capable of completing the following tasks for prototype health products: industrial development, manufacturing, clinical testing, and licensure by national regulatory authorities.

Health Product A can be produced in a number of different ways. The PSRC believes that one or more of these production methods could be viable for commercial scale-up.

The Public Sector Research Centre
[insert a description of the PSRC including governance, funding, research programs, goals, history, capabilities, etc.]

_____

_____

_____

Participating Scientists
The following scientists have played a leading role in the development of methods for synthesizing Health Product A as described in the attached documents. [attach copies of relevant publications]

_____

_____

_____

and their collaborators.

Mode of Operation
The PSRC has the ability to mobilize assistance for the health-product development process by a variety of means including financial, technical, and in-kind support.

Companies should contact the PSRC to initiate an agreement on a development project.

The following issues are open for discussion with respect to a collaboration agreement:

- Product development including consultation on details of manufacture, adjuvanting, packaging, heat stability, etc.
- Cost sharing of the manufacture of sufficient health product for Phase I through Phase III trials.
- Assessment and planning for the introduction of the health product into private-sector markets.
- Assessment and planning for the introduction of the health product into public-sector markets.

(Continued on Next Page)

Box 2 (continued)

- Development of regulatory standards through interactions with national regulatory authorities and the World Health Organization.
- Conduct of Phase I through Phase III trials in developed and developing countries in a variety of populations.
- Obtaining regulatory approval in developed and developing countries.

Intellectual Property Rights
Details on patent applications will be discussed with interested parties following execution of a suitable confidentiality agreement. The PSRC possesses extensive know-how, which will be essential for the cost-effective implementation of a health-product development program.

Desired Product
The envisaged health product is expected to consist of _____. Further information on specific methods for health product manufacture is provided in the attached documents.

In the developing world, the principal use of the product is expected to be _____ _____. In the developed world, the health product may find use in _____. See the following dossier for further discussion of potential market.

Submission of Expression of Interest
At this time, a letter containing the following information is requested:
- the nature of your interest in this project
- if you wish, a summary of the capabilities and experience of the organization
- names of other collaborators or partners
- an indication of the types of assistance/collaboration desired from the Institute

Interested parties are requested to write to the PSRC _____ _____. Submissions are requested prior to _____.

For further information, contact either [name 1] _____or [name 2] _____ _____ of the PSRC at telephone _____ or fax _____ _____ or write to them at [e-mail address] _____or the above address.

Review and Contracting Procedure
Interested parties will be contacted to arrange for meetings and development of collaborative agreements.

Background on Health Product A and Collaborating Scientists
Health Product A is involved in acute, chronic, and _____. Health Product A is widespread in both developing and developed countries and infects _____. Infection persists throughout life. Health Product A transmission is primarily by _____ _____.

(Continued on Next Page)

Box 2 (continued)

Health-Product-A–associated diseases are significant causes of morbidity and mortality.
For example, in developing countries _____.
In developed countries, it leads to significant morbidity_____.

Short biographies of collaborating scientists [include as an attachment]

Market Potential for Health Product A

Scientific and other References

Source: Mahoney[10]

Confidentiality Agreements: A Basis for Partnerships

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ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute and Adjunct Professor, Cornell University, U.S.A.*

ABSTRACT

Confidentiality agreements (also called nondisclosure agreements, confidential disclosure agreements, and secrecy agreements) are contracts that govern the disclosure of confidential information by one party (the disclosing party) to another party (the receiving party). Confidential information is exchanged for a promise of secrecy. The disclosure may be unilateral, bilateral or multilateral. Confidential information disclosed in a confidentiality agreement might pertain to scientific research results and data, chemical compositions and formulas, software development information, recipes, laboratory methodology, and manufacturing techniques trade secrets (in the form of valuable know-how and/or show-how). The confidential information has value precisely due to the fact that is known to only a few, that is, open disclosure will be injurious to this value. Confidentiality agreements often precede licensing negotiations or the acquisition of IP (intellectual property) rights and serve to strike an appropriate balance between the needs of the disclosing and receiving parties. A confidentiality agreement can either stand alone or be included as part of a broader agreement. An appropriately drafted confidentiality agreement should contain a list of standard provisions and exceptions. In special cases, where the disclosing party wishes to carefully protect the confidential information, the agreement might also include extra strong clauses and articulated security provisions.

1. INTRODUCTION: BUILDING TRUST

Before entering into a relationship, a level of trust between the parties must be established. This trust is the basis for a confidentiality agreement, which is often the first step in developing a mutually advantageous relationship. For example, a confidentiality agreement often precedes licensing negotiations or the acquisition of intellectual property (IP) rights.

Depending on the perspective, whether a person or party is disclosing or receiving confidential information, the disclosing party will want the receiving party to maximize protection whereas the receiving party will want to minimize constraints. However, the disclosing party often wants to disclose information, for example, as a first step in licensing negotiations or other business development activities, or as required by a know-how licensing agreement. But even the receiving party may see problems in terms of future constraints imposed by the agreement and its ability to use the received information. In the end, a confidentiality agreement is intended to strike an appropriate balance between the needs of a disclosing party and the needs of a receiving party.

Confidential information is often passed from one party to another when materials are transferred, during collaborations, and in some types of licensing agreements. A confidentiality agreement is the simplest form of almost any agreement, and confidentiality clauses generally form an integral part of most other agreements. But confidentiality agreements are also entered into separately for the sole purpose of disclosing confidential information, although perhaps they

Kowalski SP and A Krattiger. Confidentiality Agreements: A Basis for Partnerships. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

are used less often for that purpose. It is important to note that obtaining third-party confidential information may not always be a good option. The knowledge could block important future research or otherwise adversely affect the business of a receiving party.

2. CONFIDENTIALITY AGREEMENTS DEFINED

Confidentiality agreements (also called nondisclosure agreements, confidential disclosure agreements, and secrecy agreements) are contracts that govern the disclosure of confidential information by one party (the disclosing party) to another party (the receiving party). The disclosure may be unilateral, with one party disclosing confidential information to only one other party; bilateral, with two parties mutually disclosing information; or multilateral, with three or more parties disclosing information among themselves.

With regard to a confidentiality agreement, confidential information is exchanged for a promise of secrecy. Confidential information is information that is of value precisely because it is not generally known to competitors or to the public. Such information might pertain to scientific research results and data, chemical compositions and formulas, software-development information, recipes, laboratory methodology, manufacturing-techniques trade secrets (in the form of valuable know-how and/or show-how), and so on. What matters, within the context of the confidentiality agreement, is that the information is of value due to its state of being relatively unknown, and, therefore, open disclosure would be injurious to this value.

3. KEY PROVISIONS

As stated above, confidentiality agreements come in many different forms and lengths and should be adapted to the particular circumstances and legal environment.But they all have the same essential components and purpose: to ensure that a privileged communication to a third party is treated as confidential. But, along with the standard terms of any agreement, such as boilerplate contract terms, confidentiality agreements include a number of terms that are important. Box 1 provides a fairly typical confidentiality agreement used by a university.

The following agreement is a sample of a one-way, or unilateral, confidentiality agreement. Two-way agreements, through which two parties mutually disclose confidential information follow the same approach in principle, except that both parties usually have the same obligations to each other. Specific samples of unilateral and bilateral agreements from different organizations are available for download on the *Handbook's* Web version.

3.1 *Disclosing party*

It should be noted that the disclosing party does not necessarily need to be the party who actually owns the confidential information. The disclosing party may instead be a party that lawfully possesses the information and is legally permitted to disclose it.

3.2 *Receiving party*

Receiving parties, particularly in large organizations, are parties to a confidentiality agreement. The receiving party may thus be a series of individuals, depending on the complexity of the disclosure. In such cases, confidentiality agreements, and disclosures, are made at different stages whereby, initially, one individual or a small department receives the confidential information. For example, if the receiving party is not confident that the information is really worth binding the entire large institution to an agreement, an individual may be nominated to receive the confidential information as a first step before subsequent agreements are executed. Unless otherwise articulated in the confidentiality agreement, every person within the organization that is named as a party may share the confidential information with every other person within the same organization. However, as per specific disclosure provisions in the agreement, disclosure may be limited to persons who "need to know," or to certain departments, or to only scientists within a specific research group, for example.

Box 1: Unilateral Confidentiality Agreement

This Agreement, effective on _____ ("Effective Date"),
is by and between _____("Disclosing Party"),
with offices at _____, and
_____ ("Receiving Party"),
with offices at _____.

The Disclosing Party intends to disclose certain Confidential Information to the Receiving Party for the following purpose (the "Purpose"):

Now, therefore, in consideration of the Disclosing Party making such confidential information available to the Receiving Party, the Receiving Party hereby agrees as follows:

1. As used in this Agreement, the term "Confidential Information" means any technical or business information furnished by the Disclosing Party to the Receiving Party in furtherance of the Purpose in connection with the Purpose, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form. Such Confidential Information shall include, without limitation, trade secrets, know-how, inventions, technical data or specifications, compilations of information, records, testing methods, business or financial information, research and development activities, product and marketing plans, and customer and supplier information.

2. Confidential Information shall not include disclosed information to the extent that the Receiving Party can demonstrate that such disclosed information:

   (a) was in the public domain prior to the time of its disclosure under this Agreement;

   (b) entered the public domain after the time of its disclosure under this Agreement through means other than an unauthorized disclosure resulting from an act or omission by the Receiving Party;

   (c) was independently developed or discovered by the Receiving Party without use of the Confidential Information;

   (d) is or was disclosed to the Receiving Party at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary relationship with the Disclosing Party and having no obligation of confidentiality with respect to such Confidential Information; or

   (e) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that the Disclosing Party receives prior written notice of such disclosure.

3. The Receiving Party agrees that it shall:

   (a) maintain all Confidential Information in strict confidence, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its directors, officers, employees, consultants, and advisors who are obligated to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information for the purposes of this Agreement;

   (b) use all Confidential Information solely for the purposes of this Agreement; and

   (c) upon the conclusion of the Purpose, or earlier at the request of the Disclosing Party, return to the Disclosing Party all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the Receiving Party.

(Continued on Next Page)

Box 1 (continued)

4. The term of this Agreement is for the duration of one (1) year from the Effective Date ("Termination").

5. The obligations set forth in this Agreement shall remain in effect for a period of five (5) years after Termination, except that the obligation of the Receiving Party to return Confidential Information to the Disclosing Party shall survive until fulfilled.

6. The Receiving Party acknowledges that the Disclosing Party claims ownership of the Confidential Information disclosed by the Disclosing Party and all intellectual property rights in, or arising from, such Confidential Information. No option, license, or conveyance of such rights to the Receiving Party is granted or implied under this Agreement.

In Witness whereof, the Parties hereto have caused this Agreement to be executed.

DISCLOSING PARTY	RECEIVING PARTY
Signature: _____	Signature: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

3.3 *Purpose of the confidentiality agreement*

As with any agreement the definition and description of the purpose are important for any confidentiality agreement, with the aim of avoiding confusion and later disagreement. The text could read:

… to evaluate XXX technology of the Disclosing Party, or

… to evaluate entering into a sponsored research agreement, or

… to evaluate the information to assess entering into a license agreement

Such language provides an additional caveat as to how the confidential information may be used within the context of the confidentiality agreement. That is, in addition to who may be a receiving party and what the confidential information entails, purpose further specifies, or restricts, how the information may be used.

3.4 *Limitations on disclosure*

Information received under a confidentiality agreement cannot be disclosed to a third party that is not a party to the agreement, even if such disclosure takes place under a separate agreement. There are also examples when a receiving party believes that the disclosing party has a separate confidentiality agreement with a third party. This might tempt the receiving party to disclose the confidential information to this third party, perhaps mistakenly believing that the third party might already have had access to the particular confidential information from the disclosing party. Such disclosures to third parties are not permitted (unless specifically allowed).

3.5 *Important exceptions*

Confidentiality agreements usually contain exceptions to the receiving party's obligation to maintain the confidence of the confidential

information. These clauses are not generally points of negotiation. Different agreements may include different exceptions, though the following five are fairly typical:

1. The information that was in the public domain prior to the time of its disclosure.
2. The information was already known by the receiving party.
3. The information entered the public domain after the time of its disclosure under the agreement through means other than an unauthorized disclosure resulting from an act or omission by the receiving party.
4. The information was independently developed or discovered by the receiving party without use of the confidential information.
5. The information is or was disclosed to the receiving party at any time by a third party having no fiduciary relationship with the disclosing party and having no obligation of confidentiality with respect to such confidential information.
6. The information is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, for example, a subpoena for production of the information pursuant to a grand jury proceeding.

The fourth point is particularly important for academic research establishments. The following example serves to illustrate the point: Yuri works at a university in the biochemistry department. He has no connection with, nor knowledge of, a particular set of confidential information. Yuri independently develops an innovation that relies on the same general knowledge as that of another researcher, Irina, at the same university but in the department of physical chemistry. With that general knowledge, Yuri developed his invention that concurrently leads to valuable data. Nearly identical data had been obtained by Irina under a confidentiality agreement from the BioChem company. That confidential data has been previously obtained by Irina.

Evidently, both professors, Yuri and Irina are employed at the same university but in different departments. Yet Irina's confidentiality agreement is between BioChem and the university as a whole since the Office of Sponsored Programs signed it on behalf of the university. Since Irina never shared the data with Yuri, Yuri may be under no obligation of confidentiality in regard to the specific data he developed himself.

Referring now to the fourth point in the list above, if a provision is included in the confidentiality agreement such that information independently developed or discovered by the receiving party (someone at the university) without the use of the confidential information will be an exception to confidentiality, then Yuri is under no obligation to keep the information secret. If this exception were not included in Irina's confidentiality agreement with the BioChem company, then Yuri would not be able to publish information about his innovation without placing Irina at risk of breach of the confidentiality agreement with BioChem. Once Yuri made his data public, Irina likewise is no longer under an obligation to keep her data secret (providing it is identical) since the data is now public. This is perhaps the single most important exception to keep in mind when drafting confidentiality agreements for research institutions.

4. OTHER POSSIBLE CLAUSES

Nongrant of rights. In some confidentiality agreements, the disclosing party will state that there is no confusion about the intent in disclosing confidential information. This is to prevent the receiving party from later claiming that, by disclosing the confidential information, the disclosing party implied the granting of, to the receiving party, additional rights or licenses. This limitation could read:

Nothing contained in this Agreement shall be construed as an obligation to enter into any further agreement concerning the Project or Confidential Information, or as a grant of license to the Confidential Information, other than for the Project.

Limitations to disclose. Certain limitations may apply to the amount of information to be disclosed. Language such as the following can be included in specifying such a limitation:

The amount of Confidential Information to be disclosed is completely within the discretion of the discloser.

Limitations on the use of the information. Certain agreements contain a specific clause that states certain limitations on the receiving party's use of the confidential information, for example:

The receiving Party may not use the Confidential Information for commercial or noncommercial research (or for the production of prototypes; or for obtaining regulatory approvals) without the prior written approval of the disclosing Party.

Representation. In some cases, a receiving party may demand representation. Language such as the following can be included to address this issue:

Discloser of Confidential Information represents that the disclosure of information is not in violation of any commitment or obligation to any former employer, present employer, or any other party and that discloser has the right to make such a disclosure and to make the promises and agreements expressed herein.

Such representations are sometimes used when individuals disclose information.

Requirements for documentation. There are no standards as to whether disclosed confidential information should be documented. Especially in an academic setting, where disclosing and receiving parties are scientists and converse by phone and e-mail, such a requirement would, in many cases, be ignored or forgotten. However, if included, the following clause may be used:

To the extent practical, Confidential Information shall be disclosed in documentary or tangible form marked "Proprietary" or "Confidential." In the case of disclosures in nondocumentary form made orally or by visual inspection, the discloser shall have the right or, if requested by the recipient, the obligation to confirm in writing the fact and general nature of each disclosure within a reasonable time after it is made.

Extra strong clauses.[1] Occasionally the disclosing party may want the confidentiality agreement to provide as much protection as possible. This will be the case when information to be disclosed is of great value and importance to the disclosing party. Under such circumstances, the disclosing party can include extra strong clauses in the agreement. These provisions will not alter basic obligations articulated in the agreement, but rather clarify and emphasize the gravity of said obligations. Examples of extra strong clauses could include:

- The receiving party is forbidden to use the disclosed confidential information to make inventions or other valuable developments.
- If the receiving party uses the disclosed confidential information to make inventions or other valuable development, then all rights to such shall be assigned to the disclosing party.
- The receiving party will not attempt to replicate the disclosed confidential information.
- The receiving party will not engage in detailed research for the purpose of investigating the details and aspects of the disclosed confidential information.
- The receiving party will not use the disclosed confidential information in a manner that either confers commercial benefit on the receiving party or places the disclosing party at a commercial disadvantage.

Security.[2] Security is, naturally, a critical consideration in any confidentiality agreement. Common provisions in agreements state that the receiving party must treat the disclosed confidential information with the same degree of security as it does its own confidential information, or there can be a clause that specifies reasonable and proper measures to safeguard and ensure security. However, if the disclosing party wants to make certain that a specific level of security is established and maintained, then the following types of provisions might be included in the confidentiality agreement:

- Disclosed confidential information must be stored in designated, locked storage spaces.
- Only designated individuals can have access to the disclosed confidential information.

- Copying the disclosed confidential information is strictly prohibited.
- Disclosed confidential information cannot be taken from the premises.
- Any viewing of the disclosed confidential information must be duly recorded in a log.
- All disclosed confidential information documents have unique identifier numbers and all are marked, in red, "CONFIDENTIAL."

5. CONCLUSIONS

There are two simple rules to keep in mind when dealing with confidentiality agreements (and, in fact, with any agreement): First, if there is no trust between the parties, then perhaps it is best not to proceed with the agreement, no matter how simple the agreement may be. On the other hand, a confidentiality agreement may be a rational first step in developing the trust needed to build a relationship that may lead to further collaboration and new opportunities. Second, by entering into a confidentiality agreement with another party to receive their confidential information, it is important to ensure that everyone in the organization who has access to the confidential information is well informed of the obligation to keep it confidential. ■

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1 This section is based on UNICO. 2006. UNICO Guides: Confidentiality Agreements. UNICO; Cambridge, U.K. www.unico.org.uk. The UNICO Guide provides additional and valuable discussions on confidentiality agreements, including a range of template agreements.

2 Ibid.

Specific Issues with Material Transfer Agreements

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ABSTRACT

In the health and agricultural sciences, biological materials were once freely and widely exchanged. But more and more, these materials have gained commercial value. Public sector institutions, as well as private companies, have recognized, therefore, that proprietary protection of these materials may be necessary. Material transfer agreements (MTAs) are legal instruments that define terms for the transfer of tangible biological materials between or among two or more parties. MTAs are bailments that transfer possession but not title: the party who transfers the materials retains full ownership; the party who receives the materials holds them in trust. Transfer is governed by contract, ideally specifying the term of the transfer, how the materials may and may not be used, and other related issues, such as confidentiality. In addition, an MTA may contain licensing provisions for the transfer of embedded intellectual property (IP) rights (patent rights). Hence, an MTA can be a hybrid instrument, covering the transfer of both tangible property (via bailment and contract) and intangible property (via licensing of patent rights). Biological materials transferred using MTAs include reagents, cell lines, antibodies, research tools, insertional mutant populations, genome sequence databases, novel vectors, and plant genetic resources. Due to divergent institutional priorities, material transfers between the private and public sectors are generally more complex than those between public sector institutions.

1. INTRODUCTION

There is a long history of sharing biological materials, such as plant germplasm or genetic stocks, and for the most part this has been done freely and often without any form of a legal agreement. This has not typically been the case in health research, where reagents, cell lines or antibodies that have potential therapeutic implications have been transferred under specific agreements that define the terms of the transfer. In both agricultural and health research, the increasingly sophisticated research approaches that rely heavily on access to biological or bioinformatic resources created by other researchers have dramatically increased the need for researchers to share research tools. This trend has been advanced further by the investment of federal agencies (notably the National Science Foundation [NSF] and the National Institutes of Health [NIH]) and private companies in the development of genomic resources that are intended primarily as vehicles for further discovery of gene function and/or gene regulation. These types of biological and bioinformatic resources (such as insertional mutant populations, genome sequence databases, and novel vectors) are the most problematic with regard to sharing, because they are the research tools that can lead to potentially valuable discoveries, invariably leading to the question of who will own or control those downstream discoveries.

The NIH considers the sharing of research tools so important to future research progress that the agency issued strong guidelines on the appropriate terms for transfer of research materials that contribute to, or result from, NIH-funded

Bennett AB, WD Streitz and RA Gacel. 2007. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

research.[1] Similarly, the NSF has issued guidelines for data and materials release and requires investigators to describe the timing, constraints, and means of release of materials developed, particularly for programs (such as the Plant Genome Research Program) that focus on the generation of research resources and tools.[2]

Plant genetic resources represent another area of increasing concern regarding how freely these resources can be exchanged. Even those plant genetic resource centers that are most committed to the free exchange of germplasm now utilize specific agreements to govern the transfer of seeds, if only to specify that the recipient cannot seek intellectual property (IP) rights on the materials (the African Rice Center, WARDA; Box 1 [see end of chapter])[3] or to ensure that the recipient understands that there is no warranty on the transferred material (Tomato Genetics Resource Center; Box 2 [see end of chapter]).

Scientists have traditionally shared research materials freely, and, indeed, an important criterion for scientific publication has been the ability of other researchers to experimentally reproduce and thereby test published results. The ability to replicate results will often rely on access to the underlying biological materials or information, but that access is not assured today. So what has changed? Probably the most significant change has been the narrowing of the gap between fundamental research and commercial developments, particularly in health research, but also in agriculture.[4] Materials that at one time would have been useful almost exclusively for fundamental research purposes are increasingly seen as having direct commercial value, and this trend has generated a new breed of researchers and companies that focus on leveraging novel research tools to discover new commercially valuable traits, genes, or compounds. Particularly, in the case of companies, they may be reluctant to share their "crown jewels" without making sure that their business interests are protected. As a result of the Bayh-Dole Act, many universities actively use the patent system as a means to transfer research results to industry. In addition, universities increasingly conduct research that is sponsored by industry. As a consequence, they may have concerns similar to those of private companies. So a company that traditionally had little concern over a university's use of its property may now be appropriately concerned that its proprietary materials may lead to valuable inventions or even to fueling a competitor's business interests. Universities and nonprofit research institutions have also become much more aware and protective of research materials. The result has been a slow but steady evaporation of unrestricted transfers of research materials between scientists, in general, and particularly between industry scientists and those in universities.

With growing regularity, the sharing of research materials takes place under material transfer agreements (MTAs). MTAs are legal agreements (bailments) that govern the transfer of a tangible property between parties. For example, the University of California, Davis, executed over 470 MTAs in 2005, and this number had been increasing every year since 2001. At the same time, the *complexity* of MTAs is increasing dramatically, with restrictions and obligations potentially reaching far beyond the material itself, to data or inventions made using the material and/or to derivative materials. As a consequence, each MTA has begun to take on the complexity of a license agreement, and a high level of skill and time are required to ensure that the MTA can be executed without compromising key principles and will not conflict with other agreements. Hence, an MTA can be a hybrid instrument: covering the transfer of both tangible property (via bailment and contract) and intangible IP (via licensing of patent rights). To complicate things even further, provisions of an MTA may stipulate how any future IP rights, arising from the use of the materials transferred, will be allocated.

Because MTAs are contractual agreements between two or more parties, the agreements typically do not have the geographic or temporal limitations of patented technologies (patents are territorial, issued by countries, with limited terms, typically 20 years from filing) and, consequently, can be much farther reaching than the scope of patent rights. It is interesting to note that an evaluation of the property rights associated with "GoldenRice" indicated that 44 patented products or processes and at least 15 materials, many of which were governed by

MTAs, were potentially used in its development.[5] In navigating the intellectual and technical property landscape surrounding "GoldenRice," Potrykus reported that the restrictions imposed by one MTA had been particularly problematic.[6]

Just as universities are experiencing an increase in the use of MTAs for receiving and disseminating materials, so are companies. One large pharmaceutical company indicated that it had six administrators dealing with more than 1,000 MTAs in the year 2000 and that many of these agreements required lengthy negotiations. Some companies have questioned whether it is worth their while to exchange research tools with university scientists at all.[7] In our own experience, agreements for transfer of research materials from industry to the university often have a low priority for attention within company legal departments, particularly because such transfers are often only incidental to, or may actually compromise, their main commercial interests. We estimated that 10%–25% of MTAs received from industry for incoming materials to the University of California were never executed because the terms compromised fundamental academic principles or created legal obligations that the university cannot fulfill. An example of a deal-breaking term in an MTA is one that specifies that the provider maintain ownership of data resulting from use of the materials. This term could prevent publication or prevent the continuation of the very research that the material was intended to advance. Thus, universities in general are in a situation in which the exchange of research materials is of increasing and indeed critical importance, but both universities and private companies are having difficulty finding easy ways to share these resources. As Eisenberg summarized *"Although there are many points on which they disagree, most people from each of these quarters seem to agree that the problem is growing rather than diminishing."* [8]

2. WHAT IS A MATERIAL TRANSFER AGREEMENT?

Fundamentally, an MTA is a *bailment*, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties. In addition to the tangible property rights being owned by the provider, the material(s) may be the subject of a patent or patent application. In this case, the MTA may need to account for the transfer of IP rights as well as the transfer of tangible material. Transfer of IP rights would be in the form of a license, for example, to make, use, sell, and so forth, that is, a license is permission to do what would otherwise violate the provider's IP rights. This chapter deals with materials that are intended to be used for research purposes, usually in the absence of planned research collaboration between the provider and recipient. Such a collaboration could be accommodated by a separate *collaboration agreement* that would accompany the MTA. The MTA defines the rights of the provider and recipient with respect to the materials and derivatives of the materials.

At most institutions, researchers themselves are not authorized to sign either outgoing or incoming MTAs for their institutions. The MTAs must be reviewed and approved by an authorized institutional official. Agreements that are not signed by an institutional official may not be valid or enforceable. These functions usually reside in the Office of Research Administration (Sponsored Programs) or the office that manages IP and technology transfer for the institution. Because the researcher utilizing the material(s) is ultimately responsible for fulfilling the obligations of the MTA, most MTAs require the signature of the recipient of the material acknowledging their recognition of their responsibilities and duties under the agreement.

3. STRUCTURE OF A MATERIAL TRANSFER AGREEMENT

An MTA can range in size from a few hundred words on one page to several thousand words on more than a dozen pages. The NIH's "Simple Letter Agreement for the Transfer of Materials" (Box 3 [see end of chapter]) is an excellent example of

a short, easy-to-understand, one-page MTA. The Simple Letter Agreement requires no negotiation and is used by academic institutions throughout the United States to transfer materials, and, in the case of research consortia composed of multiple academic or nonprofit institutions, this type of agreement can be modified to provide an umbrella for easy transfer of materials between consortium members. On the other end of the spectrum, a complex and lengthy MTA from a company willing to provide innovative and highly proprietary materials can take years to negotiate.

The standard MTA used by the Davis campus of the University of California (Box 4 [see end of chapter]) represents an MTA that a university would use to provide materials to another university. An MTA, regardless of its length and complexity, may incorporate many if not all of the following:

- a preamble
- definitions
- a description of use of the materials
- confidential information
- IP rights
- warranties
- liability and/or indemnification
- publication
- governing law
- termination
- signatures
- exhibits or appendices

3.1 *The preamble*

The preamble of an MTA is like an abstract of a manuscript or a prologue to a novel. The preamble lays the groundwork for the MTA and sets the stage for the legally binding terms and conditions that follow. The preamble identifies parties to the agreement and specifies the MTA's effective date. It may also include the addresses of the parties. It may even contain recitals or whereas clauses describing the material, the goal of the research, and the intent of the parties.

3.2 *Definitions*

An MTA may have a separate section to define specific terms such as *materials*, *use of the materials*, *modifications*, or *inventions*. On the other hand, an MTA may define these terms as they first appear within the agreement. In a third approach, an MTA may define the terms that will be used throughout the agreement in a separate section for definitions and define the terms that are used only in one or two sections as they first appear within the agreement.

The definition of *materials* should be limited to that of the actual materials being transferred, including progeny and unmodified derivatives, and should not include substances or inventions created by the recipient of the materials. *Progeny*, as defined in the Uniform Biological Material Transfer Agreement (UBMTA), are unmodified descendents of the original material. Progeny can include a virus from a virus, a cell from a cell, or an organism from an organism. Unmodified derivatives, according to the UBMTA, are substances created by the recipient that constitute an unmodified functional subunit or an expression product of the original material that was provided. Unmodified derivatives can include purified or fractionated subsets of the original material; progeny or products thereof; subclones of unmodified cell lines; transcription and translation products, such as RNA and protein derived from provided DNA; reverse transcription and reverse translation products, such as DNA synthesized on a template using provided RNA; monoclonal antibodies secreted by a hybridoma cell line; and chemically synthesized copies. Since a provider usually asserts ownership of materials, the definition of materials should not overreach to modifications, derivatives, crossbred progeny (in animals), mutants, or other substances that are not being provided by the provider.

3.3 *Use of the materials*

An MTA specifies how the recipient can and cannot use the material. Usually, the MTA contains a blank space for the researcher to include a description of the research use with the material. Sometimes an MTA has a separate appendix with a very detailed description of the intended research use. An MTA will usually prohibit the recipient from using the materials in a manner other than that intended by the original research. An MTA will also typically prohibit provider's material from being tested in humans and used in plants and

animals consumed as food. Other prohibitions may include using the material in research that has IP obligations to third parties, or with other materials from third parties, or transferring the material to third parties or even to other researchers within the recipient's institution. Finally, most MTAs have prohibitions for the material to be used for commercial purposes.

3.4 *Confidential information*

Often, providers of materials include, on the MTA form, proprietary or confidential information. Therefore an MTA may contain a provision to protect the provider's confidential information. Confidential information can be defined as "information, data, or material, in written or other tangible form related to the material, that is identified as confidential at the time of disclosure." However, confidential information should ***not*** include information that is:

- generally known to the public at the time of disclosure to the recipient
- already in the recipient's possession at the time of disclosure by the provider
- disclosed to the recipient on a nonconfidential basis by a third party having the right to make such disclosure
- independently developed by the recipient without the use of the confidential information disclosed by the provider as evidenced by written records
- required to be disclosed by law or governmental rule or regulation

The MTA should include language to make clear to the provider that the above information is not considered confidential.

An MTA may also specify that the recipient of the confidential information treat it as confidential and maintain it in confidence for a certain period of time. A long period of nondisclosure, for example, over five years, may be very difficult for a university to manage. Generally, an MTA may require that all confidential information be marked "Confidential" and be reduced to writing. Reducing confidential information to writing places an additional administrative burden on both parties, but it does make it easier for the recipient to know precisely what information must be kept confidential.

The MTA may stipulate that the recipient can disclose the provider's confidential information only to the recipient's own personnel who have a need to know and who use the confidential information. The MTA may also require that the recipient take the same steps and use the same methods to prevent the unauthorized use or disclosure of the provider's confidential information as the recipient would take to protect its own confidential information. Requirements such as these are generally appropriate when confidential information is being exchanged.

3.5 *Intellectual property*

Nearly every MTA will address IP matters such as the disclosing of inventions, the prosecuting of patents and plant variety protection certificates, and the granting of options and licenses. IP rights language is perhaps the most challenging language to negotiate. An MTA may contain overarching IP language that can reach to a researcher's and/or institution's past inventions and future inventions, which may have little or nothing to do with the materials provided, and could impact the researchers ability to continue doing related research.

The MTA may specify that the recipient disclose, assign, and/or license any inventions to the provider, free of any royalties and fees. While most institutions will agree to certain licensing rights, they are generally unable to assign an invention because doing so may violate:

1. the Bayh-Dole Act if the invention resulted from research funded by the U.S. federal government
2. the Tax Reform Act of 1986 by possibly jeopardizing the U.S. federal tax-free status of bonds that were issued to build or improve research facilities
3. the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, by restricting the accessibility of research materials

4. an institution's own principles, policies, and practices if the invention was not developed for the public benefit
5. other laws, regulations, rules and policies

It is generally reasonable to grant a limited subset of IP rights to the provider of the materials. For example, to the extent that the recipient is legally able to do so, the recipient could grant a nonexclusive royalty-free research license to any inventions that necessarily use or necessarily incorporate the material and are conceived and first actually reduced to practice in the performance of the research. The recipient, in many cases, may be able to grant a first right or an option to negotiate a non-exclusive or exclusive commercial license to such inventions. In some cases, when a provider provides innovative and valuable compounds, a recipient may have to grant a nonexclusive, royalty-free research license to such inventions if the provider is concerned about being blocked from practicing new uses for its materials especially when the provider is performing or sponsoring similar research.

3.6 *Warranties*

An MTA nearly always stipulates that the material does not come with any warranties. A typical warranty clause, usually written in capital letters, may read:

PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

The language is nearly always written in uppercase letters to make the clause stand out.

3.7 *Liability and indemnification*

An MTA usually stipulates that the recipient of the materials assumes all liability for damages that may arise from the recipient's use, storage or disposal of the material, and modifications. In addition, many providers will stipulate that the recipient indemnify, hold harmless, and defend the provider against any claims, costs, or other liabilities that may arise as a result of recipient's use, storage, or disposal of the material. A number of state institutions, for example in Alabama, Georgia, Kentucky, New York and other states, are prohibited from indemnifying other parties and must limit their indemnification to the extent permitted by state law. In addition to recipient liability, some MTAs will make the providers liable for losses, claims, or demands made by the recipient, or made against the recipient by any other party, that are due to the provider's negligence or misconduct.

3.8 *Publications*

An MTA should enable the recipient of the materials to publish or present the results of the recipient's research using the materials without the approval of the provider. An MTA can require that the recipient send the provider a copy of any proposed manuscript, abstract, poster session, or presentation prior to such publication or presentation so that the provider can review it, provide any comments, or request the removal of the provider's confidential information. A review period of 30 to 45 days is sufficient for most providers and is acceptable to most academic recipients. The MTA may require that the publication or presentation be delayed for an additional period of time to allow for the filing of patent applications. An additional period of 30 to 45 days is sufficient for most providers. An MTA can also require the recipient to acknowledge the provider for providing the materials in any publications or presentations.

3.9 *Governing law*

An MTA may specify that it is governed by the laws of a particular jurisdiction, state, or country. This may present a problem in cases in which the provider and the recipient are located in separate jurisdictions, states, or countries. Most providers and recipients will agree to be silent on governing law.

3.10 *Termination*

An MTA should specify an expiration date for the agreement. Otherwise, the recipient's obligations will continue forever. The parties should be able to terminate the MTA earlier by providing advance, written notice. When the MTA expires or terminates, the recipient is generally required to stop using the material and may be required to return or destroy any remaining material. A termination clause may also delineate certain obligations that survive termination. These surviving obligations may be related to areas dealing with confidentiality, IP, warranties, liability, and indemnification. The MTA can always be extended by the mutual agreement of both parties.

3.11 *Signatures*

The signature section is usually the last part of an MTA. A typical MTA may have the signatures of the following individuals:

- the authorized official of the organization or company receiving the materials
- the researcher receiving the material
- the authorized official of the organization or company providing the materials
- the researcher providing the material

Some MTAs may require only the signature(s) of the authorized official and/or the researcher of the recipient of the materials. Researchers may sign as acknowledging, reading, and/or understanding the MTA but should not sign as legal parties to the MTA. Doing so could place them at risk of being personally liable and being sued in a court of law.

3.12 *Exhibits or appendices*

An MTA may include an exhibit or appendix that is attached to the end of the agreement. In many cases, the attachment is a detailed description of the research, a protocol, or a long list of materials. Sometimes confidential information is put in the exhibits or appendices so that it can be redacted more easily than if it were put into the agreement.

4. MATERIAL TRANSFER BETWEEN UNIVERSITIES

Sharing of materials between university scientists is generally less problematic than transfers between industry and academia, primarily because the cultures and motivations of each institution involved in the exchange are similar. In the United States, most universities readily transfer materials for academic research purposes under terms that typically have no restrictions other than a requirement not to transfer the materials to third parties without approval or notification. These transfers are often accomplished using the NIH-facilitated UBMTA[9], the NIH's Simple Letter Agreement, or an equivalently benign agreement. The UBMTA incorporates a very narrow definition of the material to be transferred and the agreement does not give a provider rights beyond the "*original material, progeny and unmodified derivatives*." This narrow definition and the lack of "reach through" to new materials and to new research results is the hallmark of agreements between universities that greatly facilitates these transfers.

When a problem does occur in a transfer between academic institutions, it is usually because the material has been exclusively licensed and the terms of that agreement impose some constraints on the institution providing the material. However, this problem is usually avoidable, particularly if such exclusive licenses specifically reserve the right to use the materials for internal research purposes and to transfer the materials for research at other academic institutions. For example, the University of California routinely incorporates the following clause into its exclusive license agreements:

Nothing in this Agreement will be deemed to limit the right of The Regents (i.e. University) … to make and use the Invention … and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.

5. MATERIAL TRANSFER FROM PRIVATE COMPANIES TO UNIVERSITIES

Material transfers between private and public sector institutions are typically much more complex than transfers between two universities and are much more prone to failure, particularly when the transfer is from a company to a university researcher.[10] What are some of the features of these MTAs that create difficulties, particularly for

universities? Contrary to popular belief, the primary issues for most universities do not concern the ability to profit from licensing future inventions, but center on:

- a few fundamental academic principles
- the need to avoid incurring unfunded financial obligations
- the need to avoid creating conflicting legal obligations with third parties

These issues primarily reflect most universities' concern with protecting the fundamental mission of the institution and their low tolerance for financial or legal risk.

5.1 *Dissemination of research results*

The single most obvious and fundamental principle for the university and university researchers is to preserve the unrestricted ability to publish their research results. The freedom to publish can be restricted by MTAs when the provider requires editorial rights in a publication or the right to approve and, by inference, to disapprove a publication. Publication restrictions can show up in MTAs in indirect ways as well. For example, the material itself may be specified as confidential, making a meaningful publication impossible. Of particular concern are the serious consequences that a publication restriction can have on students, whose future depends so heavily on publication. Clearly, this is one principle a university cannot compromise and the principle is so widely recognized that one would think it would not even be on the table for discussion. However, it occasionally is.

Typically, the material provider's underlying concern is not to restrict academic publication but to protect its confidential information related to the material and to preserve patentability of inventions. Both are legitimate concerns and can usually be met by agreeing to remove a company's confidential information from publications and to delay publication for a limited time (usually 60 to 90 days) to permit the evaluation of potentially patentable inventions and to file patent applications, when appropriate. Universities readily agree to these types of provisions, but further restrictions on publication rights are typically nonnegotiable.

5.2 *Rights in research results*

Universities also need to preserve the ability of their researchers to use their own research results in future research. This may seem obvious, but if a provider of material insists that it own the results of research conducted with its material (sometimes including data, inventions, and reports), researchers and universities can lose all access to these products of their own research, making it difficult, if not impossible, to perform any follow-on research. An example of how this appears in an MTA would be a case in which a provider asserts ownership of new substances created by the university researcher while using its proprietary material, sometimes reaching to substances or compositions that don't contain the original material in any form (often referred to as *reach through* rights). This type of provision could have an impact on publication as well, since many journals require that materials discussed in a paper be made available for replication of the research. Yet in this case such availability would be controlled by the material provider, not the researcher. In many cases, a for-profit provider may have a legitimate reason to insist on retaining ownership of any modifications of its original material. For example, if a vector that took years to create could now be easily modified to incorporate new functions, the provider would be understandably reluctant to relinquish rights to improvements that can now be relatively easily incorporated. In these cases, it may not be appropriate or possible to share this material. However, in many cases this kind of provision is the result of a provider using too broad an approach to ensure no possible loss of its own rights. Negotiations can often identify a balanced solution in which the provider is assured that it maintains ownership of its proprietary material, and while a recipient may own the narrow improvement it created, the provider would still own the original material if it continued to be included as a component.

5.3 *Conflicting legal obligations*

Perhaps the most difficult issue presented by MTAs is the potential for entering into agree-

ments that create conflicting legal obligations. This situation routinely arises because, while the material is coming from one source, the funding for the research is usually provided by a different source, typically public agencies but also, potentially, other private companies. To the extent that the MTA and relevant funding sources carry IP obligations, it is easy to see how conflicts can arise. While such obligations are typical of private research support, public funding also carries legal IP obligations to the government. The most prominent of these obligations includes requirements in the United States under the Bayh-Dole Act, such as, a prohibition on assigning title to inventions to third parties, the provision of a nonexclusive license to the government to practice or have practiced the invention on behalf of the government, and the right of the government to march in. Clearly, the university cannot enter into an MTA that creates a new obligation that is in conflict with such obligations of law or its contractual obligations to others. For example, if access to a particular research tool or material requires that the provider be offered an exclusive license to inventions, then this restricts the project from receiving any other material or research funding that carries a similar obligation—exclusive access to inventions from the same project can be given only once! The university and its researchers need to be very careful in determining how important are specific inputs to the project, and they may need to decide which IP rights can be apportioned to research sponsors and/or material providers and prioritize those rights. It is clear from the complexity of inputs to research projects and the increasing complexities of ownership of research tools and materials, that access to the full set of tools for certain projects may simply be impossible. This situation is analogous to that which has been described as the "tragedy of the anticommons" where the fragmentation of IP ownership becomes so complex that no single entity can acquire all the rights it needs to develop products.[11] In a similar sense, the fragmented ownership of research materials or information can impact the practical ability to conduct fundamental research or at least to do so using the most efficient research tools.

5.4 *Public benefit of university research*

Universities, particularly public universities and those whose research is supported largely by public funds, have an obligation to see that their innovations are made available to the public in a diligent and timely manner. In the United States, this obligation is based on the Bayh-Dole Act, which has a stated objective "to promote … public availability of inventions," as well as on the philosophical missions of most universities. One means of accomplishing availability is through the licensing of inventions to private companies that can invest the often substantial additional R&D effort required to produce real products. The public benefit obligation can be compromised by MTAs that require the granting of a nonexclusive, royalty-free license to inventions back to the provider. If the company were not interested in commercializing the invention, the existence of its nonexclusive, royalty-free license could prevent other companies from entering into a license, because they would lack the exclusivity needed to allow them to invest in the development of the technology, effectively "shelving" the technology. A solution that is often acceptable is involves linking such a license very narrowly to inventions that are dependent on the company's material. These inventions represent the company's legitimate business interest and are inventions that, typically, only the company providing the material would be in position to commercialize. While broader language seeking a license to inventions less closely linked to the material will not necessarily prevent a university from signing an MTA, such language should certainly provoke a careful evaluation of the situation.

5.5 *Fair consideration*

Most universities seek a financial return in exchange for the commercial use of their research results. Public institutions, in particular, are concerned that the public funds that are used to support the institution should not be used to indirectly support private companies. These considerations color the expectations of universities, particularly if the provider of a material seeks free license to resulting inventions. Here, the interests of the university's administration and researchers may diverge, with researchers needing, primarily,

to gain access to the material to advance their research and with the administration seeking to preserve the fundamental principles of the university and avoid costly legal battles. Where interests are divergent, the situation can become very complex. In our experience, a common underlying interest of all parties is to enable and accelerate research progress, and in most cases solutions can be developed that satisfy the essential needs of all parties. Unfortunately, developing these solutions can take a long time and, as mentioned earlier, for many private companies, negotiating MTAs for university researchers is a low priority in relation to the many IP-related transactions that may be more critical to the company's primary business interests.

6. CONCLUSIONS

Overall, the transfer of materials between researchers has been getting more difficult, and it appears that the days of open exchange of materials, particularly from researchers in industry to academic researchers in the life sciences, are over. While some domains of free exchange continue to thrive, and some funding agencies and foundations are actively promoting open exchange of materials, these are becoming exceptions rather than the rule. Both universities and private companies have legitimate interests, which they are trying to support when engaging in material transfers. When these interests collide, it can be difficult to find common ground. However, the mutual interest of both research-based private companies and of universities is to support research advances; and when both parties keep this overarching objective in mind, material transfers usually are possible. ■

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1 Marshall E. 1999. New NIH Rules Promote Greater Sharing of Tools and Materials. *Science* 286: 2430–2431.

2 Silverthorne J. 2003. Ensuring Access to the Outcomes of Community Resource Projects. *Plant Physiology* 132:1775–1778.

3 The sample agreements found at the end of this chapter are also available for free download at www.ipHandbook.org. An Adobe® Acrobat® reader or Microsoft® Word® are required. The Web site also contains many additional IP sample agreements.

4 Rai AK and RS Eisenberg. 2001. The Public and the Private in Biopharmaceutical Research. In *Proceedings of the Conference on the Public Domain*, Duke Law School: Durham, North Carolina. www.law.duke.edu/pd/papers/raieisen.pdf.

5 Kryder RD, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property-Components of Pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No. 20. ISAAA: Ithaca, New York. www.isaaa.org/kc/Publications/pdfs/isaaabriefs/Briefs%2020.pdf.

6 Potrykus I. 2001. Golden Rice and Beyond. *Plant Physiology* 125: 1157–1161.

7 Eisenberg RS. 2001. Bargaining over the Transfer of Research Tools: Is This Market Failing or Emerging? In *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (eds. RC Dreyfuss, DL Zimmerman and H First). Oxford University Press: New York. pp 223–249.

8 See *supra* note 6.

9 ott.od.nih.gov/newpages/UBMTA.pdf.

10 Pool R. 2000. Material Transfer Agreements. In *Finding the Path: Issues of Access to Research Resources*. National Academic Press: Washington, D. C. www.nap.edu/catalog/9629.html.

11 Heller MA and RS Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280:698–701.

Box 1: Material Transfer Agreement (MTA) for plant genetic resources held in trust by the Africa Rice Center (WARDA)[1]

The plant genetic resources (hereinafter referred to as the "material") contained herein are being furnished by Africa Rice Center (WARDA) under the following conditions:

- Africa Rice Center (WARDA) is making the material described in the attached list available as part of its policy of maximizing the utilization of material for research, breeding and training. The material was either developed by Africa Rice Center (WARDA); or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made available for any agricultural research, breeding and training purposes under the terms and conditions set out in the agreement on 26 October 1994 between the Africa Rice Center (WARDA) and the Food and Agriculture Organization of the United Nations (FAO).

- The material is held in trust under the terms of this agreement, and the recipient has no rights to obtain Intellectual Property Rights (IPRs) on the material or related information.

- The recipient may utilize and conserve the material for research, breeding and training and may distribute it to other parties provided such other parties accept the terms and conditions of this agreement.

- The recipient, therefore, hereby agrees not to claim ownership over the material, nor to seek IPRs over that material, or its genetic parts or components, in the form received. The recipient also agrees not to seek IPRs over related information received.

- The recipient further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the material available, is bound by the same provisions and undertakes to pass on the same obligations to future recipients of the material.

- Africa Rice Center (WARDA) makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

- Upon request, Africa Rice Center (WARDA) will furnish information that may be available in addition to whatever is furnished with the material. Recipients are requested to furnish Africa Rice Center (WARDA) with related data and information collected during evaluation and utilization.

(Continued on Next Page)

1. This MTA covers materials which are being transferred before the entry into force of the International Treaty on Plant Genetic Resources for Food and Agriculture. The Treaty envisages that Africa Rice Center (WARDA) will enter into an agreement with the Governing Body of the Treaty, once the Treaty enters into force. Africa Rice Center (WARDA) has indicated its intention to conclude such an agreement with the Governing Body. This agreement, in line with the Treaty, will provide for new MTAs and benefit-sharing arrangements for materials transferred after the entry into force of the agreement. The attention of the recipient is drawn to the fact that the details of the MTA, including the identity of the recipient, will be made available to the public.

2. This does not prevent the recipients from releasing the material for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in this MTA are complied with.

Box 1 (continued)

- The recipient of material provided under this MTA is encouraged to share the benefits accruing from its use, including commercial use, through the mechanisms of exchange of information, access to and transfer of technology, capacity building and sharing of benefits arising from commercialization. Africa Rice Center (WARDA) is prepared to facilitate the sharing of such benefits by directing them to the conservation and sustainable use of the plant genetic resources in question, particularly in national and regional programs in developing countries and countries with economies in transition, especially in centers of diversity and the least developed countries.

The material is supplied expressly conditional on acceptance of the terms of this Agreement. The recipient's acceptance of the material constitutes acceptance of the terms of this Agreement.

Box 2: Material Transfer Agreement (MTA) for requesting plant materials from the C.M. Rick Tomato Genetics Resource Center (TGRC)

THIS AGREEMENT is made by and between The Regents of the University of California ("THE REGENTS") on behalf of the C. M. Rick Tomato Genetics Resource Center ("TGRC"), and _____ _____("RECIPIENT"). THE REGENTS asks that the RECIPIENT agree to the following before the RECIPIENT receives the plant materials requested from the TGRC.

1. The TGRC will make substitutions, as necessary, for items that are currently unavailable for distribution. For large requests, the TGRC may delete some items, as needed, to reduce its workload and accommodate other requests. The TGRC will provide a packing list detailing which accessions ("MATERIAL") have been shipped.
2. The MATERIAL is provided free of charge and, except as stated herein, without restrictions by the TGRC to support research, breeding, and/or educational projects involving tomato. The RECIPIENT may distribute the MATERIAL to third parties under an MTA that includes the language of terms 3, 4, 5, and 6.
3. THE REGENTS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, REGARDING THE FITNESS OR MERCHANTABILITY FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
4. The MATERIAL has not been thoroughly evaluated by the TGRC. THE REGENTS MAKES NO WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, REGARDING THE ACCURACY OF THE INFORMATION PROVIDED BY THE TGRC; THE QUALITY, HEALTH, OR PHYTOSANITARY CONDITION OF THE MATERIAL; OR THE GENETIC IDENTITY OF THE MATERIAL, INCLUDING ITS ORIGIN, PURITY, TRUENESS TO TYPE, GENETIC BACKGROUND, AND THE PRESENCE OR ABSENCE OF ANY TRANSGENES. The RECIPIENT is responsible for verifying that genetic identity is correct in its own plantings, and the RECIPIENT will notify the TGRC of any potential problems it observes with the MATERIAL, such as aberrant segregation, incorrect phenotypes, unexpected traits, or other problems.
5. Unless prohibited by law, the RECIPIENT assumes all liability for damages it incurs and for claims by third parties which may arise from the RECIPIENT's use, storage or disposal of the MATERIAL. RECIPIENT shall hold harmless, defend, and indemnify THE REGENTS against any claims, costs or other liabilities which may arise as a result of the RECIPIENT'S use, storage or disposal of the MATERIAL.
6. The RECIPIENT shall acknowledge the TGRC as the supplier of the MATERIAL in any publications which result from the RECIPIENT's use of the MATERIAL, and shall provide the TGRC with copies of the relevant publications.
7. Before the TGRC can send the MATERIAL, the RECIPIENT or other authorized official of the RECIPIENT's organization, must sign and deliver this MTA by mail, facsimile, e-mail or in person to the TGRC at the following address:

C. M. Rick Tomato Genetics Resource Center
Department of Plant Sciences (Mail Stop 3)
University of California, Davis
One Shields Avenue
Davis, CA 95616, U.S.A.

Tel.: +1-530-754-6059
Fax: +1-530-752-9659
tgrc@ucdavis.edu
http://tgrc.ucdavis.edu

CERTIFICATION BY RECIPIENT OR OTHER AUTHORIZED OFFICIAL:
I have read and understand the conditions outlined in this Agreement and I agree to fully abide by them in the receipt and use of the MATERIAL.

Signature, Name and Title: _____

Institution: _____ Date: _____

Box 3: Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL _____ _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.

2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

3. The MATERIAL will be used for teaching or not-for-profit research purposes only.

4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.

5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from the RECIPIENT'S use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist:_____

Provider Organization: _____

Address:_____

Name of Authorized Official: _____

Title of Authorized Official:_____

Certification of Authorized Official: This Simple Letter Agreement has ☐ / has not ☐ [check one] been modified. If modified, the modifications are attached.

(Continued on Next Page)

Box 3 (continued)

_____ _____ _____ _____

Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____

Recipient Organization: _____

Address: _____

Name of Authorized Official: _____

Title of Authorized Official: _____

Signature of Authorized Official: _____

Date: _____

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____

Recipient Scientist Date

Box 4: Material Transfer Agreement with the University of California, Davis

This Agreement is made this _____ of _____, by and between THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, as represented by its Davis campus, ("UC DAVIS"), having an address at the Office of Research, Technology and Industry Alliances, Technology Transfer Services; University of California, Davis; 1850 Research Park Drive, Suite 100; Davis, CA 95616-6134, and ___ _____ ("RECIPIENT"), having its principal place of business at _____ (collectively "the PARTIES").

RECIPIENT has requested from UC DAVIS the MATERIAL defined in Section 1.B. below for the RESEARCH USE defined in Section 1.F. below by the RECIPIENT INVESTIGATOR(S) defined in Section 1.G. below. In consideration of the supply of MATERIAL from UC DAVIS to RECIPIENT, the PARTIES agree as follows:

1. Definitions

A. "ORIGINAL TRANSFERRED MATERIAL": The physical material actually delivered to the RECIPIENT by UC DAVIS, as identified in Exhibit A attached hereto.

B. "MATERIAL": ORIGINAL TRANSFERRED MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES.

C. "PROGENY": Unmodified descendant from the MATERIAL. Examples include but are not limited to: virus from virus; cell from cell; and organism from organism.

D. "UNMODIFIED DERIVATIVES": Substances created by the RECIPIENT that constitute an unmodified functional sub-unit or an expression product of the ORIGINAL TRANSFERRED MATERIAL. Examples include but are not limited to: purified or fractionated sub-sets of the ORIGINAL TRANSFERRED MATERIAL; PROGENY or products thereof; subclones of unmodified cell lines; transcription and translation products (e.g., RNA and protein derived from provided DNA); reverse transcription and reverse translation products (e.g., DNA synthesized on a template using provided RNA); monoclonal antibodies secreted by a hybridoma cell line; and chemically-synthesized copy or copies.

E. "MODIFICATIONS": Substances created by the RECIPIENT that either contain or incorporate the MATERIAL or were created through the use of the MATERIAL.

F. "RESEARCH USE": The scientific RESEARCH USE specified in Exhibit A.

G. "RECIPIENT INVESTIGATOR(S)": The RECIPIENT's scientific investigator(s) specified in Exhibit A.

H. "CONFIDENTIAL INFORMATION": Information, data or material in written or other tangible form related to the MATERIAL that is identified as confidential at the time of disclosure. CONFIDENTIAL INFORMATION does NOT include information that is:

(i) generally known to the public at the time of disclosure to the RECIPIENT;

(ii) already in RECIPIENT's possession at the time of disclosure by UC DAVIS;

(iii) disclosed to RECIPIENT on a non-confidential basis by a third party having the right to make such disclosure;

(iv) independently developed by RECIPIENT without the use of the CONFIDENTIAL INFORMATION disclosed by UC DAVIS as evidenced by written records; or

(v) required to be disclosed by law or governmental rule or regulation.

(Continued on Next Page)

Box 4 (continued)

2. Terms and Conditions

A. Use

i. The RECIPIENT shall use the MATERIAL solely for the RESEARCH USE. Any other use of the MATERIAL by the RECIPIENT is expressly prohibited without the prior written consent of UC DAVIS. In addition, the RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including, but not limited to, those related to research involving the use of animals or recombinant DNA. The MATERIAL may not be used on any human subjects or for commercial purposes or any other use other than the RESEARCH USE.

ii. RECIPIENT will not analyze the MATERIAL for chemical composition or physical structure or have or allow any component of the MATERIAL to be analyzed or make any use of any such analysis. The RECIPIENT will not alter the chemical structure of the MATERIAL in any way.

B. Tangible Property Ownership: UC DAVIS retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

C. Confidentiality: Any CONFIDENTIAL INFORMATION disclosed by UC DAVIS to RECIPIENT shall be treated as confidential and maintained in confidence by RECIPIENT for five (5) years after disclosure. RECIPIENT shall not disclose any CONFIDENTIAL INFORMATION of UC DAVIS, except to its own personnel who have a need to know. Without limiting the foregoing, RECIPIENT agrees to take the same steps and use the same methods to prevent the unauthorized use or disclosure of CONFIDENTIAL INFORMATION of UC DAVIS as it takes to protect its own CONFIDENTIAL INFORMATION or proprietary information.

D. Distribution: RECIPIENT agrees NOT to transfer the MATERIAL or MODIFICATIONS to anyone other than to one who works under the direct supervision of the RECIPIENT INVESTIGATOR within the RESEARCH USE without the prior written consent of UC DAVIS.

E. Disclosure, Inventorship, and Intellectual Property Rights

i. Disclosure: The RECIPIENT shall promptly notify UC DAVIS of any potentially patentable discoveries or inventions made through the use of the MATERIAL, whether or not made within the specified limits of the approved RESEARCH USE. The RECIPIENT shall promptly supply UC DAVIS with a copy of the invention disclosure.

ii. Inventorship: Inventorship shall be determined according to United States patent law.

iii. Intellectual Property Rights: Collaborative efforts of UC DAVIS and the RECIPIENT may create inventorship rights under United States patent law as well as under the law of any applicable jurisdiction in which a party or the PARTIES may elect to file patent application(s). Each party shall own its undivided interest in joint inventions. The PARTIES shall cooperate in discussing and securing intellectual property rights to protect potentially patentable inventions.

iv. No Implied Rights: The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied license or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of UC DAVIS, including any altered forms of the MATERIAL made by UC DAVIS. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS or any related patents of UC DAVIS for commercial use or any other use other than the RESEARCH USE.

(Continued on Next Page)

Box 4 (continued)

F. Warranty and Licenses:

i. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. UC DAVIS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

ii. If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for profit-making or commercial purposes, the RECIPIENT agrees, in advance of such use, to negotiate in good faith and conclude a license agreement containing terms typically required in license agreements executed by UC DAVIS. It is understood by the RECIPIENT that UC DAVIS will have no obligation to grant such a license to RECIPIENT, that future licensing rights, if any, may be subject to preexisting contractual obligations of UC DAVIS, and that UC DAVIS may grant exclusive or non-exclusive commercial licenses to others.

G. Liability: The RECIPIENT assumes all liability for damages that may arise from its use, storage or disposal of the MATERIAL and MODIFICATIONS. UC DAVIS will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use, storage or disposal of the MATERIAL and MODIFICATIONS by the RECIPIENT. The RECIPIENT agrees to indemnify, hold harmless and defend UC DAVIS against any claims, costs or other liabilities which may arise as a result of RECIPIENT'S use, storage or disposal of the MATERIAL.

H. Publication of Research Results: The RECIPIENT may publish or present results of research relating to the MATERIAL, provided the RECIPIENT provides UC DAVIS with a copy of any proposed manuscript, abstract, poster session or presentation at least thirty (30) days prior to such publication or presentation. UC DAVIS shall review such publication or presentation for CONFIDENTIAL INFORMATION or patentable material and may request a delay of the proposed publication or presentation for up to an additional thirty (30) days to allow for the removal of CONFIDENTIAL INFORMATION or the filing of patent application(s). Unless UC DAVIS directs otherwise, any publication or presentation reporting the research carried out with the MATERIAL shall contain proper referencing in academic journal format, acknowledging UC DAVIS as the source of the MATERIAL.

I. Termination:

i. Date: This Agreement will terminate on the earliest of the following dates:

(a) on completion of RECIPIENT'S current RESEARCH USE with the MATERIAL;

(b) on thirty (30) days' written notice by one party to the other; or

(c) (_____) years from the date of execution of this Agreement by UC DAVIS.

ii. Surviving Obligations: Obligations with respect to Tangible Property Ownership (2.B.), Confidentiality (2.C.), Distribution (2.D.), Disclosure, Inventorship, and Intellectual Property Rights (2.E.), Warranty and Licenses (2.F.), Liability (2.G.), Publication of Research Results (2.H.), and this Section (2.I.ii) shall survive termination.

iii. Return of MATERIAL: As directed by UC DAVIS, RECIPIENT shall stop using the MATERIAL and shall return or destroy any remaining MATERIAL on the termination of this Agreement.

(Continued on Next Page)

Box 4 (continued)

J. Applicable Law: The validity and interpretation of this Agreement and legal relations of the PARTIES in the performance of this Agreement shall be governed by the laws of the State of California without regard to conflicts of law provisions.

K. Notice: Any notice required under this Agreement will be considered properly given and effective on the date of the postmark if mailed by prepaid postage first-class certified mail; on the date of delivery if delivered in person; or on the date of receipt if mailed by any global express carrier service that requires the recipient to sign the documents demonstrating the delivery of such notice. Notice shall be given to the designated authorized official at the address provided below:

FOR THE REGENTS OF THE UNIVERSITY OF CALIFORNIA:

Authorized Official:	Executive Director, Technology and Industry Alliances
Address:	Technology Transfer Services, Office of Research, Technology and Industry Alliances, University of California, Davis 1850 Research Park Drive, Suite 100
City, State, Zip:	Davis, CA 95616-6134
Country:	USA
Telephone:	530.757.3432
Fax:	530.758.3276

FOR RECIPIENT:

Authorized Official: _____

Recipient Institution: _____

Address: _____

_____

City/State/ZIP: _____

Country: _____

Telephone: _____

Fax: _____

3. Complete Agreement

This Agreement constitutes all the agreements between the PARTIES, both written and oral with respect to the subject matter hereof. All prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, between the PARTIES are hereby canceled.

(Continued on Next Page)

Box 4 (continued)

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	RECIPIENT
Name:	Name:
Associate Director, Technology Transfer Services	Title:
Date:	Date:

UC DAVIS INVESTIGATOR and RECIPIENT INVESTIGATOR acknowledge reading and understanding this Agreement and shall abide by the terms and conditions thereof.

UC DAVIS INVESTIGATOR	RECIPIENT INVESTIGATOR
Name:	Name:
Title:	Title:
Date:	Date:

Exhibit A

1. ORIGINAL TRANSFERRED MATERIAL:
2. RESEARCH USE:
3. RECIPIENT INVESTIGATOR (name):

How to Draft a Collaborative Research Agreement

MARTHA BAIR STEINBOCK, *Deputy Assistant Administrator, Office of Technology Transfer, U.S. Department of Agriculture, Agricultural Research Service, U.S.A.*

ABSTRACT

A collaborative research agreement has five major parts: (1) statement of objectives, (2) statement of work, (3) general provisions, (4) budget, and (5) list of materials. This chapter provides a step-by-step discussion of the issues that need to be addressed in each part of the agreement, emphasizing the importance of crafting an agreement that is mutually beneficial and, above all, clearly written. Whereas all parts of any agreement are important, for collaborative research agreements, extra care should be taken in describing the objectives and work of the collaboration, the research plan, and the mechanisms for agreeing on changes in the research plan. Partnerships grow and change; this invariably leads to the need for amendments. Arguably, many of the best collaborative research agreements need numerous amendments in order to reflect the evolving needs of the parties involved.

1. INTRODUCTION

The objective of writing a collaborative research agreement is to clarify for both parties what they are trying to accomplish together and to clearly set forth the rules that will govern the collaborative effort. A good partnership must be mutually beneficial, and an effective collaborative research agreement will help both parties understand and accept mutual benefit as a goal. Of course, simply writing that an agreement is mutually beneficial does not make it so. An effective agreement must be based on an actual win-win relationship, one that is truly mutually beneficial. So to start with, the concept of the collaborative research project must involve a research project through which both parties benefit from the work that will be done.

A poorly written agreement can tear apart an otherwise harmonious relationship. On the other hand, a well-written agreement, in which all parties understand their responsibilities, will build and strengthen a productive scientific relationship. An effective agreement will be clear both to the researchers doing the research work and to the managers of both parties. And a well-written collaborative research agreement can lay the groundwork for moving the results of research toward commercialization.

For the sake of simplicity and to facilitate discussion of the issues involved, the chapter focuses on one scenario: developing a research agreement between a National Agricultural Research System (NARS) government laboratory and a private company. Many of the points made are equally valid for collaborative research agreements between other types of entities.

2. PARTS OF AN AGREEMENT

Most collaborative research agreements have five general parts. The agreements can be somewhat flexible in the terminology they use. The names

Steinbock MB. 2007. How to Draft a Collaborative Research Agreement. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

assigned to the subparts are not terribly important. What is important is that the agreement covers each the following points:

1. statement of objectives
2. statement of work
3. general provisions
4. budget
5. list of materials

The first part of the collaborative research agreement is commonly called the statement of objectives. This explains the overall setting of the agreement. It describes what the parties want to accomplish together and why the collaboration is important.

The second part of a well-drafted collaborative research agreement is called the statement of work. This may sometimes be called the research plan. It describes the research that the parties propose to conduct and includes which approaches will be undertaken and which methodologies will be used. Most importantly, this part of the agreement specifies who is responsible for what and specifies the due dates for completing each part of the research project.

The third part of an effectively written collaborative research agreement is called the general provisions. These are sometimes known as the legal provisions. They cover a series of important details, the mechanisms of collaboration, and the rules by which the collaboration will be conducted.

The fourth part of a agreement is the budget. This part sets forth the resources that each party needs and contributes to the collaborative research project.

For collaborative research agreements in which biological or other materials (germplasm, plant parts, biotech components, and so forth) are passed from one party to the other for use in the project, the agreement typically includes an additional section called the list of materials. This section is often attached as an appendix to the agreement. In some cases there may be more than one appendix, since the materials being used and transferred may change over the course of the project.

In its simplest form, the list of materials should provide a unique name for each item that is sent to the project, as well as the quantity of each item and the dates those materials were transferred from one party to the other. By updating the list of materials each time new materials are sent from one of the collaborating researchers to the other, all parties are assured of having a current and complete list.

2.1 *Statement of objectives*

The statement of objectives should be concise and clear. Use terms that nonscientists will readily understand and avoid the excessive use of scientific jargon. The statement of objectives should explain the real-world issues that the collaborative research agreement will address. It should articulate both the what and the why of the collaboration. When someone outside of the science community reads the agreement, they should be able to tell why the parties believe it is important to undertake the collaboration. In addition, the statement of objectives should clearly specify the scientific goals of the collaboration. Care should be taken to differentiate long-term goals, which may happen years after the agreement is completed, and short-term goals, which will be accomplished by the end of the agreement.

Consider the following examples from two statements of objectives from actual agreements:

- *Good:* to develop, test, and evaluate transgenic tomatoes expressing the "N" gene, which encodes for resistance to tobacco mosaic virus.
- *Not as good:* to determine basic breeding biology, including ploidy levels of a resistance biotype of *Lolium*.

The first one is quite well written. It clearly and specifically explains the objective. From this clear statement, most readers will get a feel for what the agreement hopes to accomplish.

The less well-written statement vaguely states the goal. Phrases like *basic breeding biology* do not really mean much unless they are further defined, and terms like *ploidy level* may not be well understood by the nonscientific community. Remember, the goal of the statement of objectives is to set the stage for the agreement by clearly stating what the parties hope to accomplish.

2.2 *Statement of work*

The next part of a well-written collaborative research agreement is what is often referred to as the statement of work. This is by far the most important part of the agreement. Sometimes, the statement of work is attached to the agreement as an appendix. This is not to diminish its importance in any way. It is merely a convenience to have this research plan slightly separated from the general body of the agreement. The advantage of having it self-contained is that it will be easier for the scientists to relate to it, and in the event of modifications to the work plan, it can be more easily amended.

The statement of work contains the scientific objectives, methodologies, and approaches. It should be broken down into subsections, with each section explaining what "partner A" will do and what "partner B" will do, with the time frames and benchmarks specifically laid out.

In drafting this section of a collaborative research agreement, the parties must work together closely. The other parts of a collaborative research agreement can be initially drafted by a technology transfer officer and/or intellectual property management officer and then can be exchanged between the partners for review, comment, and negotiation. But the collaborating researchers themselves should prepare a first draft of the statement of work, which can then be edited by the technology transfer officer. This is because the collaborating scientists are the ones who really understand the complexity of what is to be undertaken, and it is the scientists who must fully embrace the plan that is developed.

Within the statement of work, there should be a section stating the project's scientific objectives. With complicated or longer projects, there may be many objectives and subobjectives. In such cases, the use of a numbering or outlining system makes the objectives clear and readable.

Each objective in the statement of work should be followed by a description of the methodologies and approaches to be used to address the scientific questions involved. Further, each objective must include very clearly what each partner (the institute scientists and the company scientists) will be doing, separately and collaboratively. This statement of responsibilities is perhaps the most critical element of a research agreement because without a clear understanding of responsibilities, the partners may have unrealistic expectations and become frustrated. If it is unclear who will be doing each piece of experimentation, both parties may be sitting back, waiting in vain for the other to produce something. *It cannot be stressed enough that it is very important to break down each of the scientific objectives of the statement of work into tasks and clearly state who is responsible for each.*

Another point to consider is to quantify the work that is to be done. It may not be necessary to use exact numbers (for example, the types and replications of an experiment or the number of test tubes you will be using), but do insert general guidance about the size and scope of the collaborative research. For example, if you are going to do a feeding study and will be using 30 mice per replication, state that in the agreement. That way both parties will be clear as to the order of magnitude of the data types that are to be generated and the level of resources needed for their part of the work. Researchers often believe they understand what the other has in mind, but without written descriptions, such assumptions often lead to misunderstandings. For example, if an institute researcher says he or she will "field test" a new variety, he or she may have in mind a half-hectare plot necessary to generate enough plants for a publication, while the company scientist has in mind 100 hectares. So, be as clear as you can about the sizes or numbers of replications and other quantifiable aspects in the statement of work.

Another aspect that is very important is to build-in time frames and benchmarks. Generally, you want to have built into the statement of work at least an indication of when each party should have completed their responsibilities under each objective or subobjective. Often researchers will object that time-frame specifics make them feel pressured, but such a plan will help the collaborating scientists make progress in an orderly fashion. It also helps prevent one party from having to wait for the other and causing lost time. Time frames are important to make the experimentation run

smoothly and they help the partners garner the resources that will be needed to move the project along.

Benchmarks are important to help measure work progress. They specify that at a certain point both parties expect certain pieces of data to have been generated, certain parts of the experiments to have been completed, or certain questions to have been answered. You will want to write these goals as benchmarks. In a larger agreement, with multiple objectives and multiple people involved, sometimes there may be activities that will flow sequentially (one has to be completed before another can begin). Other research may be occurring simultaneously in parallel experiments. In these complicated situations, project-management software can be helpful when preparing the statement of work.

A collaborative research agreement can grow to be a lengthy document. However, you should not think that it is like a grant application that can be 20, 30, 40 or more pages. A collaborative research agreement is not designed to convince an outside party that the work is worthwhile, nor does it aim to show that either of the collaborating scientists are high-quality researchers. Rather, it should clearly spell out the respective research that the partners will be doing. So, a statement of work should only be as long as it needs to be to ensure that both parties know what is expected of them. A typical agreement will be 10–15 pages, and the statement of work is often no more than two or three pages.

3. GENERAL PROVISIONS

The next part of a collaborative research agreement is the general provisions. This is the body of the agreement that covers the how of working together and provides mechanistic guidance to the scientists at the institute and at the company, as well as to managers. Normally, an institute or an entity has a standardized set of general provisions that has been reviewed by their legal counsel and that can serve as a starting point for negotiating agreements. Each person studying this chapter should consider developing such template agreements. In the process of such development of template agreements, a person can often begin to fully understand which points are negotiable and which legal provisions are required by organization policy or law. At the same time, collaborative research agreements should be as user-friendly as possible and avoid unnecessary stipulations.

There are a wide range of typical general provisions. These include a public disclosure/publication policy, which addresses how the parties will communicate with each other and the outside world; reports; confidentiality issues; the important issues of intellectual property management and technology transfer from the institute to the company; regulatory approvals; indemnity and liability statements; dispute resolution plans; and provisions for termination. This part of the agreement should also spell out an amendment procedure and name the persons responsible for the agreement, both managerially and scientifically, at the institute and the company.

3.1 *Publications*

Public disclosure is a crucial part of any research agreement. Science is driven by the need to publish, and scientific careers depend on such publications. Public disclosure, including publication in patent literature, keeps innovation going. The phrase *public disclosure* is a broad term that includes many types of disclosure of research results. Public disclosure can include any form of public dissemination of research results: articles, abstracts, poster sessions, both informal and formal seminars, talks, information posted on the Internet, and grant applications. Most organizations that enter into collaborative research agreements will want to put some limitations on the right to public disclosure. Such a delay in public disclosure may be necessary to ensure that patent applications can be filed for discoveries made under the agreement.

A publication clause should protect the interests of both parties. Generally, there is a statement that both parties reserve a right to review and comment on all public disclosure by the other party. Typically, a specific time frame (usually 60 or 90 days) is set up for such a review. Often there is also a provision written into the collaborative research agreement stating that one party requires

the other party to delay public disclosure of project-derived information for a specific length of time to allow for patent preparation or exclusive use by the other party. The bottom line is that a well-written agreement should clearly state all such limitations of public disclosures.

3.2 *Confidentiality*

Another aspect of the general provisions involves confidential information, sometimes called confidential business information, or CBI. It is important for the collaborative research agreement to differentiate between two types: (1) confidential information that a party brings into the project and that predates the agreement, and (2) confidential information that is generated under the agreement and that the parties generated while working together and conducting project experiments. A collaborative research agreement should specify how both types of information are to be handled by the parties.

For information that is created by one of the parties prior to or outside the scope of the agreement, you may find it helpful to use the terms commonly found in a confidentiality or nondisclosure agreement. Like any confidentiality agreement, these clauses should specify a time limit during which the information is to be kept confidential. Typically, such time limits are between two and five years after the end of the collaboration or from the point the information is generated. If the parties have an earlier signed nondisclosure or confidentiality agreement, that document may simply be referenced in the collaborative research agreement or the collaborative research agreement can state that it replaces the confidentiality agreement.

The confidential treatment of information generated under the project will be closely tied to the treatment of intellectual property (IP) and tangible property.

3.3 *Intellectual property*

Perhaps the most important section of the general provisions deals with the intellectual property and tangible property (TP) provisions. This section is important because what motivates most collaborative research is the potential for gaining access to such IP/TP as may be created under the collaborative research agreement. For an institute, working with a company is an effective way to transfer technology. Many believe that it is the most effective and efficient way for research results to move from the laboratory, through a development process by the company partner, and finally into the marketplace. Without such provisions, the benefits of collaboration may be lost.

The first step in drafting this section is to clearly define IP and TP rights.

IP rights are rights under various types of statutory protection. These IP rights include the intangible property rights obtained from:

- issued patents and patent applications
- plant variety protection (or a breeder's rights) applications and granted certificates
- copyrights (including software)
- trade secrets
- trademarks and service marks

TP rights are the second broad class of property rights. These include ownership rights in various classes of biological materials, germplasm, databases, business plans, research plans and protocols, laboratory notebooks, and the like. They involve the ownership of things that one can touch, see, taste, smell, and hear.

The second step in dealing with IP/TP issues is to establish who owns what. The collaborative research agreement should clearly state that all IP/TP contributed to the collaborative research, but predating the project, should be owned by the party who contributed its use to the project. This is why there should be a clear inventory of all IP/TP that either party contributes to the project.

For example, if the company has a genetic construct or a genomics database that the collaborators will use, then whether or not these contributions are covered by a filed or issued patent or some other sort of statutory protection, these contributions need to be clearly identified in the agreement. Similarly, if the institute brings germplasm lines, a site-specific promoter, or a transformation vector into the project, these too should be identified and documented in the agreement.

In this way, collaboration can be promoted because each party recognizes and acknowledges the other party's ownership of the contributed materials.

After establishing an inventory (in the list of materials) of the IP/TP that is brought into the project, the next step is to clearly establish how the ownership of new property discovered under the project (new IP/TP) will be determined. In a typical collaborative research project there is the potential for three classes of new IP/TP:

1. New IP/TP that is solely discovered by the institute researcher
2. New IP/TP that is solely discovered by the company researcher
3. New IP/TP that is jointly discovered by the institute researcher and the company researcher

In collaborative research, many of the discoveries fall into class three. A well-written collaborative research agreement will address how and by whom the ownership determinations are to be made in cases in which the IP/TP is discovered by one party or the other.

Globally, patent laws differ. Under the patent laws of nearly all countries outside the United States, inventorship is determined by whomever files the patent first (and has been involved in the discovery process). In the United States, inventorship is determined by first-to-invent and ownership follows inventorship, that is, ownership goes to whoever files first. This is the so-called first-to-file approach. It is therefore necessary for a collaborative research agreement to address the matter of ownership determination, or refer to the national laws of the partners.

Normally, inventorship is determined when the patent attorney talks with the researchers. If a patent is being sought in the United States, great care must be taken to include on the patent application only the actual inventors (those researchers who make the creative, intellectual contributions to the discovery). If someone who is not an inventor is named as an inventor on the patent application, this will prevent the issuing of a legitimate U.S. patent.

In a first-to-file country, the rules for the determination of actual inventorship are different. As in a first-to-invent country, ownership follows inventorship. So, whoever files first will be listed as the inventor and as the owner. Clearly, it is important to understand the rules of the country in which the patent filing is taking place. Yet it must be remembered that if the new IP/TP is to be protected in the United States (and other first-to-invent countries), regardless of where the research takes place, the rules of first-to-invent apply to all patent filings.

In general, if only employees of the institute are listed as inventors, then the institute owns the invention. If only employees of the company are listed as inventors, then the company owns the invention. However, if at least one employee of the institute and one employee of the company are listed as inventors, then the invention is jointly owned by both the institute and the company. Regardless of whether the patent filing is in a first-to-invent country or a first-to-file country, it is important to address the matter of patent ownership in a well-written collaborative research agreement. However, equally important than patent ownership are the rights that are granted under the patent.

A key part of the IP provision is what the agreement is actually promising in terms of the granting of licensing rights, or the "grant." Normally, the parties enter into a collaborative research agreement in order to obtain access to the discoveries that flow from the collaborative project.

The scope of the grant must be considered very carefully. For example, if the scientists are conducting mer research and are seeking a technology for disease resistance, it is possible that the technology may apply to other plants as well. Thus, the collaborative research agreement should be clear that the grant is for a license for mer only (or for some other agreed-upon subset of plants). This will be a key point in the negotiation of the agreement. Normally, one party will want a very broad grant of rights and the other party will keep trying to narrow the grant.

The next thing to consider is whether the grants will be for *an option* to a license or an *actual*

license. There are pros and cons to both approaches. Granting an option, with a preset fee structure, is sometimes all that will be requested, because such an option allows both parties adequate time to thoroughly evaluate the invention before signing an actual license. On the other hand, one party may strongly prefer a direct grant of a license, with the business licensing terms clearly spelled out, because this reduces the amount of uncertainty.

Granting an option normally makes a great deal of sense because it is very difficult to predict what IP/TP will be generated. Further, it is difficult to predict the value of such new IP/TP. Therefore, agreements that give a direct grant of a license and fully spell out the license terms can lead to a gross miscalculation of the new IP/TPs worth, either undervaluing it or overvaluing it. If the IP/TP is overvalued, this would likely act as a disincentive for future development of such IP/TP. If the new IP/TP is significantly undervalued, this may act as a block on the future relationship of the parties because one party has been treated unfairly.

With either approach, the collaborative research agreement should include time frames during which the party who receives the option to a license must decide whether it wishes to execute its option and take a license. The option grant should not be open ended. This will allow another licensee to be sought if the collaborating party does not wish to develop and market the new IP/TP.

Likewise, it is important to specify the license grant's level of exclusivity. Is the license (or the option to a license) for an exclusive license or a nonexclusive license? Is the license exclusive by country or region? Is the license limited by crop? By product? By time? Or, is the license more general? Most companies (and many other collaborators as well) will want some sort of exclusivity in their license (or option to a license). It may be adequate for such a collaborating partner to have an exclusive right for some specified time period, or for a certain well-defined field of use, or for a certain licensed territory, or for a combination of these. Most organizations are reluctant to put their resources into an agreement if the organization is not assured of an exclusive license because their competitors may also seek a license.

The negotiation of the grant of intellectual property is a key part of the collaborative research agreement. Take time to think it through clearly and come up with a solution that meets the needs of both parties.

3.4 *Amendments*

The last part of the general provision section is the amendment process. Strong partnerships grow and change; therefore, agreements need to be amended. In fact, many of the best collaborative research agreements need constant amendments. It is not unusual for a collaborative research agreement to be amended as often as every six months or every year. This is because the researchers often identify dynamic, new opportunities that the partners want to explore together. Thus, a well-written agreement can be amended so that the statement of objectives, the statement of work, and the budget reflect the new needs.

All amendments should in writing and signed by the proper authorities as an appendix to the agreement. Guard against informal amendments that may sneak in as the project gains momentum and the researchers become excited. If they are not written down, such amendments can lead to disputes and litigation. So make it clear to everyone that all significant changes in the research must be written and appended to the agreement.

3.5 *Termination*

All agreements should have a specific date upon which the cooporation ends. Termination clauses may be added that stipulate when and under what conditions each party may elect to terminate the agreement before the end date. The end date may be extended through the amendment process, if both parties agree. This is common in successful collaborations.

4. BUDGET

The fourth section of a well-written collaborative research agreement is the budget. There is a tendency to view this as the most important section because it documents the funding that the parties

contribute. This, however, is an improper emphasis. While it is true that public sector agricultural research is grossly underfunded, and therefore funds obtained from collaborating partners have an extremely important place in the overall research budget, collaborative research should never be viewed principally as a way to raise revenues. Collaboration is much more than that. Concentrating only on research funding overlooks both the use of the agreement as a means of technology transfer and as a way to build an intellectual synergism that can result when researchers collaborate.

Developing the budget must begin with a clear statement of work. This will help determine for the collaborators the amount and the timing of the resources required for the collaborative project. This is the starting point. There must be enough funding to undertake the project without detracting from other projects that are already underway.

Staff time should be considered, as well as tangible resources (such as space and equipment that will be required to support the project). For example, if one partner will need to recruit graduate students, technicians, or other personnel, then salary and benefit costs for the new staff must be included. Also, do not overlook in-kind contributions that a collaborating partner may be able to provide. A company, for example, may have very specialized equipment, expertise, formulation technology, or access to facilities that would be extremely costly for an institute to procure on its own. The value of such in-kind contributions should be noted in the budget.

The budget for a collaborative research agreement should be absolutely clear *as a research budget* and be totally separate from any sort of licensing revenue that might be projected. The budget should also specify when the payments will be made and clearly indicate when the contributed in-kind resources will be provided.

5. LIST OF MATERIALS

The final section of a collaborative research agreement is the list of materials. As with the budget, this section provides a clear listing of the TP that each party provides to the project. This is critical because all such materials were developed outside of the project and are owned by one partner or the other. They are *not* new TP that will be divided according to the granting clauses. Rather, materials that are included in the list of materials are fully owned by one of the collaborators. Sometimes items listed in the list of materials have IP rights associated with them; sometimes they do not.

In truly collaborative research, the list of materials may have to be amended on a regular basis. This will require the agreement to be amended easily (as noted above). A well-written collaborative research agreement, the list of materials will dynamically respond to the emerging needs of the researchers.

6. CONCLUSION

Collaborative research agreements can be extremely beneficial to both partners. No single entity ever has adequate money, resources, and intellectual capacity to do all the research it might want to do. Forming partnerships can be an effective and economical way of accessing resources. Collaborative research agreements, moreover, are often the first step in establishing longer-term partnerships. They can be effective technology transfer tools, as well. The benefits are much more than monetary. Taking the time to think through and discuss the terms of the collaborative research agreement helps foster communication between partners and sets the project on a path for success. Indeed, good partnerships spur creativity and help innovation to serve the public welfare.

Lastly, it should be said that writing and negotiating a collaborative research agreement might seem like a very difficult process. In fact, a first attempt to write such an agreement usually is difficult. The good news is that each time one does it, the process gets easier. ■

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Drafting Effective Collaborative Research Agreements and Related Contracts

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ABSTRACT

Best practices in IP (intellectual property) management are built on a foundation of licensing and contracting expertise. A contract defines a bargain that parties enter into, and, as such, defines the relationship and the expectations of the parties. It is therefore critical to carefully draft contracts that clearly, and objectively, indicate the intentions of the parties. Avoid stilted, legalistic jargon when drafting contracts; instead, strive for direct, simple, and accurate language. In written agreements, be sure to include the terms and provisions covering the grant itself, such as payments, dispute resolution, intellectual property emerging from the R&D, IP ownership and confidentiality, and other related legal terms and definitions. However, remember that generic templates do not exist. The relationship and goals of the parties will define how the agreement is structured. The actual document will also vary, depending on whether the parties are public or private sector entities, on whether the license is a collaborative-research agreement or a sponsorship agreement, and on the business and legal culture.

1. INTRODUCTION

Human relationships are the engine of innovation; they drive the creative use and management of intellectual property (IP). Patents, trademarks, and copyrights provide mechanisms through which actors in the private and public sectors can build relationships, coordinate activities, assign responsibility, and allocate the benefits arising from innovation and its distribution. The contract links these actors and the various IP regimes. Contracts, which define in legal terms the form relationships take, mediate the interaction among those with knowledge, skills, and/or resources in order to create something new, improve what already exists, or distribute what has already been created. In this chapter, we first discuss some of the basic tenets of good contract drafting, that is, emphasizing clarity and simplicity and avoiding the slavish use of standard-form contracts, which may contain provisions unsuitable to specific contracting cultures and contexts. Later in the chapter, we discuss sound drafting practices for research contracts and for more complex collaborative research and sponsorship contracts.

Because contracts are about relationships—with all the ambiguities, pitfalls, and excitement of human relationships—contracts are difficult to capture on a dry document composed by lawyers. A written contract can never fully describe a relationship nor the full set of contractual arrangements that embody the relationship. The extent to which judges and arbitrators interpreting a dispute rely on the written document itself—in contrast to the external evidence about the relationship between the parties—varies from jurisdiction to jurisdiction. For example, in common law jurisdictions, contractual interpretation tends to be more contextual, with greater allowance made for external evidence about the broader relationship. The civil law, however, tends to

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focus more on actual contractual wording and the dictates of the *civil code*. However, irrespective of jurisdiction, the written contract is the strongest objective manifestation of the intentions of parties as they enter into a relationship.

Parties can most easily avoid disputes if the contract describes, as fully and simply as possible, the bargain made by the parties. This notion has important consequences for contract document drafting. Long-winded sentences, boilerplate provisions and impossible-to-understand definitions only complicate lives and understanding in a futile attempt to remove doubt concerning, and ambiguity of, complex and evolving relationships. Such lengthy documents are not only unreadable by the actual signatories to the contract but do little to provide guidance to the business people and judges who may eventually have to settle disputes based on those documents.

Instead of thinking about contractual documents as an attempt to pin down every last aspect of a relationship between parties in complex legal jargon, this chapter suggests a different approach, one drawn from the experience of large corporate law firms: explain the provisions of the bargain as simply as possible, in a logical sequence, using plain language. By explaining the bargain in a clear and accessible manner, not only are the chances better that the parties will comply with the essence of the contractual relationship, but also business people and judges will resolve disputes in conformity with the fundamental intentions of the parties.

Undoubtedly there is temptation to use standard form contracts and boilerplate provisions to lower transaction costs and legal fees, but in the end, the use of poorly written or inappropriate contractual provisions may lead to greater costs, rather than save money. That is not to say that every contract need be drafted from scratch; the use of contractual precedents is a judicious use of legal resources. Select precedents that are well written and constructed. Parties to the contract should question the relevance of each provision to the bargain within the appropriate cultural context. When using clauses from standard form contracts, the key question to ask is: do you understand the language and does it accurately describe the arrangements between the parties, given the cultural and legal context?

1.1 *Explaining the bargain: The art of contract drafting*

If one were to read court decisions about contracts, one would soon see that judges struggle not as much to determine what the documents say, as to determine the nature of the relationships underlying the contracts. When judges find this difficult because the contract document is confused and convoluted, they are more likely to misinterpret the original agreement between the parties. Such misinterpretations lead to decisions that run against the allocation of responsibilities and benefits that the parties originally intended, increasing uncertainty and undermining the business rationale for the contract. What judges seek to find in contractual documents are objective indications of what the parties intended to do: Who was to take on what risks? Who was to benefit from the results of the contract? How were the parties to deal with disputes and controversies? Judges want to understand what the parties bargained for so that they can figure out who should do what, when, and where.

A good contractual document is one that sets out the bargain as clearly and simply as possible; a bad document is one that muddles it with too many words, arcane language, and legal mumbo jumbo. The job of a lawyer is to identify the essence of the relationship so that the parties and judges understand exactly what the business deal is about. This involves setting out the contract in a structured way that focuses on the essential elements of the bargain.

The simplest contract is one in which one party promises to deliver something to another in return for something (monetary or otherwise). If a dispute arises, the parties agree to follow a set procedure (such as arbitration or mediation) or to sue in court (litigation).[1] This progression should be defined in the contract (for example, mediation procedures, followed by binding arbitration).

Further, the agreement should clearly explain *how* one party is to deliver something to the other, the heart of what Article 1 should cover. Article

2 should deal with payment: to whom should the payment be made? in what currency? in which form (electronic, bank draft, for example) and when? One could also add a few sentences dealing with late payments: will there be interest charged and, if so, how much? how would a currency crisis (for example, currency cannot be exported out of the country) be dealt with? The third article deals with resolving problems: steps to be taken if the receiving person is unsatisfied with what was delivered, either in terms of quality or quantity; how the parties would resolve the conflict; what the first person should do if he or she is not paid. The parties can agree to litigation or arbitration but may first prefer to set up a mechanism through which they can elevate the problem to senior management who, presumably, want to avoid the costs and embarrassment of going to court or arbitration.

The key to drafting these articles is to keep the essence of the bargain clear and as uncomplicated as possible. Sentences should be short, free of vague adjectives, and be written in the active voice. The vocabulary should be accessible both to business people (with technical knowledge but limited legal knowledge) and judges (with limited technical knowledge but with extensive legal knowledge). Use correct grammar and a simple vocabulary. If the document would get low grades from a secondary school teacher, do not use it. In fact, sometimes legal disputes turn on grammar. One recent commercial dispute in Canada, worth $2 million (Canadian), was resolved on the basis of a rogue comma.[2]

After the parties explain the main provisions of the bargain, the parties will need to define words and phrases used in the contract. The parties should include clauses that take into account the local law that applies to the contract. These clauses can have important implications for the bargain, and so writing them requires expert legal knowledge. Such clauses can deal with what would happen if there were natural disasters or labor strikes, or how much leeway is given with regard to time lines, or how to calculate exchange rates. This information must be relevant to the local area, however, because the detailed legal rules of one place, say California, U.S.A., may be quite different from the detailed legal rules in another place, say Uttar Pradesh, India.

Written contractual documents depend to a large extent on local customs. That is, the contract can be meaningful only within the set of business practices and norms that exist in the place where the contract is to be performed. As practices and norms vary tremendously, so do the contractual documents that serve to reflect contractual relationships. So, for example, contractual documents in the United States tend to be very detailed and long, while a contractual document on a similar topic will be shorter and much less detailed in Germany. Exporting one style of contractual document from one place to another can be risky, since the business people and courts will have difficulty interpreting a document written for a different place with different customs. This is another good reason to avoid a slavish devotion to standard-form contracts and why this chapter does *not* include a sample contract with boilerplate provisions, but instead sets out only the main elements of a contract.

Of course, when the parties are from two different places, say Uttar Pradesh and California, the parties must adopt a more generic style of contractual language that reflects, to the extent possible, the practices in both jurisdictions. This is not principally for legal reasons; the contractual document will be interpreted in accordance with the laws and customs of only one of the jurisdictions. Rather, the effort to reflect both cultures is important to maintaining business relationships, since people from both places must feel comfortable with the contractual document.

Finally, it is helpful to recognize that, while legal systems abound, there are two principal ones that govern most commercial contracts: the common law and the civil law. While some countries use hybrid legal systems (for example, Oman, Puerto Rico, and Indonesia), most contracts dealing with collaborations and research will be subject to one or the other of these two systems. Usually, common law countries are former colonies of the United Kingdom and follow the English legal system, while civil law countries are generally the former colonies of continental European powers.

Common law and civil law systems are usually similar in result, but there are differences in law and in practice that could ambush the unwary. For example, for a common law contract to be enforceable there must be an exchange of something of value, called consideration. Consideration can be in the form of money, return promises, action, or forbearance. On the other hand, civil law does not require consideration. Therefore, a failure to provide consideration (for example, a license with no payment and no obligation of confidentiality) may not be enforceable in the common law. Another difference between the two legal systems is that the civil law imposes background obligations of good faith as well as more limits on what can be the subject of a contract than does the common law. However, these differences are relatively rare. They are unlikely, in most cases, to affect collaborative or research agreements greatly. The bigger difference is one of style: common law contractual documents tend to be longer and more detailed, while civil law contractual documents tend to be short and refer to the civil code for more detail.

1.2 *Contracting to innovate*

Contractual documents that deal with innovation should follow the general rule of contracts: explain the bargain in simple, straightforward sentences. Clarity and simplicity are, once again, the keys to a successful contractual document. If the contract is well drafted, neither the institutions involved nor judges will misunderstand the responsibilities of the parties involved. Following the rule does not, of course, avoid all conflict, but minimizes it and provides business people and courts a framework within which to resolve disputes.

1.2.1 *The license*

Traditionally, a license is a grant of permission for a party to enter onto the physical property of another, that is, an agreement not to hold the party liable for illegal trespass. With respect to intellectual property (IP), a license is a promise not to sue a party for actions that would otherwise constitute infringement. In other words, a license is permission to make use of another's IP under carefully laid out conditions and terms.

There are a variety of contracts, and associated documents, that relate to intellectual property. A basic license is the simplest of these contracts. The first article of a basic license should describe the rights being licensed (patent rights, copyright, trade secret rights, data-use rights, and so on) and the scope of the license (limitations on geography, users, and time). Article 1 should provide sufficient detail so that the business people and judges understand as clearly as possible both the nature and the limitations on what is being licensed. Article 1 should also discuss any ancillary license (for example, a license back or cross-license).

The second article should deal with payment. Is there, for example, an up-front fee? Are there royalty payments and, if so, how long will royalty payments have to be made? How and when should payments be made? The third article will set out the dispute-resolution mechanism: arbitration, courts, and/or some form of mediation.

One should supplement these articles with an explanation of what brought the parties together and what their goals are. The contract also should either acknowledge or reject relevant local laws regarding liability for problems that may arise (those within the parties' control, such as failure to pay, and outside their control, such as flood or fire). The contract should clearly state which country's (or state's) law applies and so on. The parties should take care in setting out definitions and should include these at the end (or in the introduction, if one prefers). The other issues can be dealt with in a concluding article that would include mundane, but essential topics, such as how the parties are to notify one another.

Other forms of contractual documents dealing with intellectual property expand the license agreement and may, in addition to the basic license, include articles dealing with matters such as information exchange, staff, and IP rights (as in a consortium research agreement).

1.3 *Types of contracts*

Just as there are no real limits to the bargains we can make, there is no limit to the type of contracts we can create. As circumstances change, new technologies are introduced, and business people and lawyers try to identify new niches, we

encounter new ways of contracting. The imagination is the only thing that limits what a contract can be about. Therefore, instead of trying to cover all possible forms of contracting with respect to innovation—an impossible task—we will concentrate on a discussion of the main types and leave it to the reader to imagine different scenarios. Since the key is, as always, to be clear and transparent, one can adapt the basic forms of contractual arrangement covered here to other circumstances.

The remainder of the chapter concentrates on two types of contracts: research contracts and collaborative research or sponsorship agreements. The collaborative research and sponsorship agreements are the more complicated and incorporate most of the basic terms of the research contract.

Heeding the warning against using standard-form agreements, the discussions below will concentrate on some of the principal issues that arise in the various types of contract. However, one must adapt the contractual arrangements to the fundamental underlying relationship and not get overly caught up in presenting minutiae.

2. RESEARCH CONTRACTS

A research contract is one in which a researcher seeks to obtain the rights to use some knowledge (be it patented or protected as a trade secret) to advance his or her research project. That is, the rights obtained are an important ingredient in the carrying out of a research project, whether at a public, not-for-profit, or for-profit institution.

A basic outline of a research contract would include the following:

- Article 1: the license
- Article 2: payment terms and process
- Article 3: problem escalation and dispute resolution
- Article 4: intellectual property emerging from research (where applicable)
- Article 5: confidentiality and publication rights
- Article 6: legal terms, such as what to do in case of an "act of God" or other intervention, timing issues, and notification procedures
- Article 7: definitions

The simplest form of research contract would begin, in Article 1, with a holder of intellectual property granting a license (that is, promising not to sue for infringement) to a researcher in order to allow the latter to make use of a certain technology for a defined research use. Generally, however, research contracts are more complex, and the license forms only one part of the broader research contract. The contract may include a promise to provide a sample of the material.

Material transfer agreements are discussed more fully elsewhere,[3] but it is worth noting that these agreements are not only particularly significant for research, but are also often the most problematic of contracts to negotiate. There are real worries about the sharing of research materials and results in a research environment that is increasingly industry funded, competitive, and focused on commercializing research results. These agreements also give rise to significant practical difficulties, such as the time and labor needed to prepare and transfer research materials, and the need to internationally ship biological material.[4]

The research contract may call for a payment (often nominal, to cover expenses) in cash as well as in-kind (for example, a promise not to do or disclose certain things). The contract may also discuss how to resolve disputes over exactly what was licensed (for example, slight variations on the initial technology), payment amounts (how to handle the production of material that was never used), and so on.

That is the basic bargain. With a clearly written contract, one has already avoided most possible conflicts. There remain, however, a few contentious issues that we cover here in more detail. These include publication rights, confidential information, tricky licensing concerns, payment, and rights to the results of the research performed.

2.1 *Publication rights*

It is seldom the case that a technology is solely protected by patents that are available for review by the public, and it is bad business practice to use only patents if other forms of business protection are also available. Therefore, when a party licenses the use of a certain technology, that party

often must provide associated confidential information. To protect the party against the disclosure of this information, he or she often asks for a right to approve any publications. In addition, if the research may result in new information that may affect the technology owner's interests (the research shows that the technology does not work or works better than expected), the technology owner may wish to have time to prepare for this eventuality prior to any public disclosure. This also would lead the owner to seek the right to approve publications.

Given the interests of technology owners to guard against uncontrolled disclosures, these owners may insist that a clause be added to the research contract providing that the researcher may only publish articles after first getting permission from the technology owner or after first giving the technology owner enough time to prepare itself for the publication. Delays of three to six months for the technology owner to review publications to ensure that no confidential information is disclosed are reasonable, provided that the article's author is permitted to submit the article to the journal for a confidential review during this time. As normal peer-review processes usually take at least this much time, it provides little inconvenience to the author.

If the technology owner also has the right to *new* inventions coming out of the research (usually this only happens in a sponsored-research setting, which will be discussed later), then the owner may also reasonably request a publication delay in order to assess the publication for any disclosure that could threaten the patentability of the new invention.

2.2 *Confidential information*

Patents often represent only a part of a technology, for example, an early prototypical embodiment of an invention. The remainder, such as secrets and know-how, are protected under most legal regimes as trade secrets or as confidential information. In addition, the research conducted under a contract may result in the creation of new confidential information. The person who possesses confidential information can only prevent others from disclosing it, for example, to a competitor, if a confidential relationship exists between the person and the party to whom the information was initially disclosed. One of the best ways of ensuring this protection from disclosure is through a contract.

The obligation to maintain confidentiality will often be reciprocal. The technology owner may seek to include a confidential information clause in the research contract to prevent the researcher from disclosing confidential information initially disclosed by the owner. The researcher may wish to insert this type of clause into the contract to protect the results of his or her research effort.

It is important to pay attention to how broadly one defines the term *confidential information*. A narrow definition can be clear, but may leave out important information. A broad definition may, on the other hand, prevent the parties from getting on with their work. Therefore, both parties to the research contract should review the definition carefully and make sure it is clear to them. There are several mechanisms that can increase clarity. First, one can limit confidential information to material that is clearly identified (because it is marked *confidential*) or limit confidential information to clear and discrete categories of information (for example, business plans or customer lists). Caution should be used in accepting an open definition (for example, "Confidential Information includes but is not limited to … ."), especially where there is no requirement that the confidential information be specifically marked as such. In addition, some courts may strike down an overly broad confidentiality provision. This is because they sometimes see these provisions as contrary to public policy, since they limit competition.

Overall, the scope of what is held to be confidential should not be so broad as to prevent publication of research results and the use of research by others. Moreover, since what should be kept confidential will depend on how the information is to be used, no single definition will apply well in all cases.

The contractual provisions dealing with confidential information should make clear to whom the information may be disclosed (for example,

other researchers, including graduate students in the same and other institutions, and so on). Care should be taken to ensure that the obligations would not prevent doctoral students or post-doctoral fellows from publishing theses and making presentations.

The confidentiality provisions should also include a sunset clause that would end the obligation of confidentiality under a variety of circumstances, including situations where the information is made available to the public through no fault of the receiving party and cases where a court requires that the information be disclosed.

Finally, the contract should set out how much care must be taken by the person receiving the information to keep it confidential. For example, must the receiving party lock away the information in a safe, or can he or she leave it filed in office filing cabinets? This is important, since it establishes the level of precaution the receiving party must undertake to protect the information, and how the party ought to address inadvertent disclosures. The agreement should also specify what information the recipient of information is entitled to keep after the expiration of the contract and what must be returned or destroyed.

2.3 *The license*

The researcher's freedom to carry on research using a patented, or otherwise protected, invention is determined by the scope of the license. A license may be narrow and provide only for a defined field of use, such as use in conjunction with certain vectors, or the license may be broad and cover all research. The broader the scope, the more freedom the researcher has to conduct research.

The researcher needs to recognize the counterintuitive fact that receiving a license to an invention does not guarantee that he or she is entitled to use the invention. The researcher may need, for example, regulatory approval, or may need to license other inventions from the same or different providers. It is therefore critically important for the researcher to determine, normally with the assistance of the licensor, how he or she will be able to legally use the invention.

A license can be a nonexclusive license, a sole license, or an exclusive license. A technology owner who grants a nonexclusive license is permitted to grant the same or a similar license to anyone else (however, the owner may not grant someone else a sole or exclusive license). Unlike a nonexclusive license, an exclusive license incorporates two promises. The first is the license itself, that is, a promise not to sue the researcher for patent infringement. The second is a promise by the technology owner to neither use the invention himself or herself nor grant a license to anyone else. Coexclusive licenses, prevent the owner from granting a license outside of an identified group. A sole license is similar to an exclusive license except that the technology owner retains the right to use the invention herself or himself. Normally, the greater the degree of exclusivity requested, the greater the royalty paid by the researcher, since fewer sources of revenue are available to the technology owner. In an academic setting, researchers usually require only nonexclusive licenses. In the private sector, especially where a technology is key to developing a particular application, a research organization may need an exclusive or co-exclusive license that justifies the investments needed to bring the technology to the market. This is often the case if the research organization faces a significant risk or the market for the technology is expected to be small.

Some inventions in the biotechnology field, such as genetic inventions and platform technology, tend to represent upstream inventions: these are inventions that are needed in a large variety of settings and applications. Granting exclusive or sole licenses over all applications (generally referred to as fields of use, in-license agreements) for these types of inventions is not recommended. Indeed, the Organisation for Economic Co-operation and Development (OECD) has recently issued best practice guidelines for licensing genetic inventions that emphasize the general preference for nonexclusive licensing for genetic technologies.[5] However, we can infer that nonexclusive licensing is more broadly preferred, especially for platform technologies. One study indicated that exclusive licensees often fail to actually invest the necessary funds to move a technology forward.[6] This may happen if the licensee lacks funds or loses interest in developing the

technology. Thus, strong exclusive relationships are generally not the best way to advance research or commercialization.

If an exclusive license is necessary, particularly with respect to very early-stage research, it is best to narrowly define fields of exclusive use for the invention so that the technology owner has the flexibility to permit researchers in other fields with different applications the freedom to conduct research. Where an exclusive license is required, the parties should draft the license to include provisions that enable the technology owner to take back the rights granted in certain circumstances. These circumstances might include the failure of the research organization to develop the invention in the manner described in the license agreement, failure to fully exploit all aspects of development for the invention, or failure to sublicense as appropriate. These take-back provisions should address, for example, the loss of the license, the conversion of the exclusive license into a nonexclusive license, or the reduction in scope of the exclusive license.

To preserve the freedom of researchers, in general, to engage in research for humanitarian purposes, licenses should, whenever possible, explicitly recognize the rights of third parties to conduct humanitarian research. This can be accomplished by having one of the parties retain the right to provide licenses to others who plan to carry on such work. The parties may even go so far as to impose an obligation to do so in specifically defined circumstances. When seeking to include this type of provision, a lawyer should be consulted in the relevant country to make sure that the obligation is enforceable, especially in case of bankruptcy.

One important, but occasionally overlooked, element of a license is a description of the organizations and people that are entitled to benefit from the license. Without such a list, the default is that the license will apply only to the licensee. Where the research is being used by researchers at several institutions, or several locations, or by research teams from multiple corporate entities within the same family of companies, the license must be drafted so as to permit all of the researchers to use the technology. To accomplish this, the license should specifically permit the research organization signing the license with the right to allow others to use the invention through a sublicense. On the other hand, the technology owner will often want to ensure that this group does not become too large. Thus, it is in both parties' interests to specifically define the group to which access to the inventions will be provided. In addition, the license should identify all countries where the researcher requires access to the invention.

2.4 *Payment*

In general, those who receive a license for an invention pay a combination of up-front fees and ongoing royalties for the right to use the invention. Where the technology is a research tool and the market for the technology consists primarily of those conducting research, a market price will be charged. In the case of research agreements, however, it is standard practice to either not demand these fees or to set them at a rate that compensates the technology provider for out-of-pocket expenses. There are other cases where a fee will normally not be requested, such as where the license is provided as part of a cross-license arrangement or where the parties wish to contract for the provision of know-how related to research that falls within existing research exemptions. Where payment is required, the amount of the fees depends on many factors, including the scope and nature of the license, the type of invention, and whether the researcher is sponsored by the private or the public sector. In general, care must be taken in establishing up-front fees, especially where these fees may present a barrier to access.

2.5 *Rights to intellectual property created through research*

Research conducted using licensed innovation may itself result in patentable inventions. Some of these inventions may relate to the licensed-in technology. For example, they may constitute a modified or improved form of the original technology, or they may be substantially different. If the research agreement is silent on the ownership of these new inventions, then the researcher or the researcher's employer, or a combination of

the two, would be entitled to hold a patent over it, depending on the IP policy of the particular research institution. This means that the original technology owner would, in the absence of any agreement to the contrary, normally have no IP right to this new invention and, therefore, no right to use the new invention, let alone control access to it. This situation can be changed through an appropriate assignment, through grant-back clauses, or through license provisions in the research contract.

2.5.1 *Ownership*

In the research setting, ownership of intellectual property developed using licensed-in technology should generally remain with the researcher or the researcher's employer. This is especially true where the research takes place at a university or public research center and where public funds are used to conduct research. Thus, reach-through license agreements, in which the original technology owner claims rights to research resulting from the use of licensed inventions, should generally be avoided.

The situation is different for sponsored research where the researcher is essentially hired to conduct research for the original technology owner. In this case, it is appropriate for the researcher to assign IP rights to the technology owner, since the default rule would leave the intellectual property in the researcher's hands. Where there is an assignment, the researcher should ensure that other researchers, graduate students, and postdoctoral fellows working on the project understand this and agree to transfer intellectual property to the original technology owner.

The contract should also set out whether the researcher or the original technology owner has the responsibility to file and maintain patents for the new inventions. Normally, this would fall on the party who ends up with the patent or who holds an exclusive license to the invention.

2.5.2 *License back*

The research contract would not normally include a license back from the researcher to the original technology owner for inventions made during the course of the research. This is because the risk and responsibility for new inventions rests with the researcher, not the original owner. The situation is slightly different with respect to improvements to licensed-in inventions. In this situation, the original technology owner may wish to have access to those improvements both for his or her own sake but also for the sake of his or her other licensees. It may be appropriate for the researcher to license back improvements on a nonexclusive basis to the original technology owner, to the extent that this is necessary for the owner and his or her other licensees to continue using the (improved) invention. A reasonable royalty may be required. The scope of the license back should not be so large as to prevent the researcher from licensing the improvement to other parties.

2.6 *Alternative structures for research relationships*

Researchers will often require access to many inventions to accomplish their work. Indeed, a researcher may be required to purchase many licenses to carry out a particular research project. The need for multiple licenses, referred to as patent stacking, can lead to problems, because the costs, in terms of both time and money, associated with obtaining those licenses to a large number of patents simply is prohibitive. In order to avoid potential problems, license agreements need to ensure that the total royalty burden faced by the researcher is reasonable. This can be accomplished by setting a maximum total royalty burden that the researcher must pay to all licensors. To the extent that the total royalty burden exceeds that amount, the researcher would pay the technology owner a *pro rata* amount of the total royalty burden. The owner may wish, however, to set minimum royalty rates.

Alternatively, licensors and licensees may wish to contemplate creating patent pools, patent clearinghouses, or other open-source means to ensure that researchers at both public and private institutions have access to basic technology. License agreements would then be standardized and ensure access to a variety of inventions at a reasonable cost.

A patent pool is an arrangement in which "*two or more patent owners agree to license certain*

of their patents to one another and/or third parties."[7] Patent pools bring together patent holders in a specific area of innovation, such as a viral genome, to facilitate the efficient use and development of a technology. The patents are *pooled* because the arrangement allows inventors in the pool to use all their patented inventions under favorable licensing terms. The group then shares any benefits that may materialize from this arrangement. The motion picture industry, aeronautics firms, and those developing new DVD technology have all successfully used patent pools to advance their respective technologies.[8]

There are many challenges to setting up a patent pool. For example, patent pools may trigger anti-competition laws.[9] Second, researchers may choose not to join in the patent pool because, even though these pools reduce research transaction costs and spread risk, they also decrease the potential for large profits. Thus, parties need to strike the right balance between research goals and profit motives.[10]

Open source patent systems share the goal of promoting the free dissemination of research between inventors and the public, in contrast to the creation of marketplace monopolies. Open source systems can be directed at end products or research tools used to develop products. There are several functioning examples of open source patent systems. One such initiative is the Public Patent Foundation (PPF). It facilitates the creation of free zones in which patents are pooled and made freely available to other participants.[11] The PPF accomplishes this by granting nonexclusive and royalty-free licenses to participants. Another example is the Biological Innovation of Open Society (BIOS). It involves technologies that have already been granted patent rights. Focusing on research tools rather than on final products, BIOS (like PPF) has established licensing terms to achieve their specific goals.[12] One final example of an open source patent system is the Tropical Disease Initiative (TDI). With this system, inventions are not necessarily subject to patent rights. TDI's aim is to maintain an accessible Web database to facilitate research and development and to make research information readily accessible to researchers.[13]

3. COLLABORATIVE RESEARCH AND SPONSORSHIP AGREEMENTS

While the research contract normally provides a one-way flow of technology from the technology holder to a researcher, more complex arrangements exist. This section considers two of them: the collaborative research agreement and the sponsorship agreement.

A *collaborative research agreement* involves multiple partners, often a mixture of private and public sector actors, working together on a particular research project. The partners each contribute an amount of money, skilled talent, and technology to a central pot that they then harness to conduct research. Usually, the private sector actor either obtains the intellectual property to the resulting research or, more often, a priority right to license that intellectual property. By adding additional players and providing a more-complex ownership scheme for the resulting technology, collaborative research agreements form a more-complex transaction than the one-way flow of technology in the research contract.

A basic collaborative research agreement would include the following

- Article 1: joint obligations to participate in the collaborative research effort
- Article 2: a high-level description of what each party brings to the research project (money, technology, material, skills) with cross-references to articles 3, 4 and 5. The details of each party's contribution may be attached as an appendix to the agreement.
- Article 3: payment terms and process stipulations
- Article 4: licenses from the various parties to use pre-existing technology (including a mechanism to add additional technology)
- Article 5: a list of materials needed to be transferred to conduct the research
- Article 6: provision for who holds intellectual property emerging from the research
- Article 7: licenses to technology emerging from the research (including who has the right to license-out the technology)
- Article 8: allocation of financial returns from the use or license of emerging technology and payment terms

- Article 9: addition and removal of collaborative team members
- Article 10: management structure that will be used to supervise the research and research results
- Article 11: problem escalation and dispute resolution
- Article 12: confidentiality and publication rights
- Article 13: legal terms, such as what to do in case of an "act of God" or other intervention, timing issues, and notification procedures
- Article 14: definitions

A *sponsorship agreement* is a research contract instigated by an actor, usually in the private sector, for the benefit of that actor. In some ways, it is research for hire. However, when the researcher or research organization being hired is in the public sector, the agreement normally also creates knowledge for that organization or the research community in general. As in the collaborative research agreement, the sponsor will normally, in addition to providing a license to original technology, pay for the research and retain certain IP rights in the outcome of that research.

The basic structure of a sponsorship agreement includes the following:

- Article 1: a description of the research to be conducted by the researcher
- Article 2: payment terms and process stipulations
- Article 3: the license to any technology necessary to conduct the research
- Article 4: any materials needed to be transferred to conduct the research
- Article 5: ownership of intellectual property emerging from the research
- Article 6: any license to use technology resulting from the technology
- Article 7: problem escalation and dispute resolution
- Article 8: confidentiality and publication rights
- Article 9: legal terms, such as what to do in case of an "act of God" or other intervention; payment schedules and other timing issues; and notification procedures
- Article 10: definitions

Both collaborative research and sponsorship relationships are complex and so the nature of these relationships will be context dependent. This means that one should avoid the automatic use of standard-form agreements and ensure that the contract is context specific. The more complex the contract, the greater the need for clarity and structure.

3.1 *Confidential information*

The discussion that follows presumes the reader understands the content of the previous discussion with respect to research contracts, and thus only highlights areas of particular importance and adds provisions not required for the ordinary research contract. The reader is thus advised to read carefully the previous section on research contracts before continuing further.

A research sponsorship or collaborative research relationship is designed to build new knowledge and new inventions. While some of these inventions may be patented, others may be held as trade secrets. In the latter case, the agreement should normally establish how to ensure trade secret protection. In virtually all collaborative research or sponsorship agreements, all parties will be obliged to maintain confidentiality, in order to protect both what was brought into the research project and what is to be produced through the research partnership. Unlike standard research contracts, it is highly likely that, with both collaborative research and sponsorship agreements, information will likely flow back and forth between a number of parties, perhaps in different jurisdictions. The agreement must therefore clearly provide for information sharing and for a mechanism to keep track of who has accessed what information and when. Such provisions will not only help maintain control over the information, but make it easier to identify which party is responsible for any security lapses, should they occur. It is also important, in cross-jurisdictional agreements, to ensure that confidential information provisions are enforceable in all relevant jurisdictions.

The parties should carefully describe what should be done at the end of the project with confidential information that is brought into or created through the project. Thus, the agreement should specify whether, at the end of the research, other participants in the research project are entitled to use the confidential information brought into the project by another party. Similarly, the parties must determine who will be entitled to use information created through the research program and for what purposes.

In order to ensure that confidential information can be licensed to others, it is also important for the agreement to stipulate which of the parties is entitled to make decisions about the licensing of the information. In the absence of such a provision, it will be difficult to transfer confidential information developed through the research program to eventual licensees of the technology.

3.2 *License to contributed patented technologies*

Participants in a research project will likely bring with them not only confidential information, but patented technology for use in the course of the research. Given the evolving nature of complex research projects, the parties are unlikely, at the beginning of the project, to know exactly which technology they will each need to contribute. To handle this problem, the agreement should list the technology and associated patents that need to be included in the project. The parties should establish a mechanism through which additional technology (and associated patents) can be added, for example, a committee that formally approves the addition of new items to the technology and patent list. By establishing such a mechanism, the contract provides transparency to the participants and yet includes flexibility to adjust to new developments.

3.2.1 *License scope and nature*

Unlike a standard research contract, which licenses technology to one party, in the collaborative research agreement and occasionally in the sponsored research agreement, the license will need to extend to all research participants at all institutions. Therefore, the agreement needs to describe the set of persons who are entitled to use the technology, as well as set out a mechanism to add additional researchers and institutions who may later join the project.

Normally, material or information contributed through a sponsorship or collaborative research agreement will be licensed on a nonexclusive basis to those carrying out the research. It is good practice to include these provisions even in countries where a formal research exception exists, given both ambiguities in the law and differences between the legal rules in different countries. The parties should ensure that the scope of the license is sufficiently broad as to accommodate changes in research direction.

Where there are multiple parties to an agreement, the contract should provide a mechanism through which participants can withdraw. This is particularly important for bankruptcy issues that otherwise could plague ongoing research. Such a mechanism can also address any changes in status of one of the participating institutions (for example, a subsidiary company merging with its parent company). These agreements should normally state that the remaining parties are entitled to continue using material or information and should also stipulate the process for adding new parties to the collaboration, subject to national bankruptcy and competition laws as well as other contractual obligations.

Once again, one must recognize that a license by itself does not guarantee that the licensee or other parties named in the agreement can actually use the invention.

3.2.2 *Payment*

As licenses granted to researchers actively contribute to the research effort, they are usually provided either free of charge or at a reasonable rate.

3.3 *Rights to intellectual property created through research*

One of the most important goals of the sponsorship or collaborative research arrangement is to develop a new technology that can be commercialized. Because of this, some of the key IP provisions in these agreements relate to the

intellectual property produced through the research, rather than to existing inventions.

3.3.1 *IP rights associated with the sponsorship agreement*

If a sponsor wishes to alter the default legal provision that the researcher or employer retains IP rights to research results, the agreement ought to clearly specify the respective ownership stake of each of the parties in inventions resulting from the research. The sponsor and researching organization ought also to specify which of them has the power to make decisions about the licensing of these inventions. This need not be the same as the ownership entitlements, although it frequently is. The parties should also specify which of them has the responsibility to file and maintain patents, with respect to the inventions. In normal cases, the sponsor holds the IP rights and the obligation to maintain patents.

3.3.2 *IP rights associated with the collaborative research agreement*

The ownership of intellectual property that results from a research collaboration can be difficult to determine. Often the institutions have different sets of rules governing the ownership of intellectual property. Some institutions may leave intellectual property in the hands of their researchers and students, while others will claim ownership to the intellectual property. In reality the issue of ownership is more complicated, since ownership rules often depend on who funds the research (that is, the government, a philanthropic foundation, or the private sector). Furthermore, on a practical level, it may be difficult to assess which party has the greater claim to inventions made during the course of the research.

In the above circumstances, the parties would be well advised to specifically address the question of which of them will obtain ownership of patents and other IP rights. If the parties fail to address this issue, they risk blocking further development and use of research results arising from the collaboration. Ownership may also be particularly important with respect to avoiding seizure by others, as in the case of bankruptcy. The parties ought also to specify which of them has the responsibility to file and maintain patents over those inventions.

A related issue is which party or parties will have the power to make decisions about the future use of intellectual property, including decisions concerning licensing out technology developed during the course of the research program. What is important here is not actual ownership, but which party has control over the use and further licensing of those inventions.

In general, no matter which party or parties own the technology and associated intellectual property, all of the parties ought to have the right to use the developed technology on a nonexclusive basis for internal use and the use of their subsidiaries. There may, however, be cases where such an arrangement is not practical or effective (for example, when the parties do not plan to work on the technology after the research project and prefer to license it exclusively to a third party).

The power of a party with the right to grant licenses to others should not be unconstrained. For example, the collaboration agreement should normally provide that licenses over research tools or platform technology developed through collaboration should be nonexclusively licensed. If that is impossible, and the collaboration agreement provides that resulting technology can be licensed exclusively, there should be limits. An exclusive license should preserve the right of all collaborating researchers, and preferably all researchers anywhere, to continue conducting research on the technology and using it in a teaching environment. Second, any exclusive license should ensure that further development and use of the technology is not blocked. This can be accomplished through the use of provisions that enable the collaboration to nullify licenses in certain well-defined circumstances (for example, the failure of the future license holder to develop the technology in the manner described in the license agreement, to fully exploit all aspects of development for the technology, or to sublicense as appropriate). The nullification provision can take the form of a loss of the license, the conversion of the exclusive license into a nonexclusive license, and the reduction in scope of the exclusive license.

Just as the issues of technology *ownership* should be separated from *control* of the technology, so should the issue of ownership be separated from that of *revenue allocation*. What is critical is that the agreement clearly states how licensing and other revenue is to be divided among the collaborators.

4. CONCLUSION

The best contractual document is one that, once signed, is never looked at again. This can be the case when the parties have so well described their relationship that it is obvious who is to do what and who bears the risks. In the unfortunate and rare situation where a dispute arises, a clearly drafted contract is essential for assisting both the business people administering the contract and the judges that may be called upon to interpret it to find an appropriate and fair solution.

The basic elements of a bargain between parties, whether with regard to a simple research contract or to more complex sponsored research or collaborative research agreements, determine the structure, language, and length of a contractual document. The goal of the contract drafter is to capture the main components, laying them out in order of importance to the overall relationship between the parties. While legal detail cannot be ignored, it should take second place to clear drafting practices. ■

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1 See, also in this *Handbook*, chapter 15.3 by EJ Min.

2 Robertson G. 2006. A $2-Million Comma? Au Contraire, Rogers Tells Aliant. *Globe and Mail* 16 October, 2006: B1.

3 See, also in this *Handbook*, chapter 7.3 by A Bennett, WD Streitz and FA Gacel.

4 Walsh JP, C Cho and WM Cohen. 2005. View from the Bench: Patents and Material Transfers. *Science* 309: 2002–2003.

5 In order to address these concerns, OECD member countries agreed to *Guidelines for the Licensing of Genetic Inventions* used in health care. The guidelines set out principles and best practices for those in business, research, and health systems who enter into license agreements for genetic inventions used for human health care. The guidelines are targeted at those involved with innovation and the provision of health services, particularly those involved in the licensing of the inventions. Overall, the guidelines seek to foster the objectives of stimulating genetic research and innovation while maintaining appropriate access to health products and services. www.oecd.org/document/26/0,2340,en_2649_37437_34317658_1_1_1_37437,00.html.

6 Colyvas J, M Crow, A Gelijns, R Mazzoleni, RR Nelson, N Rosenberg and BN Sampat. 2002. How Do University Inventions Get Into Practice? *Management Science* 48: 61–72.

7 U.S. Department of Justice and the Federal Trade Commission. 6 April 1995. Antitrust Guidelines for the Licensing of Intellectual Property. 4 Trade Reg. Rep. CCH. See also Goldstein JA, TJ Ebersole and MC Guthrie 2005. Patent Pools as a Solution to the Licensing Problem of Diagnostic Genetics. *Drug Discovery World* Spring:86-90.

8 Clarke J, J Piccolo, B Stanton and K Tyson. 2000. Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? United States Patent and Trademark Office: Washington, DC. www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

9 Ibid.

10 Verbeure B, E Van Zimmeren, G Matthijs and G Van Overwalle. 2006. Patent Pools and Diagnostic Testing. *Trends in Biotechnology* 24: 114–120.

11 Feldman R. 2004. The Open Source Biotechnology Movement: Is It Patent Misuse? *Minn. J.L. Sci. & Tech*. 6: 117–167.

12 Ibid.

13 Maurer S, A Rai and A Sali. 2004. Finding Cures for Tropical Diseases: Is Open Source an Answer? *Minn. J.L. Sci. & Tech*. 6: 169–175.

The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access

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ABSTRACT

Nonassertion covenants (nonasserts for short) grant permission to third parties to practice a patent they would otherwise infringe. Legally, nonasserts are patent-infringement settlement agreements that are designed and drafted with the purpose of preemptively resolving future infringement disputes. Nonasserts can take three forms: (1) an agreement between two parties, (2) an agreement among several parties, or (3) a public statement. A nonassert can specify the release of only certain patent rights or fields of use, or it can be broad and specify release for entire patent families, including future inventions in a certain area. Public statements effectively place rights to patents, or elements thereof, into the public domain. Nonasserts nevertheless need to specify, precisely, which rights are granted in order to avoid ambiguity that could lead to equitable estoppel.

Nonasserts can have wide-ranging implications in terms of enhancing public sector R&D. One application could be with patent rights covering research tools that are critical for accelerating the development of essential biotechnological applications. Specifically targeted nonasserts can also be effective instruments for industry to permit the use of patented inventions anywhere in the world, provided such use is for the express purposes of addressing specific humanitarian needs in developing countries. This could have broad-ranging and significant positive impact, as this approach reduces transaction costs, encourages innovation to help the poor, and accomplishes this without any loss of commercial opportunities.

1. INTRODUCTION

The concept of a *nonassert agreement*, or nonassertion covenant (NAC),[1] has become well known in 2006 in the context of open-source software. During that year, several major software companies such as Sun Microsystems and Microsoft Corp. announced that they would not seek to enforce any of their enforceable patents with respect to defined portions of products related to certain Web-based applications. Similarly, IBM proclaimed that it would not assert its rights with respect to 500 of the company's patents on open-source software implementations. Similarly, the Massachusetts Institute of Technology (M.I.T.) and other public entities also use nonasserts in the biotechnological areas.

The use of nonasserts spans a broad range of applications. This chapter presents the main types of nonasserts, provides sample language from actual nonassert agreements, and discusses the broader implications of the use of nonasserts to respond to the overwhelming need for new approaches in humanitarian licensing as public institutions strive to bring about global access.

2. FORMS OF NONASSERTS

A nonassert is an implied license. Put differently, a nonassert is an agreement that certifies that the party or parties to the implied agreement will not

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assert or defend certain rights that they possess. Such rights are typically related to patents. A nonassert can take one of three forms:

- an agreement between two parties (bilateral)
- an agreement among several parties (multilateral)
- a public statement (proclamation)

When drafting a nonassert, the owner of the intellectual property rights who pledges that it will not enforce its rights should use precise language to specify which rights exactly will not be enforced and whether or not any field-of-use restrictions will apply. If the terms are left vague or ambiguous, the ambiguity could leave open the possibility of equitable estoppel at some time in the future.[2] This means that a person or party could overcome an infringement action and become an unintended beneficiary of the nonassert, continuing to use the intellectual property with impunity (perhaps on the grounds that the nonassert was *misleading* and that the unintended beneficiary would be *materially prejudiced* if the patentee could assert his or her rights).

Box 1 provides a sample of a public nonassert statement from the software industry and Box 2 gives a public nonassert statement from biomedical area.

3. THE BENEFITS OF NONASSERTS

Nonasserts are an important instrument of industry for promoting open standards or for the establishment of industry standards. In the form of public statements, nonasserts provide a number

Box 1 : Nonassertion covenant from the software industry: Microsoft Open-specification Promise

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Microsoft irrevocably promises not to assert any Microsoft Necessary Claims against you for making, using, selling, offering for sale, importing or distributing any implementation to the extent it conforms to a Covered Specification ("Covered Implementation"), subject to the following. This is a personal promise directly from Microsoft to you, and you acknowledge as a condition of benefiting from it that no Microsoft rights are received from suppliers, distributors, or otherwise in connection with this promise. If you file, maintain or voluntarily participate in a patent infringement lawsuit against a Microsoft implementation of such Covered Specification, then this personal promise does not apply with respect to any Covered Implementation of the same Covered Specification made or used by you. To clarify, "Microsoft Necessary Claims" are those claims of Microsoft-owned or Microsoft-controlled patents that are necessary to implement only the required portions of the Covered Specification that are described in detail and not merely referenced in such Specification. "Covered Specifications" are listed below.

This promise is not an assurance either (i) that any of Microsoft's issued patent claims covers a Covered Implementation or are enforceable or (ii) that a Covered Implementation would not infringe patents or other intellectual property rights of any third party. No other rights except those expressly stated in this promise shall be deemed granted, waived or received by implication, exhaustion, estoppel, or otherwise.

"Covered Specifications" [...] applies to the identified version of the following specifications. New versions of previously covered specifications will be separately considered for addition to the list.

[List of Specific Web services]

Source: Microsoft Corporation.[3]

Box 2: Nonassertion Covenant from the Biomedical Area for Tuschl I siRNA Patent Applications

In order to facilitate widespread distribution of an important class of research reagents, the Massachusetts Institute of Technology, the Max Planck Gesellschaft zur Förderung der Wissenschaften e.V., The Whitehead Institute for Biomedical Research, and The University of Massachusetts ("the Patent Owners") now announce that they will not assert the patents listed below against companies that sell or use DNA vectors which induce production of siRNA endogenously, provided that such vectors are only used for research purposes, and provided that the RNA that mediates RNA interference is not isolated from the transformed cells. The Patent Owners intend to enforce the patents listed below against any use not specifically listed above.

The patents included in this announcement are listed below. Further continuations, divisionals, issued patents, and reissuances are included as well.

"RNA Sequence-Specific Mediators of RNA Interference"
by David P. Bartel, Phillip A. Sharp, Thomas Tuschl and Phillip D. Zamore

- Australia Serial No. 2001249622, Filed March 30, 2001
- Brazil Serial No. P10107536-5, Filed March 30, 2001
- Canada Serial No. 2404890, Filed March 30, 2001
- European Patent Convention Serial No. 01922870.9, Filed March 30, 2001
- Israel Serial No. 151928, Filed March 30, 2001
- Japan Serial No. 2001-573036, Filed March 30, 2001
- Korea Serial No. 200270123832, Filed March 30, 2001
- New Zealand Serial No. 522045, Filed March 30, 2001
- Patent Convention Treaty Serial No. US01/10188, Filed March 30, 2001

"RNA Sequence Specific Mediators of RNA Interference"

- United States of America Serial No. 09/821,832, Filed March 30, 2001
- United States of America Serial No. 10/255,568, Filed September 26, 2002

Source: M.I.T.[4]

of advantages over traditional open-standards committees or institutions:

1. Through nonasserts, the standards development is streamlined and the standards implementation proceeds faster since free licenses promote adoption. Importantly, nonasserts can be issued unilaterally without the need for any complex negotiations with third parties (such as open-standards committees).
2. Commitments not to enforce certain patent rights can be highly specific or broad, or both. Under the somewhat stringent U.S. antitrust laws, broad industry collaborations may not be permitted in an environment where multiple competitors meet in the same place.
3. Also related to antitrust concerns is the limitation on specific price or terms whereby price fixing and market manipulation allegations may arise. Standard-setting initiatives among competitors always entail the potential for incurring significant legal risk.
4. Nonasserts in the form of public statements carry no enforcement cost. In essence, they are *self-executing*. Once proclaimed, no legal staff time is required to negotiate licenses. Everyone gets the same deal and the deal is free.

The result of the acceptance and use of nonasserts in the software industry is that a growing "patent commons" has emerged supporting open-source software.

In agricultural biotechnology (agri-biotech) applications and health-related research, nonasserts are also emerging as an elegant solution to certain well-defined problems. These solutions include:

- **A tool for the management of liability.** License agreements carry certain liabilities even if the agreements contain all the necessary safeguards and warranties. This is especially the case with agri-biotech applications where little certainty exists, because discussions on global liability and redress regimes are ongoing.[5]
- **Access to research tools.** Nonasserts can provide access to patented research tools, for example (as illustrated in box 2 below), by removing intellectual property barriers that would otherwise inhibit the research tool's use by those who most need but can least afford it. Specifically, nonasserts can provide access to critical research tools for use in designated institutions that conduct R&D specifically to address needs in developing countries. But the use of nonasserts goes further: even drugs or vaccines could be manufactured in countries where such drugs or vaccines (or processes) have been granted for the express purpose of producing them for developing countries.
- **Reduction of high-transaction costs associated with negotiating bilateral or multilateral licensing agreements.** The negotiation of any license agreement is a time-consuming endeavor. In cases where the license is for humanitarian purposes in particular, the licensor generally gains no material benefits and often places the negotiation of such agreements at the bottom of the priority list. Nonasserts, even bilateral ones, are relatively easy to negotiate as they primarily require agreement on two fairly simple aspects:
  - listing of the patents (or other forms of intellectual property protection)
  - specific permitted use, or limitations to the permitted use, or both

To be clear, nonasserts are not a form of a patent pool. This distinction is important with regard to liability management associated with the commercialization of products, particularly in the drug, vaccine, and food biotechnology areas. A patent pool is an explicit granting of right to other parties. A nonassert, on the other hand, is a pledge not to sue someone who would otherwise infringe on a right. As such, a nonassert can also be viewed as a preemptive infringement-settlement agreement, granting permission to practice the patent in spite of the actual legal infringement thereof.

Box 3 provides a sample nonassert that is based on an actual agreement signed by two U.S. institutions, a company and a university. In the case of humanitarian licensing, certain restrictions may be included such as the limiting of use to not-for-profit humanitarian purposes for the exclusive benefit of people in developing countries or even to for-profit entities solely for humanitarian purposes in developing countries.

5. CONCLUSIONS

From a legal perspective, nonasserts are preemptive patent-infringement settlement agreements that are designed and drafted with the purpose of resolving future infringement disputes. Nonasserts, therefore, in essence, release certain patent rights into specified sectors. These sectors are often the public domain when it comes to software and often bilateral agreements in applications related to health and food biotechnology. But there are no reasons really why nonasserts could not become a more widespread tool in fostering important advances and innovation to address needs in developing countries.

Bilateral nonasserts should find much more common use as the problems with equitable estoppel are almost moot. Due to privity (in other words, the degree of relationship between or among the parties), the closer the relationship, the less likely will be the potential for misunderstandings that could trigger equitable estoppel. Hence, an agreement between two parties, or an agreement among several parties, is a sufficiently close relationship to permit communications to resolve any misunderstandings or ambiguities, much as with a license agreement.

But a patentee's public declaration of nonenforcement of a patent via a nonassert can have wide-ranging implications in terms of enhancing public sector R&D. This would be the case especially with patent rights covering research tools, and particularly in the United States due to limitations on research exemptions, which are critical for accelerating the development of essential biotechnological applications in both the health and agri-business areas. Carefully drafted, targeted nonasserts permitting the use of these tools—anywhere in the world—for developing-country–public-sector R&D institutions (and/or for commercial purposes for the exclusive use to address humanitarian needs could therefore have broad-ranging and significant positive impact. This approach reduces transaction costs, encourages innovation to help the poor, and accomplishes this without much cost, time, or loss of commercial opportunities. ■

ACKNOWLEDGEMENTS

Thanks go to Stanley Kowalski for having brought to my attention the important issue of equitable estoppel.

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1 They are also called nonassert agreements (when between two parties) or Covenant Not to Sue.

2 "*Equitable estoppel [is] an equitable defense to a claim of patent infringement available when a defendant has prejudicially relied on the patentee's misleading conduct concerning his intentions to enforce a patent. The Federal Circuit [has] adopted a three-part test for equitable estoppel, under which the defendant [being sued in an action for patent infringement] must show: (1) The patentee, through* misleading conduct*, led the alleged infringer to reasonably infer that the patentee did not intend to enforce its patent against the alleged infringer. (2) The alleged infringer relied on that conduct, and (3) Due to its reliance, the alleged infringer would be* materially prejudiced *if the patentee is allowed to proceed with its claim. When an alleged infringer establishes the defense of equitable estoppel, the patentee's claim is entirely barred [that is, an alleged infringer may continue to practice the patented technology].*" McCarthy JT, RE Schechter and DJ Franklyn, 2004. *McCarthy's Desk Encyclopedia of Intellectual Property*: Third Edition; The Bureau of National Affairs, Inc.: Washington, DC.

3 www.microsoft.com/interop/osp/default.mspx; see also www.oasis-open.org/committees/security/ipr.php for other samples.

4 http://www.web.mit.edu/tlo/www/industry/nonassert_statements.html.

5 See also in this *Handbook*, chapter 17.18 by RY Boadi.

Box 3: Nonassertion Covenant in the Form of a Bilateral Agreement

Date: 21 March 2007
To: Institute
From: Company
Subject: Nonassertion Letter under U.S. Patent No. X,XXX,XXX

Thank you for your interest in using Patented Technology owned by Company in your endeavors aimed at improving the health and well-being of people in developing countries of the world. Company is willing not to assert its rights under Company Patented Technology you requested, as further described below.

As background, Company's understanding is that your work aims at the development of _____ _____ for use in _____. Company is willing to not assert Company U.S. Patent No. X,XXX,XXX nor any of the patents' foreign counterparts, divisionals or continuations in part, or any other rights that Company may have now, or hereafter, related to the technology contained in the patents specified against Institute, or their trustees, directors, officers, employees, affiliates, their agents, licensees, or successors in interest.

This Nonassertion Letter is limited to the aforementioned Patent and provided that such patented technology is used solely for the production of _____.

In consideration for Company's Nonassertion Letter as described herein, Institute, their affiliates, agents, licensees and successors of interest, agree to not assert any patent or patent application against Company, it affiliates, agents, licensees, or successors that would prevent Company, its affiliates, licensees, agents, licensees, or successors or customers of each, from practicing, for any purpose(s), under the claims in the Company patents specified above. Upon change of control of Institute or assignment by Institute to any party or entity, Institute shall concomitantly impose the obligation to implement this Nonassertion Letter to Company with respect to such acquirer or affiliate.

COMPANY MAKES NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING (1) THE CONDITION OF THE INTELLECTUAL PROPERTY THAT IS THE SUBJECT OF THE NONASSERT, (2) THE MERCHANTABILITY AND FITNESS OF ANY MATERIAL, RESULT, OR PRODUCT FOR A PARTICULAR PURPOSE, (3) NONINFRINGEMENT OR MISUSE OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY, OR (4) SAFETY OF EMPLOYEES, WORKERS OR PURCHASERS OF PRODUCTS MADE USING THE COMPANY PATENTS.

Accordingly, Institute and their affiliates, agents, licensees, successors, and customers shall have sole discretion, responsibility and full liability for their activities, provided for under this Nonassertion Letter, including the research, design, manufacture, and potential sale of products pursuant to this Letter. Institute shall hold Company, and its affiliates, officers, employees, and consultants harmless from and against any and all claims, suits, obligations, causes of action, liability, costs and damages, injuries to persons (including those that may result in death) or property (including, without limitation, loss of use), product liability claims, claims for damage to the environment or from the use, handling, or storage of materials and any other claim, whatever the cause may be, based upon, arising out of, or related to the acts or omissions of an Institute and/or its affiliates and/or any of their employees, officers, employees, and consultants or other persons acting on behalf of the Institute or under Institute's control, in connection with the Institute's execution, delivery, performance of, or failure to perform, or practice of its rights granted under this Nonassertion Letter.

Please indicate your acceptance of the terms in this Nonassertion Letter by signing two copies and returning one fully executed copy of the original to me at your earliest convenience.

Best regards and all the best in this endeavor,
Company Officer

SECTION 8

Inventors and Inventions

Introduction to IP Issues In the University Setting: A Primer for Scientists

MARTHA MUTSCHLER, *Professor, Department of Plant Breeding and Genetics, Cornell University, U.S.A.*
GREGORY D. GRAFF, *Research Economist, PIPRA, and Visiting Research Fellow, Department of Agricultural and Resource Economics. University of California, Berkeley, U.S.A.*

ABSTRACT

Intellectual property (IP) is inherent to many of the research, teaching, and extension functions of the university, and IP issues can occur in all phases of the corresponding programs. A research program may utilize IP generated and protected by others in its planning and execution phases. As a research program advances, decisions made regarding disclosure of results may affect whether or not discoveries made by the program can eventually be protected.

A successful research program will generate discoveries—and therefore IP—and decisions must be made regarding whether to protect, and how to deploy, those discoveries. The decisions must consider the management of IP as well as the goals and priorities of the research program and the university. It is also important to consider IP in the teaching and extension functions of the university, including the creation or use of written materials, software, networked resources, or designs.

IP and IP issues are not the sole or even the primary focus of a university. However, failure to properly consider IP issues can lead to frustrating and costly problems. Fortunately, realistic and efficient management of IP in research, teaching, and extension requires only a minimal working understanding of the issues and an ability to access on-campus assistance in dealing with them.

This chapter presents basic information that any scientist should know about IP, discusses the importance of IP management in a scientist's work, and reviews additional sources of information regarding IP. We hope, this chapter will assist the reader in avoiding simple yet costly errors in IP management.

1. WHY YOU SHOULD LEARN ABOUT IP AND TECHNOLOGY TRANSFER

1.1 *Faculty and staff*

A working understanding of intellectual property (IP) is needed to realistically evaluate and manage IP issues and make informed decisions, from starting and running programs to deciding how best to handle the resulting inventions. Lack of basic information regarding IP and technology transfer issues can result in problems that are costly in terms of time, opportunity and money. You must take an active role in decisions regarding IP management within your program. This will have an impact on the directions you provide to undergraduate and graduate students, postdoctoral fellows, and/or technicians working in your program.

Ignoring IP management issues will not make them go away. Failure to manage IP and make informed decisions are de facto decisions that may result in outcomes that are undesirable and irreversible. Errors made by students and staff in your program can materially affect IP issues. Regardless of whether you knew of the errors when they occurred, you may still be ultimately responsible.

Acquisition of the basic information regarding the management of IP by faculty and staff need not be difficult or time consuming. You are not expected to become an expert in IP

Mutschler M and GD Graff. 2007. Introduction to IP Issues In the University Setting: A Primer for Scientists. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

management and technology transfer, just to be sufficiently aware of the issues so that you can use the resources available to avoid problems and maximize your opportunities. This chapter provides many links in the text to important online resources. Pertinent additional resources are listed in the endnote.[1]

1.2 *Graduate students, postdoctoral fellows, and technicians*

Obtaining a basic understanding of IP is an important part of your training, whether your future career lies in government, academia or industry. Basic IP training is important to how you will proceed in your research. Do not assume that your advisor or supervisor—or the technology transfer office (TTO)—can reverse the effects of IP errors you make. Your status as a student or postdoctoral fellow, and thus your status of being "in training," does not alter the regulations regarding the use of IP protected by others or the requirements that must be met for any inventions you generate to be properly handled. In fact, basic IP training is important in the direction of staff you may be responsible for supervising in the course of your activities.

1.3 *Difficulties caused by a lack of IP knowledge*

Depending on the nature of the error, misjudgments in handling IP issues can result in difficulties protecting your discovery or licensing your invention. Even if these difficulties are surmountable, they can be extremely frustrating, time consuming, and costly. Errors may even result in the complete loss of opportunity to protect your discovery, or in a severe narrowing of the scope of protection obtained. Reduction or loss of opportunity to market your discovery/invention can result. In fact, you may even suffer a reduction or loss of opportunity to use your own discovery or incur liability due to an inadvertent infringement of IP protected by others. However, with proper IP protection and management, you can decide how to handle the intellectual property you create as you see fit and make sure that you receive the rewards that mean the most to you.

1.4 *Applying basic information*

As university faculty, staff, and students, you are not expected to become experts in the management of IP. However, acquisition of some basic information about management will allow you to:

- make informed decisions day to day, to avoid errors that are time consuming and costly
- know when to contact IP/TT personnel
- interact efficiently and successfully with the university's technology transfer staff
- achieve your goals

Furthermore, remember that there is most definitely a lack of sufficiently trained personnel in the field of university IP management and technology transfer, and thus considerable employment opportunities exist if this area appeals to you.

Further information. To find out more about employment opportunities, see the Association of University Technology Managers (AUTM) Web site: www.autm.net/directory/job_list.cfm.

2. UNIVERSITY INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER POLICIES

A university will have a policy covering intellectual property that will be available to all university personnel. All personnel are required to operate according to this policy. The university home page is a central site for searching for university policy on many topics. Your university may also have a policy office, a technology transfer office or research foundation, and a office of university counsel.

2.1 *Bayh-Dole and university policy*

The policy of any U.S. university must conform to the obligations imposed by the Bayh-Dole Act (Public Law 96-517). The Bayh-Dole Act is intended to promote investment by the private sector in commercialization of federally funded research discoveries for the public good. It includes preferences for small businesses and for manufacturing in the United States. Under Bayh-Dole, a university is required to file patents on those inventions they elect to own and to encourage collaboration with industry to promote the utilization of inventions.

Rights retained by the government under Bayh-Dole include a nonexclusive license to practice the patent and march-in rights. *March-in rights* allow the government to "march in" and take over an invention if commercialization of an important invention is not being executed with due diligence by a university or licensee. The government has not, to date, invoked march-in rights, but it is possible that someday march-in rights could be applied. One situation that could warrant such action might be one in which a drug or vaccine is needed to control a pandemic.

Further information. To find out more about the background of Bayh-Dole as well as its implications for university IP policies in the U.S., see the Web site of the Council on Government Relations (COGR), "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations," October 1999. To find our more about similar legislation in developing countries see chapter 6.1.14 by Gregory D. Graff titled "Echoes of Bayh-Dole: A Survey of IP and Technology Transfer Policies in Emerging and Developing Countries" in this *Handbook*.

2.2 *Ownership of intellectual property*

A central part of IP policy at any organization concerns the ownership of intellectual property. The approach differs somewhat between corporate and university contexts.

2.2.1 *Typical corporate policy*

In industry, employment contracts regarding the issue of IP ownership are binding. A company usually holds total ownership of ideas and inventions, while an employee's salary is considered the compensation to an employee/inventor for his or her "inventing services" rendered to the firm. Noncompete clauses are often included in employment agreements and apply when an employee leaves the company.

2.2.2 *Typical university policy*

In the university, employment contracts or IP agreements are likewise binding with regard to the issue of IP ownership. University policy covers all personnel, including faculty, postdoctoral fellows, technical staff, graduate students, and visiting scholars. The employee contracts usually assign property rights in all IP to the university, but the inventor(s) typically are given a significant share in any revenues that are earned, typically in the range of 25% to 50% of royalties. One major exception to the policy of assigning IP rights to the university involves copyrighted materials (with some exclusions). In addition, the IP agreement covers inventions and creations in the individual's area of employment. Thus, if a molecular biologist invents a better lawn mower at home in his or her free time without use of university resources, that invention would not be included under the employment agreement.

3. THE UNIVERSITY TECHNOLOGY TRANSFER OFFICE

3.1 *A university's IP, licensing, or technology transfer office executes its IP policy*

The university's IP or technology transfer office is your most important source of information and assistance. The structure and functions of such an office may differ somewhat from institution to institution. Most often the technology transfer office will be in or affiliated with the office of research, although in some cases it may be an independent foundation owned by or affiliated with the university. Most university IP or technology transfer offices will evaluate inventions and pursue appropriate protection for them. Some offices will also market or license the inventions.

The technology transfer office will indicate what materials you must provide so that the transfer manager can service your needs. Reasonable expectations regarding this process will make it as efficient as possible and prevent misunderstandings. The technology transfer personnel will not be experts in your area of endeavor. You must provide them with detailed information regarding the creation and characteristics of your invention. Expect that creating this documentation—and working with the IP/tech transfer personnel to create the documents supporting a utility patent

or other forms of IP protection—may require as much time and effort as creating a collaborative grant proposal or a major publication.

Further information. For general information about university technology transfer offices see the following:

- G Graff, A Heiman and D Zilberman. 2002. University Research and Offices of Technology Transfer, California Management Review, vol. 45, no. 1. are.berkeley.edu/~ggraff/Graff-Heiman-Zilberman-CMR-2002.pdf
- EM Rogers, J Yin and J Hoffmann. 2000. Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities, Journal of the AUTM. www.autm.net/pubs/journal/00/assessing.html

3.2 *The mission of the IP or technology transfer office*

The mission of a technology transfer office as the responsible agent, fiduciary, or trustee for the university's intellectual property is to:

- foster creativity and inventiveness at the university
- support the university's educational and research missions
- enhance and protect the IP interests of the university and its employees
- manage IP for the benefit of the university's research and educational enterprise and its inventors

The roles of the office—in providing for the protection and commercial development of inventions—are typically to:

- determine what type of protection, if any, is possible and desirable for an invention
- evaluate commercial potential of an invention
- obtain the appropriate intellectual property protection
- locate suitable commercial development partners or research and developmen collaborators and market the intellectual property to them
- negotiate and manage licenses over the intellectual property

4. IP AND TECHNOLOGY TRANSFER ISSUES THAT MAY AFFECT UNIVERSITY SCIENTISTS ON A DAILY BASIS

Important issues and agreements that may affect university faculty or staff members include the documentation of work with appropriate recordkeeping methods, the use of materials and methods originating elsewhere, dealing with collaborators outside the university, executing legally binding agreements, and publicly disclosing research results.

4.1 *Documenting work: Notebooks, films, electronic information, and beyond*

Work must be efficiently and fully documented. Documentation can of course be important for the preparation of publications, reports, and grant proposals, and it can be essential for the preparation of documentation supporting an application for IP protection and for supporting IP rights in the rare event that they are challenged. The types and quality of documentation are important, but there are ways this can be done efficiently, so that proper documentation is not an undue burden.

Further information. For good examples of guidelines for keeping notebooks, see the following:

- Cornell Center for Technology, Enterprise, and Commercialization, "Lab Notebook Guidelines." www.cctec.cornell.edu/cctec/researchers/protocols/guidelines/index.cfm
- Northwestern University, Technology Transfer Program, "Maintaining Laboratory Notebooks." www.northwestern.edu/ttp/investigators/lab_notebooks.html
- Florida State University, Office of IP Development and Commercialization, "Notebook Guidelines." www.techtransfer.fsu.edu/notebookguidelines.html

4.2 *Using materials or methods originating elsewhere*

The issue of using materials or methods originating elsewhere arises in a number of ways or under various circumstances including the use of copyrighted material and the use of protected materials or processes. Using protected materials and

processes in research could end up affecting your *freedom to operate* (FTO).

4.2.1 *Using copyrighted material*

There are standard rules governing the use of copyrighted materials in publications, teaching, and research. University libraries can provide information regarding the use of copyrighted materials for such purposes as class readings and reserve lists. A university's information technology (IT) or computing policy may cover, specifically, the use of copyrighted material on course Web pages. Often the university counsel rather than the technology transfer office handles copyright issues on campus, including the acquisition of copyrights on materials owned by the university.

4.2.2 *Using protected materials or processes*

Protected materials and processes vary widely, depending upon the field of endeavor. They can include such things as:

- vectors used in genetically engineering organisms
- enzymes, reagents, and other supplies used in a laboratory
- computer programs

The use of protected materials or processes leads to the question: Do you have full freedom to operate in your research program, or do unrecognized, unresolved FTO issues exist?

4.2.3 Freedom to operate

Freedom to operate indicates that you are "free" to use all of the materials, methods, and other resources needed for your programs and projects and that this use does not infringe on the property rights of others. Just as your invention may be protected because you are using some form of intellectual property, the inventions of others may also be protected. Use of such protected inventions of others, without permission, might constitute infringement of their rights. The legal and appropriate use of protected inventions may require a formal agreement or license with the inventors.

Published does not mean unprotected! A *publication* by the scientist about a discovery or invention merely indicates that if there is protection, the application for that protection predates the publication. You must be aware of IP protection of any materials or processes you use in your programs and projects.

A *research exemption* might apply to your use of the materials or methods in your work at the university, but this cannot be assumed in all cases. In U.S. patent law there is no formal research exemption for university research. However, there are strong social norms in place such that patent owners have virtually never exercised their property rights against university researchers for conducting academic research. There are several practical limitations that prevent patent lawsuits from being filed against university researchers:

- In most cases it is a benefit to patent holders to have academics testing, validating, and refining the technologies they already own.
- It may be difficult to define what damages are suffered by the owner of a patent if the technology is used in an academic research project.
- Because establishing a clear precedent against research use of patented technologies by universities could open the door for widespread litigation against universities—thereby slowing down the pace of academic research and draining public resources—patent owners generally view the pursuit of such cases as detrimental to their own long-term interests, or, if more shortsighted, simply conclude that it is highly unlikely that any judge or court would want to establish such a precedent by ruling in their favor.

Thus, there is something of a *de facto* research exemption for university research.

FTO problems resulting from the use of others' proprietary materials and methods are more likely to show up further downstream, such as when you attempt to patent and commercialize the results you obtained. Your technology and any patents you might receive are likely to be dominated by their patents. If your invention embodies their technology (for example, if you create a

plasmid that contains their promoter), then they may be able to stop you from commercializing your invention altogether.

To prevent or at least to be cognizant of such risks, consider freedom to operate issues when you start using any new method or material, not after your project is completed. After all, a patent holder is not obligated to give you a license. If in doubt whether freedom to operate issues apply to your work, contact your technology transfer office representative.

Examples of FTO issues are, in fact, common in the university setting. Be aware of materials or methods that can be used *for research purposes only*. Examples of this can be found in the fine print in molecular biology supply catalogs. Likewise, be aware of limitations in an agreement allowing use of protected materials or processes. The agreement may limit you to use for research purposes only, or it may restrict you to a certain range of use for commercial products, affecting your ability to protect and commercialize any inventions that may result from your work.

It is advisable to search the patent literature just as you would search for recent publications in your line of research. While this might seem tedious or redundant, in fact there can be important fringe benefits. Someone may have already made the discovery or invention you are pursuing. If a patent already exists, you can study it to determine whether your project can proceed as planned, should be modified, or if you should seek a license to the patented invention. In addition, patents can be an excellent source of information. Since an application must fully disclose the invention, including the best method for its *practice*, a patent document may provide more detail on how to reproduce a result than a peer-reviewed research publication.

Further information. Your technology transfer office representative or university counsel should be approached regarding concerns or questions on freedom to operate, as ultimately it is a legal question. Other chapters of relevance in the Handbook are:

- Intellectual Property Freedom to Operate: The Law Firm's Approach and Role, by GM Fenton, C Chi-Ham and S Boettiger. www.ipHandbook.org
- Freedom to Operate: The Preparations, by SP Kowalski. www.ipHandbook.org
- Freedom to Operate Strategies: Why the Public Sector Needs to Learn How to Manage Risk, by A Krattiger. www.ipHandbook.org

4.3 *Dealing with outside collaborators*

It can be critical to discuss and document collaborative agreements in the development of a project. Consider which part of the work will be performed by each cooperator, how responsibility and credit will be shared, and who will be authors on publications. It is best if such questions are considered at the onset of a project and are reassessed as the program continues. Problems are most likely to occur if this is put off until a discovery is made.

4.3.1 *Material transfer agreements*

A *material transfer agreement* (MTA) is a legal agreement used when giving material to others that limits the rights they have to use the material and lists their obligations with regard to use of the material. In short, it details the conditions of the agreement between the owner of protected IP and the party wishing to use it. An MTA is executed if you want to use material or methods protected by others or if others want to use materials or methods protected by you. An MTA must be crafted carefully since it will be legally binding. And it must be created and signed before the transfer of the material in question occurs, not after the fact.

Consult with your technology transfer representative regarding any MTA needed for obtaining other's materials or for the release of your materials. However, different offices of the university may manage MTAs for incoming materials (often sponsored programs or the research office) and for outgoing materials (often the technology transfer office).

Further information. To learn more about material transfer agreements see the following:

- Cornell Center for Technology, Enterprise, and Commercialization, "Material Transfer

Agreements." www.cctec.cornell.edu/cctec/researchers/protocols/mta.cfm
- Northwestern University, Technology Transfer Program, "Material Transfer Agreements (MTAs)." www.northwestern.edu/ttp/investigators/material_transfer.html
- Council on Government Relations (COGR), "Material Transfer in Academia." www.cogr.edu/docs/MTA_Final.pdf

4.3.2 *Confidentiality and confidentiality agreements*

A *confidentiality agreement* is a legally binding agreement regarding the disclosure and use of confidential proprietary information. A confidentiality agreement should be in place before either sharing proprietary information with another party or seeking proprietary information from another party.

Consideration of confidentiality agreements can be different in a university setting than in an industry setting. A faculty or staff member may be asked to sign a confidentiality agreement if he or she is consulting for a company outside of the university. In this situtation, the *individual* signs, and is obligated by the agreement, *not the university*. Faculty and staff are not empowered to obligate the university under a confidentiality agreement and attempting to do so may make them personally liable. The offices that are authorized to sign these agreements and create a legal obligation for the university are typically in the technology transfer office (signatory authority for licenses, agreements, contacts, and so forth dealing with inventions) or an office such as sponsored programs or the office of research (signatory authority for outgoing grant proposals and agreements accompanying incoming funds from the funded grants).

For example, the representative of a company interested in possibly licensing intellectual property handled by the technology transfer office would sign a confidentiality agreement before obtaining detailed information on the technology. Drafting and obtaining signatures on the confidentiality agreement is handled by the technology transfer office for the inventor. This helps assure that the agreement is properly drafted, and that the correct individuals sign the agreement.

4.4 *What constitutes public disclosure?*

A *public disclosure* is made when an inventor reveals previously undisclosed (that is, secret) information to members outside the circle of inventors and the personnel they directly supervise. There is interplay between the need for secrecy, in order to be able to protect an invention, and the need to reveal information to operate a program within a university where disclosure and transparency are the norm. The presence of various functions important to the university—educating students, publishing, efforts to acquire grant funding, and others—which are generally not part of a corporate environment, might have ramifications regarding disclosure. Among the many different vehicles for disclosure are lectures, discussions, seminars, group meetings, annual reports, grant proposals, and radio and TV interviews.

Unintended public disclosure can have major ramifications for protection of intellectual property. The more valuable the invention, the harder companies will search for any inadvertant disclosure that will invalidate IP protection.

Further information. A good discussion of disclosure by publications and by posting online can be found in these online publications:
- GP Malilay, AM Mueting and AS Viksnins. 1996. Prior Art: Silent Time Bombs that Can Blow Away Your Licensing Deals. *Journal of the AUTM*, pp 18–28. www.autm.net/pubs/journal/96/3-96.html
- SJ Braman. 1996. Are Your Patent Rights Disappearing over the Internet? *Journal of the AUTM*, pp. 29–31. www.autm.net/pubs/journal/96/4-96.html

5. SO YOU (THINK YOU) HAVE AN INVENTION! GREAT! WHAT NEXT?

5.1 *Overview*

There are a few things that are important to understand about working with the technology transfer office. Foremost, it is essential for the

inventor to be actively involved in all of the phases of the protection and marketing of the invention. There are two main reasons for this: first, the inventor has unique, detailed knowledge that is critical to the characterization and description of the invention and the drafting of the patent and its claims; and second, inventors often have useful leads, such as company contacts, that will assist in the marketing of the invention. Collecting the information and documentation needed to draft a disclosure and a patent application takes time and effort on the part of the inventor, something on the order of the time and effort required to write a major publication or grant proposal. If you expect to seek patent protection for your invention, you need to make the commitment and create time for it. This will make the process run far smoother.

It is helpful to remember that the breadth of research covered at a university is often far greater in scope than that at even the largest of companies. At the same time, university technology transfer offices have less staffing than analogous offices in industry. As a result, a technology transfer officer at a university may be dealing with more inventors and a broader scope of inventions than his or her counterparts in industry. Input from the inventor will directly assist the technology transfer staff in bringing projects to successful completion.

Cooperative, responsive inventors often have the best experiences, since they enable the technology transfer staff to provide prompt and complete service.

The steps in the technology transfer process follow a typical pattern:

- *disclosure*: starting the process of protecting/marketing an invention
- *evaluation*: deciding whether the invention should be protected and, if so, how
- *protecting*: proceeding with an application (also called prosecution)
- *marketing*: finding a licensee
- *licensing*: making a deal

5.2 *Invention disclosure*

The inventor's role in disclosure is to provide information, including:

- a description of the invention
- details about the funding of the research that led to the discovery
- an explanation of why the invention may be important or valuable in industry
- reasons why companies might be interested in the invention
- the identity of the inventor (or inventors)
- a description of how the invention was made

Remember, a clear, detailed disclosure allows the technology transfer staff to serve you better and faster.

The technology transfer officer's role in disclosure is to help the inventor fully describe the invention by considering the material provided and asking questions to elicit further information or details. In the process of discussing the disclosure and deciding upon a protection and licensing strategy, the technology transfer officer will conduct an intellectual property audit. This will reveal whether there is any preexisting IP that may affect the process.

Further information. Details regarding the disclosure process, including forms, can often be found on a university's technology transfer office Web site. Some examples include:

- Cornell University, Center for Technology, Enterprise, and Commercialization, "Invention Disclosure Process." www.cctec.cornell.edu/cctec/researchers/disclosures/index.cfm
- University of California, Office of Technology Transfer, "Disclosing an Invention." www.ucop.edu/ott/faculty/disclose.html

5.3 *Evaluation*

The purpose of evaluation by the TTO is to determine what the technology does and what its commercial potential may be. For example:

- Is it a research tool, software, compound, new method, diagnostic, or therapeutic?
- Does it fill an unmet need, or fill a need better than current methods?
- What is the size of the potential market or markets?

- Would it have competition from other technologies in those markets?
- What companies are in those markets?
- Who is investing in those markets? Why would investors be interested in the technology?

Answering these questions will enable the TTO to estimate the commercial value of the technology.

5.4 *Deciding whether and how to protect*

After disclosure and evaluation of an invention, decisions must be made as to whether to protect the invention and, if so, how. These decisions are made jointly by the inventor(s) and the technology transfer office, based upon all of the technical and legal information available and based upon economic considerations.

Some disciplines routinely employ a particular form of protection for the technology generated in that discipline. Examples include copyrights on writings; patents on vaccines, medicines, chemicals, engineered processes and materials; design patents on figures, graphics, or artwork; and plant patents or plant variety certificates (PVCs) on new varieties of plants.

In some areas, protection has long been possible but not routinely employed by universities. For example, plant patents have been available since 1930; however, prior to 1982 the apple breeding programs at the Geneva Agricultural Experiment Station in New York developed and released apple varieties without protecting them. These unprotected cultivars include a number of widely grown varieties, such as Empire (1968), Jonagold (1972), and Liberty (1978). However, cultivars released after 1982 were protected using plant patents and are generating returns to the inventors and their research units. These protected cultivars include Freedom (1983), Empress (1988), Royal Empire (1990) and Fortune (1995).

In some areas, the possibility of protecting IP is a more recent development. For example, before changes were made in the interpretation of U.S. patent law beginning in the 1980s, it was not possible to protect inventions involving modified life forms with utility patents.

It is important to realize that the laws, interpretations of laws, and strategies used in protecting intellectual property develop and change over time. It is the responsibility of the technology transfer office to keep abreast of these developments and to advise and assist university inventors as needed.

5.5 *Marketing and licensing*

An invention will not generate financial returns for a program unless it is successfully marketed and licensed. Depending on the nature of an invention, the personnel of the technology transfer office may or may not have a comprehensive list of potential licensees for the technology. The inventors may play a critical role in providing such information.

Depending on the invention, and the companies interested in the invention, the license granted may be *exclusive* (made to only one company, with that company holding all rights to sublicense) or *nonexclusive* (made to more than one company). In some cases, a license to a company transfers rights to the invention for just a limited subset of its potential uses, rather than for any and all possible uses. The decision as to the nature of the license granted (that is, the uses it will cover) is made by the technology transfer office in consultation with the inventor, and is thoroughly negotiated with the licensee.

There are other options as well. In some cases, the university, through the technology transfer office, encourages use of the invention in the development of a new start-up venture.

Patents require periodic servicing, such as periodic payment of fees to the U.S. Patent Office (PTO), which is managed by the technology transfer office. The technology transfer office also manages the license: receiving and distributing payments, billing the licensee, and monitoring whether the terms of the license are being respected by the licensee.

If an invention is valuable, it is not unusual to find companies infringing the property rights over it by using the invention without a license. If this is determined to be occurring, the technology transfer office will take the lead in rectifying the matter, seeking assistance as needed from

the inventor. This involves a series of steps, from contacting the infringing company and requesting that it either cease infringement or obtain a proper license, to filing a law suit. The more valuable the invention, the more likely it is that some company will test the resolve of the university to assert its IP rights. Such situations occur regularly, but they are manageable, given the proper expertise on the part of the technology transfer office and other legal counsel representing the university.

Marketing and licensing is obviously a large and complicated endeavor. The best information regarding this process can be obtained from representatives in the technology transfer office.

6. TYPES OF INTELLECTUAL PROPERTY PROTECTION

6.1 *Overview*

Types of IP protection tend to be specific to particular kinds of creations or technologies, but they are not always mutually exclusive. There are instances when an invention may be protected by more than one type of IP.

The types of protection vary in many features including:

- requirements to acquire the protection
- cost
- type of technology covered
- type of protection afforded
- length of time provided

A full study on any one type of IP protection would be a book in itself. What follows is a brief introduction to each of the types of IP protection that might be of possible use to a university researcher.

6.2 *Patents: utility patents, design patents, and plant patents*

A *utility patent* is what most people think of when they hear the word *patent*. A utility patent is a grant of a property right by the U.S. government to the inventor for a term of 20 years.

The applicant is required in the patent application to fully disclose the invention, and, in so doing, to fully describe the best means of practicing the invention so that an expert in the relevant field of technology (one *skilled in the art,* in patent terminology) can actually make and use the invention relying only upon the information presented in the application.

Subjects of patents can be any of the following:

- *mechanical devices*: a machine or device
- *processes*: methods of doing or creating something, for example, a diagnostic or therapeutic method
- *articles of manufacture*: the paper clip is the classic example
- *compositions of matter*: a new formulation of plastic, a new alloy, a new medicinal compound
- *improvements* in any of the above

Certain characteristics are required for an invention to be patentable. The invention must, of course, be of proper subject matter. It also must be novel. The invention must be something that would not be obvious to an expert in the field. And the invention must have some useful application industrially or commercially (that is, the invention is not *trivial*).

There are two types of patent applications: a *regular application* and a *provisional application.* (A provisional application merely starts the ball rolling and gives the inventor one year to file a regular application.)

Once granted, a U.S. patent gives the owner of the patent the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing it to the United States for the term of the patent. It is important to remember that patents are country specific. For instance, a patent granted by Canada gives the owner of that Canadian patent similar rights within Canada. It is up to the inventor and their technology transfer office to decide in which countries to apply for foreign patents (which *foreign filings* to make). In those countries where rights are not sought or granted over a technology, it is, in effect, left to the public domain (unless some other means of protection is utilized.)

The inventor or inventors must be listed on the patent application. The question of inventorship—*Who is the inventor?*—is sometimes a point of contention, so consider this carefully. The rules used under U.S. patent law to determine who is an inventor for purposes of patent protection are very different from the means generally used to determine who should be an author on a publication. Inventorship depends specifically on the claims of patent. A person who gives pivotal advice, even just once, in the course of a research project could be an inventor. A technician doing much of the work under supervision, but not making decisions, would probably not be an inventor. However, if the technician made unexpected observations or suggestions critical to the development of the invention, he or she might well be an inventor. Advice from the university IP/technology transfer office may be useful in cases in which inventorship is unclear.

Further information. To learn more about inventorship, see SH Lieberstein. 1998. Relevant Concepts in Determining Difficult Disputes Over Ownership. *Journal of the AUTM*. www.autm.net/pubs/journal/98/lieberstein.html.

6.2.1 *Utility patents*

A utility patent is costly in terms of time and effort. The time and effort you spend on filing and prosecuting a utility patent could be equivalent to the time and effort you would spend on producing a major publication or a large collaborative grant proposal.

A utility patent is also costly in terms of money. The cost of a U.S. patent application typically ranges from about US$15,000 to US$30,000, although it can cost more. Costs of foreign patent applications depend on the country but typically are within a similar range in Germany, England, France, Australia, and Japan. After a patent is issued, there are patent maintenance costs to cover. At times, there are additional costs for defending the application or the patent. The more valuable a property is, the more likely it is to be challenged, either as an *interference* (issuance of a conflicting patent claiming some of the same technology) or as an *infringement* (actions of a company using the technology without permission).

At most universities, patent costs are initially borne by the office of technology transfer, but they are the first thing to be reimbursed once revenues begin to come in when an invention is licensed. It is crucial to consider whether a license on the invention is even likely to return more than the costs of applying for, maintaining, and defending the patent; otherwise, perhaps a less costly form of protection should be used. A good rule of thumb is that if the technology is not worth defending, one should not be applying for a patent. Consultation with a technology transfer representative can help to determine if a utility patent is the appropriate means of protecting the invention.

Further information. For useful information, in increasing order of detail and complexity, on the requirements and protection afforded by utility patents, see the following:

- L von Bargen Mueller. 1995 (with revisions by JT Sorensen, 2002). *An Inventor's Guide to Patents and Patenting*, AUTM Educational Series No. 1
- American Bar Association, "Inventor's Committee: Short Description of the Patent Process." www.abanet.org/intelprop/comm106/106patent.html
- U.S. Patent and Trademark Office, "Frequently Asked Questions about Patents." www.uspto.gov/web/offices/pac/doc/general/faq.htm
- U.S. Patent and Trademark Office, "A Guide to Filing a Utility Patent Application." www.uspto.gov/web/offices/pac/utility/utility.htm
- American Bar Association, "Comprehensive Information on Patents." www.abanet.org/intelprop/comm106/106general.html

6.2.2 *Design patents*

A *design* is a visual ornamental feature, such as a logo, embodied in, or applied to, some article of manufacture (for example, a mug, sweatshirt, or poster), the shape of a bottle or the shape of headlights of a car. *Design patents* protect new, original, and ornamental designs for an article of manufacture. The design patent protects the appearance of design on the item, and not the

structural or utilitarian features of the item—that is, the design of the logo, not the cloth of the sweatshirt or the ceramic of the mug. The term of protection in the United States is 14 years from the date the grant is awarded.

A design patent application must include:

- a preamble stating the name of the applicant, the title of the design, and a brief description of the nature and intended use of the design
- drawings or photographs of the design claimed (Since this is the critical part of the design patent, the PTO site listed below has considerable detail about this portion of the application.)
- a written description of the elements of the design, shown in the drawing or photograph
- a written description of the features of the design
- the single claim for the design
- an executed oath or declaration by the applicant

Further information. To learn more about design patents, see the Web site of the United States Patent and Trademark Office, "Frequently Asked Questions (FAQ) about Design Patents." www.uspto.gov/web/offices/pac/design/desfaq.html.

6.2.3 *Plant patents*

A *plant patent* protects a distinctive new variety of an asexually reproduced plant. Asexual reproduction is the creation of identical genetic copies of a plant without using genetically reproducing seeds. Asexual reproduction includes the use of:

- root cuttings
- apomictic seeds
- bulbs
- slips
- rhizomes
- runners
- corms

...and methods such as:

- grafting and budding
- division
- layering
- tissue culture
- nuclear embryos

Most plants covered by plant patents are horticultural crops, such as apples, raspberries, and almonds, or ornamentals, such as rhododendrons, roses, and tulips. For historical reasons, tuber crops, such as potatoes and Jerusalem artichokes, were specifically excluded from consideration. For the purpose of plant patents, algae and macro fungi are allowed; bacteria are not.

A plant patent application must meet the same requirements of utility patents. The plant to be protected must have been developed or discovered by the applicant. It must fulfill the requirements for novelty and nonobviousness. The plant cannot have been sold or released in the U.S. more than one year prior to the date of the application.

A plant patent must include a complete description of the botanical features of the plant and the characteristics that distinguish that plant from known, related plants. A drawing or photograph of the plant showing its most distinguishing characteristics and text describing what is being shown in the drawing or photograph help to document the plant's novelty.

Once granted, the *plant* that is protected includes mutants, hybrids, and genetically transformed plants. The grant lasts for 20 years from the date the application is filed. During this period, the plant patent protects the inventor's right to exclude others from asexually reproducing, selling, or using the plant so reproduced. As with utility patents, when the plant patent expires, the subject matter of the patent (that is, the plant variety) enters the public domain.

Further information. To learn more about plant patents, see the Web site of the United States Patent and Trademark Office, "General Information about Plant Patents." www.uspto.gov/web/offices/pac/plant/.

6.3 *Plant variety protection*

Plant variety protection (PVP) is a means for protecting sexually reproduced plant varieties. Plant variety protection is a form of IP administered and granted by the U.S. Department

of Agriculture (USDA), rather than the U.S. Patent Office. This is basically the U.S. version of plant breeders rights, as agreed upon internationally under the convention known as UPOV (International Union for the Protection of New Varieties of Plants). A PVP grants 20 years of protection (for new varieties of plants) from date of issue (and 25 years for trees and vines). A PVP cannot be granted for uncultivated plants or materials found in nature.

PVP regulations require that the plant cultivar to be protected must be:

- *novel or new*: cannot have been sold in the United States for more than one year
- *distinct*: is clearly different from other common varieties of the crop
- *uniform*: has no more variability than other varieties of the crop
- *stable*: remains unchanged when reproduced, particularly with regard to the distinctive characteristics of the variety

In the application for the PVP, the applicant provides the genealogy of the variety and describes the variety and its novelty. A public deposit of seed of the variety is also required.

Protection provided by the PVP applies to the single variety claimed. The PVP prevents others from selling, sexually or asexually reproducing, or distributing without a license from the holder of the PVP. Since the mid-1990s, a PVP also prevents others from producing a hybrid variety using the claimed variety as a parent.

Exclusions to the protection include use of the cultivar in breeding, by farmers saving seed for their own use, and for the sale of limited amounts of seed.

Further information. To learn more about plant variety protection, see the Web site of the USDA Plant Variety Protection Office. www.ams.usda.gov/science/PVPO/pvpindex.htm.

6.4 *Copyright*

Copyright provides legal protection of an original work set down in a fixed form or medium of expression. The term of protection for works owned by corporate entities is the lesser of 95 years from publication date or 120 years from the creation of the copyrighted work. The term of protection for works owned by individuals is the life of the author plus 70 years.

Items that can be copyright protected include:

- literary works
- musical works, including accompanying words
- dramatic works, including any accompanying music
- pantomimes and choreographic works
- pictorial, graphic, and sculptural works
- motion pictures and other audiovisual works
- sound recordings
- architectural works

Examples of things that cannot be copyright protected include:

- ideas or concepts
- lists showing no originality
- titles, names, short phrases, and slogans
- type styles
- factual information
- public domain information
- works not fixed in tangible form

A copyright gives to the holder the right to reproduce one or more copies of the protected work. Notwithstanding copyright protection, other parties, such as archivists, educators, and members of the media may reproduce protected works for certain types of use known as *fair use*. The copyright also gives certain limited rights to distribute or disseminate copies, prepare derivative works (including translations), and perform or display publicly (with exceptions for instructional use, broadcasting, and religious services). Excluded from the *fair use* are digital movies, digital games, and similar products since the entry into force of The Digital Millennium Copyright Act in late 1998.

At most universities copyright issues are handled by the university counsel, rather than the technology transfer office, with possible exceptions for some technologies, such as software, involving both copyright and utility patents for protection.

Further information. To learn more about obtaining copyrights or using copyrighted material, see the following Web sites:

- Cornell University, "The Copyright Information Center." www.copyright.cornell.edu
- Stanford University Libraries, "Copyright and Fair Use." fairuse.stanford.edu
- Indiana University and Purdue University Indianapolis, "Copyright Management Center." www.copyright.iupui.edu
- Library of Congress, United States Copyright Office. www.copyright.gov

6.5 *Trademark*

A *trademark* is essentially a brand name, which is used to identify or distinguish in the marketplace one company's goods from another's. A trademark includes any word, name, symbol, or device, or any combination of these. Many of the products we buy sport trademarks, from Sunkist oranges and Coke, to Levi Strauss jeans, Dell computers, and Intel microprocessors.

There are other types of "marks" as well. The *service mark* is similar to the trademark, but the service mark identifies a service or the source of a service, rather than goods or the source of goods (for example, a cleaning service, rather than mops and brooms). A *certification mark* identifies a "*regional or other geographic origin, material, mode of manufacture, quality, accuracy, or other characteristics of goods and services.*" A *collective mark* is a type of trademark or service mark used by the members of a collective group and indicates membership in the organization.

Trademarks, and the other types of marks, are handled by the U.S. Patent Office. Application involves filing a form, along with a drawing of the mark to be protected and specimens of the mark. (The specimen will be a prototype of the design, such as a label or tag, which incorporates the mark.) Before one files an application, it is advisable to run a search to check that the mark is not already registered. With proper maintenance (use, renewal, and so on) a trademark can be perpetual.

At most universities, the university counsel handles trademark and service mark applications. Properties that many universities protect by copyright, design patent, and perhaps trademark, are the university's name, logo, and other symbols, such as a mascot. Some universities—particularly those with well-known sports programs—earn considerable funds through the licensing of their protected names and logos for merchandise.

A department wanting to use the university logo, for example, on a T-shirt being designed for an upcoming symposium, must first obtain permission from the office that is responsible for trademarks and such.

Further information. To learn more about trademarks, see the Web site of the U.S. Patent and Trademark Office, "Basic Facts about Trademarks." www.uspto.gov/web/offices/tac/doc/basic/.

6.6 *Trade Secrets*

A *trade secret* is secret or confidential information that gives the company that possesses the information an advantage over companies that do not possess it. Trade secrets can protect any information that provides a competitive advantage. Examples include a process, method, composition, or recipe. The recipe for Coca-Cola syrup, and many other food and beverage products are protected as trade secrets. A trade secret has a far longer term of protection than a patent. A trade secret is in force as long as the secret information is kept secret and not made publicly available.

A trade secret protects information, quite simply, by keeping it secret. Trade secrecy laws make it illegal for someone to obtain the secret by misappropriation (for example, breaking into the vault in which the secret is kept). Of course, a product must be able to be used or marketed without revealing the secret to be protected as a trade secret (for example, the product must not be able to be reverse engineered). If someone innocently, independently discovers the same information, they can use it without infringement. Indeed, the second discoverer could in fact apply for a utility patent, in some instances.

By university policy, no secret research is conducted at the university, but an invention that results from research could, in some instances, be protected by trade secret at least temporarily,

pending an application for another form of IP protection.

6.7 *Bailment Law*

Some inventions can be marketed without the formal protection of a patent or other form of IP protection though the use of *bailment law*. Under this approach, control over use and dissemination of the invention is obtained by careful use of material transfer agreements and licenses. Where applicable, this method reduces paperwork and the costs of preparation and application for patents or other forms of protection. The method would require careful coordination with the technology transfer representative.

Further information. To learn more about bailment law, see PM Simpson, Jr. 1998. Use of Bailment in Transferring Technology from a University. *Journal of the AUTM*. www.autm.net/pubs/journal/98/simpson.html.

7. SUMMARY

Managing the IP issues that arise in the course of university research and teaching functions is important. Though sometimes the issues are complex, the management of these issues *can* be handled efficiently, reducing time commitment. The goal of this chapter is to provide basic information to enable university scientists/inventors to manage intellectual property and technology transfer issues. The university scientist need not be an IP expert. The ability to protect some forms of IP is fairly recent, having undergone or even still undergoing rapid changes in interpretation and strategy. Being knowledgeable and capable in these areas is the task of those university personnel in the technology transfer office and the outside legal experts who work with the university on IP and technology transfer. Researchers/inventors should consider how they want to handle IP issues during day-to-day work and know whom they should contact when they have new IP or technology transfer issues. They should not hesitate to use these resources whenever needed. ■

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1 This chapter provides many links in the text to important online resources. Pertinent additional resources are:

Braman SJ. 1996. Are Your Patent Rights Disappearing Over the Internet? *Journal of the AUTM*, pp. 29–31. www.autm.net/pubs/journal/96/4-96.html.

Cornell Center for Technology, Enterprise, and Commercialization. Invention Disclosure Process. www.cctec.cornell.edu/cctec/researchers/disclosures/index.cfm.

Cornell Center for Technology, Enterprise, and Commercialization. Lab Notebook Guidelines. www.cctec.cornell.edu/cctec/researchers/protocols/guidelines/index.cfm.

Cornell Center for Technology, Enterprise, and Commercialization. Material Transfer Agreements. www.cctec.cornell.edu/cctec/researchers/protocols/mta.cfm.

Cornell University. The Copyright Information Center. www.copyright.cornell.edu.

Stanford University Libraries. Copyright and Fair Use. fairuse.stanford.edu.

Council on Government Relations (COGR). 1999. The Bayh-Dole Act: A Guide to the Law and Implementing Regulations. www.cogr.edu/docs/Bayh_Dole.pdf.

Council on Government Relations (COGR). 2003. Material Transfer in Academia. www.cogr.edu/docs/MTA_Final.pdf.

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Northwestern University Technology Transfer Program. Maintaining Laboratory Notebooks. www.northwestern.edu/ttp/investigators/lab_notebooks.html.

Northwestern University, Technology Transfer Program. Material Transfer Agreements (MTAs). www.northwestern.edu/ttp/investigators/material_transfer.html.

Public Law 96-517, Patent and Trademark Act of 1980, 37 C.F.R. Part 401, reported in the Federal Register, vol. 52, no. 52, March 18, 1987, pp. 8552–8563.

Rockman HB. 2004. *Intellectual Property Law for Engineers and Scientists*. Wiley-IEEE Press: Hoboken, New Jersey.

Rogers EM, J Yin, and J Hoffmann. 2000 Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities. *Journal of the AUTM*. www.autm.net/pubs/journal/00/assessing.html.

Simpson Jr, PM. 1998. Use of Bailment in Transferring Technology from a University. *Journal of the AUTM*. www.autm.net/pubs/journal/98/simpson.html.

United States Department of Agriculture. Plant Variety Protection Office. www.ams.usda.gov/science/PVPO/pvpindex.htm.

United States Patent and Trademark Office. Basic Facts about Trademarks. www.uspto.gov/web/offices/tac/doc/basic/.

United States Patent and Trademark Office. General Information about Plant Patents. www.uspto.gov/web/offices/pac/plant/.

University of California, Office of Technology Transfer. Disclosing an Invention. www.ucop.edu/ott/faculty/disclose.html.

Valauskas CC and C Innes. 1999. Copyright Protection of Software, Multimedia, and Other Works: An Authors Guide. AUTM Educational Series, No. 4.

Von Bargen Mueller L. 1995. An Inventor's Guide to Patents and Patenting. AUTM Educational Series, No. 1.

How to Start–and Keep–a Laboratory Notebook: Policy and Practical Guidelines

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ABSTRACT

A laboratory notebook is an important tool that goes well beyond research management and can have important implications for issues ranging from intellectual property management to the prevention of fraud. This chapter discusses the key elements of a laboratory notebook, types of notebooks, what should be included in the notebook, ownership issues, archiving, and security. The chapter provides sample notebook pages that illustrate some of the recommended practices.

1. WHAT IS A LABORATORY NOTEBOOK?

Although you may think you will remember what you did and why you did a certain experiment in a week's time, YOU WILL NOT! And nor will anyone else in your laboratory. Hence the need for laboratory notebooks. In short, a laboratory notebooks is:

- a daily record of every experiment you do, think of doing, or plan to do
- a daily record of your thoughts about each experiment and the results thereof
- the basis of every paper and thesis you write
- the record used by patent offices and, in the case of disputes, courts of law (in the event you file patents on your findings)
- a record that would enable successive scientists, working on the same project, to pick up where you left off or reproduce your results

2. TYPES OF LABORATORY NOTEBOOKS

The following items explain a few important things to know about lab notebooks and how they may be used:

- Hardbound books with numbered pages show that no pages have been deleted or added.
- In companies or institutions aimed mainly at producing patentable products, carbon copies of each page are often required. In addition, each page may have to be signed and dated both by the scientist and by an independent witness within two weeks of work being done. This scientist should be someone who is likely to be traceable in some years time, if needed, to confirm reading and counter signing. The witness should not be likely to be named as a co-inventor in a patent application. The counter-signatory should sign and date each page of the notebook to confirm that she or he has read and understood the entry and is satisfied that the entry has been accurately and correctly written.
- It is advisable to keep different notebooks for different projects or different aspects of the same project. Notebooks should be clearly identified on the outside cover.

Thomson JA. 2007. How to Start—and Keep—a Laboratory Notebook: Policy and Practical Guidelines. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

3. WHAT GOES INTO A LABORATORY NOTEBOOK?

On the front cover of the notebook should be a description of what is contained in it (for example, cloning of the X gene and characterization of its product). The first and last dates of entry should also be written on the front cover.

The following items explain a few important things that need to be recorded inside the lab notebook. ***Remember, everything must be written in ink or other permanent medium.***

- a detailed account of every planned and executed experiment with the amount of detail that would enable a scientist "*skilled in the art*" to determine what had been done, why it had been done, and what the results were
- dates accompanying every entry, account, or record
- protocols, reagents, lot numbers in each entry, and where appropriate, sketches, descriptions, and so on
- explanations of the significance of each experiment, as well as the observations, results and conclusions of the experiment
- details of each experiment (Remember, what may seem trivial or obvious at the time your experiment was conducted, may later be of critical importance.)
- personal comments (It is a living document, so stamp it with your own personality. Comments such as *"SUCCESS AT LAST!! THIRD TIME LUCKY :)"* are highly appropriate. However, do not make sweeping statements, such as, "*This procedure is worthless*" or "*We infringe X's patent with this procedure.*" Statements like this could affect the future patentability of your research.
- photographs, computer generated data, and so forth should all be stuck into your notebook in such a way that they will not come loose (see Figure 1). If the format of these data is too large for your laboratory notebook, sign and date such data and file them in a loose-leaf ring file that can clearly be identified. Record the location of these documents in your notebook.
- cross-references (If you have already described an experiment earlier, or if you have used a standard protocol and have not deviated from the previous descriptions of the experiment for your current one, you may reference the earlier information instead of writing it out again. For example, if you are starting a new experiment on page 48 and are using the same protocol as already described on page 22, write on page 48, "*following the protocol as described on page 22 of this laboratory notebook.*")
- using preprinted forms can save time, if your experiments involve common, standard procedures (see Figure 2)
- information with regard to any data that has been electronically captured (These data should be accessible to any scientist "skilled in the art." Such electronic data should be backed-up and archived weekly.)

Corrections must be made by drawing a single line through the entry (see Figure 3). If you leave more than four lines at the bottom of a page, cross through the area to indicate that those lines were unused (see Figure 4). Never use Whiteout.

Remember, laboratory notebooks and their contents are ***confidential*** and of great value. Store them in safe places and report any loss or theft to your supervisor immediately. When you leave your laboratory for any length of time, inform your supervisor of the whereabouts of your laboratory notebooks. When you leave the institution permanently, ensure that your notebooks are handed over to your supervisor.

4. WHO OWNS THE NOTEBOOK?

The person or organization who is paying the bills owns your laboratory notebook. In most cases this will be the company, university, or research institute who employs you or your supervisor.

In the case of universities, you will probably find that employees enter into a contract that stipulates that all inventions developed while employed are the property of the university. Universities, and some companies, have agreements that income generated from discoveries

Figure 1: Example of a Gel Photograph Pasted into a Laboratory Notebook

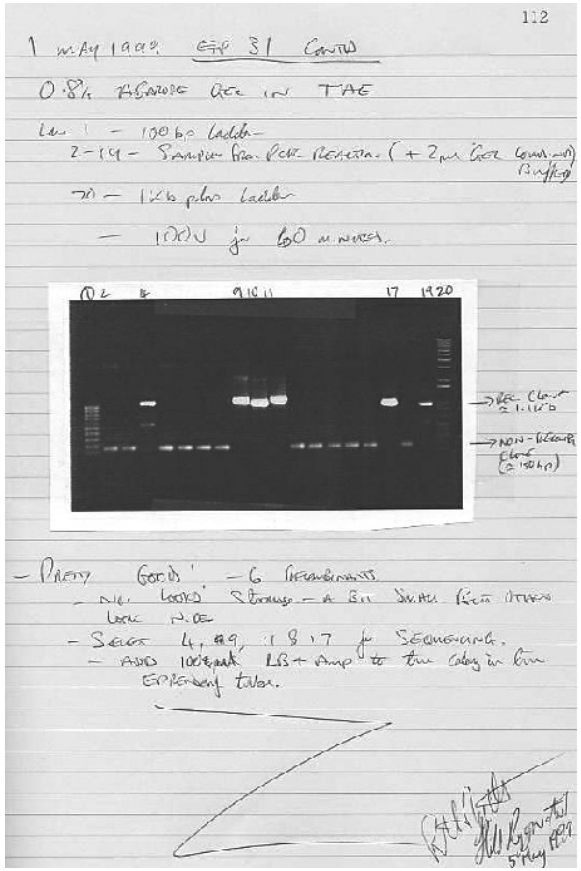


Figure 2: Using a Preprinted Form for Standard Reactions Saves Time

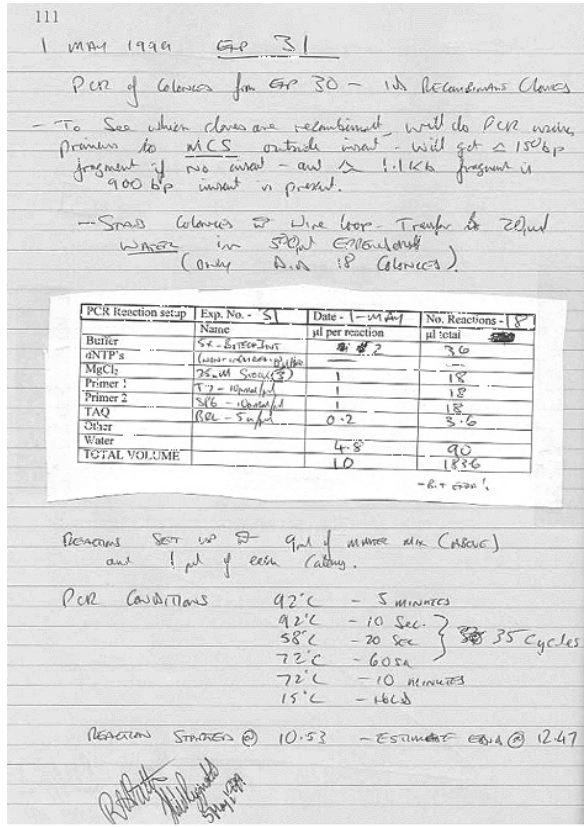


Figure 3: If You Make Mistakes, Correct Very Clearly

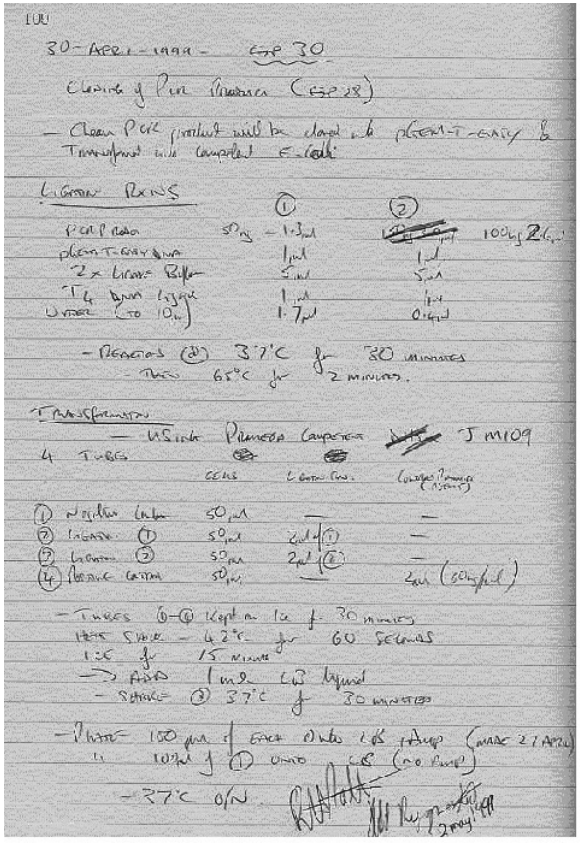


Figure 4: Draw a Line to Fill Empty Space

made by employees and/or students, will be divided between the institution and the discoverers.

5. HOW DO YOU KEEP COPIES OF LABORATORY NOTEBOOKS?

Some laboratory notebooks come equipped with carbon copies. These types are the best and safest. If your notebook is not of this type, you should make photocopies of the complete notebook. But why do you need copies?

- Once you have completed a laboratory notebook, your supervisor will probably want to keep the original. You will therefore need copies to help you in completing your research. You will often need to check back on what you did a few months ago.
- You might leave your institution before you have time to write up your research for publication or patenting. You will need a copy of your notebook to enable you to do this. Your supervisor will also need a copy to ensure correctness of data and interpretation. (The latter is just one reason why it is so important for you to comment on your data in your lab notebook, making suggestions, interpretations, and so forth.)
- Another scientist might have to take up where you left off. Although your supervisor will have your lab notebook, your successor will also need to have a copy to help her or him continue your work. It will be essential that your results can be repeated.

6. HOW DO YOU ARCHIVE YOUR LABORATORY NOTEBOOK?

Archiving means keeping your notebooks in a system that allows easy access. Your supervisor or institute will probably have an archival system in operation for this purpose. Here are some recommendations for archiving:

- The best option is a lockable bookcase, or cupboard, or a locking file cabinet.
- Label your notebook along the spine with your name, the project, and the start and end dates for the notebook.
- Make sure your supervisor knows where your notebooks are stored!

7. HOW DO YOU PROTECT YOUR LAB NOTEBOOK?

It is essential to protect the security of your records. Here are some important practices to follow:

- When you leave the lab each day always leave your lab notebook where your supervisor can find it, preferably in the same place. It is not necessary to lock it away every night, although it is a good habit to form.
- Lock your lab when you are the last person to leave. If you are not sure whether anyone else will return to the lab, play safe and lock it. People will soon learn to keep their keys with them!
- If your supervisor allows you to keep past notebooks, make sure she or he knows where they are.

8. CONCLUSIONS

A laboratory notebook is an important tool that goes well beyond research management, and keeping good records has implications for issues ranging from intellectual property management to the prevention of fraud. Institutions should have a comprehensive policy that should be rigorously implemented (see Box 1 for guidelines for a notebook policy). ■

JENNIFER A. THOMSON, *Professor, Department of Molecular and Cell Biology, University of Cape Town, Private Bag, Rondebosch 7701, South Africa.* jennifer.thomson@uct.ac.za

Box 1: Laboratory Notebook Policy

The following policy is a document originally prepared by SWIFFT at Cornell University in the context of its collaboration with the centers of the Consultative Group on International Agricultural Research (CGIAR). The policy itself is based on actual policies that are in effect in several leading research centers and companies, but has been adapted to reflect the specific needs of public sector research institutions.

Background

Many public organizations are entering a new era and are considering protecting their own inventions and engaging in research with other organizations, both public and private. These new relationships, often based on collaborative research agreements, may require precise documentation of certain activities and results. Laboratory and research practices will frequently need to be carefully formalized and noted in ways that will allow future IP auditors to review the authenticity of results and certify the dates of occurrences. Such practices are important for potentially patenting possible discoveries made by these institutions or by their collaborators, especially when seeking patent protection in the United States.

Recording procedures are generally spelled out with respect to standard laboratory notebook practices. These procedures inform all staff about the process for daily establishing and maintaining of laboratory records that could become primary evidence for the resolution of disputes or litigation. In court, dates of invention, description of an invention, and research techniques can be established through carefully kept laboratory notebooks.

In order to achieve the goal of maintaining court-ready documentation, a bound laboratory notebook, in whatever format, must be:

- an honest representation of the research work done by the researcher
- regularly written (daily recording is normally recommended)
- routinely witnessed (at least weekly) by another scientist
- duplicated when completed, if the researcher would like a working copy
- archived in a secure place and/or by a secure method.

The policies and procedures outlined below can be modified to suit almost any organization's needs and existing IP policies and to harmonize the lab notebook policy with other institutional tools. It is essential, however, that any laboratory notebook policy be consistent with other laboratory procedures, that all research staff be well trained in the execution of the policy, and that the adopted policies be systematically enforced.

Laboratory Notebook Policy

The purpose of this policy is to ensure that the institution is sufficiently protecting its inventions, research, and products, so that discussions or allegations during disputes or litigation are based on documented fact. This includes such things as the date of an invention or a description of the invention or research, the dates or research techniques that were used, and the like. In order to do this, the laboratory notebook, in whatever format, must be an honest representation of the research work done by the institution, and must be acceptable to a court, the U.S. Patent and Trademark Office, and other offices whose charge is regulating statutory protection of IP. Therefore, certain standards apply to each type of notebook.

Guidelines

1. General

All ideas and data must be entered into the laboratory notebook. Entries must be complete enough that another scientist would have little or no trouble understanding and repeating the experiments.

(Continued on Next Page)

Box 1 (continued)

Each page must be signed, and dated each day, by the scientist running and recording the experiment, and signed and dated by a witness, if not immediately, then at least within one week of the scientist's signature.
In deciding the exact procedures to follow, it is important to keep in mind that any type of laboratory notebook must achieve two goals:

1. Reflect its own integrity
2. Corroborate information independent of the person doing the research

Thus, the condition of the laboratory notebook must reflect that it is a clear and accurate representation of activities that have taken place in the lab and that none of the information has been falsified: any changes made to the recorded information should be clear and obvious and the new information should be able to be compared with the old; and the notebook should be completely in tact, with no pages missing or illegible. A witness who has not been involved in the experiment, by signing and dating the notebook, must attest (by virtue of signing) that the information, experimentation, and/or ideas that occurred were recorded on the date indicated.

2. Types of laboratory notebooks

A. Hardbound notebook

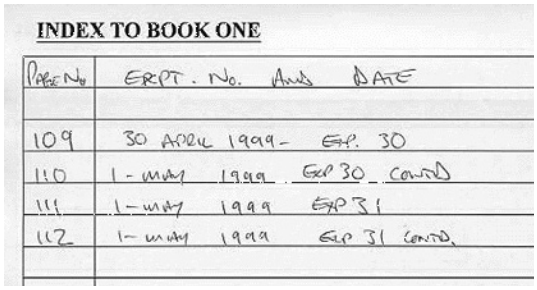
- Laboratory notebooks are checked out from the designated librarian in the department or office specified and returned to the designated technician immediately upon being filled, to be microfilmed.

- When signing out a new laboratory notebook, the researcher will notice that the laboratory notebook is numbered, is permanently bound, has index pages (Figure 5) and that all pages are prenumbered.

- The researcher should enter a new experiment in the index each time a new experiment is started.

- Use each page in order. Leave no blank pages between experiments.

Figure 5: An Index at the Back Makes Your Notebook More Useable



INDEX TO BOOK ONE

PAGE No	EXPT. No. AND	DATE
109	30	APRIL 1999 – EXP. 30
110	1 – MAY	1999 EXP 30 CONTD
111	1 – MAY	1999 EXP 31
112	1 – MAY	1999 EXP 31 CONTD.

- Record enough information so that a scientist "skilled in the art" could pick up your laboratory notebook and easily determine what had been done, why it had been done, and what the results were. Entries should include procedures, reagents, lot numbers, where appropriate, sketches, descriptions, and so on. The purpose and significance of the experiment as well as observations, results, and conclusions should be made clear. Remember, what may seem trivial or obvious at the time experiments are conducted, may later be of critical importance.

- If procedures have already been described in an earlier experiment or have used a standard protocol, and the researcher has not deviated from the previous descriptions of the experiment for the current one, the researcher may reference the earlier information instead of writing it out again. For example, if the researcher was starting a new experiment on page 42, and was using the same protocol as already described on page 25, he or she

(Continued on Next Page)

Box 1 (continued)

could write on page 42, "Following the protocol as described on page 25 of this laboratory notebook."

- All data should be entered, in ink, directly into the laboratory notebook.

- Corrections should be made by drawing a single line through the entry. Erasers or whiteout should never be used. The researcher should initial each lineout, and if possible, add next to each lineout a note of explanation, such as, *"wrong data."* The researcher should never tear pages out of the laboratory notebook. Pages may be copied for the researcher's own use, but never removed.

- At the end of each day the researcher should put a line or a cross through any unused space on that day's page(s) in the laboratory notebook. If a blank line is left between paragraphs, there is no need to lineout the one line, but if a number of lines have been left at the bottom of the page, they should be marked through. This could prove it was impossible to enter additional information in the laboratory notebook, in those empty spaces, at a later date.

- If additional information, such as a machine-generated table or graph, an original photo, or autorad, is part of the experiment and is small enough to be attached in the notebook, the information should be attached using a permanent adhesive or nonremovable tape. The researcher should sign his or her name over the border of the attachment, crossing over onto the laboratory notebook page. Signing in this way would clearly show, if at any time in the future the attachment had been removed.

- If the additional data is too large for the laboratory notebook (for example, a computer printout that is a few pages long), such additional data can be signed and dated; countersigned and dated by the witness; and given an appropriate ID number. The researcher should note on such additional data which laboratory notebook and which page number the additional data is referenced. Then, in the laboratory notebook the researcher should reference the additional data's ID number and note the secure-storage location where the additional data is being held. Preferably, a drawer with a set of files that are always used to store oversized information should be used. A summary of the data can be placed in the laboratory notebook. The same sort of procedure should be followed with any samples that are to be kept.

- Each original page of the laboratory notebook must be signed and dated by the researcher and by a witness. A witness should be someone who has read each entry, who is competent to understand what he or she has read, but who is not a co-inventor. Each research group should designate a person who is responsible for assigning permanent witnessing partners. However, if the assigned witness is not available when needed, another person who fulfills the appropriate criteria may be used.

- If any changes are made after pages are signed or witnessed, the changes must be initialed and dated by both the researcher and a witness. Care should be taken to use the current date when signing or witnessing a laboratory notebook.

- Ideas should be recorded in the laboratory notebook, as these may be important in determining a date of invention.

- It is important to return completed laboratory notebooks to the designated person as soon as possible to ensure a duplicate copy of the laboratory notebook is captured on microfilm

(Continued on Next Page)

Box 1 (continued)

or other permanent media. This process will be expedited so that the notebook can be returned quickly to the researcher. A laboratory notebook can be retrieved at any time during the microfilming process, if needed. Upon completion of the microfilm process, the laboratory notebook will be returned to the researcher, for use as reference in the laboratory, or put into permanent storage at the researcher's request. One microfilmed copy will be kept in the library for access at any time. One other copy of the microfilm copy will be put into secured storage in the designated location.

B. Hardbound notebooks containing electronically captured data

- At laboratories where a large amount of data are generated and stored in the computer, a written laboratory notebook, with all of the guidelines referred to above, is still required. In this setting, however, much of the data referred to in the laboratory notebooks may exist in electronic files. The laboratory notebooks should contain a summary of the information in those files and also give the name of the file (and format) in which the data are stored.

- The electronic data should be backed up and archived weekly. A new and separate file should be provided as a place to store data. Details of these files and the back-up procedure should be described to all researchers and managers in a memo. These backed-up files should never be opened except for litigation or U.S. Patent Office matters.

C. Hardbound notebooks generated by computers

- The same guidelines apply to hardbound notebooks generated by computers as for hand-written laboratory notebooks. The difference is that rather than purchasing a laboratory notebook and writing in it, research activity is documented electronically. The documentation is printed out on a regular basis and then bound to form a laboratory notebook. The printed material should be clearly labeled with the information that will appear on the front of the bound book and sent to the appropriate person or department for binding. Once bound, the laboratory notebook will be assigned a number, recorded, and returned to the researcher or archived, upon request.

- Each experiment is to be described and each page should be numbered and signed, countersigned, and dated. Each week these experiments are to be saved in the special data file as described in a memo. Also, as with hardbound notebooks, data such as small graphs, photos of gels, and so on, which can be attached to the laboratory notebook page should be attached using the same methods as described above.

- Even though it may be a convenient way of recording experiments, electronic documentation is not the recommended way, for a variety of reasons. If a number of experiments from different days are printed on one page, for example, and the page is only signed and dated after the last entry, it may be difficult or impossible to pinpoint dates of specific activity, especially an exact date of invention.

Documentation of Inventions

W. MARK CROWELL, *Associate Vice Chancellor for Economic Development and Technology Transfer, University of North Carolina at Chapel Hill, U.S.A.*

ABSTRACT

Documentation of research is a critical aspect of best practices in IP management. This is true because research and development activities that give rise to inventions must be thoroughly documented in order to successfully manage patents, including determining patentability, drafting and prosecuting patent applications, and later, if the need arises, protecting patents against third party challenges, for example, a patent interference proceeding. Maintaining, for each invention, a complete record of who made the invention, when it was made, and how it was made, must therefore become a formal component of a university's policy and training programs and must be carried our according to specific protocols. An organized and methodical approach to documentation will support patent management, provide a readily accessible source of critical information, ensure the capture of maximum value of inventions, and protect patent portfolios against challenges when, and if, the need arises.

1. INTRODUCTION

Documentation of inventions is an extremely important issue, and yet this relatively straightforward activity is one of the most forgotten, overlooked or, simply, carelessly neglected aspects of invention management. A lack of attention to this activity can result in the loss of patent rights that the applicant would otherwise possess. The technology transfer office has a responsibility to facilitate understanding among researchers of the importance of keeping good records. In addition, the technology transfer office must establish fail-safe systems for documenting and diligently pursuing the invention disclosures that the office receives.

Why is record keeping so important? In a research environment, good research records are essential for a number of reasons—including for assisting the institution in meeting its progress-reporting requirements to research sponsors, for documenting expenditures, and for promoting research integrity. However, for the technology transfer manager, U.S. patent laws provide an altogether different reason for promoting good practices in invention documentation.

Among the first lessons that U.S. technology managers learn is that the patent laws dictate that a patent is awarded to the first party to invent. In the United States, unlike virtually every other country, priority of invention is established by the first-to-invent rule. However, the majority of nations follow a priority rule by which the party who is first to file is entitled to a patent. What this means, then, is that a contest can ensue between parties who dispute priority of an invention, that is, who was actually first to invent.

Crowell WM. 2007. Documentation of Inventions. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Second Edition, Part VI: Chapter 2).

Such a contest is adjudicated by the U.S. Patent and Trademark Office (PTO), Board of Patent Appeals and Interferences, in an administrative proceeding called a *patent interference*. The patent interference proceeding determines who was the first to invent, has priority, and thus is entitled to the patent.

So, when two competing patent applications claim the same subject matter, the PTO declares an interference, that is, the patent applications "interfere" with each other. Each inventor then seeks to prove priority of invention, and reliable evidence is sought that can document which party was, in fact, the first to invent. Under U.S. patent law, the inventive process, by definition, begins with conception of an invention and proceeds to reduction to practice (either actual construction of the invention *or* filing of a patent application with the PTO). To comply with patent law, the first party to conceive a patentable invention must carry out certain activities to proceed with reasonable diligence toward the development and patenting of an invention. In other words, it is possible that the first to conceive an invention can fail to prevail in an interference proceeding if he or she did not diligently work toward reduction to practice of the invention or did, in fact, diligently work toward reduction to practice but *cannot produce any documentation* as evidence to prove having done so. Therefore, an inability to prove who is the first to conceive, or a lack of evidence to refute a charge that an inventor was not diligent in pursuing an invention, can lead to the loss of valuable patent rights to which the inventor and institution may otherwise have been entitled.

Therefore, within the notoriously complex context of an interference proceeding, careful documentation of inventions and the inventive process, from conception to reduction to practice, will be extremely important in order to prevail if such legal challenges arise. In addition to interference proceedings, patents are, not infrequently, challenged on such grounds as incorrect naming of inventors or newly raised references that challengers argue should have been submitted to the PTO as proof of prior art at the time of the patent application. In such situations, research records can be invaluable for documenting who contributed to the invention and the critical dates and facts of conception and reduction to practice of the invention; these dates would refute the claim that raised references identified relevant prior art if the records documented conception and reduction to practice (invention) as having occurred before the raised references. This example underscores the importance of maintaining clear, meticulous chronological records. *Nothing* will substitute for comprehensive records if, and when, complex legal challenges to a patent or patent application arise. Always assume that there could be trouble, and assemble records accordingly so as to protect valuable investments in research, development, and commercialization.

2. THE PRACTICAL IMPORTANCE OF RECORD KEEPING

In reality, there are occasions on which an invention disclosure form (IDF) itself, or possibly a grant application, will be the first viable record that a researcher has adequately, and diligently, proceeded through the inventive process, from conception of the invention through to reduction to practice. In such cases, the technology transfer office must ensure that such records are safely stored, properly witnessed, and readily available when the need arises. A lot depends on such care being taken, and an investment in managing and maintaining records will pay off in the long term.

U.S. patent practice places immense importance on witnessed records when two or more parties claim the same invention. For example, an applicant involved in an interference proceeding must be able to prove the date of conception (the date when the inventor formulated in his mind a definite and complete idea of the invention) and the date of reduction to practice (the date when the conceived invention was actually built, with every element of the conceived invention) even if it is not yet commercially perfected. It is critical to make clear to staff that the IDF used by the technology transfer office must avoid using language that refers to date of *first* conception or date of *first* reduction to practice. Should legal adjudications

arise, such a statement could be construed to be an admission that no earlier conception or reduction to practice occurred (when in fact it has), significantly damaging the institution's position in a priority contest. Instead, the IDF should simply ask that the location of records documenting conception and reduction to practice be identified.

In addition to documenting the dates of conception and reduction to practice, the PTO interference proceeding may turn on the diligence shown by the contending inventors. In this situation, the inventors' witnessed records must demonstrate that the invention's development, including the act of filing a U.S. patent application, was pursued in a reasonably diligent manner, pursuant to the statutory requirements of U.S. patent law. In an interference proceeding, the party that can prove that it was the first to conceive will likely be awarded the patent. If one party proves it was the first to conceive of an idea, but a second party conceived of the idea and pursued reduction to practice in a more diligent manner, the second party may prevail in the interference proceeding.

In the private sector, most industrial research is carried out under guidelines that impose strictly enforced record-keeping practices as a matter of routine practice. Often, these records are made on a daily basis, dated, witnessed, and stored. If researchers working under such conditions are the inventors named on a patent application involved in an interference proceeding, proving the date of conception and reduction to practice should be without ambiguities and informational gaps and, hence, relatively simple and straightforward.

On the other hand, research record keeping in universities can be lax to the point of sloppiness, and, in such cases, much more challenging to organize and manage. Laboratory research tends to be conducted at any and all hours of the day, and researchers often find it difficult to find the resources, witnesses, or other means by which documentation can be facilitated. Furthermore, the culture of some universities is such that practices of this type historically have been viewed as inappropriate or unnecessary. Researchers may neither understand, appreciate, nor wish to be inconvenienced by attending to detailed and chronologically consistent documentation, and thus simply perceive such a requirement as another annoying administrative burden. Indeed, in some laboratories, directors of research might push staff to maximize time at the bench and minimize time at the desk; record keeping will inevitably suffer as a result of such prioritization of time. And in some cases, graduate students who come and go, and who work on research projects, believe, or perhaps are told, that laboratory notebooks belong solely to the students. If important facts about the conception or reduction to practice of an invention are included in such notebooks, the documentation may not be available (that is, it has "walked away" with the student) at some future date when a patent is being challenged.

Despite any difficulty that universities may face with strict record-keeping protocols, the importance of this activity cannot be overlooked. Most research universities now have active patenting and licensing programs, and sound research documentation and record keeping is an essential component of successful programs. This cannot be ignored or left to chance; there is just too much at stake, and the stakes only get higher.

3. GUIDELINES FOR RECORD KEEPING

Good laboratory record-keeping practices should not be driven merely by IP (intellectual property) concerns. Good laboratory records have long been viewed as "good science," and good laboratory records can be extremely helpful if a lab should ever face charges (however specious) of scientific misconduct. Essentially, the same record-keeping practices that are considered good science and appropriate for responding to scientific misconduct charges are also good practices for purposes of managing, securing and protecting IP rights.[1]

The following guidelines for record keeping are contained in the North Carolina State University manual of patent and copyright procedures and are highly recommended:

1. A good practice is to use bound notebooks for records. Entries should be made on a daily basis. The use of a "diary format"

provides a day-to-day chronology. (This can be extremely important in documenting diligence or other important issues.)
2. Use the notebook to record a conception (a complete description of a means to accomplish a particular purpose or result, ideally including all elements of a conceptualized invention), laboratory data, drawings, or other observations. Each entry should be dated, headed with a title, and continued on successive pages.
3. Entries in the notebook should be made in ink. Under no circumstances should entries be erased or "whited out"; a line should be drawn through text or drawings that are being deleted, and the corrected material should be entered. Any blank spaces on pages should be drawn through.
4. Any material that cannot be incorporated into the notebook should be glued in and referred to in a notebook entry.
5. All entries in the notebook should be signed, dated, and witnessed (by at least two people) at the time they are made. Witnesses should have read the entered material and be capable of understanding it but be impartial observers of the work and have no direct stake in the outcome. The witnesses could be, for example, colleagues from another laboratory in the same department. An extremely important or unusual discovery or observation (a potentially patentable invention) may warrant having more than two witnesses. Multiple inventors may not serve as witnesses for each other. If important records lack the requisite witness signatures, the records should be signed as soon as possible after the records are created. Even a witness signature made days or weeks after the record was created is evidence that the document existed prior to the date on which signature was made.
6. Laboratory heads should set aside a time for all in their laboratory staff to stop working at the bench (or, in agricultural research, the greenhouse or field) and record entries into their notebooks. This time should be carefully and consistently observed. Be sure to invite individuals who can witness the entries immediately after they are made.
7. In the event that notes are kept on a computer, be sure to make the appropriate entries into the computer system at the end of each day. Each daily entry should be printed out, signed, and witnessed, following the same procedure as that recommended for written notebook entries. The final printed, signed, and witnessed document should be glued into a notebook.
8. Identify a safe method for storing and monitoring the records. Research data related to pending or issued patents should not be destroyed. Therefore, a retrievable archive system needs to be organized, implemented and maintained. Such an investment will pay for itself many times over in the event of a patent dispute.

4. CONCLUSIONS

In general, best practices in documenting laboratory research serves two purposes: scientific and legal (IP management and patenting). These purposes are not mutually exclusive, and indeed there is considerable overlap, as the means to the two objectives are entirely consistent. Best practices in documentation will provide the researcher with a clear record for assembling publications, grant proposals and, in the event of fraud or misconduct allegations, a clear record for establishing the facts. Similarly, a best practices approach to documenting research will greatly facilitate managing issues related to IP management and patenting. This could include, but is not limited to, patent application drafting and prosecution, patent challenges by third parties, and evidence production for patent interference proceedings. Each of these will require documentation of research and development activities. Documentation policy must, therefore, be carefully and thoughtfully institutionalized, as part of every university's required protocols. Such procedures and requirements should be an integral part of overall IP management and training that the technology transfer office provides to the university administration, staff, and scientists. A lot of value might be at

stake. The investment in building capacity and appropriate IP management systems will pay off in the long term. ■

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1 See, also in this *Handbook,* chapter 8.2 by JA Thompson.

Invention Disclosures and the Role of Inventors

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ABSTRACT

This chapter is intended to assist intellectual property professionals, in working with inventors, to develop a high-quality invention disclosure and, eventually, to prosecute a patent application. Major topics include the importance of data records, utility and reduction to practice of inventions, understanding prior art (including the inventors' own art), and determination of inventorship.

1. INTRODUCTION

Invention disclosure is more than the simple completion of an institutional or corporate form to satisfy some policy requirement. It includes a complete description of something novel and nonobvious given in such a manner that anyone of ordinary skill in the particular art could reproduce the invention. The disclosure represents the first official recording of the invention and, if done properly, can establish an irrefutable date and scope of the invention. Often the disclosure document has been used to defeat challenges to dates of invention, inventorship, invention scope, and prior art. Conversely, improperly written invention disclosures many times have resulted in disastrous losses of patent rights.

This chapter explains the nuts and bolts of invention disclosures (as well as some of the nuances), beginning with the responsibility of scientists to disclose inventions even before they are made and ending with the use of disclosures to create defensible patents.

2. CONCEPTION OF AN INVENTION

The term *invention* is occasionally confused with the term *idea.* According to the U.S. Code of Federal Regulations, (37 C.F.R. §501.3(d)), an invention is defined as "*any art, machine, manufacture, design or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws.*" An idea, by definition, is limited to a thought, existing only in the mind; an idea may or may not be patentable as a concept. Only inventions can be patented, not ideas.

In the legal sense, the conception of an invention occurs when someone has mentally developed an idea that is novel, nonobvious, and exists in enough enabling detail that someone of ordinary skill in the relevant area of science could practice the invention. Conception does not necessarily require actual reduction to practice of the invention, but it does require that the invention be thought through completely. The degree to which the conceptualization is incomplete should not be such that it is renders the invention inoperable.

Commonly, a complete conception occurs over a lengthy period of time and may involve

McGee DR. 2007. Invention Disclosures and the Role of Inventors. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

other contributors. The date on which such conception is deemed to be complete, that is, it satisfies all aspects required of an invention (novelty, nonobviousness, and enablement), is considered to be the date of invention. The date of invention may be, but is not required to be, either the actual date of reduction to practice of the invention or the filing date of the patent application (constructive reduction to practice).

3. INVENTORSHIP

Those individuals who contribute to an enabling concept are known as the inventors. Inventorship is, therefore, restricted to the intellectual concept. It does not extend to those persons who may reduce the invention to practice but did not contribute to the invention's conception.

Inventorship relies on specific claims ultimately approved by the patent office for the granted or issued patent. Since patent prosecution most commonly involves changes to the claims filed with the application, the inventors may change.

One of the most frequently misunderstood and contentious issues between scientists and the intellectual property (IP) professional is the confusion between inventorship and authorship. As described above, inventorship is a legal determination based on the contribution to the enabling concept embodied in at least one allowed claim. An individual who has spent extensive time and effort in the laboratory reducing an invention to practice is not an inventor in any sense unless he or she has also contributed to at least one claim.

Teams of scientists conduct most research. As such, research team members are constantly discussing technical aspects of the research; over a period of time, an idea may emerge that has been jointly developed. From the idea, an invention may be described. Frequently, conflicts arise when an author is not included as an inventor on a patent application and believes that the work performed in actual reduction to practice should mean that he or she be designated as an inventor. Unintentionally including a noninventor or excluding an inventor can usually be corrected in the patent office. However, intentionally including a person as an inventor who did not contribute to a claim is patent fraud and would render the patent invalid if discovered. Intentionally excluding an inventor could likewise render a patent invalid.

It is the responsibility of potential inventors to make a good faith effort to determine who among themselves are actual inventors. Ultimately, inventorship must be examined by the patent attorney of record to ensure that the inventors included on the patent filed are, in fact, inventors.

4. PREPARING THE INVENTION DISCLOSURE

4.1 *Education of inventors before they disclose*

The IP professional should never assume that the scientists in his or her organization are aware of when, how, to whom, and why to properly make an invention disclosure. As with many other business practices, acceptance of the patenting process begins at the top of the organization. If top management does not endorse patenting, then no one else will either. An effective education program, concerning the policies, practices, and practical understanding of the patent process, is a must for staff of the organization. The program must be continuous, since new staff will not be aware of the process, and existing staff will need to review the process on a frequent basis. The best time to educate new employees is during their orientation programs. Instruction should be supplemented at regular periods during the year to all potential inventors. Only the technology transfer office (TTO) is really qualified to educate these scientists.

4.2 *Duty to disclose*

It is essential that employees be aware of and follow the employer's policy for duty to disclose an invention. Many organizations have a policy that requires all employees to disclose to the employer all inventions made during the course of employment. Depending on the specific policy, the duty to disclose may extend beyond employment to include inventions made outside of employment, such as inventions made while consulting for another company or at home.

4.3 *When the inventor calls*

For the TTO to succeed, inventors must be confident that their inventions are going to receive a thorough evaluation of their patentability and commercialization potential. Nothing will alienate an entire cadre of inventors more quickly and completely than if the TTO treats inventions superficially or capriciously. The TTO must give careful attention to every invention disclosure, regardless of its content.

4.3.1 *Understanding your institution's IP policies and your country's IP laws*

The IP official must be the expert on his or her company and institutional IP policies and practices. These policies and practices must be carefully and patiently explained to each inventor. Likewise, all laws pertinent to any aspect of IP must be understood by the TTO and communicated whenever needed to the inventor.

4.3.2 *Understanding the inventor's timing of public disclosures*

One of the most common complications accompanying an invention disclosure is a publication or a pending publication. If publication is imminent, then a provisional patent application may be the only recourse to avoiding loss of patent rights. In the United States, a grant application is not considered a publication until the Notice of Grant Award is sent. Therefore, it is essential to completely understand the nature and content of the intended publication in order to determine whether or not it will actually contain an enabling disclosure of the invention. It also is necessary to know when the invention will be disclosed. Abstracts for scientific meetings are now commonly e-mailed to participants months before the meeting date. Depending on the specific invention, an abstract may easily be an enabling disclosure, so it is important to question each inventor to determine if and when a publication and/or abstract may occur. Many times a disclosure (such as a speech) does not provide enough detail to constitute an enabling disclosure. The TTO should obtain copies of all speeches, technical presentations, pending grant applications, and so forth, and maintain these with the patent file wrapper.

4.4 *Getting the big picture*

When an invention is disclosed, the IP professional should clearly understand not only the technical details of the invention but also how the new invention may relate to other inventions as a portfolio. Additionally, the inventor may be prolific and so it is important to know if there are additional invention disclosures anticipated by the inventor and, if so, whether those should be combined with the invention disclosure at hand. This knowledge could greatly influence whether and/or when to file a patent application and what the scope of the patent application may be in light of other existing or expected invention disclosure forms. The inventor must provide the IP professional with his or her plans to continue conducting research related to the invention. This is especially important if the invention has not been reduced to practice.

If the invention disclosed is incomplete because the inventor has not completed an enabling concept, or if reduction to practice is necessary to determine enablement, then the inventor must be clearly told what deficiency is present. The invention disclosure form will be held by the IP professional with no action taken until the inventor provides a complete disclosure. Periodic follow-up with the inventor is advisable to ensure that he or she remembers to provide the information necessary to complete the invention disclosure form.

4.5 *Inventorship versus ownership*

The duty to disclose should be not be confused with the assignment of an invention. Disclosure of an invention means merely that the invention has been described in complete (that is, enabling) detail. Assignment means that ownership of, that is, legal title to, the invention has been given by the inventor to another party (for example, the employer). Employers commonly combine the duty to disclose and the assignment of inventions on a single form to be signed by the new employee upon reporting to work. But this is not always done, so the actual language must be carefully reviewed. The combination of the duty to disclose and the assignment of invention into a single, signed document is convenient in case there are

ever any questions later during a patent prosecution of the ownership of an invention.

For certain government organizations, the duty to disclose may go beyond mere policy compliance and have additional legal consequences if timely and complete disclosure is not made.

4.6 *When the invention disclosed is co-owned*

Collaborative research projects between separate entities are common. Usually these projects are described in a contract, grant, or interinstitutional agreement. These documents will usually contain one or more sections that address co-inventorship and co-ownership of IP developed during the term of the agreement. Nothing should be assumed about the ownership of IP before thorough review of the agreement has been completed. Once ownership has been determined, the other party may need to be notified upon receipt of an invention disclosure form and prior to filing a patent application. Frequently, the other party will have an opportunity to participate in some manner during the IP process.

If an invention has been made by co-inventors and at least one of the co-inventors is from a second entity, and if there is no contractual agreement between the entities, then a decision has to be made as to whether to inform the second entity of the invention disclosure form. Prior to disclosure, it would be advisable for the two institutions to sign a two-way confidentiality agreement to avoid public disclosure and subsequent loss of rights. Additionally, in first-to- file countries, the first party should file a patent application prior to notifying the second party. Subsequent agreements, such as an interinstitutional agreement, can be made to define each party's rights and determine how patent prosecution costs will be shared.

5. WHEN TO DISCLOSE AN INVENTION

It is good practice to disclose an invention as soon as it *is* an invention. Filing an invention disclosure declares the invention, the inventors, and the date of invention. Even if a patent application is never filed, a properly completed invention disclosure may be able to provide some protection against subsequent patent applications filed by other parties that could prohibit the first party from being able to practice something it invented. This precaution may be especially helpful in the United States, where first to invent takes precedence over first to file. Most importantly, without a *timely* disclosure, no decision can be made about whether or not to file a patent application to preserve IP rights. Occasionally, a delay in disclosure may be appropriate, for example, if the inventor is continuing to conduct experiments that may provide better enablement or broader utility, which would provide broader claims should a patent be sought. However, the decision to delay filing an invention disclosure should be made in consultation with appropriate IP managers.

If an inventor is unable or resistant to completing an invention disclosure form (See Box 1 at end of chapter for a sample invention disclosure form.), then an interview with an IP professional/ TTO officer of the same institution for the purpose of disclosure may be required. Completing an invention disclosure without the inventor's input is not recommended, however, since the inventor is, naturally, more familiar with the invention than anyone else. If a patent application is prepared from an invention disclosure that has been obtained from an interview, the patent application may take longer and cost more to prepare. Ultimately, each inventor must critically review and affirm that the invention has been correctly and completely described in the patent application. In the United States, each inventor must sign a declaration affirming that the invention has been correctly and completely described, in order to meet the filing requirements of the U.S. Patent Office.

In some countries, patent offices do not require filing an invention disclosure in order to file a patent application. Under certain circumstances, however, other government agencies may require that invention disclosures be filed.

5.1 *Where to submit an invention disclosure*

Invention disclosures may be submitted wherever the employer's policy dictates, for example, with a company's own IP department or outside patent counsel or with an academic institution's TTO.

In the United States, patent law provides for a disclosure document program that allows an inventor to submit an invention disclosure to the U.S. Patent and Trademark Office (PTO). The program is described in detail in the Code of Federal Regulations (37 C.F.R. §1.2.1(c)). It is especially beneficial to individual inventors who are not affiliated with an employer, because the program provides evidence of disclosure that may avoid the necessity of disclosing, to witnesses, information the inventor wishes to keep confidential. The U.S. PTO will keep the invention disclosure for two years and then discard it unless it is referred to in a pending patent application. The disclosure document program is not a substitute for filing a patent application and provides no filing date for a patent application.

5.2 *Confidentiality of an invention disclosure*

To avoid the potential undesired publication of an invention prior to filing a patent application, all invention disclosures should be submitted confidentially. When disclosure is made by an employee to a fellow employee, it should be clearly understood that the disclosure is to be kept confidential. As such, the disclosure would not be considered a publication in most cases. In very large institutions, the presumption of confidentiality may not exist. Consequently, if challenged by an outside party, such disclosure may be deemed by the patent to have not been a confidential disclosure but a publication. Even within an organization, therefore, it is always important to verify confidentiality prior to disclosure and to execute a confidentiality agreement, if needed.

5.3 *Content of an invention disclosure form*

There is no set format for an invention disclosure form; however, there are certain types of required information common to all invention disclosure forms. Examples of the forms can be easily obtained from the Internet by selecting any search engine and entering *invention disclosure* in the search box. Numerous forms from institutions all over the world are available.[1] All the forms have certain things in common: most request similar kinds of information. Box 2 at end of chapter lists items that appear commonly on the forms.

6. USE OF LABORATORY NOTEBOOKS AS INVENTION DISCLOSURES

Laboratory notebooks are frequently relied upon to ascertain the actual date of invention and to identify the inventor. Unfortunately, most lab notebooks are incomplete, illegible, and not witnessed, or witnessed erratically—if they are kept at all. However, if kept appropriately, a laboratory notebook can easily suffice as an invention disclosure. The information must *at least* include a detailed description of the invention and signed and dated pages by the inventor and appropriate witness(es). The actual discovery (that is, the invention) must be clearly explained.

IP professionals should educate scientists about the need for complete disclosure if the notebook is to be useful at all. The scientists should also be trained to avoid writing off-hand remarks in the notebook (for example, "this was an obvious experimental approach" or "I used an obvious extension of Dr. X to conduct this research" or "there is a paper that is prior art to my research"). Such notebook disclosures would be discoverable during litigation and could result in loss of patent rights. As always, scientists should be counseled to completely disclose the invention and to provide only absolutely truthful disclosure.

7. ASSIGNMENT FORM

An assignment is the transference of legal title to an invention. Assignment of all inventions may be made in advance of any discovery by executing a general assignment agreement. During patent filing, assignment of an invention may be required by the patent office. The employer should obtain a second assignment of the specific invention being filed as a patent application because it provides the patent office with a simple, clear assignment record. However, if an inventor cannot be reached or is unwilling to provide a signed assignment, then the original general assignment agreement can serve as evidence of assignment of that invention.

Under U.S. patent law, all assignments for patent applications and issued patents must be recorded. This requirement may vary in other countries.

7.1 *What to do in the absence of a previous assignment when there is a duty to disclose*

Occasionally during the preparation of a patent application, the IP professional discovers that there is no record of assignment. A signed acknowledgement of an employee's duty to assign may also be lacking. These are serious issues, because ownership of a patent is joint and severable; any owner can act independently of a co-owner. In other words, co-owners can separately practice an invention or license it without a co-owner's permission. Therefore, obtaining clear assignment of an invention is extremely important.

7.2 *Obtaining signatures for duty to assign and assignment documents*

As soon as it is discovered that an inventor has not fulfilled the duty to assign or has not executed an assignment document, the TTO officer should promptly review the organization's policies to see if they are clear. In addition, he or she should look for other records that may include the employee's signed acknowledgment of compliance with corporate or institutional policies. For example, employee policy handbooks frequently contain sections relating to IP. It is common practice for human resources departments to obtain from employees written acknowledgement that they have read, understand, and will comply with all policies. This written acknowledgement may be useful if an inventor does not wish to provide a written assignment for an invention.

Next, the IP professional should contact the inventor, in person if possible, and explain why an assignment is necessary. If a duty-to-disclose agreement has not been signed, then the IP professional should explain to the employer why signing a duty-to-disclose agreement is important. If the institution has a policy that provides inventors with compensation, such as royalties, then the IP professional should go over those policies as well. He or she should have the agreements ready to be signed in duplicate and provide the inventor with a copy. (The original should be kept on file.) Explain that additional assignments for any future inventions will be needed and why.

It is advisable not to ask anyone to sign an agreement upon which the signature date is different than the actual date of signing—it may undercut the validity of the document. The agreement can, however, specify an effective date in the text that predates the signature, providing that no intervening and conflicting agreements have been executed.

8. DILIGENCE WHEN FILING A PATENT AFTER RECEIVING THE INVENTION DISCLOSURE FORM

Because the U.S. PTO has a first-to-invent rule, U.S. patent practice includes an obligation of diligence to proceed with the filing of a patent application once an invention is completed. A filing delay can, under certain circumstances, result in a loss of patent rights. This most commonly occurs when a second, independent party invents and files a patent application after the first party's date of invention, but before the first party's filing date. If a lack of diligence by the first party can be shown, the second party may prevail and win the patent filing. Obviously, diligence in filing is rendered a moot issue in first-to-file countries.

9. UPDATING A SUBMITTED INVENTION DISCLOSURE FORM AND COMBINING DISCLOSURE FORMS

Frequently, when an invention disclosure form is submitted, it represents ongoing research. As such, it may not meet the standards of patentability or commercialization potential to warrant a patent filing. Regardless, an IP professional should receive the invention disclosure form and assess whether or not to file a patent application. Alternatively, he or she could hold the invention disclosure form in anticipation of receiving new data or matter from the inventor. The inventor may then file a subsequent invention disclosure form as an addendum to the first form. Invention disclosure forms on related matter, if combined, may greatly strengthen a patent application with broader claims.

If the second invention disclosure form contains the best method of practicing the invention

or new matter, then the date of invention may be that of the second invention disclosure form and not the first.

10. PATENT PREPARATION FROM THE INVENTION DISCLOSURE FORM

A properly completed invention disclosure form will greatly enhance the ability and speed with which the patent attorney is able prepare the patent draft. Expediting this process can dramatically lower attorney fees. To aid in the process, the attorney should receive a complete copy of the invention disclosure form, copies of all references, clear instructions about the most important aspects of the invention that need to be claimed in the patent application, and an explanation of why these aspects are important. The patent attorney will be able to craft a patent application properly only if the client clearly describes its strategic objectives within the context of the invention.

Most inventors are unfamiliar with the patent prosecution process, and so the IP professional should clearly describe the process to the inventor and explain how he or she will be expected to assist in it. The inventor should be introduced to the patent attorney, and the employer should take care to ensure that a good, productive working relationship is established between the inventor and the patent attorney. The inventor is the expert and will need to provide the patent attorney with substantial assistance in drafting the invention background, the technical description of the invention, and access to any known references. After filing, the inventor will likely assist the patent attorney in providing technical rebuttal for issues raised by the patent office. Depending on the particular patent application, the inventor's involvement can occasionally require a substantial amount of time.

Patent counsel will prepare and file the patent application based on the invention disclosure form. It is the responsibility of the patent counsel to prepare a complete and enabling disclosure of the invention. Most often the patent attorney will discuss the invention at length with the inventor, in order to ensure that all its features are understood. During these discussions, the patent attorney will develop the broadest claims possible without becoming an inventor.

11. MAINTAINING INVENTION DISCLOSURE FORMS

Each TTO should establish a database of invention disclosures and a secure-storage facility where original copies of invention disclosure forms are filed. A fireproof file cabinet is a good example of such a facility. Invention disclosure forms should be retained for the life of any related patent. Duplicate copies should be stored off-site. An outside patent firm will frequently provide this service. The disclosure document program at the U.S. PTO will maintain an invention disclosure form only for two years, unless the invention disclosure form is referenced in a pending patent application.

12. INVENTOR'S CERTIFICATE

An inventor's certificate may be filed in lieu of a patent application. The certificate will contain a detailed description of the invention and most of the components of a patent application. An inventor's certificate is, therefore, similar to an invention disclosure form. However, unlike an invention disclosure form, the inventor's certificate is part of a legal process (established in accordance with each country's respective patent laws and procedures) to publicly recognize the inventor(s) as an inventor for a defined invention as of a specified date.

An inventor's certificate *is not* a patent and *does not provide any of the IP protection rights provided by patenting*. Instead, many countries commonly use certificates to provide a monetary reward for an invention for which no patent is intended.

13. MARKETING INTELLECTUAL PROPERTY THROUGH AN INVENTION DISCLOSURE

It is common practice among academic institutions to market IP using the information contained in invention disclosure forms. Because

the invention disclosure form contains enabling detail of an invention, premature disclosure of such information prior to filing a patent application could destroy patent rights. Care must be taken to provide only general, nonconfidential information that does not include any enabling information. If a patent application has been filed but not yet published, then the filing date or patent application number should not be disclosed. Unauthorized parties can use these numbers to obtain confidential information about a pending application. If the patent application has been filed, then including information contained in the pending application is acceptable. The disclosed information in marketing abstracts made available for previously unpublished patent applications should be updated after the application is published. It is inadvisable to include inventors' names in marketing abstracts as points of contact; instead, the name of the licensing professional should be used.

Many institutions provide nonconfidential abstracts of IP on Web sites, which usually organize the abstracts and contact information into databases by technology area. These databases can be efficiently marketed by technology area through mass e-mailing or mailings to potential licensees. ■

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1 For example: http://research.ucdavis.edu/homecfm?id=OVC,2,1025.

Box 1: Sample invention disclosure form

[Insert Institution or Company Name Here]

CONFIDENTIAL

1. **TITLE OF INVENTION:** _____

2. **OVERVIEW OR PURPOSE OF INVENTION:** _____

3. **BRIEF DESCRIPTION OF INVENTION:**
   Provide a brief abstract of the invention including novel embodiments of the invention.

4. **DETAILED DESCRIPTION OF INVENTION:**
   Provide in plain language a numbered list of what attribute(s) you, the inventor, believe is/are useful about the invention.

   Provide a complete, enabling description of the invention. Include all descriptions, steps, processes, and other data and information necessary, so that someone of ordinary skill in the art could reproduce and practice this invention. If the invention is a composition of matter, provide a complete formulary and any other information necessary to completely and accurately describe the composition. If the invention requires software that has been developed as part of the invention, provide a detailed program flow chart and copies of the software. Provide detailed drawings and a description for any apparatus.
   Attach additional sheets if necessary.

5. **BACKGROUND (Optional):**
   If known, describe the state of the art as set forth in patents or journal references (identify by patent number or journal citation, if possible) and indicate how the invention overcomes any disadvantages to or problems in this art. *Attach additional sheets if necessary. Also attach complete copies of the references.*
   If any inventor knows of any art relevant to the invention, please provide such information through description below with appropriate literature references. All cited references should be attached to the invention disclosure form.

(Continued on Next Page)

BOX 1 (CONTINUED)

6. **CONCEPTION:**
Provide the date upon which a complete, enabling concept was known by the inventor(s).

Invention conceived on: _____

First written record: _____

7. **FIRST DISCLOSURE TO OTHERS:**
Provide the complete names and anyone to whom you have disclosed your invention in enabling detail and the dates on which you made the disclosures.

Date: _____ Name: _____

Date: _____ Name: _____

Date: _____ Name: _____

Indicate how the disclosure was made (for example, orally or through a presentation, report, or publication). Provide copies of any documents or other media you used to make the disclosure.

_____

_____

_____

_____

8. **FIRST REDUCTION TO PRACTICE:**
Provide the date of first preparation or isolation of compound molecule or microorganism; date of first use of process, or date of construction of apparatus.

Date: _____

9. **FIRST SALE OR PUBLIC USE OF INVENTION:**
Describe and provide the date of any sale or public use made, or planned to be made, of your invention in the United States or in any foreign countries. Provide details of any sale, use or disclosure. The description should tell whether or not the use was for testing purposes, and if there was an effort or intention to maintain secrecy around the invention after the use commenced.

_____

_____

_____

_____

10. **PROGRAM OR CONTRACT:**
Was the invention made during the course of your work on a specific program, grant(s) or contract?

Yes _____ No _____

If no, provide an explanation of how and where the invention was made.
If yes, provide below the name and applicable number of the funding agency.

Fund source Grant or contract number

_____

_____

(CONTINUED ON NEXT PAGE)

BOX 1 (CONTINUED)

11. CONTACT INFORMATION
Provide the specified information about the inventor(s).

Signature of inventor: _____ Date: _____

Printed inventor name: _____

Affiliation: _____

Mailing address: _____

Citzenship: _____

E-mail: _____

Telephone: _____

Signature of inventor: _____ Date: _____

Printed inventor name: _____

Affiliation: _____

Mailing address: _____

Citzenship: _____

E-mail: _____

Telephone: _____

12. WITNESSES:
The invention was described to me by the above inventor(s), the description was examined and clearly understood.

Signature of witness: _____ Date: _____

Printed name: _____

Affiliation: _____

Signature of witness: _____ Date: _____

Printed name: _____

Affiliation: _____

Box 2: Information requested typically in an invention disclosure form

Inventor
This should include the complete name of the inventor and his or her employer affiliation and complete mailing address.

Invention
An invention should include a title of the invention, a short abstract, and a detailed description of the invention. The advantages of the invention should be clearly described. The inventor(s) should include as many features, embodiments, and uses of the invention as possible.

Date of invention
This is the date the invention was conceived in enabling detail. U.S. patent law (35 USC §104) provides for the establishment of a filing date when an invention is made abroad, as long as certain provisions are met: 1) the inventor must be domiciled in the United States or a North American Free Trade Agreement [NAFTA] or World Trade Organization [WTO] country; 2) the invention has been conceived in either the United States or a NAFTA or WTO country; and 3) the inventor must be serving in a NAFTA or WTO country on behalf of one of those countries. Such a provision may or may not be available in countries other than the United States. The provision may have no significance at all for first-to-file countries.

Date of actual reduction to practice, if applicable (may be the date of invention)
Actual reduction to practice is not required but is helpful when preparing the patent application.

Applicable research funding sources, if any
It is very important to know whether the invention has been funded by an entity, other than the inventor's employer, that may have ownership/licensing rights.

Date of public disclosure of the invention
This may be critically important if the date creates a statutory bar for patenting. If the date is in the future, then it provides a timeframe within which a decision of whether or not to file a patent application has to be made. Copies of any publications (for example, manuscripts, handouts, posters, electronic presentations, and slides) should accompany the invention disclosure form. In addition, any relevant supportive scientific references should be copied in full and attached to the invention disclosure form.

References
The inventor should include complete references and photocopies of any other related science he or she is aware of that could potentially be cited by the patent examiner as novelty-destroying or as rendering the invention obvious. There is no duty for the inventor or the attorney of record to conduct a literature search to determine whether there is any prior art to the present invention. But if the inventor or the assigned institution is made aware of any such art, then it must be disclosed to the patent office. There is no duty to provide the patent office with an opinion of the relatedness of any reference cited to the patent office. The examiner is responsible for making such a determination.

The inventors should be instructed not to provide written admission, directly or indirectly, that any reference is prior art. In some countries such a statement is viewed as an irrevocable admission that the reference is true prior art that renders the present invention as non-novel and/or obvious.

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Box 2 (continued)

List of potential competitors/licensees
Since inventors are knowledgeable in the area of science related to the invention, they are usually also knowledgeable about who is working in that area. This is valuable information, since it provides direction in finding potential competitors, potential licensees, and potential areas of prior art that can be reviewed before filing a patent application to help determine patentability and claim drafting. Also, one can build a better patent portfolio by reviewing patents and file wrappers filed by another institution or company.

Witnesses
Usually, at least two witnesses are required on an invention disclosure form. A witness should be scientifically competent to understand the details of the invention and not directly affiliated with the research being disclosed (for example, an inventor on the invention disclosure form or a principle investigator of the research).

Signatures of all inventors
It is critical that at least one of the inventors has signed the invention disclosure form, otherwise, the form cannot be considered to have been perfected. The TTO at the institution should try to obtain original signatures from each of the inventors as soon as possible.

Receipt of electronically filed invention disclosure forms
Faxed signatures are generally accepted worldwide as sufficient evidence of an executed document. Electronic signatures do not yet have such wide acceptance. Consequently, it is recommended that invention disclosure forms not be sent electronically without the subsequent conveyance of an original, signed copy.

SECTION 9

Evaluation and Valuation of Technologies

Evaluating Inventions from Research Institutions

LITA NELSEN, *Director, M.I.T. Technology Licensing Office, U.S.A.*

ABSTRACT

The patenting strategies of research institutions are based on three key decisions. The first involves whether or not to file a patent. This decision must be based on sound information about the market, the uniqueness and usefulness of the invention and/or technology, the likelihood of being able to obtain patent protection, factors related to the inventor, and the potentially paradoxical impact of patenting on the institution's social and humanitarian responsibilities. The second decision involves whether to market the invention to established companies or to develop a spinout business. The third involves how much to charge for a license. Related to all of these decisions is the key question of whether patenting is the most effective route to global access. Negotiating licensing agreements that are fair to the research institution, the private company, and developing countries can be challenging because research institutions may have difficulty determining fair market values. In addition to outlining a process for obtaining these values, this chapter offers some rough numbers for guidance. In general, the author concludes that it is far better to conclude a deal than to wait for the best agreement while fighting interminably for perfect financial terms.

1. INTRODUCTION

This chapter discusses how to evaluate new inventions arising from research at universities and other research institutions. It considers early, "university-stage inventions" arising out of basic research, rather than development projects. Most of these university-stage inventions will require substantial investments in both money and time to develop them into marketable products. Such investments will usually be very risky; neither the practicality of the technology nor its ultimate market acceptance will be known with any certainty.

It is assumed that the research institution's interest is primarily in the social functions of technology transfer: bringing new medicines and other useful products into public use, enhancing the competitiveness of industry by encouraging the use of new technology, and enhancing economic development and job creation. Revenue from royalties is assumed to be a secondary consideration. (Even in the United States, the Bayh-Dole Act, which gave U.S. research institutions the right to own and license out inventions from government-funded research, was enacted in the cause of economic development—not as a mechanism for funding the institutions. Twenty-five years later, the revenue produced, though useful to the institutions, makes up on average only a small percentage of their research budgets.)

2. THE EVALUATION PROCESS

Technology transfer offices evaluate early-stage inventions in order to make three decisions:

1. whether or not to file a patent on the invention

Nelsen L. 2007. Evaluating Inventions from Research Institutions. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

2. whether to market the invention to existing companies or try to do a spinout
3. what to charge for the invention

Fortunately, these three decisions do not usually have to be made at the same time. And, of course, if the answer to the first question is no, then the other two questions are moot.

2.1 *Decision 1: Whether or not to file a patent*

It is assumed that money for filing patents is available but limited. The decision to file a patent should take into account answers to the following questions:

1. Is this invention likely to get awarded a patent with broad enough claims to protect a product or a product line—not just a minor variation of an existing technology?
2. If patented, will this invention likely attract a licensee or investment for commercialization that will produce enough of a return to the institution to justify the patenting expense?
3. Is patenting the right route to maximize social access to the technology?

The answer to the first question on patentability is fairly easy to determine with relative (though not absolute) certainty. If time allows, a search of the literature that includes past and published pending patents will reveal prior art. When possible, this search is best done by a professional search librarian working side-by-side with one of the inventors. If potentially important prior art is found, a patent agent may be called in to evaluate its significance and the likely claims to be achieved by patent filing. The prior art search may also turn up dominating patents that may have to be taken into account.

The second question—will the technology attract investment for commercialization if it is patented—is far more difficult than the first to answer with any certainty. Market research studies take both time and labor. If the technology transfer office receives many invention disclosures (at the Massachusetts Institute of Technology [M.I.T.] we receive about 450 disclosures per year), there will not be enough resources to perform a market research study on every one. In addition, there may not be enough time for such a study before publication (particularly in academic institutions with a policy against delaying publication for patenting or other commercial reasons). The requirement for confidentiality before patenting also limits the depth of any market research study.

Finally, it must be realized that the more innovative the invention, the harder it is to get good market feedback. Potential users of new technology cannot easily judge the value of something they have never thought about before. Business histories are replete with gross underestimations of the potential of innovative products (for example, photocopy machines and home computers). Innovative inventions from basic research in universities should expect to suffer similar challenges.

So what is a technology licensing office to do?

Below are some questions to consider. They will be answered, for the most part, through discussions with the inventors, some library work perhaps, some discussions with potential users or investors maybe, and the experience and judgment of the technology transfer staff.

2.1.1 *The market*

It will be important to try to answer these questions about what the market for the invention might be:

- What need does this invention satisfy? Is this a major, well-recognized need or a minor one?
- How is this need being met now? Or is it satisfied at all?
- What size is the market? Huge, large, small, miniscule? (As will be discussed later under pricing, more precision here is not usually needed by the patent holder, although much more precision will be needed by the licensee or investor.)
- Is the market already established, or will it need developing?
- Is this a growing field or a dying one?

2.1.2 *The technology*

The institution will need answers to these questions about the new and existing technology and how to develop the invention:

- How would this technology change how the market presently addresses the need?
- Is the new technology not only different from what is already available, but better? If better, what are the major benefits it offers?
- How certain is it that the technology will work? Can this be demonstrated to a potential licensee or investor?
- How long and how much money will it take to develop the invention into a commercial product?

2.1.3 *Likely degree of patent protection*

Answering the following questions will help decision makers determine whether obtaining a patent is worth the expense:

- Did the prior art search (or what is known about the state of the science) indicate that broad claims are likely?
- Is the invention at such an early stage in product development that the patent will expire before products reach the market? (Sadly, many have seen their patents expire just as the market began rapid growth.)
- Is the field moving so quickly that patents are irrelevant? By the time the patent issues, will the invention be obsolete? (This is not uncommon for software patents in the United States.)
- Can practice under the patent be detected, thus allowing for patent enforcement against infringers? (It may be impractical to enforce the patent if the manufacturing method is simple and requires no special materials, and the invention is not evident in the final product.)

2.1.4 *The inventor*

Inventor participation in the development of university-stage technology is usually critical. The inventor is most familiar with the technology and is most likely to have a vision for its use. Some inventors (particularly students or research associates) may wish to leave the research institution and join (or help form) a company. Most professors or senior researchers, however, will probably choose to stay at the research institution, although they may consult or work part time for the company developing the invention.

On the other hand, if the inventor has no interest in seeing the technology developed and will not help to market the patent, these tasks can be hopeless.

The following questions should be considered to decide how effective the inventor might be in finding a licensee or investor for the technology. As we shall see, not all of the findings should be documented!

- Is the invention in the inventor's major field of research? If not, is he or she at all familiar with the market's needs for the invention?
- Does the inventor have business connections in the field of the invention?
- Is the inventor famous? (It's a lot easier to market a patent with a Nobel Laureate's name!)
- Will the inventor be cooperative in meeting with potential licensees or investors to share his or her vision of the invention's potential and the means of developing it?
- Does the inventor have realistic expectations about the magnitude and uncertainty of the development task and the potential financial returns?
- Can relationships with investors or companies proceed reasonably or is the inventor too naïve or overly paranoid?

2.1.5 *Social responsibility*

In terms of public policy, patents are two-edged swords. They can protect investments very effectively. Moreover, the licensing of university patents has been shown to stimulate much earlier investment than the placement of inventions in the public domain. They can also bring much-needed revenue to research institutions (although the revenue potential of university-stage inventions has been much exaggerated). On the other hand, patents can limit investment in new technologies when the patent holder (or exclusive licensee) does not invest in all of the fields that can use the patented technology. Patents can also sometimes be used to maintain high prices on necessary products by excluding competition.

As a side note, patents are particularly paradoxical in the development and distribution of drugs and vaccines for diseases in developing countries.[1] Indeed, if effective drugs and vaccines for all diseases in developing countries existed and could be manufactured at low cost, a social philanthropist might wish that no patents existed, since in theory the absence of patents would allow competition, leading to lower prices and wider availability. But in the absence of effective drugs and vaccines, patents may be necessary to ensure profits for pharmaceutical companies, thus encouraging commercial investment in the research, development, and clinical testing of new drugs and vaccines. This paradox puts a special burden on technology transfer professionals. When licensing health- and agriculture-related patents from nonprofit research institutions, technology transfer professionals must try to patent strategically to protect profits in developed countries and encourage commercial research and development. At the same time, they must use mechanisms to assure that the poor can access the final products.

When deciding whether patenting a new invention is in the public interest, the following issues, among many others, should be considered:

- Is this technology self-evidently useful without substantial further investment in development? Will it be widely used even if it is not patented but put in the public domain?
- If the answer to the previous questions is yes, can the patent-holding institution nonetheless devise a nonexclusive licensing strategy that allows revenue to be generated without impeding the use of the technology?
- If the technology requires substantial high-risk investment, and therefore patenting and exclusive licensing is warranted, should patents be foregone in developing countries to encourage generic competition? (This approach is reasonable, under some circumstances, for health and agricultural patents.)
- Can the patent holder require sublicensing of other mechanisms to promote low-cost manufacture and distribution in the public sector of developing countries?
- If the drug or vaccine is expected to be used only in developing countries, with little or no market in developed countries, will market aggregation through patenting and limited licenses create a sufficiently profitable market that will encourage development and clinical testing?
- Should the patent holder carve out free use of a patented research tool for nonprofit research institutions?

2.1.6 *Local considerations*

The decision to patent depends, to some extent, on the institution and its geographic location. For example:

- In under-developed regions (of both developed and developing countries), technologies well-suited to local industry and the technology skills of the region, especially, may be promoted to create jobs and strengthen the local economy.
- Public institutions, more than private institutions, may emphasize technologies that will enhance local economic development—particularly if technology transfer is one of the metrics that legislators use to decide how generously to fund a given institution.
- Medical institutions may decide to patent a product with a relatively small market, because of the potential benefit to patients.

In all, this set of challenges is formidable. For any given invention, most of the answers will be guesses at best; still, these should be *educated guesses*, and the judgment of the technology licensing office may be all that is available. Both the technology licensing office and, even more importantly, the senior administration of the institution must realize that a decision to file a patent is a decision to take a risk. Patents are expensive, and patent budgets are limited. Nonetheless, decision makers must realize that although it is easier to say no than yes, the sin of *omission*—not filing a patent on a technology that later becomes important—may be worse

than the sin of *commission*, the filing of a patent that is never licensed. Decision makers should consider that if the requirements for patenting are too stringent, then only a few of the inventions submitted to the technology licensing office will be accepted for patenting. This will be discouraging to researchers and will result in fewer inventions reported in subsequent years.

2.2 *Decision # 2: Whether to market the invention to existing companies or license to a spinout*

Licensing to an existing company has many advantages over licensing to a spinout (a new company specifically formed to develop the licensed technology). An existing company already has its infrastructure in place, including management. The company usually has sufficient funds to develop the invention, and its financial health often can be readily assessed. The company also usually has distribution channels, and its brand name and market access will make final distribution of the product easier and more effective. From the research institution's point of view, the license agreement is much easier than spinout agreements, and potential conflicts of interest are far less likely.

This is not to say that licensing to an existing company has no difficulties and disadvantages. For one, it is difficult to get the attention of an existing company (particularly a large one) with new but unproven inventions. Existing companies have already set their research agenda and priorities, and a new technology needing development could cause disruption. It is also difficult to find within a large company a "champion" who will enthusiastically support a new technology that is not his or her own when it runs into the inevitable problems in development.

The single biggest disadvantage of licensing to an existing company is the risk that the company will lose interest in the technology, or, perhaps worse in the case of an exclusive license, that it will retain some interest in the invention but that the project will be given less priority and inadequate resources. When things do go wrong, it is often difficult for large companies to identify the right person to provide information or to negotiate a change in the license agreement.

The advantages and disadvantages of licensing to a spinout are almost the reverse of those for licensing to an existing company. At the beginning, at least, the spinout will be dedicated to developing the invention as its first priority. It will also usually be working very closely with one or more of the inventors; moreover, the research institution itself knows the people involved. The financial arrangements of the license may include both shares of stock and royalties, giving somewhat more assurance that the institution will get at least some return from its license. And, if the company's strategy does diverge from the original technology (or the technology doesn't work), although there will not be any royalties on the patent, the equity shares may become liquid and reward the research institution for its role in starting the company.

Spinout companies represent a substantial risk of conflict of interest, which can be on the part of the inventor/researcher or on the part of the institution itself. Frequently, both the inventors and the institution will own stock in the company. This can lead to an unhealthy interest in the company's fortunes—the parties involved may encourage the institution to make concessions on future IP, to sequester data from publication, or to misuse institutional resources or staff time. The situation is exacerbated if the institution also invests its own funds in the company. Thus, research institutions need well-crafted and well-enforced conflict of interest policies if they plan to engage in spinning out companies around their technologies.

Spinout companies are also fragile. They must find management talent and raise investment money. They are highly dependent on the talent of the management team, and a bad hire can set the company back for a year or more. A spinout company often has difficulty in marketing and developing distribution channels. In hard economic times, further investment may be very difficult to attract, and the research institution's equity shares may become valueless due to a down round of investment or a low-price sale to an acquiring company, made in desperation. And, because of the complexity of equity investments, the technology transfer agreement is likely to be

considerably more difficult to negotiate than a conventional license.

The advantages and disadvantages of conventional licenses and spinouts will be different for different inventions. A spinout may be preferred when the following criteria are met:

- The invention is a ***platform technology*** that may lead to not just one but many products. It is difficult to justify the risk of a spinout when only a single product is envisioned. Also, a spinout company is more likely to try to exploit the full range of potential applications of the technology, while an established company will more likely focus on a single addition to its existing product line.
- There is no existing industry making similar products. It is difficult for a new company to compete in an established market unless the technology is overwhelmingly superior.
- The market is large enough to justify the risk. This is particularly true for technology requiring substantial investment in development. Since the failure rate of spinouts is often high, investors expect a very large return on their investments from the winners. A small market, therefore, will not be sufficient.
- Strong intellectual property (IP) protection exists in the country in which the spinout exists and/or in the major markets to which it intends to export. Patents are the primary protection for small companies against larger companies that enter a market after a technology is proven successful. Without them, the market strength of a large company that is the second to enter the market can overpower the innovating small company.
- At least one credible inventor will join the company as founder, consultant, and/or employee (the most important criterion). Without this ***human technology transfer,*** it will be almost impossible to raise investment money and much more difficult to develop the technology.

In reality, the choice between a conventional license and a spinout often is made for the technology transfer office. If the inventor is not interested in contributing to the spinout, it is unlikely to be successful. On the other hand, if the inventor wants to form a spinout and there are no clear reasons why this is impractical, then it is not advisable for the technology transfer office to "take the baby from its parent" and give the job to an existing company. Such an act would likely cause political problems in the research institution and could also discourage future inventors from reporting their inventions.

2.3 *Decision #3: What to charge for the invention*

Although research institutions may engage in technology transfer primarily for social benefit, most nonetheless expect to reap a reasonable financial return from those licenses. The company expects to make a profit from the product with the proviso that concessionary terms may be appropriate for critical public goods where the markets are small, or the ability to pay is very limited.

Under the usual (profit sector) conditions, how does a technology transfer office decide what is a reasonable return from licensing a particular invention? Unfortunately, all too many technology licensing offices spend far too much time trying to evaluate the total *value* of embryonic inventions in some supposedly scientific manner. Calculators are kept running on Net Present Value calculations and other more abstruse formulae, when the major inputs to the formulae—cost of developing the technology, cost of manufacture, the market adoption cycle, and the ultimate market size—are all unknown and cannot even be reasonably estimated. Thus, the calculations often fulfill the "garbage in/garbage out" axiom, producing largely meaningless results.

Fortunately, technology transfer offices are almost never asked (or able) to sell a technology outright for a single lump sum. (Few companies or investors would be willing to pay any substantial sum up front for unproven technologies even if the research institution was willing to make the offer.) Thus, the full worth of an invention need not be calculated at the time the technology is transferred. License agreements and spinout agreements share the risk of this uncertainty between

the research institution and the company through a combination of payments, some at the beginning of the license and others later, depending on future sales or the company's future success.

In a ***conventional license to a company***, the financial components of the license may include (among possible other terms, such as sublicensing fees):

- a license issue fee: a negotiated amount payable at the time the license is executed
- license maintenance fees: annual fees, usually creditable against royalties in any year where royalties are payable (Thus, the license maintenance fees function as "minimum royalties" in years when the product is sold.)
- patent cost reimbursement: almost always required by universities
- milestone fees: usually applied only when the technology is very risky and requires significant investment (Meeting a milestone—such as approval for clinical testing or regulatory approval for sale—validates the technology, allowing the research institution to expect more rewards after the relatively low initial license fees.)
- running royalties: usually a percentage of sales (Major value is expected here, but it is contingent on the technology's success and on the market's acceptance of the product.)

In a ***license to a spinout company***[2], the financial components may include:

- a license issue fee
- license maintenance fees
- patent cost reimbursement
- milestone fees
- running royalties
- shares of stock (in other words, equity) in the company

Shares of stock may or may not be the major source of return for the research institution. Equity in the company is certainly the riskiest component for the institution. In harsh economic climates, the company may have a difficult time reaching liquidity (that is, public stock trading status or acquisition by a larger company). In addition, if the company has to raise more money later from investors and its progress-to-date has not been good (or the economic climate for investment is bad), the company may have to accept funding in a "down round investment" that makes the initial stock almost worthless.

If both running royalties and stock are taken, then each is usually lower than if the deal were "pure cash" or "pure equity." In addition, license fees are usually lower than from a large company, since a new company will typically be cash poor and will need to use its cash to develop the technology.

The main point for both conventional licenses and spinouts is that if the technology is successful the major financial returns will be from license fees and/or equity. With both conventional licenses and spinouts, the returns are linear. That is, once a running royalty rate is set (for example, 4% of net sales), then the formula will make "appropriate returns" regardless of whether the sales of the final product are US$100,000 per year or US$100 million per year:

- If the sales are only US$100,000 per year, then the company pays the research institution only US$4,000 per year; a small but fair number, since the sales have not been high.
- If the sales are US$100 million per year, then the research institution receives US$4 million per year, reflecting the large success of the product.

Similarly, if the research institution takes 100,000 shares of founders stock from a total of one million shares of founders stock issued, representing 10% of the company, in exchange for the technology (the total number of shares, one million in this case, is totally arbitrary: the percentage of the total is what counts), then:

- If the share price at liquidity is US$50 per share (reflecting a successful company), then the university will receive US$5 million.
- If the share price is low, reflecting a "desperation acquisition" price of only US$0.50 per share, then the research institution will get only US$5,000. (This is not unheard of.)

It is worth reiterating that the research institution does not need to know the total value of the technology at the time of licensing/spinning out, because the linearity of running royalties and/or equity determines the amount the institution will receive. The acquiring company (or spinout), however, must have a much better estimate of the final value of the technology and of the cost of developing it, since the spinout must balance the cost and risk of developing the product within the market against expected sales and profit returns. Fortunately, industrial concerns and financial investors have better resources for making these estimates.

3. SO, WHAT ARE THE NUMBERS?

This section is a risky one to both write and read. People often ask for numbers, but the problem is that there are no *typical* numbers, because there are no *typical* deals; each one is unique. The section does, however, attempt to provide some guidance on numbers. Those presented here are all based on personal experience with U.S. and U.K. institutions and all depend on the following:

- the importance of the technology to the final product
- the type of product
- the uniqueness of the technology and the final product
- the typical profitability of that type of product and/or the industrial sector
- whether the IP is the key IP for the company or only a small piece of its holdings
- the strength and breadth of the IP
- whether the IP includes:
  - only present patent rights
  - additional know-how for which the research institution can command return (most know-how is in the public domain)
  - a "pipeline" to future technology and patents from the research institution (a dangerous precedent if the pipeline is too wide)
- whether the company will have to license blocking patents from third parties
- the state of development of the technology
- how much and how long it will take to develop it
- the cost of development in the country in which the company resides
- the state of the economy—including the state of the stock market and the investment climate in both the country of origin and, if different, the country of the licensee
- the negotiating power of the research institution relative to the company
- the negotiating skill of the research institution

The amount of equity the university gets will depend on all of the above variables, as well as on the extent to which the research institution "incubated" the technology and spinout company before the technology left the institution. For example, the amount (or percent) of equity will be lower if the university merely licenses the academic-stage invention to a newly incorporated company and higher if the university invests in showing proof of practical concept or in developing a prototype of the final product. The level of equity will be highest if the university assists in forming the company itself, devising and writing the business plan, hiring the management team, helping the company raise money, and even allowing the company to be housed in the laboratories of the research institution for the company's first year or two of life.

With those caveats, the typical ranges are given in Box 1 for license fees and royalties for a conventional license, based on U.S. experience, with the further caveat that some deals fall outside of these ranges.

4. CONCLUSION

The task of evaluating and pricing early-stage technology is more art than science. (This is true for negotiation too.) Success requires a general knowledge of product development, manufacture, and markets, plus knowledge of the pricing for comparable technologies (when the information is available), plus experience. Technology transfer offices primarily learn from their own experiences and by studying the

experiences of similar institutions. If the offices can attract and retain both talented staff and commitment from their administration, they will get better with time.

No deal will be perfect. Some will fail. It is important to remember, however, that it is far better to conclude a deal with a company that will competently develop the product than to wait for the *best deal* or to fight interminably for the best financial terms. Only when the technology is developed and brought to market will the public benefit. And that is ultimately why universities and their technology licensing offices are in business. ■

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1 See also in this *Handbook*, chapter 1.4 by L Nelsen and A Krattiger.

2 See also in this *Handbook*, chapter 13.1 by A Brown and J Soderstrom.

Box 1: M.I.T.'s License Fees and Royalties

(U.S. dollars)

Conventional license (without equity)

- License Issue Fee: $10,000–$200,000
- Annual license fee (minimum royalties): $20,000–$200,000 (often beginning low and increasing by year until the amount reaches a plateau)
- Milestones (when present): $50,000–$1,000,000 (the latter when Food and Drug Administration approval for marketing is gained for a major drug)
- Running Royalties: 0.5%–7% (the lower range for process improvements or commodity products; the higher range for noncommodity products and patents with product claims) This may be still higher for software and for composition of matter patents on drugs.

Based on U.S. and U.K. experience, the following division of equity is typical for a spinout after it has raised $1 million in investment. It assumes lower license fees and royalties:

Spinout Company Equity Shares After $1 Million of Investment

Venture investor:	33%
Research institution's share based on IP alone:	5%–7%
(If) Research institution does extensive incubation:	10%–15%
Research institution total:	15%–22%
Employee stock option pool:	20%
Founding entrepreneurial team:	25%–32%

If no incubation was provided by the research institution, then the entrepreneurial team's share may be 40%–45%.

Technology Valuation: An Introduction

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ABSTRACT

This chapter explains the basics of the various ways of estimating value of a new technology, focusing on the importance of agreeing on the value before finalizing a technology transfer deal. Indeed, value is simply the negotiated amount arrived at between two parties. Although there are many ways to place a value on a technology, most licensing deals focus on royalty amount, since it spreads the risk between the technology provider and the developer. The percentage assigned to royalty has to be negotiated. Several factors will affect royalty value: level of market demand, the improvement the technology can bring to the final product, whether or not other investments will be needed to develop the final product, and, most importantly, the predicted rate of uptake in the marketplace. Some understanding of these factors, or at least the procedures used to estimate them, will enhance one's ability to negotiate a deal that will both help bring the technology to market and nurture the relationship between the parties, thus facilitating any future technology transfer deals.

1. INTRODUCTION

What is *value* and what are *valuation techniques*? Value is what a willing buyer and a willing seller have agreed upon as the basis for the exchange of property or, in our case, intellectual property (IP) rights. The critical point is finding a particular value that is agreeable to both the buyer and the seller. The first task, and the most difficult one, is assigning realistic values (that the partners can agree on) to the various factors in the system. Simply put, valuation is the process of estimating a mutually agreed upon value for a product or an intellectual property that will enable its transfer from seller to buyer. People use many techniques to reach this value. A perfect valuation scenario would be one where both the buyer and seller walk away each thinking it got the best deal.

Although we may not realize it, we use valuation techniques every day. For example, an individual might not hesitate to pay US$6 for a hamburger, but would certainly *not* be willing to pay US$50 for the burger. This is because we perceive the value of a burger to be within a limited range. The benefits we derive from a burger are not expected to cost more than the money we are willing to spend; otherwise, one will eat elsewhere. From the buyer's point of view, the cost, benefit, and competing alternatives determine what we will pay, and, therefore, determine a value. That value will change depending on where we are, how hungry we are, and how far the nearest better alternative is. From the seller's point of view, the questions are: How much can I charge for the burger? What is the demand for my burgers? How many different alternatives are there? How is my product distinct and superior to the alternatives?

This chapter provides background knowledge on technology valuation that is particularly relevant to IP rights in agriculture. The chapter aims to heighten readers' awareness of the important

Potter RH. 2007. Technology Valuation: An Introduction. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

issues and methods involved in technology valuation when negotiating the sale of rights to a new technology as well as in other circumstances.

2. VALUATION OF INTELLECTUAL PROPERTY

Much energy has been spent determining methods for valuing intellectual property, technology, or products. All available approaches require different amounts of data and serve different purposes (limitations are inherent regardless of the approach taken). A brief overview of the most common approaches to technology valuation is provided in this chapter. More detailed discussions are found elsewhere in the *Handbook*.[1]

The valuation of intellectual property tends to be very complex, since the task of valuation involves determining the present value against a future technology or product. Various methods have been developed that use greater or lesser amounts of economic theory. In the end, as the value will usually be a negotiated figure, what is most important is to find a method that both parties agree will produce a value they can accept.

The most common method of valuation is a process of *discounted cash flow*, which calculates the present value of future revenues. *Present value* reflects the price a purchaser of the intellectual property is willing to pay now, in order to receive anticipated cash from future sales of the product. Different variables and factors can be built into this, such as the risk of the technology not delivering promised returns, but obviously it is hard to accurately estimate the future cash flows from intellectual property or from an undeveloped, untested technology. The closer one comes to a final product, the more realistic will be the estimate of future cash flow. Waiting until near the end of product development to negotiate royalties can, however, give rise to serious problems in reaching a negotiated settlement.

Most valuation models rely on market data, which, at best, can provide only a range of probable values. For a revolutionary new product, direct market data is often unavailable and *proxies* (or existing products on the market) are used as substitutes. The complexity of valuation arises from the challenge of identifying useful, appropriate proxies. The more appropriate data one uses, the more accurate the valuation will be.

Furthermore, the individual and specific value of assets will vary widely. Understanding how these specific values are statistically distributed will greatly help estimating value, since including a probability of receiving a specified return aids decision making. Wherever an individual component has a range of possible values, knowing the statistical distribution over this range can make the overall valuation more accurate and also allow one to estimate the probability that this value will actually be achieved.

The following sections identify several valuation approaches and provide a short explanation of each. To illustrate this, each approach is explained with reference to a fictional, ongoing negotiation, between the University of Costa Rica and Mer Seeds SA de CV, over a commercial-use license for a root-rot-resistant gene isolated at the university. The gene has been transferred into a line of a root crop called mer, which Mer Seeds intends to cross with their elite breeding lines.

2.1 *Cost approach*

The cost approach is based on covering costs of developing a new product. Using this approach, the University of Costa Rica would seek to charge a one-time fee to cover all research and possible patenting costs for isolating the gene and producing the transgenic root-rot-resistant mer. While this approach is a highly relevant one for pricing an article produced for sale, the approach is rarely used to assign a value to a piece of intellectual property, because the cost to develop something is not usually related to the value of any intellectual property it contains. One version of the approach is to calculate anticipated future costs of developing similar technologies—in effect, using the proceeds from the sale of this technology to pay for developing the next one. This approach, however, is highly subjective and difficult to justify.

Still, knowing the cost of development of a particular technology is often useful and relevant when calculating the relative inputs of parties into a joint venture. If, instead of licensing a technology, an institution enters into a joint

venture to develop a product, initial investments into the joint venture often control the share assigned to each party. A university or research institution may not have adequate financial resources to develop a product from a technology, but the institution could justifiably claim a share of a joint venture based on the investment in the project up to that point, as well as the product's potential value.

2.2 *Income approach*

A *pure income* approach is carried out by discounting future anticipated revenues (cash flows) several years into the future. In our scenario, this approach is used when the University of Costa Rica asks Mer Seeds SA de CV how much it would be willing to pay now for a certain return in the future (for example, US$10 million in 10 years time). The big drawback to this approach is that there may be no sales, market, or cost data from which to predict future revenues. Furthermore, the method relies heavily on allocation of risk: determining what the chances are of a disappointing return (or even of no return at all) and who should take this risk, the university or the company? Risk estimates are crucial for determining whether to invest in a new technology, but they are too often based on little more than gut feeling.

2.3 *Market approach*

The market approach requires finding a similar or comparable technology to the one being evaluated. In our scenario, the University of Costa Rica would look for other root-rot-resistant mer plants on the market and determine how much farmers are using and paying for the seed. So, the valuation would rely on finding sufficient data about similar transactions to arrive at an accurate estimate of the value of the new product. The inherent weakness of this approach is the difficulty of obtaining data for a truly novel product.

2.4 *Hybrid approaches*

The more common approach is to use a hybrid of income and market methods of valuation. This combines the benefits of market comparability and the business community's familiarity with the income approach. In our example, Mer SA de CV would use its experience with similar products to estimate what farmers would pay and how quickly the market for the seed would grow to produce the estimated income. This method is usually applicable where there is prior experience and sufficient information. Where products are being developed in-house (for example, in a large company that performs all or most of the research and development), calculating the net present value of a new product is based on this hybrid method. Decisions on funding products are made by estimating a certain minimum net present value.

2.5 *Royalty rate method*

Because royalties give the inventor a return on sales of the final product, royalties are often used to share the risk between the inventor and the developer. Parties often use a royalty rate that has been agreed upon in the past for similar technologies; that rate is then applied to anticipated revenue streams. Because of the risk-sharing nature of this method (if the product does not become a success, the royalty amount is low), this is a common approach to licensing technology. But the approach does not always result in a valuation of the technology itself. Indeed, royalty rates are often determined arbitrarily, with little or no relation to the added value the technology may give to the product. For example, in our scenario, if an initial collaborative research agreement between the University of Costa Rica and Mer Seeds limits the university to a maximum royalty of 5% of gross revenues, then, if the technology increases the value of Mer seed products by more than that, the university loses. Another problem with arbitrarily applying royalty rates, in this case, is that if Mer Seeds were to combine several traits in one variety, then the company might be unable to afford to pay 5% royalties to each technology provider if the combined added value was insufficient.

3. THE PRODUCTION SYSTEM

To accurately value a new technology, the existing production system must be understood in order to see where the new technology will be applied. While agricultural systems vary due to climate

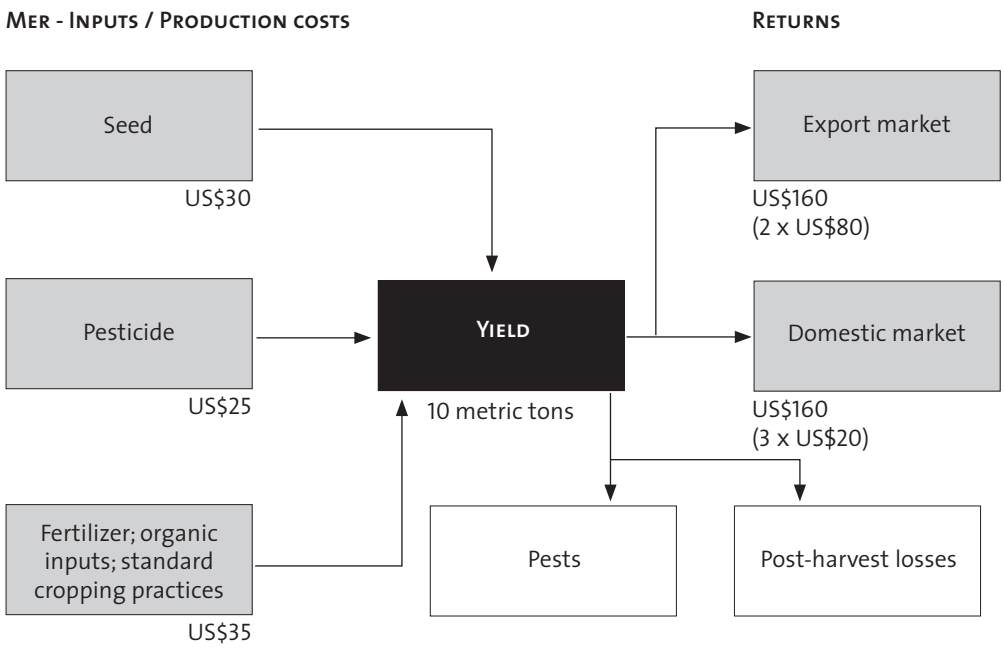
and local soil conditions, data do exist on input (costs) and output (benefits)—as in any field. Because of the complex interrelationships among agricultural markets, competition is hard to estimate, but data does exist upon which to base assumptions. As modern agricultural products rely more and more on biotechnology, a relatively new field, for which there is little information and substantial risk that there will be no product at all, valuation becomes more difficult. To illustrate the complexities of agricultural systems, we use an input/output or cost/benefit model based on the harvest of mer (see Figure 1).

The diagram depicts average returns per hectare of mer in Latin America. Input costs, such as for seed, fertilizer, and pesticide, have been derived by converting to U.S. dollars from the average costs in Latin America of those items. Similarly, yield in metric tons (MT) was calculated by taking conservative yield figures and deducting average post-harvest and pest losses to arrive at the final yield per hectare for the average mer farmer. Returns are divided between those from mer that is consumed domestically (Domestic) and those from mer that is exported (Export). On the basis of this model, production costs are US$90 and returns are US$220. A new product that reduces inputs (pesticides, in this case, of root-rot-resistant mer) can be calculated to increase returns by the amount that the pesticides cost.

4. VALUING IP RESOURCES

Sometimes, all of the IP resources of a company or institution need to be valued. Valuing these resources can provide a value for the whole company, including its intellectual property and physical resources, or it can reveal the input a company is investing in to developing a product, excluding

Figure 1: Hypothetical Cost/Income Model for Mer Production in Latin America



Note: The online version of the *Handbook* (www.ipHandbook.org) contains a downloadable Microsoft® Excel spreadsheet, which readers can use for modeling cost/income scenarios.

the technology that is being negotiated. In our hyphothetical example, Mer Seeds can point to the intellectual property that it already owns, for example, existing mer varieties, to show that the company is investing significant resources into developing the new product and also to show that the gene being obtained from the university will be worth only a portion of the total added value. Knowing such figures is relevant for joint venture negotiations.

One complication in these calculations is the need to value nonformal intellectual property: the know-how, experience, and expertise that reside in the company, and in its employees, and that may not be protected by patents and trademarks. Institutions that consider only the value of formal intellectual property stand to lose from overlooking this form of intellectual property.

4.1 *Excess earnings/residual value*

The excess earning/residual value approach places a valuation on an entire business, rather than a single technology. The approach is appropriate only if a company has just one major-platform technology and its business is based purely on products related to that technology. Using a period of five or more years immediately prior to the valuation date, a percentage return is assigned to the average annual value of tangible assets used in a business. This return is deducted from average earnings of the business for the same period, and the remainder, if any, is considered to be the amount of the average annual earnings from the intangible assets of the business. Since this method is based on past data, it is not necessarily useful for valuing a novel technology, but it may be used to value a company's existing technologies. which will allow for the determination of how much of an input one side is making in a negotiation. For example, Mer Seeds could use this method to value its existing germplasm in order to show that the varieties coming out of the transgenic project are just as much due to their germplasm as to the transgene. The main flaw in this model, however, is the assumption that excess earnings above and beyond the return on tangible assets are solely attributable to intangible assets. Such thinking can lead to an error in valuation because it assumes that the business is maximizing the exploitation of all of its intellectual property.

4.2 *Technology factor method*

The *technology factor method* is a modification of the income or excess earnings approaches that addresses the shortcomings of these approaches by directly measuring the contribution of the technology to the total revenue of the business. The technology factor method can be used on one technology at a time to eliminate the limitations of the excess earnings method, in which the whole set of intangibles are valued and lumped together. The technology factor method might be applicable to Mer SA de CV if it sold many more agricultural products than just mer seeds and if most of these products had a relatively low technology input (for example, if the company distributed many agricultural chemicals produced by large multinational corporations). In this case, an overall picture would not give the true worth of the value of the company's germplasm.

4.3 *Options pricing method*

The *options pricing method* estimates the value of the technology at the point it is considered to be successful and then calculates the probability of its preliminary successes along the path to commercialization. In the root-rot-resistant mer example, basic research has already been done, but there are still the possibilities that the technology will not work in the field, that farmers will not be prepared to buy it, or that a competitor will offer a better product (such as a very cheap fungicide). It is also possible that transgenic mer will not be approved for biosafety or food safety reasons. The probability of success at each step in the process is very hard to calculate, but with each step, the value of the technology effectively rises as the risk of failure diminishes. To use this model for early estimates of value, the technology must be well defined and the statistical analyses of historical data must be significant enough to allow the appraiser to assign probabilities to the technology as it proceeds from one step to the next. This method is applicable to start-up companies during their initial rounds of financing, and also for companies developing high-risk technologies, such as pharmaceuticals.

4.4 *Technology risk/rewards method*

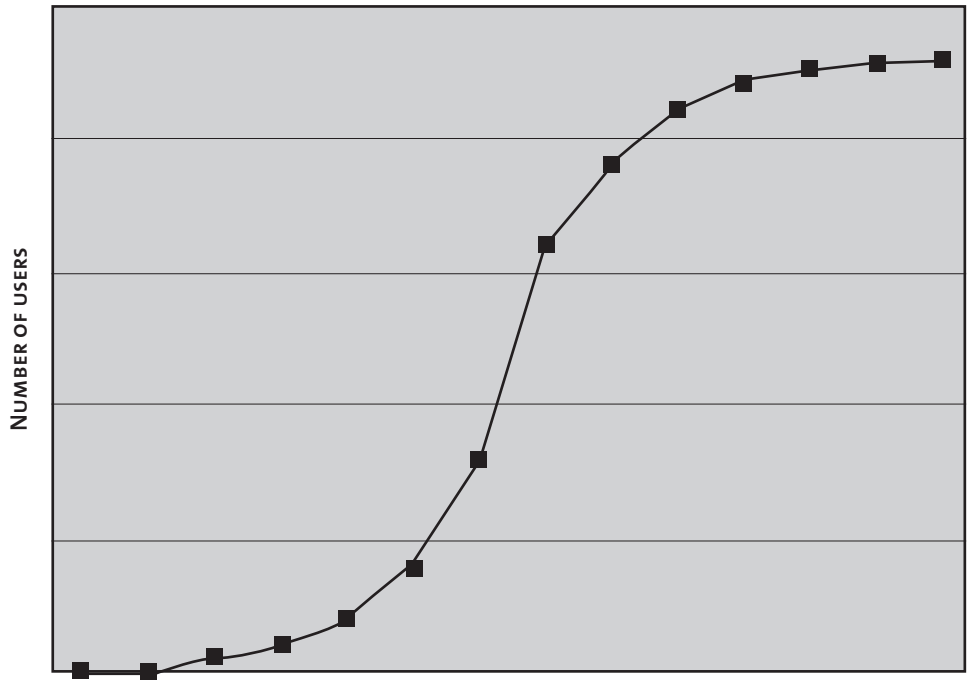
The *technology risk/rewards method* uses the value of roughly comparable technology-based businesses as a proxy for the value of patents, and then subtracts from this number the amount of cash needed to further develop the technology to a commercial stage. Thus, Mer SA de CV would first calculate the value the company could gain from the technology and then look at the investment needed to bring the technology to market. Using this number, the company would decide whether to commercialize the product and whether paying the University of Costa Rica could be afforded. One drawback of this method is the assumption that the value of technology-based companies reflects only the value of the technology, which ignores many other factors.

5. ADOPTION

One very important factor in determining the market value of a product is how much of the product is sold or used and at what rate demand for the product develops and increases. A product's success depends not just on the number of people who try it once, but on the number of repeat users. This is referred to as the *adoption process*, in which a product goes from being new in the marketplace to being an established product (or, in some cases, obsolete).

Figure 2 is a generalized adoption curve for a hypothetical new technology or product. Importantly, the rate at which a product is taken up has a great effect on the revenue that goes to the developer of the product. In this case, as often happens, initial uptake is low, and adoption grows slowly as people become aware of the product, try it out, and use it. Early adopters show the product's potential value, and gradually other consumers begin to use it. As more users see the benefits, the product spreads throughout the market. When the new product approaches full market penetration, the rate of uptake slows—there are always people who are either very late

Figure 2: Generalized Adoption Curve For a New Product



in adopting or will never adopt the product. At some point other competing products may enter the market and reduce market share, or newer technologies may arise that replace the product completely. The actual curve, therefore, will be more complex than Figure 2 suggests.

In reality, farmers are likely to be wary of initially investing heavily in an agricultural product, such as a new seed variety. Some will try it out on part of their land and, if they feel it is worth the investment, they might then plant more of the seed. Other farmers may see this and decide to try out the seed themselves. Once a certain amount of the seed is being grown, the adoption rate will increase. However, there will almost always be some farmers who will either delay adoption or not adopt at all, because they prefer traditional methods, are unwilling to change, or perhaps because their land is of such poor quality that the increased yield does not cover the increased price.

Calculating the value of a product by making sales projections (the income approach) must, therefore, consider not just the total area of land on which a seed could be used, but also include a realistic sense of the rate at which the coverage area will expand to reach the total. Meanwhile, as other products will also likely become available, the original product will be unlikely to retain its area indefinitely.

6. CONCLUDING REMARKS

As the discussions above indicate, no universal method for technology valuation exists. In fact, different methods will often be used within one organization. The method chosen depends on the kind of technology in question and whether one is a technology buyer or a technology seller. In the end, however, what most matters is the accuracy of the estimations and assumptions about whether a product will be a success and how much people will pay for it. Estimating the size of the potential market and the adoption rate for the product are both important in this process.

Negotiating is a big part of arriving at a value for your technology, but remember that developing intellectual property into commercial products through in-licensing and out-licensing is not a zero-sum game. Both buyer and seller are looking to get something good out of the deal. And these are the much-sought win-win deals. ■

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1 See, also in this *Handbook*, chapter 9.3 by R Razgaitis.

Pricing the Intellectual Property of Early-Stage Technologies: A Primer of Basic Valuation Tools and Considerations

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ABSTRACT

This chapter introduces technology managers to certain key issues and to six methods of valuation and pricing. The value of a technology to a buyer (licensee) depends upon how it is to be commercially employed, taking into account the cost of development, the time the technology takes to generate returns, the extent of such financial returns, and the risk involved in the process. At the time of a licensing/sale transaction of an early-stage technology many, perhaps all, of such factors need to be assessed and quantified by making judgments about how the future will unfold with respect to the technology being developed. This assessment and forecast assessment are the essence of all pro forma business models. Valuing license rights for early-stage technologies is in this sense no different than making other future business forecasts, though the details may differ because the forecast time horizon may be longer, the uncertainties may be greater as to the market size and profitability, the operating performance of the technology as it will be used in commercial operation may be less well defined, and other factors. The price paid for a technology transferred between parties is the amount of money (present and future) and/or the financial value of noncash assets given in exchange for the transfer of the technology, which can only occur if both the seller (licensor) and buyer (licensee) have by some process reached a common, present understanding of value that makes agreement possible.

A key consideration in valuing a technology and arriving at a price is determining what is to be provided or transferred between the parties. This may include exclusive or nonexclusive rights to specified patents, know-how, and copyrights (IP [intellectual property] rights), technical data, rights to future-seller improvements, rights to sublicense, and the like. The price can consist of any combination of a variety of types of consideration, including running royalties, fixed payments, common stock (equity), R&D funding, lab equipment, consulting services, grant backs, or access to other proprietary buyer resources.

Although sometimes used, cost-basis pricing is a poor basis of valuation, because it fails to consider a technology's value based on future commercial applications: the market pays for value to be received, not the cost to create. This chapter introduces and explains six methods for valuation and pricing that are based, to one degree or another, on the market's expectation of value.

- Method I: The Use of Industry Standards Method looks at the range of published royalties (and other forms of payment) from technology licenses within an industry category and uses that information to guide valuation of a technology currently under consideration.
- Method II: The Rating/Ranking Method looks at several existing license agreements for similar technologies, comparing and ranking a technology currently under consideration against the existing license agreements in terms of stage of

Razgaitis R. 2007. Pricing the Intellectual Property of Early-Stage Technologies: A Primer of Basic Valuation Tools and Considerations. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (*Second Edition* Part II: Chapter 4).

development, scope of IP protection, market size, profit margins, and other such factors.
- Method III: The Rules of Thumb, such as the 25% Rule (and Other Rules) Method, which apportions anticipated profits from the commercial use of the technology between the seller and buyer.
- Method IV: The Use of Discounted Cash-Flow Analysis with Risk-Adjusted Hurdle Rates Method seeks to split expected returns but adjusts basic profit and loss accounting terms to take into account the timing of investments and returns and the risks borne by both parties. The method introduces a discussion of the different possible structures of payments that are possible, as they affect both timing and risk.
- Method V: The Advanced Tools Method applies statistical methods, such as Monte Carlo simulations, to discounted cash-flow models to test the influence of various value assumptions and license terms on the possible outcomes of a deal.
- Method VI: The Auctions Method allows interested parties to bid on the technology, based upon their own independent efforts at valuing the technology, thus comparing their respective valuations, identifying the highest valuation, and striking a price based on that highest valuation.

PREFACE

Although we will consider each of the valuation methods one at a time, doing so does not suggest that only one method is to be used in any given valuation, nor does having six methods mean that all should be used in every situation. Depending on the circumstances it is likely to be advantageous to consider more than one method in any particular valuation. Yet, not all methods work equally well in all circumstances, and there is always the practical consideration of the commensurate level of valuation analysis appropriate to the magnitude of the potential licensing opportunity.

The context of the valuation and pricing discussed in this chapter and with the valuation methods is licensing (sale) generally known as *opportunity licensing*, as distinct from licensing in litigation contexts. In litigation matters there is normally a very narrow focus on certain claims of certain patents that have been infringed as of a particular date with respect to specified products and which patents are known to be valid, enforceable and infringed. On the other hand, opportunity licensing of early-stage technology is normally performed prior to a licensee's commercial use, includes deal elements other than a narrow enumeration of certain patent claims, and anticipates the potential future use for a range of products, applications, and markets.

This chapter is necessarily a short introduction to a complex subject. The author has written three published books that give a much fuller treatment of these valuation and pricing matters than is possible here. Two of the books are currently in print and available from online sources such as Amazon® and are recommended for those who are charged with valuation and pricing of technology.

- *Valuation and Pricing of Technology-Based Intellectual Property*, Dr. Richard Razgaitis, published by John Wiley & Sons, 2003.
- *Dealmaking Using Real Options and Monte Carlo Analysis*, Dr. Richard Razgaitis, published by John Wiley & Sons, 2003.
- *Early-Stage Technologies: Valuation and Pricing*, Dr. Richard Razgaitis, published by John Wiley & Sons, 1999 (now out of print, and supplanted by the 2003 valuation and pricing book).

Finally, the views expressed here, as in my above writings, are solely those of the author, and are not intended to represent the views of CRA International or that of any professional society of which I am a member or officer.

1. INTRODUCTION

One of the most interesting and challenging tasks facing a licensing manager is determining the value and price of its specific opportunities. This chapter provides an overview of useful tools and methods for this purpose and offers general observations on licensing practices.[1] Because each valuation situation depends on numerous, case-specific factors, such generalizations may not apply universally, so readers are encouraged to be cautious when drawing parallels or imagining similarities.

Pricing, of course, is a crucial issue in the commercialization process. The customer for

early-stage technologies can be viewed as a value-added reseller. Resellers will be induced to buy (license), if and only if they believe that they can conduct all the value-added activities needed and sell the result to *their* customers at a price significantly greater than what they paid to acquire the rights.

When selling rights to early-stage technologies, there are (usually) significant uncertainties facing both the owner of the technologies and the licensee. These uncertainties include important issues such as:

- Does the technology really work in a production setting as opposed to inside a cloistered laboratory?
- What product development and manufacturing activities will need to be conducted—and at what cost—to bring the technology to commercial maturity?
- Will there be any commercially valuable patent protection to bar copycats?
- What product do end users really want from the technology, and how much will they be willing to pay?
- What regulatory requirements will need to be satisfied?
- How much better is this technology than what is already available?
- Will competitors develop an even better way of meeting the end user's needs?

One way to begin to get around the pricing issue is to use royalties. The advantage of the royalty (and equity) concept is that it spreads, to some degree, these uncertainties and risks between the parties. Under a royalty (or equity) arrangement, technologies that ultimately become wildly successful in the marketplace will return high financial rewards to both the licensee and the licensor in some direct proportion to the degree of commercial sales achieved. This helps remove some of the anxiety of determining the right price—but not all of it.

Technologies that lead to highly profitable outcomes for a licensee typically warrant a higher royalty *rate* on behalf of the licensor. Similarly, smaller returns (with all relevant factors considered) warrant a lower rate. By fixing a royalty rate, an equity split, or any combination of royalties and equity, the technology transfer manager is apportioning the total financial reward between the creating organization and the commercializing organization. That split should depend on the relative value-creating contributions of both parties.

Determining a fair royalty depends on a present understanding of the commercial use and economic impact of the licensed technology. From this perspective, it is better, when feasible, to defer setting the royalty rate to the time, or closer to the time, of commercial introduction. When licensing early-stage technology, this means that the license or option agreement would leave the royalty rate unspecified. The parties would commit to engage in good-faith negotiations on this matter at a later date, preferably when a projected income statement based on more robust market and manufacturing projections was available.

But prospective licensees generally look at this approach with disfavor. They argue that the royalty rate is an important factor in reaching a decision about licensing the technology in the first place. Further, the licensees argue that they cannot commit substantial product- and market-development investments and risk facing a carnivorous licensor seeking unreasonable compensation at the eleventh hour. And there are also some good reasons why a technology seller might not prefer to defer royalty negotiations. Depending on the final royalty values, the seller might have elected to pursue a different commercialization approach (taking equity in a spinout or pursuing industry-wide nonexclusive licensing) or to find a different licensee willing to pay more for the opportunity.

Further, if a market window has closed, a reversion of rights back to the seller because of an inability to agree on financial terms may be of little business value. Clearly, it is in the interest of both parties to conduct royalty negotiations based on accurate projections of a license's economic impact. Agreements reached before the impact is known are more likely to be disappointing to either the licensee or licensor. A disappointed licensor will normally not have any

recourse as long as the licensee fulfills its end of the deal. A disappointed licensee, however, can come back to the licensor and threaten to drop the license unless it gets some relief from a royalty rate that the licensee later perceives as too high. The licensor can decline such a request, but it could be put in a difficult bargaining position because of the cost, delay, and risk associated with finding another licensee, and because the term of years remaining under the patents may have been reduced significantly while in the hands of the original licensee. A royalty rate determined well before commercial introduction can thus be viewed as a royalty cap by the buyer, regardless of what is called for in the agreement. Of course, the buyer cannot count on a seller agreeing to such a downward renegotiation in royalty rate; the buyer may face the choice of proceeding to commercialization under the agreed terms, or dropping its license and losing its own investment in the technology.

Parties seeking win-win arrangements should seek ways to make these negotiations as fair as possible, even while each party is looking out for its institution's interests. This requires as much economic information as possible and some tools for using that information. Presented in the sections below are tools and considerations in determining such splits of the commercial reward. To set the stage, consider the following excerpt from an actual letter received by a venture capitalist:

"… *we are asking for Forty Million Dollars ($40,000,000), which will provide the capital needed … . As planned, at the end of the two-year period, we will have ramped up to 100% with an expected pre-tax profit of $211,832,258.*"[2]

Now, is this a good deal? Even more importantly, what methodology could be used that would lead to a fair price for such an opportunity and form the basis for a rational decision?

Although the general principles in this chapter apply to both a licensee (buyer) and a licensor (seller), this chapter primarily looks at these matters from the point of view of the *licensor*. The *form* of an agreement is not detailed in this chapter; many differing approaches as to royalties and equity are possible. This topic is sufficiently complex to warrant coverage in other chapters in this *Handbook*.[3]

2. GETTING STARTED

Prior to delving into this discussion, it is helpful to review the definitions of two key, related terms.[4]

- *value:* an amount considered to be a suitable equivalent for something else
- *price:* the sum of money or goods asked or given for something

In this chapter, *price* will mean the quantification or specification of *value*. Price should be the expression, in monetary and other forms of consideration, of what the technology manager believes is an appropriate starting point for discussions and ultimately represents a fair exchange for the institution's willingness as a licensor to enter into a commercial agreement.

This requires that the technology transfer manager determine, from the outset, what the institution is willing to provide as its end of the bargain. Table 1 summarizes ten *sources* of value, from the perspective of a licensor of early-stage technologies.

Item No. 1 is the key source of value provided by the licensor for a typical early-stage technology agreement—the right to practice the technology described by the intellectual property (IP). The licensor may also provide something within the categories of Item Nos. 2, 3, and 4. Item No. 5 is usually a left-pocket/right-pocket grant: if the licensor agrees to pay the patent costs for the licensee, then the licensee reimburses the licensor for these costs, dollar for dollar.[5]

From the perspective of licensors of early-stage technologies, Item Nos. 6, 7, and 8 are strictly the responsibility of the licensee and are, thereby, *not* part of what is granted. Although the costs associated with these boxes may be small on average, the risks of a very significant cost associated with them on a given deal are both so large, and primarily or solely under the control of the licensee, that it is imprudent for a licensor to bear them (this is discussed in greater detail in Section 6.4).

The last two Items, Nos. 9 and 10, may involve the licensor in some way; most often, however, the licensor will grant only a willingness to assist the licensee in these activities on a cost-reimbursement basis.

Generally, therefore, the licensor of early-stage technologies is offering Item No. 1 and, possibly, Item Nos. 2–4. Within each of these boxes, figuratively speaking, are yet smaller boxes that further define the contents of the grant. For example, in Item No. 1 the license may be exclusive for all fields and territories for all patents in the technology package, for a specific application, for a specific territory, for a specific term (such as five years, after which time the licensor can license others), or exclusive but for one other licensee (a limited exclusivity, sometimes referred to as a second-source approach), and so on in a limitless array of possibilities and combinations. Each of these options will have a different economic value; accordingly, each should bear a different price. Such issues are sometimes referred to as *aspects* of value (see Section 6.2).

As the licensor, a technology transfer manager needs to determine what boxes (and contents thereof) the institution is offering as its package.

Table 1: Ten Sources of Value Relating to IP (Intellectual Property) Rights

1. Rights to practice the technology (patents, trade secrets, copyrights, trademarks)	• IP rights included • Field/territory • Degree of exclusivity • Duration
2. Commercial data	Production drawings, material balances, operating statements, training or technical assistance
3. Future improvements	From licensor, from licensee, from other licensees, rights to, payment(s) for
4. Right to sublicense	Conditions for, split of fees, improvements/grant backs
5. Patent expenses	Maintenance costs, patent prosecution, foreign filing
6. Defense of patents	Oppositions, interferences, declaratory judgment actions, claims of ownership
7. Infringement issues	Studies and opinions, freedom to practice, suits against infringers, suits by third parties
8. General indemnity	Product liability, ownership issues
9. Quality control	Testing, laboratory services, trademark policing
10. Regulatory approval	National regulatory agencies and listings such as the FDA,[a] and EPA,[b] and TSCA[c]

a U.S. Food and Drug Administration
b U.S. Environmental Protection Agency
c Toxic Substances Control Act

It is a very good practice to document the contents of the package in some detail for internal purposes, and perhaps in a more succinct fashion for initial discussions with prospective licensees. For example, part of a licensing package could include product prototypes or customized test or development fixtures, as well as data unpublished or not yet published that provides additional information on potential applications, costs, or areas of potential improvement.

Similarly, the technology professional should document in detail what the institution is seeking from the licensee as fair exchange. Some items to consider in determining this exchange are:

- royalties (often termed *running royalties*)
- other cash payments (an upfront cash payment, progress payments, or annual minimums)
- common stock or partnership interests (as partial or total offset for royalties)
- R&D funding at the institution to advance the technology or other R&D objectives
- lab equipment
- consulting agreement(s)
- improvements to inventions (so-called grant backs)
- access to proprietary and/or technical data related to the invention

There is a long list of sources of consideration that the institution may wish to seek from the licensee. By thinking through these items and writing down those that are desirable from the institution's point of view, the technology transfer manager can develop a rational framework for expectations. From a negotiating perspective, following this process can prevent the institution from being perceived as a nibbler: that is, an organization that is always thinking of something more that it should get for the deal.

3. THE CONTEXT OF PRICING

The seller's pricing expresses belief about value. Such belief arises from considering the innate economic benefit associated with the use of the technology being offered, the competitive alternatives available to a prospective buyer, and an overall negotiation strategy.

As mentioned earlier, there are an unlimited number of combinations that could be agreed to by the licensor and licensee. It is impractical to price all these combinations and offer a price list. Instead, a price is needed for what is considered to be a basic deal that is of interest to the institution and that the technology manager believes will be of interest to a licensee.

In the process of discussing an opportunity with prospective licensees, a licensing professional will learn that there are different items that each licensee wants and different values that each licensee places on what it has to grant (surprisingly, not all companies view money the same way; there can be a big difference between funding R&D and upfront cash, or between upfront cash and royalties, and so on). As new information is learned, the technology transfer manager should be prepared to reenter the pricing methodology and reconsider assumptions and elections. The technology transfer manager will also learn about the competitive alternatives that prospective licensees have use of the institution's technology. At the same time, the manager will analyze the institution's alternatives should the licensee say no.

In a free market, all participants can decide what they think a product is worth and communicate this to others. From this process, the technology transfer manager should be able to learn relevant facts that may cause the price to be reassessed. It should be remembered that participants in a free market do not consider themselves compelled to communicate what is good or undervalued about what the institution has to offer. In most instances, a technology transfer manager will only hear (or primarily hear) the bad news related to a product; some of it may be true, and some may even be relevant.

Negotiating strategy is also important. Although this subject is outside the scope of this chapter, two pricing negotiation-strategy poles illustrate the significance of negotiating strategy:

- **fixed-price seller:** The seller has made a best effort at determining a value that represents what it believes is a fair value to both

parties. This price is its bottom line, and it offers the product to all prospective buyers as a here-it-is, here-is-what-it-costs, take-it-or-leave-it proposition.

- **price maximizing seller:** The seller seeks to identify only those prospective buyers who express interest in the opportunity, which is initially priced at or near the maximum reasonably conceivable value because it is expected to be adjusted downward, perhaps substantially, due to the back and forth of what are likely to be extensive negotiations.

There is, of course, a continuum of perspectives between these polar positions. The fixed price approach (as an idealization), has the appeal of deal simplicity and speed, but may have as its result (a) no buyers and therefore no deal or (b) a deal with a buyer who would have been readily willing to pay more had it just been asked. The price-maximizing approach is really about a seller offering some flexibility on price and deal elements to attract potential buyers to engage in a negotiation that leads to mutual learning. In some respects this second approach could be better described as the deal-probability-maximizing approach because it offers an adjustability of pricing and deal elements not available in the fixed-price approach. However, the initial pricing of this second approach has to be within a range that buyers can conceivably find reasonable; otherwise buyers can be dissuaded from even initiating due diligence. The most important point to remember is that *pricing is a process*, not a one-time event.

4. COST AS A BASIS FOR PRICE

Cost is a very poor basis for pricing, although it is sometimes used. To get a sense of using cost of development as the deal price, consider the following: suppose an institution and its sponsors have invested $10 million in a particular technology that at long last has been determined not to work well enough to be used commercially. What are the chances of going out into the world of commerce and saying: Have I got a bargain. Because this technology doesn't really work, we are not going to ask for any profit. It is yours for only the $10 million we have sunk into it. The market will not value what the institution paid to develop the technology, not because it is unsympathetic to the institution's investment (and plight), but because what is important to the market (the buyer) is the value of the product, not the costs of development. If the product does not work, it has no value. What the institution has invested in its development is gone.

Consider the other extreme: An individual buys a lottery ticket for $1. It turns out to be the sole winning ticket in a $10-million lottery. Now, someone shows up and says: I'll give you $2 for your winning ticket, which will double your money. Is this a good deal? Again, the cost of the lottery ticket is irrelevant in this example. Rather, its worth after selection is what some willing party would pay to gain the benefits of ownership. For all the losing tickets together, no rational buyer would pay even a dime. For the one winning ticket, in this example, a rational buyer would offer millions of dollars, but not more than $10 million.

In the world of manufactured-commodity goods, costs and price are often closely related. Historically, pricing in such circumstances was determined by multiplying the costs of manufacture by an industry-standard multiplier. A typical historic multiplier was simply the factor *2*, so the price would be double the cost of manufacture.[6]

But in the case of high-cerebral content products, such as intellectual property, cost is an inappropriate basis. If Picasso was alive and you approached him to buy a painting, would you ask: What did it cost you to make this painting? Consider another example. The late Sammy Cahn received (it is believed) approximately US$40,000 for granting the producers of the movie, *Die Hard II,* the right to play his song "Let it Snow" in the movie's opening scenes to set the mood for the holiday season. Cahn had sold rights to "Let It Snow" many times. Cahn did not write any new music for the movie; he probably did not even provide the producers a copy of the sheet music. So what did the producers get for their $40,000? They bought merely the right to use something already existing. How was the

$40,000 determined? That is what the two parties dealing at arm's length said it was worth, not an amount based on a person-hours of labor calculation as Cahn's appropriate value for the rights to use the song.

The market pays for value, not cost. In retail software sales, the actual cost of the CD, the manual (if not on the CD), and the packaging is typically less than 10% of the price. Why are software companies seeking and able to sell their products for more than 10 times their costs? The answer again is that it is value, not cost, that the market buys.

Cost, however, does come into play when considering a prospective licensee's alternatives to entering into an agreement. A prospective licensee could seek to develop its own technology by inventing around the institution's protection to accomplish the same purpose. If the prospective licensee was convinced that it could do so in a very short period of time with a parity outcome for, say, $1 million, then the licensee would reasonably determine that the institution's technology was not worth much over $1 million, which is what *its costs* would be to get what the institution has without buying what the institution is selling.[7]

When it comes to cost, it is the costs for the prospective licensee that are considered. Whether the seller's costs for developing the technology were $10 or $10 million is basically irrelevant. Another important, usually misunderstood, point is how to determine the seller's costs. In the lottery ticket example, the costs are easily known—it is printed on the ticket. But in the case of technology development, such costs are very difficult to estimate. Consider the variety and range of questions to be answered: Have we collected all the direct costs back to the very beginning of the development? Do we even know how to define the *beginning*? Did we include the value of all the contributions made to the project by products, services, insights, intellectual property, and so on, that were contributed at no recorded cost to the project? Have we excluded costs associated with development efforts that are not being offered to prospective licensees? Have we deducted "bad judgement" costs (which no reasonable R&D program should have spent)? Or should such "misspent" costs be recognized as a natural part of R&D? When parties talk about the seller's costs, they are usually talking about a number residing in some seller cost account used to track certain kinds of investments, and not the result of a carefully considered analysis of all the activities and value invested by the seller.

5. PRICING METHODS

If cost is not a good way to determine price, what is? Sections 5.1–5.6 of this chapter consider methodologies for answering this question. These methodologies include:

- Method I: The Use of Industry Standards
- Method II: The Rating/Ranking Method
- Method III: Rules of Thumb, such as the 25% Rule (and Other Rules)

- Method IV: Use of Discounted Cash-Flow Analysis with Risk-Adjusted Hurdle Rates
- Method V: Advanced Tools
- Method VI: Auctions

The goal of these following discussions is to develop tools and thinking. Producing an "answer," to the question posed at the beginning of this section is not the goal of this discussion, because the world of technology rights makes it impossible to determine a price in the abstract.

5.1 *The Use of Industry Standards Method*

Having dismissed cost as a basis for pricing, the next most logical approach is to use industry standards; the reason for this is that such an approach serves decision makers well in many other areas of experience.

Suppose you want to rent office space. The coin of that realm is commonly expressed as dollars per square foot per year (DSFY). Ranges for DSFY in the United States are from about US$1 to more than US$50. However, when consideration is restricted to a particular city and a region within that city (downtown/prime, downtown/periphery, outer belt, suburbs, inner-city warehouse district, and so on), the DSFY range will shrink remarkably, say to US$6 to $12. Then,

when one further specifies level of amenities (Bigelow® carpets versus linoleum), and what is included in the rate (utilities, janitorial services, parking, security, partitioned office layout versus open and bare) the range narrows even further, say US$10.25 to $11. So it is with many other goods and services, from haircuts to paper clips.

Why can't this approach work for rights to early-stage technology? The problem is primarily the absence of a track record for comparable products bought and sold under known (or knowable) terms. In the office space example, there are many properties, many buyers (lessees), and many sellers (lessors). This results in many transactions of relatively standardizable terms agreed to by parties that had numerous alternatives to entering into the agreement, which were considered and evaluated before signing. It is the tangibility of what is purchased, the frequency of purchases, and the public knowledge of the purchase that makes it possible to apply industry standards.

In the case of early-stage technology licensing, it is often unclear what products can or will be ultimately introduced. The number of similar transactions on which to determine price are too few, and frequently it is impossible (or difficult) to know what price other licensees/licensors have paid in similar deals. Nonetheless, there does exist *some* public and private data on early-stage-technology licensing and in many instances something useful can be learned from it.

One example of published financial data for licensing agreements is that obtained by surveying. Among the more famous examples are tables published based upon transactions between a Japanese company and a non-Japanese company. Prior to liberalization of Japanese foreign exchange regulations in the 1980s, foreign parties licensing technology to Japanese parties were required to receive government approval of licensing terms. The Japanese government published annual statistics related to licensing. A typical table is shown in Table 2. In some respects, this table is more complete than most since it includes upfront payments and minimum royalties. As is typical of such tables, there is a frequency of occurrence entry for selected royalty-rate ranges for each of several categories of technology licensed. The best way to assess how useful such a table might be is to think about how its existence would lead a technology transfer manager to reach some decision about the price of something.

Consider the pricing of a medical device such as a blood glucose monitor. Reviewing Table 2, the closest category is probably electrical, but is this really what was meant by electrical? What does this table reflect for upfront payments? Half of the agreements contained a provision for upfront payments, and half did not.[9] Now what? What guidance does this table give about whether to have such a payment and its amount? What is the modal (most common) value for running royalties? None! Now what? Should the royalty be priced at zero? The percentage of cases the royalty was negotiated within the shown ranges can also be determined using Table 2, but where does the institution's product fit? Finally, look at the minimums row. What can a technology transfer manager do with this information?

The problem is actually even worse. The agreements that comprise the table each included a whole panoply of exchanges, only some of which were summarized in Table 2. How can a technology transfer manager shrink all of these different considerations down to just one number, a royalty rate, and compare the institution's opportunity with these published outcomes? Further, there can be instances of royalty base ambiguity. Staying with the hypothetical medical-device example and our bold assumption that "electrical" data may have some relevant teaching, we can envision instances where the entire device being sold is covered by the licensed subject matter, whereas in other cases the license could be about a limited feature or function within a much more extensive device. In such cases, how was the *royalty-rate* data used by the parties? Did they agree in both of these cases to use the selling price of the complete medical device, or did they in the second instance agree to use as the royalty base some smaller amount than the full selling price of the device because of the limited application to a single feature or function? There is no way to tell from the table. There are also other concerns about this table. It is limited to technology

transferred into Japan in the early/mid-1970s. And what relevance would these rates have for licensing technology to be used in the U.S.?

A more recent industry standard survey is available, which also offers more distinguishing categories.[10] One of the tables is shown in Table 3—does it provide the technology office manager more useful information?

Again, use the test. How would this data help a technology transfer manager make a decision? Consider the categories of pharmaceuticals, general manufacturing, and other. Each royalty-range category has an entry for each of these. Unfortunately, all that can be discerned is that most royalties are in the range of 0%–10% and that pharmaceuticals are generally higher than manufacturing. One wonders about the category of telecommunications. Does this mean that all royalties for this industry fall in the range of 10%–15%? (No, as it turns out: there was only one survey respondent.) The paper from which Table 2 has been prepared contains a lot of good information, but a technology transfer manager should recognize its limitations as a guide for setting a royalty.

None of this discussion is intended to disparage the efforts of those gathering and publishing this data. Determining effective ways of

Table 2: Use of Industry Standards to Determine Royalties
(Data set obtained from review of all agreements filed in Japan)

		Industry Type				
Terms of Payment	Classification of Technology	Chemical	Metal	Machinery	Electrical	Others
Initial payment	Required	100	54	223	119	231
	Not required	65	37	187	119	220
Running royalties	< 2%	5	6	16	32	28
	2% > *x* < 5%	42	24	119	55	126
	5% > *x* < 8%	12	8	112	24	119
	> 8%	7	4	24	11	17
	Others	48	28	80	54	69
	None	51	21	59	62	92
Minimum payment	Required	38	19	116	35	186
	Not required	127	72	294	203	265
Subtotal		165	91	410	238	451
No fee, royalty		16	4	11	2	15
Total		181	95	421	240	466

Source: Science & Technology Agency[8]

valuing (pricing) technology is extremely difficult, and this author cherishes every scrap of information found. Everyone's efforts to extricate and publish anything that might help technology professionals in this valuation process are applauded. The goal here is simply to caution the reader about the limitations of using industry standards for setting royalties and other license considerations.

Let us now consider, as examples, other sources of financial information about license agreements. The references that follow should not be taken as recommended norms or standards, but illustrations of information that can be found by investigation.

Lita Nelsen of M.I.T. has published a table of standards that is an example of more useful data than the above broad Japanese license agreements. The table below represents a narrower class of licensors (M.I.T. and similar universities) and provides a narrower distinction of categories as well as a narrower range of typical royalties. A recast version of data she has published is shown in Table 4.

Table 3: A Recent Royalty Data Set Obtained by Survey
(Licensing-out royalty rates by industry royalty rate category)

Primary Industry	0%–2%	2%–5%	5%–10%	10%–15%	15%–20%	20%–25%	Over 25%
Aerospace		40.0	55.0	5.0			
Automotive	35.0	45.0	20.0				
Chemical	18.0	57.4	23.9	0.5			0.1
Computer	42.5	57.5					
Electronics		50.0	45.0	5.0			
Energy		50.0	15.0	10.0		25.0	
Food/Consumer	12.5	62.5	25.0				
General Manufacturing	21.3	51.5	20.3	2.6	0.8	0.8	2.6
Government/University	7.9	38.9	36.4	16.2	0.4	0.6	
Healthcare Equipment	10.0	10.0	80.0				
Pharmaceuticals	1.3	20.7	67.0	8.7	1.3	0.7	0.3
Telecommunications				100.0			
Other	11.2	41.2	28.7	16.2	0.9	0.9	0.9

Clearly Nelsen's data covers wide ranges in royalty rates, from 0.1% to 20%, a factor of 200. Even within one category, the range between the high and low ends can be a factor of five or more. Further, it is likely that there exist "outliers" from such ranges that M.I.T. would license at rates below the bottom end of the range and perhaps, for major breakthroughs and extensive IP portfolios, may expect values above the top of the range. The data illustrates another trend that appears in other examples: those products and industries with traditionally high operating margins (profits), such as pharmaceuticals and software tend to exhibit higher royalty rates compared with, say, the materials industry.

Other authors have published tables of royalties for the purpose of establishing reasonable expectations of both licensors and licensees. Table 5 is a table published by Corey and Kahn for the medical industry.[12]

The table's context is well defined (early-stage technologies out of research labs), the categories are comparatively precise (diagnostics in vivo), and it includes guidelines on up fronts and minimums. However, note that there is an important economic difference between the ends of the royalty ranges given: 1% versus 3% or 2% versus 10%, and so on. Unless the technology transfer manager understands where the institution's opportunity fits in the range identified, it is difficult to know where to begin. Further, not *every* opportunity falls within even these broad ranges. Some opportunities will have only negligible value; others could be unusually valuable opportunities.

Tom Kiley has published another medical industry table that deals with exclusivity granted (Table 6).[14]

Kiley appears to suggest that for nonexclusive rights, the royalty should be about half of the exclusive royalty. (See section 6.3.2 for more on the 50% rule.) According to Kiley, inventions in support of a pharmaceutical (drug) warrant higher royalties (7%–15%, as his generalization) than drug delivery, diagnostic and therapeutic monoclonal antibodies (2%–7%), perhaps reflecting another two-to-one ratio.

Published price lists are another source of industry standards for pricing. Sometimes a company simply announces its royalties. One example, shown in Table 7, was published by one licensor for nonexclusive licenses for its LCD display patent.

Another example of such published rates is, or was, IBM's licensing terms. In the 1980s and early 1990s, IBM established a licensing practice—essentially a price list—that offered to license essentially all of its 34,000 patents worldwide for a 1% royalty each for computer uses (patents only, nonexclusive only), up to a maximum of 5% for all 34,000.[17] This practice does not establish 1% as a minimum per patent royalty; rather it reflects IBM's practice at one time that a licensee can *choose* any one from IBM's massive portfolio for a rate of 1%, any two for 2%, and so on. Further, because IBM does not make public its license agreements it is unknown what payment structure or amount was finally agreed to with licensees.

The main point about the LCD and IBM examples is that such published lists can lead to-expectations and, to the degree that the opportunity the technology transfer manager is pricing fits any published examples, this may influence the thinking of prospective licensees. In some cases, such proposed pricing can create a widely accepted norm in the respective industry, making it difficult for the seller to price above such a norm if the subject matter is perceived to be in a similar category. Licensees, like licensors, look to this method of industry standards (or norms or comparables). However, they may look to a different population of examples such as their own internal catalog of extensive deals that they have completed in the past to establish their expectations for financial terms.

Yet another source of industry standards are court determinations of reasonable royalties awarded in patent infringement lawsuits. Table 8 offers a summary from a paper by Mike Carpenter who analyzed a series of judgments.[18]

The main limitations of such data are that the result is very specific to the litigated subject. In addition, the maturity state of the technology is normally far beyond what may be considered as early-stage technology. Further, adjudicated reasonable royalty rates are almost

Table 4: Example Table of Royalties Developed by Experience by a University Licensing Office[11]

Product	Royalty (%)	Comments
Materials processes	1–4	0.1%–1% for commodities; 0.2%–2% for processes
Medical equipment/devices	3–5	
Software	5–15	
Semiconductors	1–2	Chip design
Pharmaceuticals	8–10	Composition of materials
	12–20	With clinical testing
Diagnostics	4–5	New entity
	2–4	New method/old entity
Biotechnology	0.25–1.5	Process[a]/nonexclusive
	1–2	Process[a]/exclusive

a Expression systems, cell lines, growth media/conditions

Table 5: Royalty Rates for the Medical Industry[13]

Technology/Industry	Earned Royalty (%)	Upfront Payments (in US$)	Minimum Payments (in US$)
Reagents/process	1–3	Patent costs	2,000–10,000
Reagents/kits	2–10	Patent costs	2,000–10,000
Diagnostics in vitro	2–6	5,000–20,000	2,000–60,000
Diagnostics in vivo	3–8	5,000–20,000	2,000–60,000
Therapeutics	4–12	20,000–150,000	20,000–150,000
Medical instrumentation	4–10	5,000–150,000	5,000–20,000 (yr. 1) 10,000–25,000 (beyond yr. 1)

always unrepresentative of arm's-length rates, as they represent royalties for patents known to be valid and infringed—conditions not typical of early-stage technologies. This litigation-particular outcome example is also quite dated, but datedness is a factor here in all of the prior examples as well, and is innate to any historical collection of data.[20] Still, a court case usually contains a wealth of information about how such rates were determined, and of course, the information is in the public record. Einhorn has published a much more current summary of reasonable royalty determinations by a court.[21] One can also search LEXIS® for even more current data. The key is to find a comparable technology, stage of development, market impact, and so on. When something comparable exists and is published, this can be very helpful.

The most valuable tool for determining industry standards for this method are published agreements for similar technologies licensed by similar institutions. As Ashley Stevens explains, publicly-traded companies will file license agreements that may have a significant economic impact on the value of the company with the U.S. Securities and Exchange Commission (SEC).[22] The Internet now enables very effective searching of disclosures made by publicly-traded companies.

Table 6: Proposed Standard Royalties[15]

	Exclusive (%)	Nonexclusive (%)
Development rDNA[a] drug	7–10	3–4
Approvable rDNA[a] drug	12–15	5–8
Therapeutic mAb[b]	5–7	3–4
Diagnostic mAb[b]	3–4	1–2
Drug delivery component	2–3	0.5–2

a Recombinant DNA
b Monoclonal antibodies

Table 7: Price List for an LCD Display Patent[16]

Vehicles	0.125%
VCRs, and so on	2%
Meters, gauges, and so on	3%
Telephones, and so on	4%
Calculators, and so on	5%

Several organizations offer, as a service, summaries of categories of such filings and copies of specific agreements. An example, taken from a talk by Mark Edwards, is shown in Figure 1.[23]

These data are unusual in that they show many of the forms of upfront consideration received by universities for having licensed their biotechnology. Underneath such summaries, however, are specific agreements now numbering in the thousands, copies of which can be found with some research. It is from such published agreements that one can gain a better understanding of what was agreed to, at least once, by two parties for something similar to what is being offered.[24]

One example of such a specific agreement is the license between the University of Houston (UH) and DuPont for the so-called 1-2-3 superconductors developed by Professor Wu of UH. The State of Texas required that this agreement be placed in the public domain. The agreement details the payments DuPont agreed to make to gain rights to UH's superconductor technology: US$1.5 million in cash upon execution of the agreement, an additional US$1.5 million upon issuance of the U.S. patent, and a third US$1.5 million upon the second anniversary of the U.S. patent. The agreement has many other interesting details, and it would be wise to study this agreement and learn as much as possible about its background and current status.

To sum up, using this industry standards method of setting prices has both positive and negative aspects:

Positive aspects of the industry-standards method include:

- The values used as the basis are based on the market.
- No calculations are required (beyond perhaps taking averages and medians or other statistical methods).
- One has some confidence of being in the range of some believed-to-be comparable reference points.

Potential negative aspects include:

- Published information is inevitably dated, and such datedness could have a material effect on the present value of a similar deal.
- The segmentation provided by surveys is normally too coarse (electrical, mechanical, telecommunications, and so on).

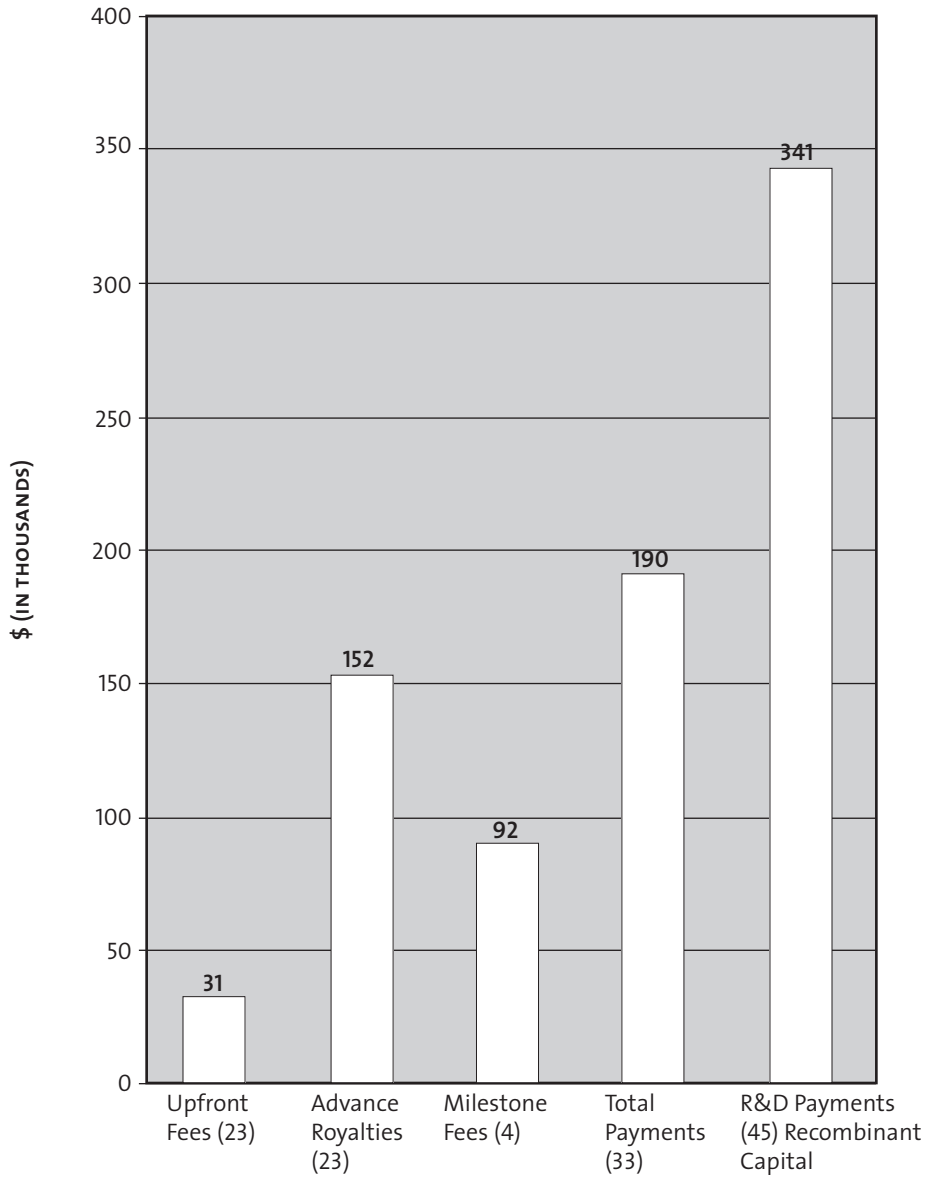
Table 8: Other Tables of Royalty Rates Based on Litigation Outcomes[19]

Product	Royalty (%)	Date	Citation
Rotary wing aircraft	2	1976	192 USPQ 612
Sleeping bag	5	1967	156 USPQ 403
Digital data transmitter	7.5	1978	200 USPQ 481
Oscilloscope	10	1977	193 USPQ 385
Computerized teaching aid	12	1978	199 USPQ 178
Toilet paper perforator	20	1977	195 USPQ 125
Airline baggage cart	100[a]	1977	196 USPQ 129

a of profit

Figure 1: Royalty and Other IP Revenue Data Based on SEC-Filed and SEC Agreements

Average Pre-Commission Payments: University/Biotechnology Licenses



Source: Recombinant Capital (Mark Edwards). AUTM presentation 1993.

- The values published normally do not provide sufficient information to determine what IP rights were provided, or to determine their significance or their strength.
- The royalty *basis* (or base) is not always explicitly defined.
- The connection of the license to the size and margins of the buyer's market opportunity is not explicitly known.
- A wide range of royalties is reported for each classification, with no clear means of discerning why some opportunities were higher valued and some lower.
- Often no information on upfront payments, minimums, or due-diligence provisions is available, all of which can be important components of value.
- The licenses often contain other provisions that directly affect the total value of the deal and are reflected in the royalty rate.
- One cannot uncover a historical agreement for exactly the same technology as that of current interest, between comparable parties, at a comparable stage of development. So one is commonly performing some interpretation of available data to apply to one's present situation.

The industry standard method works best when one deals in one technology/industry segment, especially when there are a significant number of deals involving multiple buyers and competitive sellers, much as in the real-estate rental market discussed above. The examples given here are not intended to provide representative technology values but to illustrate some of data sources that exist.

In summary, price is a very tricky idea. It occurs "between the ears" of the technology transfer manager, as well as between the ears of prospective licensees. As you can see, it is affected by all the other things that affect a person's judgment. For those who doubt this, an experiment has been published that illustrates this point.[25] Two groups of students were asked to review identical notebooks containing descriptions of seven consumer products. They were each asked to respond to each product by specifying what they would be willing to pay for the item. A summary of the findings is shown in Table 9.

Everything was identical in the two settings (A and B), except for one small thing. In setting B, there were Mastercard® logos left lying on the table. Even though all the participants understood that they were not buying the items in the book,

Table 9: Price is a Tricky Idea: What Would You Be Willing to Pay?[26]

Consumer products book	Mean in setting A	Mean in setting B	(B-A)/A
Dress 1	$27.77	$41.50	49%
Dress 2	$21.09	$33.91	61%
Tent	$69.95	$77.73	11%
Men's sweater	$13.91	$20.64	48%
Lamp	$28.36	$40.41	42%
Electric typewriter	$131.45	$165.36	26%
Chess set	$35.29	$43.15	22%

and there was no discussion as to how such items could or should be paid for, the mere presence of the logos influenced the group B students significantly.

The point of relating this experiment is that *everything* about the technology transfer manager, the institution, the inventors, and so on, are potential influences on what a licensee will conclude is a fair price.

Consider these two different settings for the same invention. In setting A, the prospective licensee goes to Nowheresville, has to drive four hours because there is no air service, steps in cow dung as he gets out of his car, meets the inventor who has no front teeth and exhibits an annoying habit of scratching his underarms, and discusses the invention in the Greasy Spoon Cafe. In setting B, the prospective licensee goes to Mostfamousuniversity, where he is introduced to the distinguished inventor (who has previously won a Nobel Prize) at the exclusive faculty club and a well-known, well-respected, high-ranking public official stops buy and says hello during lunch.

Remember, in this thought experiment the institution is selling the same invention in both settings. Even though the prospective licensee is not a student and is not buying consumer products as in the example above, the principles are the same. The licensee will likely be influenced by the setting and circumstances, which may be completely unrelated to the underlying value of the opportunity.

In the first act of a wonderful play by Arthur Miller called *The Price*, the owner of a house full of furniture is frustrated when the dealer he has invited to bid on all of it delays giving him a price. Instead, the dealer spends a lot of time understanding the context of the sale (and learns that the building is about to be demolished and that the seller has no time or patience to sell the items piece by piece). He intermittently (and politely) points out certain blemishes in objects that would otherwise have been perceived as very valuable. When the seller finally demands to hear the price, the very old man who plays the buyer simply says, "*Because the price of used furniture is nothing but a viewpoint, if you don't understand the viewpoint, it is impossible to understand the price.*" The view from the buyer's position always affects the price he is willing to pay.

One other point needs to be made about price. It is often the lever used in negotiations. Often each party to a negotiation uses price as a lever to get other things. There is a wonderful ancient saying on how buyers tend to negotiate, "Bad, bad says the buyer, but then he goes his way, then he boasts."

5.2 *The rating/ranking method*

This method applies the elements of any definition: the specification of a *genus* plus the distinction of a *differentiator.*

First, the technology transfer manager must find the genus (or family) for the institution's technology that he or she is seeking to price. Places to look include the published agreements discussed earlier, friends in the network of the Association of University Technology Managers (AUTM) and the Licensing Executives Society (LES), consultants, and the institution's files of negotiated deals. Ideally, a technology transfer manager should find at least one or possibly two or three comparable deals from such a search.

Second, this method uses some form of rating table to score (differentiate) the deal that is now being priced based on the known price of the comparable deal(s). To do this, a technology transfer manager must select a list of relevant factors. Tom Arnold and Tim Headley published a useful, extensive list of 100 possible factors in an article in *Les Nouvelles*.[27] One hundred factors, however, are far too many to evaluate, which is perhaps why the most well-known enumeration is the Georgia Pacific factors, so called because the factors were annunciated in a lawsuit involving the Georgia Pacific company and have since been widely cited with respect to litigation matters. The results of a survey published by LES asked respondents which of the primary Georgia Pacific factors they used to assess an opportunity when either licensing in or licensing out. Table 10 gives a summary of these findings.

Other approaches may use only three or four factors to simplify the analysis, such as (1) comprehensiveness of the IP protection, (2) the stage of development (or, conversely, the magnitude of licensee investment) to bring the technology to the market, (3) the size and value of the market that is expected to be won by the licensee, and (4) the sustainability of the innovation wrought by the subject technology in view of competitive alternatives both present and anticipated.

Once one has chosen the key factors, the technology transfer manager, or preferably a commercial assessment team, scores the subject opportunity compared to the reference agreement found above for each factor selected on some scale. This can be done by employing a 1 to 5 scale, with a 3 as being indistinguishable to the comparable agreements, 4 meaning the subject opportunity is better (more valuable) with regard to this particular factor, 5 meaning much better, and so on. It is usually a good idea to also include a weighting factor so that each consideration is not treated equally. This is illustrated in Table 11.

The result is a weight-averaged score. Anything greater than 3.0 would suggest that the subject opportunity is better than the examples being considered as a standard, anything less than 3.0 suggests it is worse. If a technology transfer manager has two or three standards available, it may be possible to use this method to bracket the opportunity.

Although this method is straightforward, there are some important limitations. What is a true comparable? Each agreement is a snapshot in time, no two technologies are really identical, the market is almost never the same, and the negotiators and organizations will likely be

Table 10: Example of Georgia Pacific Factors Used in Rating/Ranking[28]

Importance of Factor	Licensing In[a]	Licensing Out[a]
1. Nature of protection	4.3	4.2
2. Utility over old methods	4.2	4.2
3. Scope of exclusivity	4.1	4.1
4. Licensee's anticipated profits	3.0	3.4
5. Commercial success	3.7	3.4
6. Territory restrictions	3.7	3.5
7. Comparable license rates	3.6	3.7
8. Duration of protection	3.3	3.1
9. Licensors' anticipated profits	2.6	3.1
10. Commercial relationship	2.6	3.6
11. Tag-along sales	2.1	2.1

a A ranking of 5 corresponds to most important; 1 to least important.

different. In addition, there are many tradeoffs and exchanges in every agreement; a technology transfer manager cannot simply compare one single aspect, such as a royalty rate, and look at it without considering what else was in the agreement. What about the differentiating factors selected? Does a technology transfer manager really know what the important ones are for this opportunity? What does a 4 really mean in economic terms? Finally, what does a technology transfer manager do with the result? Suppose the technology transfer manager determines that the institution's opportunity scores a 3.8 compared to the standard. Now what? Does the technology transfer manager set expectations for the royalty at 27% better than the standard, as determined by ((3.8–3.0)/3.0)? Is the up front now 127 instead of 100? Are the minimums 64 instead of 50? Does the diligence requirement provide that the licensee must be on the market in 31 months instead of 40 months? Is the premium on late payments 3.8% instead of 3%? There are no simple answers to any of these questions. Still, performing this ranking against multiple standards and thinking through the results generally allows one to better understand

Table 11: Method II: The Rating/Ranking Method

Factors	Score (1 to 5)	X Weighting Factor	= Weighted Score
Stage of development			
Scope of IP protection			
Market attractiveness			
Sustainability of protection			
Profit margins			
Etc.			
			Average Weighted Score Compared to 3.0

the helpfulness of this rating/ranking method in a specific circumstance.

The approach also yields at least two other benefits. First, it prepares the technology transfer manager for marketing, negotiating, and sharpening his or her thinking about what the important economic factors are relating to the opportunity. It gives the manager a greater self-awareness. A second benefit is that it provides a way of dialoguing with the internal stakeholders and beneficially incorporating some of their insights.

The rating/ranking method can also be used for selecting a commercialization path. When developing a commercialization strategy, there are countless possibilities: exclusive versus nonexclusive licenses, licensing versus equity in a new start-up, going with a company in industry A as the exclusive licensee or in industry B, commitment to the industry leader versus a small company who seeks to upset the industry, and so on. The rating/ranking method can help a manager sort out the advantages and disadvantages of each of the alternatives. It can also be used with respect to different potential licensees/partners by taking into account the particular benefit(s) of the technology to such licensee; the method can help a seller differentiate among multiple potential candidates to identify those who would appear to have the most to gain from the license and would therefore be the likeliest to enter an agreement and possibly pay the most. These and other criteria can help a technology transfer manager decide upon the best commercialization path.

5.3 *Rules of thumb, such as the* 25% *rule (and other rules)*

5.3.1 *The* 25% *rule*

One of the most widely cited tools of valuation is the 25% rule. It has various manifestations, but when most managers invoke it they usually mean either of the following:

1. The royalty in dollars should be one fourth of the *savings* in dollars to the licensee by the use of the license subject matter.
2. The royalty in percent of the net sales price should be one fourth of the *profit*, before taxes, enjoyed by the licensee as a result of selling products incorporating the licensed subject matter.

Although this looks simple, it is not. One of the key issues is the degree to which the licensed subject matter accomplishes the savings or produces the profit. For example, an invention incorporated into a process may produce a savings of $1 a unit. However, when one examines in detail how such savings are attained, it may be that several other technologies developed and possessed by the licensee need to be exploited in order to realize the full $1. In such a case, does the licensor deserve 25 cents, or should the savings be discounted in some way before the one-fourth fraction is computed? The issue seems to hinge on whether the invention opens the door to an otherwise locked room called: I can save you $1, or whether the invention is a link in a multilink chain that together combine to save $1.[29]

In the second (profit) manifestation of the rule, things get even more complicated. Although net sales is generally a straightforward term to apply, profit before tax is subject to many interpretations. Normally, the royalty rate is applied to the royalty basis defined by net sales as follows: net sales price is the gross invoice price charged minus allowances for returns, and minus cash and other discounts granted, charges for packaging and shipping, and sales and excise taxes.[30]

For the purposes of this rule, there is no comparable generally accepted definition of *profit before tax*. Indeed, one of the basic problems is determining what an appropriate income statement should look like. Typically, they have the following categories:

Gross sales

Less:	returns/allowances
=	net sales
Less:	cost of goods sold (COGS)[31]
=	gross margin (or gross profit)
Less:	overheads (or G&A, for general and administrative)
Less:	sales (or sales and distribution)
Less:	other
Less:	R&D
=	Profit before tax (or EBIT, earnings before interest and tax)

The trouble usually starts below the gross-margin calculation. What overheads should be attributable to this opportunity? Should all the overhead costs currently being experienced by the licensee be included in the calculation, even though including these may reward the licensee's inefficiencies? Will the cost-of-sales allocation, which is across many products now being sold, overcharge the appropriate sales allocation for the subject opportunity? What is "other," and why is it being used to draw down the profitably before the application of the royalty? And finally, what constitutes R&D, and should it draw down profits as calculated for determining a reasonable royalty?

Underneath these questions is the difficulty of obtaining reasonable estimates for each of the numbers. Annual reports from companies that sell products like the one the institution is licensing are good places to start. Table 12 shows summaries of two large materials companies, one U.S. company and one European company, based on their income statements published in annual reports. Although the numbers reflected in Table 12 represent real data, for the purposes of this illustration, the company names have been noted as U.S. Co. and Europe Co., respectively.

As discussed earlier, one of the issues in applying the 25% rule is where to apply it. If it is applied to the EBIT line ($18,352,000, in the United States company example), it is asserted that the deductions above that line (COGS, SD&A, and R&D) are appropriate for determining the true profitability associated with the commercialization of the new opportunity being licensed.

Consider whether it is appropriate to subtract R&D from available profit. If it is not subtracted, we would get, by this rule, one fourth of 12% (11+1) or a 3% royalty. This is a lot better for the licensor, since it is 12 times the 0.25% one gets by using what remains after R&D is subtracted. But should R&D be included in the subtraction? The argument for including it is that R&D is a necessary business expense for the enterprise; without such investments, the licensee would not have the high-value, competitive products it needs to sustain its operations, and, by implication, would be unable to successfully commercialize the subject opportunity.

On the other hand, these expenses are investments for future payoffs to the company for which the licensor may not enjoy the benefits. Suppose the U.S. company had elected, in the year reported, to increase its R&D investment by $18,351,000 to pursue an antigravity invention. This would have left the grand sum of $1,000 on the EBIT line, corresponding to one-ten-thousandth of a percentage point (of sales). Why should a licensor's fair share of profits depend on the company's management pushing an R&D project to develop an antigravity material or, for that matter, any other product?

Above or below the EBIT line are even more subjective costs. If they are associated with the company's core operations, they may be appropriate. But what if they are associated with buying that new hunting lodge in Montana? Or buying up Brazilian rain forests? What about restructuring, which may be synonymous for the present cost of past folly? Again the same kinds of arguments exist on both sides. And again, what about that favorite term in accounting statements: "other." Other than what?

If the licensor agrees that all of the expenses shown are appropriate allocations against earnings, it leads in this particular year to a negative number. Now what? Does the institution pay the *licensee* a royalty to commercialize the institution's product? The point of this discussion is that each cost below the sales line should be analyzed in the context of the subject technology to determine if the EBIT percentage shown reasonably predicts the licensee's profitability in the present case. If not, adjustments to such costs should be made to correct the base on which the rule is applied.

The second example in Table 12 (European Co.) presents other problems. For competitive reasons, many companies conceal details in their statements. They may also use different terminology. In Europe, sales is normally called turnover, interest can be finance charges, and so on. This example shows a gain from investments.[32] Should the licensor receive the benefit of a higher royalty because the Europe-based company made money in one year on a good investment? Probably not. But if the company had lost money on investments, wouldn't the licensee argue that such loss

should be subtracted as an appropriate business expense? So, what about the gain?

Another way to obtain income statements is to use Ibbotson and Associates[33] and Robert Morris Associates (RMA) publications.[34] RMA, for example, annually publishes income statements of categories of companies by Standard Industrial Classification (SIC) code. Continuing with our two materials company examples, Table 13 shows the data available from the 1991 edition for SIC #2395.

In the first two columns are shown summaries for 11 smaller companies and 17 larger companies, based on assets. The right three columns provide three years of data for all of the companies in the database. Even when focusing on just the operating profit row, this gives five choices on which to apply the one-fourth rule: 4.1%, 4.7%,

Table 12: Example Applications of the 25% Rule

	Annual Report, 1991 U.S. Co.			Annual Report, 1991 Europe Co.	
	US$, in thousands	%		UK £ in millions	%
Sales	1,249,512	100	"Turnover"	454.0	100
COGS[a]	643,357	52	Other Inc.	2.2	
Gross margin	606,155	48		456.2	
"S,D,&A"	447,607	36	"Operating costs"	405.0	89
R&D	140,196	11	EBIT	51.2	11
EBIT[b]	18,352	1			
			"Investments"	(1.4)	
Interest	8,090		"Finance charges"	8.7	
Restructuring	3,697				
Other	9,674		EBT	43.9	10
EBT[c]	(3,109)	(0.25)			
	Now what? 0.25%? (0.06%)?			Now what? 2.5%?	

a Cost of goods sold (all "direct" costs of making the product)
b Earnings before interest and taxes
c Earnings before tax

7.8%, 8.4%, and 10.4%. How does a technology transfer manager choose? Taking an average yields about 1.5% as the royalty. Is this fair? Unlikely.

The root problem is getting good numbers for the profitability associated with the subject opportunity. A prospective licensee will almost surely make such a calculation. Yet a licensor will find it very difficult to get access to such information. The problem with published numbers of business enterprises—such as annual reports, 10Ks, RMA publications, Ibbotson, and other sources—is that the numbers are "smeared" over many different products, each with widely varying profitability. And once a product has been introduced, a company is inclined to keep it in the marketplace as long as it contributes to overhead, meaning it at least covers its cost of goods sold (COGS). In short, dogs in the company's profit portfolio bring down the returns of the stars. Basing a valuation on such numbers will therefore always be a very tricky business. It also ignores a company's willingness to pay more for a new opportunity, such as licensing a particular technology from which new products can be made. As a technology transfer manager becomes more experienced in various business sectors, he or she will better understand the economics of such variables—especially the company's interest in the opportunity of a new technology—allowing for better valuations (see Method IV: Discounted Cash-Flow Analysis with Risk-Adjusted Hurdle, section 5.4).

One possible remedy to these difficulties is to request that the licensee provide a pro forma (predictive) income statement for the subject opportunity. In many cases, the licensee will refuse on

Table 13: Another Example Application of the 25% Rule[35]

Minerals and Earths, Ground or Otherwise Treated[a] (SIC #2395)	11 Companies $ 500,000–$2 M Assets	17 Companies $2 M–$10 M Assets	All 1991	All 1990	All 1989
Net sales	100.0	100.0	100.0	100.0	100.0
Gross "profit"	29.9	21.8	25.4	33.8	32.5
"Op-exp"	21.5	17.7	20.7	26.0	22.1
"Op profit"	[8.4	4.1	4.7	7.8	10.4]
"Other"	1.2	0.8	1.0	1.8	1.6
"Profit before tax"	7.2	3.3	3.0	5.9	8.7
	Now what?	1.5%?	←	Average	←

a Operating without a mine or quarry crushing, grinding, pulverizing, or otherwise preparing clay, ceramic and refractory minerals; barite, and other miscellaneous minerals, except fuels. Also includes crushing slag and preparing roofing granules.

the grounds that such information is trade-secret information and that providing it, even under confidentiality terms, is forbidden. In other cases, the licensee may provide it. If so, it is a virtual certainty that what will be provided is the lower range of possible outcomes. Also, such pro forma statements may have certain cost allocations incorporated by rule or custom that may be arguable (either way) for getting to a figure to which the parties will apply the 25% rule.

Licensors sometimes call the 25% rule the "one-third rule." Licensees, on the other hand, sometimes argue that claiming even one-fourth of the profit is overreaching, given such issues as the technology's early stage of development, weak patent protection, high market risks, the extraordinary value of intangible assets to be applied by the licensee, and so on. Clearly, the many numerous factors that go into value (summarized earlier) must always be considered when applying rules of thumb. Perhaps the high risk associated with commercializing a specific opportunity means that only one-tenth is fair. And if the technology is only a small part of a very complex whole, with many other patents and proprietary technologies required of the licensee and a royalty base on the selling price of such a complex whole product, then a value much less than one-tenth can be reasonable. This last point relates to the always-relevant discussion of the royalty base that is being used with the royalty rate to determine the royalty payment. If the licensor's technology enables substantially the entire product, then the selling price of the entire product is normally the base. If the licensor's technology is only part of the entire product, then the parties may elect to still use the selling price of the entire product, but discount the royalty rate in recognition of that fact. Returning to the issue of whether 25% is the appropriate apportionment, if the commercial introduction of a well-developed, whole technology package for an attractive market opportunity is certain, then a value higher than 25% may be appropriate.

Despite these complexities, the 25% rule is well known and widely cited. One example is a citation by the court in *Gore vs. Internal Medical Prosthetics* where the judge stated, "*As a general rule of thumb, a royalty of 25 percent of net profits is used in license negotiations.*"[36] However, in the famous case of *Polaroid vs. Kodak*, the judge awarded a reasonable royalty that amounted to slightly more than 60% of the infringer's anticipated profits. The "Ten Sources of Value" (Table 1) and the rating/ranking factors must always be kept in mind, as should the overwhelming significance of differing risk perceptions of the same opportunity. If the licensee sees an opportunity as extraordinarily risky, then 25% of the profits will appear far too high. If the licensor sees it as picking the low-hanging fruit of something that can be readily commercialized by a license, 33% or more will seem reasonable. So, one should not take this "rule" suggesting there is a universal agreement that the value of "25%" covers all situations.

For more information, a summary of the history of the 25% rule is included in William (Bill) Lee's paper.[37] Our observations relating to the use of this rule are summarized below:

Positive aspects of the 25% rule method:

- Has a "feel-right" tug in certain circumstances
- Can be the basis (principle) of early agreement
- Appropriately tied to profitability
- Widely accepted (at least in the sense that lots of people have heard of it)

Difficulties with the 25% rule method:

- The lower you go below the top line of an income statement or model, the more subjective (that is, inauditable and arguable) it gets, for example, what is appropriate overhead? What are appropriate sales costs?
- The calculation, depending on how it is performed, can have the effect of rewarding licensee business inefficiency.
- Very difficult to get good income statement numbers that are not smeared over many businesses and products.
- The licensed subject matter (normally) represents only a part of the sales price; complex considerations are needed to decide whether to discount or not.

- There can be significant year-to-year variability in available income statement numbers.
- No help on upfront fees.
- There is no inherent assessment of the potential importance of third party IP and technology to a licensee's use of the subject technology.

One key piece of advice: If you use the 25% (or one-third) rule, use it *only* to develop the calculation of the *royalty rate to be based on sales*—never permit the royalty to be calculated on an as-you-go basis as a percentage of earnings before tax.

5.3.2 *The 50% rule*

Duke Leahey has outlined a 50% rule that is related to the 25% rule:[38]

- At the point of product introduction, about 50% of the total risk of product failure remains.
- If the inventing organization brings the technology to the state of product introduction, it is entitled to 50% of the total reward (profit).
- If the commercializing organization participates in premarket development costs and risks, it is entitled to more than 50% of the total reward.

From this perspective, the 25% rule represents a 50:50 participation in premarket risk. Accordingly, the 50% rule suggests that to determine a fair apportionment of profit one should assess the extent to which the premarket risks and costs will have been borne by the licensor and licensee when the product finally gets marketed. Unfortunately, this is not easy to do.

When did the invention begin? In most cases, the inventing organization and individual inventors endured a long, costly gestation that was the essential primordial ooze from which the invention emerged. It is therefore unfair to the licensor to add a $5,000 patent application and a $10,000 project that fleshed out a few numbers and contend such expenditures are equivalent to the $1 million required cost asserted by a licensee to bring the technology to the market as the basis for determining the relative, premarket contributions of licensor and licensee.

A second version of the 50% rule appears to be applied primarily in the area of software and reflects the very significant pre- and post-commercial involvement by university and R&D organizations in certain situations. When software is commercialized, many activities can be the responsibility of either the licensee or licensor. These include: performing all the bug fixes and compatibility tests of the original code, developing user interfaces, creating software manuals, making copies for distribution, packaging, finding customers, delivering copies, hot-line help for routine questions, resources for in-depth questions, new bug fixes, updates and improvements, product advertising, sales and distribution, more bug fixes, and so on. In some instances, the licensee and licensor will divide these responsibilities so that when credit for cost/risk of creating the product is ascribed to the licensor, then the resulting split is 50:50.

But there is no simple way of saying how such a split in responsibilities warrants 50:50. At one extreme, for example, the owner/developer of the software product could do everything required for commercial use, including advertising and other promotional activities, and elect to hire marketers purely on a commission basis to assist in direct sales. (This is commonly necessary when selling software that costs in excess of several thousand dollars). In such a case, the marketer is playing only a limited role in the commercial process, basically as a manufacturer's rep and may be paid a commission, ranging from 10%–20%. Taking a figure of 15%, this means the revenues from sales have been effectively split 85:15 taken as a percentage of sales in this example of a different rule of thumb.

At the other extreme, the creating organization can enter a license at an early stage in development and turn over a hard drive containing code that works but is not yet complete as a product. In this case, the licensee has to finish the code; develop all the user-friendly tools; introduce the product to the market; perform all the promotions, sales, and distribution; handle the customer; and so forth. Here, the licensee may

agree to pay a royalty in the range of 10%–25% (or even much less). Taking again a figure of 15%, this means that the revenues from sales have been split 15:85.

By using the 50% rule, or a 50:50 split of revenues, a licensor agrees to perform an additional 35% share more of services than in the 15:85 example (or the commercial partner is doing an additional 35% share more of services than in the manufacturer's rep example of 85:15). As you can see, it is unhelpful to rely too heavily on such numbers. Indeed, like any other type of licensing, once a technology transfer manager has gone through a significant number of deals, he or she will be able to recognize what deserves a 50:50 split, as well as the appropriate split for the level of involvement in particular cases.

5.4 *Discounted cash-flow analysis with hurdle rates*

Method III introduced the concept of apportioning profit by examining each party's contributions and risks incurred in creating such profit. Method IV is a more sophisticated way of performing such considerations. This method consists of determining future cash flows, then discounting these cash flows by accounting for the time over which those amounts are to be received *and* by the associated risk of receiving such cash flows. For this reason, this method is sometimes known as the discounted cash flow (DCF) method. When all such cash flows have been discounted, they can be added to determine net present value (NPV). The key to this method is the application of the risk-adjusted hurdle rate (hereafter designated by k) or the factor based upon perceived risk that is used to discount the future cash flows and will be referred to here as the "risk-adjusted hurdle rate" (RAHR). In effect, k is used to determine how the profits (or cash) resulting from the commercialization of the subject opportunity should be apportioned.

5.4.1 *Defining risk*

First, let us consider what is meant by risk. There are technical risks, market risks, and the infamous other risks, such as market erosion or the changing tastes of consumers. What are some technical risks? Although it may not be obvious, a key technical risk has to do with whether the technology works. For many reasons, a lot of inventions simply do not work. Sometimes the invention works, but only under very carefully controlled, glacially slow procedures with tiny quantities in clean rooms carried out by very experienced scientists using technicians with dexterity and intelligence that is hard and very costly to duplicate. If a product needs to be made in high volumes at low cost, there is a huge risk in taking something that works in the cleanest of clean-rooms and getting it to work in a factory.

In the category of market risk, a competitor may develop a superior product based on another technology. Customer requirements can also change dramatically. Tastes can change, and anticipated profit margins can erode or disappear. And customers, despite all the market assessment, can simply decide not to like a product. Remember New Coke? Remember Corfam? Sinclair and Commodore computers? An appetite-suppressing candy with the unfortunate name of Ayds?

Finally, all sorts of external events can sink an enterprise. Some raw material that the licensee needs to use or a product that it plans to sell can become illegal or so constrained by regulation that there is no cost-effective way to use it or sell it. Other industries can undergo upheaval to the mortal detriment of a licensee. Remember the oil embargo? The shortage of DRAM chips? Nuclear power? A key trade secret could be stolen. The patent office could deny patentability or grant broad rights to a blocking patent owned by a third party.

5.4.2 *Developing a risk-reward model*

Investors use a risk-reward model to guide their investment decision making. It is commonly expressed in some form of a graph such as the one shown in Figure 2, where increased risk demands an increased required rate of return (k), also known as the hurdle rate. The job of a businessperson is to convert the investments made in the company into returns that equal or exceed the rates of return expected by such investors. So the floor for a businessperson's expected returns

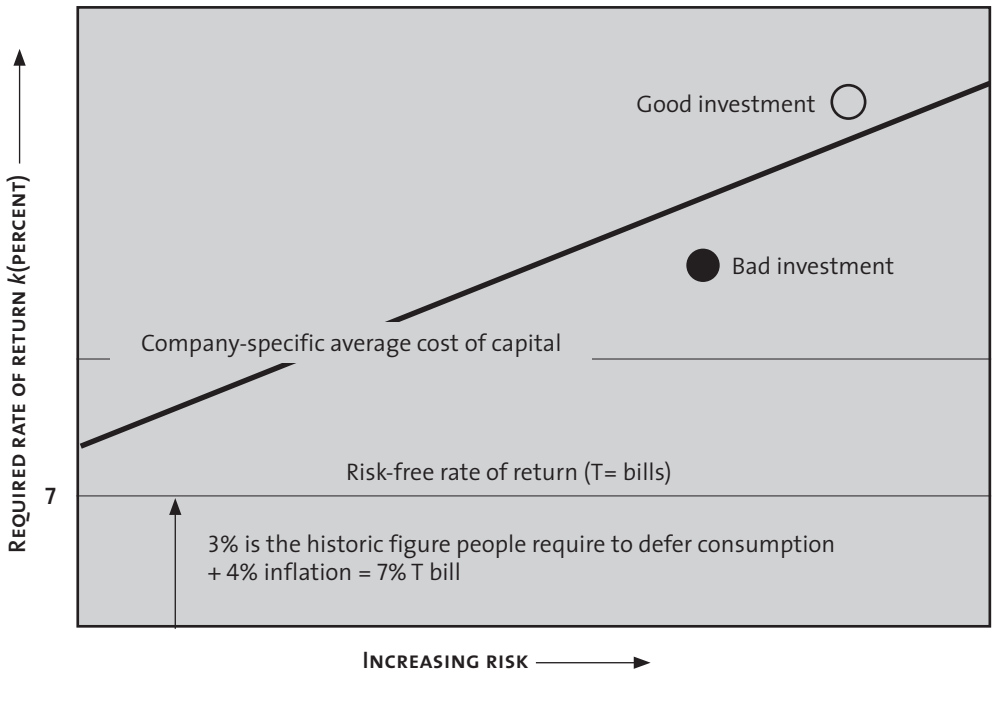
is normally the company-specific, average cost of capital (a combination of debt and equity). What makes a particular project investment good or bad at the stage of making the investment is the *perception* of whether the returns will be attractive in relation to its risks, the latter of which are determined by the company's prescribed reward-risk relationship.

From the point of view of the prospective licensee, one of the basic value questions is the degree of risk that has been eliminated by the licensor's R&D and other activities. The greater the risk reduction, the greater the perceived value (or, in other words, it is less likely that a discount will be applied to the perceived potential value of the license). From the perspective of the licensor and, particularly, the professor-inventor, this suggests that additional R&D will increase both the likelihood and the economic value of a license. But this is only true if the licensor's R&D activities are successfully applied to commercial risk-reducing activities. Investment in R&D that is directed toward improved scientific understanding and publication of an invention may or may not reduce risks associated with commercializing a product of interest to a licensee.[39] Not all motion is progress. This is yet another reason why costs are irrelevant in assessing value. Figure 3 summarizes the key steps of this method.

First, a determination must be made of the earnings before interest and tax (EBIT). This is done in the same fashion (and with the same uncertainties) as with Method III (see Table 12). Next, a provision is made for a royalty payment as yet another cost of the licensee. Initially, this value is simply a guess. Later, it will be adjusted to make the overall returns attractive to the licensee. Next, a provision is made for taxes. Throughout the 1980s and 1990s, a value of 40% was typical for combined state and federal taxes; somewhat lower projections are now sometimes made for the future. This results in earnings after tax (EAT—an easy acronym to remember).

But the EAT for a project is rarely the amount of cash it throws off. One reason is that to calculate earnings, we have subtracted from

Figure 2: Return and Risk

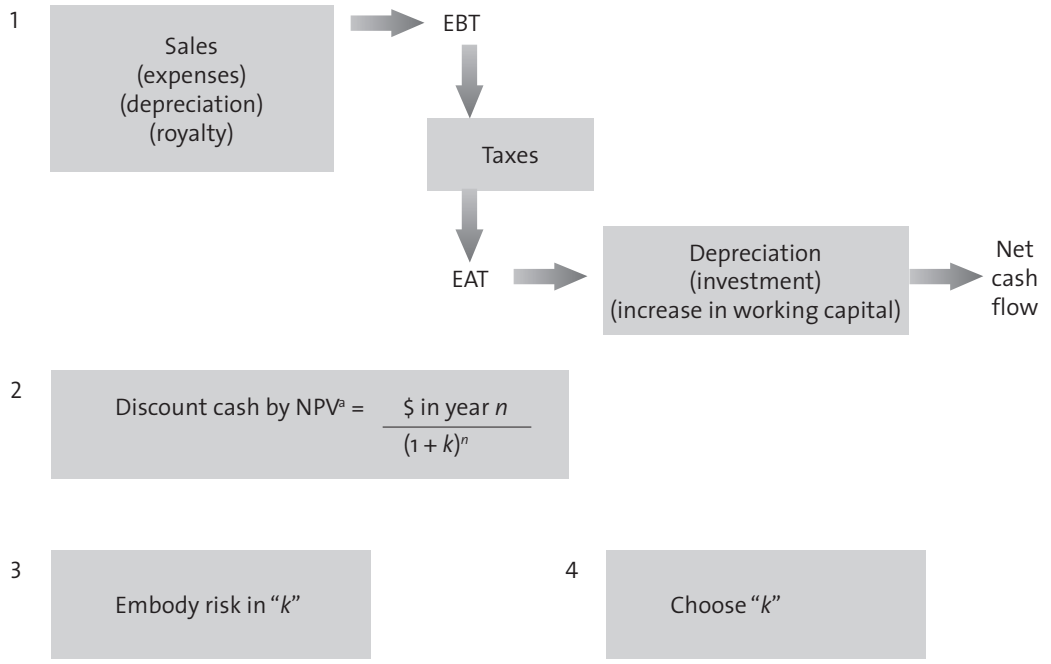


revenues some non-cash costs such as depreciation. To get a cash figure, we need to make three additional adjustments to earnings: (1) the total depreciation expenses deducted from revenues to reach EBT must be added back since they are not a current-year cash expense; (2) the current-year cash investment (such as plant and equipment) needed to produce the revenues flowing from the technology must be deducted; and (3) the year-by-year increase needed in networking capital (current assets, such as cash, receivables, and inventory, less current liabilities, such as payables—all of which tend to increase with increasing sales) must be subtracted. The result is net cash flow in current-year dollars for the projected period, normally at least 10 years of sales, or a total of 15 or more years from the effective date of the license agreement.

Next, each years' cash flow is reduced by dividing each cash flow by the term $(1+k)^n$, where k is the hurdle (or discount) rate, and n is the year from now in which the projected cash flow occurs.[41] In order to perform this calculation, estimates must be made for revenues and all relevant costs and investments year by year. This can be a formidable exercise to a first-timer, but after the technology transfer manager has done this a few times, timidity flees and the manager will find him- or herself boldly arguing about projected costs of sales in the year 2020. Table 14 provides an example calculation taken from Gordon Smith and Russell Parr.[42]

In the example shown in Table 14, a company is considering whether to buy a license for a specialty product to add to an already existing commodity product. The royalty line showing 12.6% of sales is based upon the sales of the licensed, specialty product only. The NPV of the combined net cash is shown as US$19,684. The 12.6% was used because this NPV is identical to

Figure 3: Value: Risk Plus Magnitude and Timing of Future Cash Flows[40]



a Net present value equals "*All the future benefits of ownership compressed into a single payment.*"

Table 14: Commodity Corp. Discounted Cash-Flow Analysis
(US$, in thousands)

	%	1991	1992	1993	1994	1995	%
Commodity sales	100	100,000	105,000	110,250	115,763	121,551	
Specialty product sales	100	1,000	5,000	20,000	45,000	60,000	
Total sales		101,000	110,000	130,250	160,763	181,151	
Cost of commodity sales	68	68,000	71,400	74,970	78,719	82,564	
Cost of specialty product sales	45	450	2,250	9,000	20,250	27,000	
Total cost of sales		68,450	73,650	83,970	98,969	109,654	
Depreciation expense		2,632	2,813	3,051	3,446	3,699	
Gross profit	30	29,918	33,537	43,229	58,348	68,198	38
Selling, general and administrative	24	24,240	26,400	31,260	38,583	43,572	24
Royalty payment at 12.6% of sales		126	630	2,520	5,670	7,560	
Operating income	5	5,552	6,507	9,449	14,095	17,065	14
Provision for taxes		2,499	2,928	4,252	6,343	7,679	
Net income	3	3,054	3,579	5,197	7,752	9,386	5
Depreciation expense		2,632	2,813	3,051	3,446	3,699	
Gross cash flow	6	5,685	6,392	8,248	11,198	13,085	7
Less—							
- Additions to working capital		1,200	1,800	4,050	6,103	4,158	
- Capital expenditures		2,632	3,632	4,763	7,901	5,046	
- Net cash flow	2	1,853	960	(565)	(2,805)	3,881	2
- Discount rate		0.9333	0.8115	0.7057	0.6136	4.9718	
- Present value		1,730	779	(399)	(1,721)	19,296	
Total net present value (in US$, in thousands)					**19,684**		

the NPV of not taking a license for the specialty product. Therefore, a royalty of 12.6% would be the *most* the company would pay to gain this additional product.

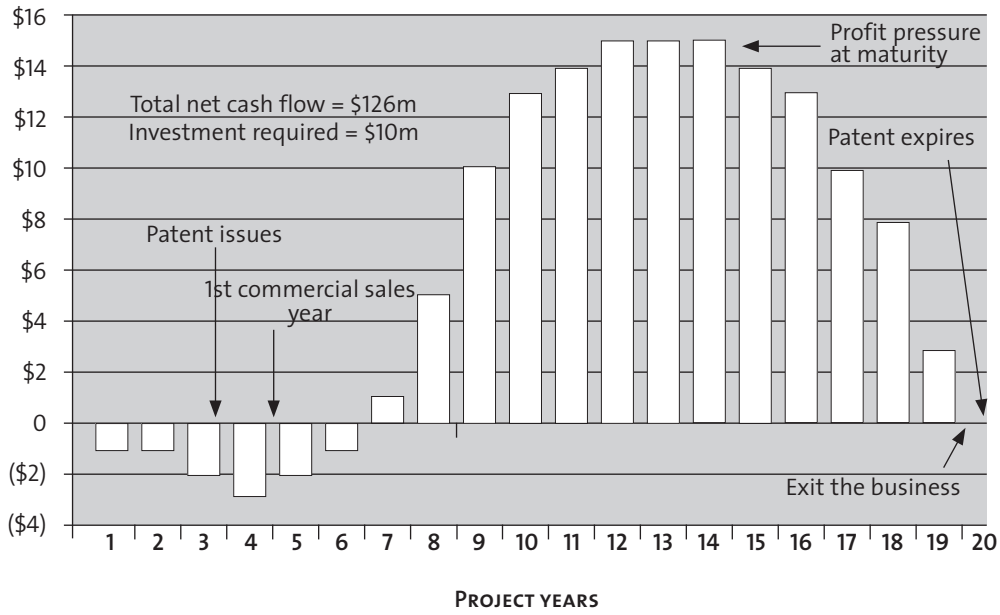
The key aspect of the above calculation is the specification of a value for *k*. Before delving into how a value for *k* might be selected, a better understanding of what *k* does to a calculation is required. Figure 4, which shows a pro forma net-cash-flow projection for a license, can help us take our first steps to understanding *k*.

At time zero, the license agreement is signed. During each of the first and second years, the licensee spends $1 million in combined upfront fees and technology development and project costs. In the third year, these costs grow to $2 million, and in the fourth year, as scale-up and production costs are incurred, they grow to $3 million. So, by the end of the fourth year, and before any sales occur, the licensee has spent $7 million. Although sales begin in the fifth year, there is still a net investment required of $2 million and again of $1 million in the sixth year. At the seventh year, the licensee finally reaches the stage where the technology does not require an additional current-year net cash investment. In this model, the licensee has had to sink a total of $10 million to get to this point (7+2+1), and in the seventh year, the project results in a net cash inflow of $1 million. Note that for most projects, the amounts of initial investment required are generally able to be estimated with more certainty than are the later-arriving profits.

Now, the market for the product is expected to take off and there is a significant growth in expected cash generated until the product peaks in the 12th year. Sales begin to decline in the 15th year, and finally end after the 19th year when the product is withdrawn from the market because it is no longer economically competitive.

Adding all the cash flows above the line, from the seventh through the 19th years, shows a cumulative $136 million. Thus, it took a relatively certain $10 million investment to get an expected return of $136 million.[43] Putting this another way, a $10-million investment starting today and extending over a period of the next six

Figure 4: Example Future Net Cash Flow



years, will yield a substantial $126 million net over the next 19 years.[44]

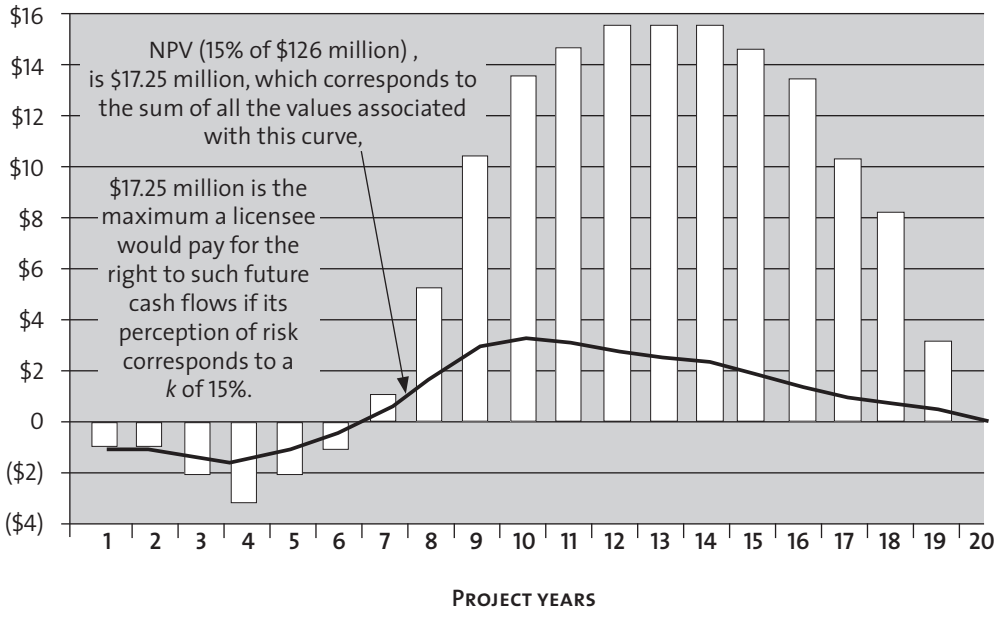
Figure 4 ignores inflation and all the risks associated with the production of those future cash flows. In accounting for inflation, a *k* value of 2%–8% (depending on our views of the future) might be used to reduce all the cash flows to the same basis so that when the return is netted against the investment the calculation is made using same year dollars, at time zero. If a *k* value of 7% is selected, each of the shown cash flows would then be divided by the term 1.07^n, where *n* is 1, 2, 3, and so on, up to 19 for each year of the projection.

However, in addition to inflation, risk must also be assessed and accounted for. The licensee's expenditures of money are comparatively certain. The returns are not. If the licensee takes the view that investments and returns should be discounted by the company's cost of capital, and such cost is, say, 15% (which includes the effects of inflation), then the cash flows of Figure 4 result in the curve shown in Figure 5.

This shows that the early-year cash amounts are reduced slightly (the curve and bars are close in the first and second years). As time progresses, there is a compound discounting of cash amounts until the cash contributions calculated by the 15% discount factor in the 19th year are almost negligible. This is because the mathematics assumes a compounding of risk with each succeeding year (in other words, more things can go wrong as more time progresses). Remember that a *k* of 15% in this model is more than the presumed rate of inflation. This is why the term *hurdle rate* is used for *k*. If the projected cash flows cannot be attractive using 15%, then this investment does not jump this hurdle and should not be made.

What Figure 5 shows is that, for a *k* of 15%, the $126 million of nominal net cash is really only $17.25 million of time zero (now) cash. This $17.25 million value is called the net present value (NPV) at a hurdle of 15%. The NPV means that, for a risk value of 15%, including inflation and all the things that can go wrong, the decision to invest in this opportunity will produce, in time, the equivalent of $17.25 million of today's dollars. By definition, this means it is worth making the investment, unless the licensee

Figure 5: NPV of Net Cash Flow at a Risk hurdle (Discount rate) of 15%



has an even better NPV opportunity at the same or lower level of risk.

Figure 6 shows the impact of various hurdle rates on the same cash values shown in Figure 5.

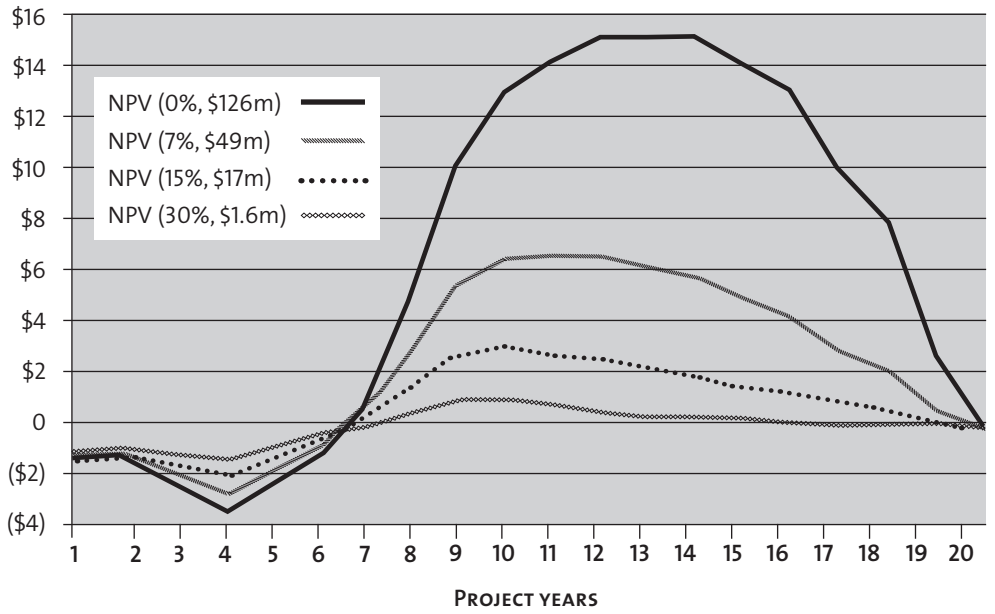
The original cash profile shown was for a hurdle rate of 0% and assessed this opportunity at $126 million net in nominal dollars. If a *k* value corresponding to a near risk-free alternative investment opportunity of 7% is selected over the period, then the opportunity is assessed at $49 million (again, and always, in today's dollars). When a hurdle rate of 15% is selected, corresponding to a low but real risk, this is further reduced to $17 million. Finally, when this opportunity is believed to contain significant technical, market, and other risks corresponding to a risk-adjusted hurdle rate (RAHR) of 30%, the NPV is reduced to $1.6 million.

The key idea of NPV is that, once the appropriate value for *k* has been selected by the licensee, then the licensee should be motivated to acquire rights to any properties that have a positive value of NPV, provided the company has sufficient resources to pursue every positive NPV opportunity. Otherwise, the licensee will select the most positive opportunities available. In any case, the licensee will still want to buy the rights to the opportunity for as little as possible, even less than the values used in computing the NPV in the first place: "Business is about paying tens for fifteens."[45]

5.4.3 *Determining k (the hurdle rate)*

Now, how is *k* determined? The discussion of Method I noted that established market prices exist for certain standard kinds of items, such as office floor-space rentals, and for standard forms of debt instruments, such as federal securities of varying maturity. U.S. Treasury securities, having essentially no "business" risk, have the lowest *k* values. For example, as of 13 April 2001, the *k* value ranged from 4.33% on two-year treasuries to 5.16% on ten-year treasuries. Bonds offered by corporations generally have higher *k* values, depending upon the perceived risk as characterized by various bond-rating agencies. However, all such rates are for broadly based investments, not a specific commercialization project, so they

Figure 6: NPV of Net Cash Flow at Various Risk-Hurdle Rates (*k*)



are normally believed to be substantially less risky (because the companies exist, their markets are known, their competitors positioned, their technology understood, and their businesses typically are somewhat diversified).

Unfortunately, there is no such table of values available for technology licenses. As was the case when contrasting office space rentals and technology commercialization opportunities, the latter do not fall into sufficiently precise categories with large numbers of published values to permit standard *k*s to be established.

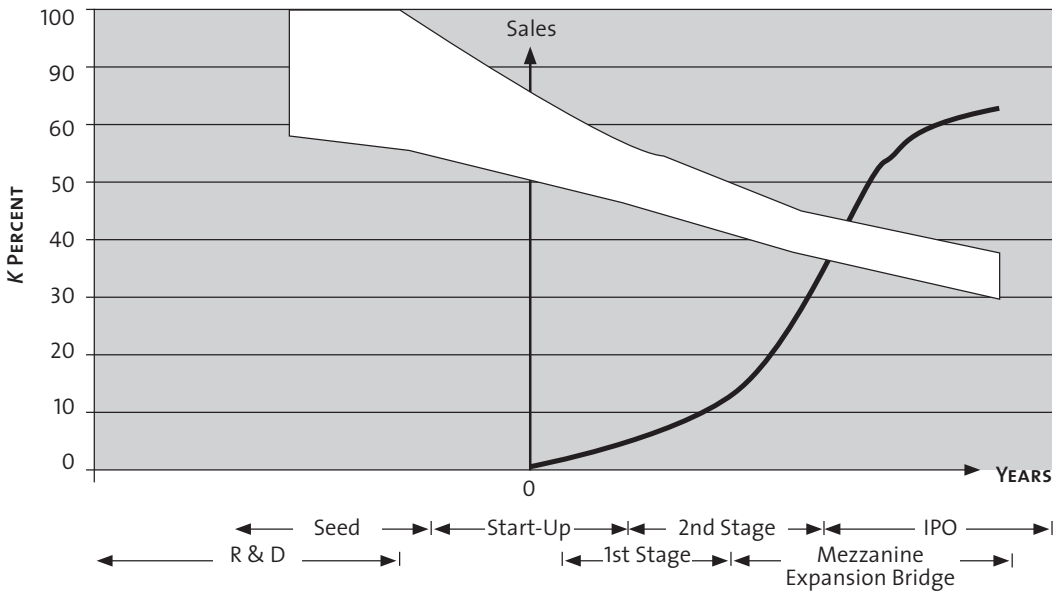
Figure 7 illustrates another type of risk consideration: business start-up risk. This is based primarily on a book by Jeff Timmons.[46]

A number of terms are used to characterize the stages of development; at times, these terms can be confusing and contradictory. In general, for capital sought prior to initial sales, the hurdle rate required by risk-capital providers is very high, 50%–100% (or even more). Once sales exist and a market can be characterized, and assuming the results are favorable, the hurdle rates can decline dramatically down to 30%–40% (depending upon assessments of competitive response, market saturation, cost of expansion, and so on). The hurdle rates used for genuine start-up situations are usually far higher than those used by an existing company, and they reflect the increased risks associated with all the activities needed to create a business ex nihilo.

So, what is a reasonable way to categorize hurdle rates? There is no simple answer to this question. However, to provide some insight the broad generalizations of Box 1 are offered for five categories of risk.[47]

Most licensing situations with existing companies will fall into Categories II and III, corresponding to hurdle rates in the range of 25%–40%. Start-up situations or companies contemplating a spinout structure normally require hurdle rates in excess of 40%, even to 50% or higher. However, as was discussed in connection with the 25% Rule, every licensing opportunity has case-specific factors that affect both value and, our present concern, risk. Just because an

Figure 7: Hurdle Rates for Start-ups



invention relates to an existing manufacturing capability with a known technology area, a potential licensee may see the risk associated with such specific invention as warranting a RAHR higher, or lower, than given in the Box below.

Figure 8 applies these five risk categories to our original cash flow example of Figure 4.

If this opportunity corresponds to Category III, the NPV ranges from a negative $800,000 (for a *k* of 40%) to a positive $1.6 million (30%). So, what originally looked like a simple decision of making a total investment of $10 million to net a total of $126 million is actually a close call. If the risk of this opportunity corresponds to a hurdle of 40%, this investment cannot be justified because the NPV is negative. Recall that, when this model was created, (an unstated) upfront payment and progress payments were assumed by the licensee to the licensor, as were continuing royalties that reduced the cash flows to those shown. Both were part of the $10 million investment. From the point of view of the licensee, this negative NPV should be a stimulus to reconsider all such IP payments to see if the negative NPV can be made positive.

5.4.4 *Reducing risk/enhancing value*

In any event, there are at least two other possibilities for reducing IP payments. First, the perceived risk may be reduced by working with prospective licensees who are either already commercially applying technology similar to the subject opportunity or selling like or similar products. The point here is that companies perceive risk differently depending upon their technology base and their existing customers. If, by this redirecting of marketing activity, a different prospective licensee's assessment of risk is now 30%, then there is the potential to gain as much as an additional $1.6 million beyond those payments embedded in the cash-flow calculation. That is a very dramatic increase in value. Furthermore, the likelihood of getting the royalties is increased because it is more likely that such a licensee will succeed (all other things being equal—and they never are).

A second approach to dealing with negative NPV outcomes is to consider what R&D and/or market development activities can reduce the risk. The real technical risk of some key aspect of the technology may be known by the inventors to be much less than that perceived by prospective buyers. A carefully directed, internally funded R&D program tackling commercial objectives can significantly reduce such risk. Of course, it is always possible that such results will go the other way. The key idea is to spend small amounts of money on critical, commercially relevant experiments—and not just gather ever-more publishable data

Box 1: What Is Reasonable *k*?

Unfortunately, the answer is: whatever the market says it is.

What does the market seem to be saying?

I. Low risk (assuredly fits into an existing manufacturing line and market) 10% to 20%; if required to maintain base product life, then *k* could be much lower, or even discarded

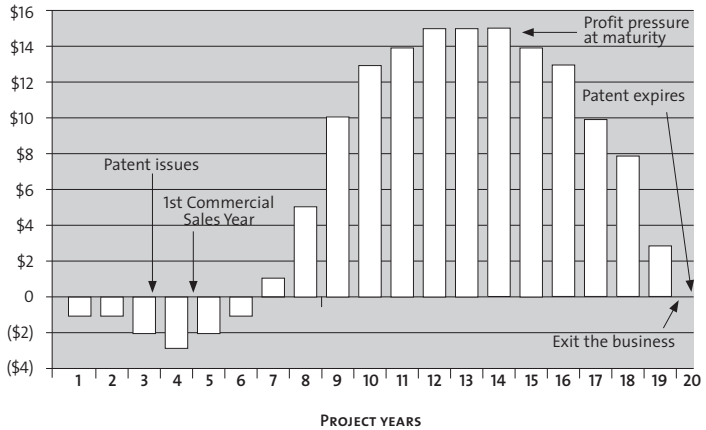
II. New product (existing manufacturing capability, known technology) 25% to 35%

III. New product and technology (still in existing business) 30% to 40%

IV. New business, product ready for sale (no R&D required) 40% to 50%

V. New business, seed funding, R&D stage 50% to 70% (or more)

Figure 8: Who Are Prospective Licensees and What Should They Be Willing to Pay?



Applied to our previous net-cash-flow model, what would an investor conclude?

Category	*k*	NPV	
RF	7%	$49m	Yes
I	10%–20%	$33–$8m	For a "New Product" category (*k*=30%): ≤$1.6m
II.	25%–35%	$4.2–$0.1m	
III▸	30%–40%	$1.6– $(0.7)m	Barely, Yes
IV.	40%–50%	$(0.7) – $(1.4)m	
V.	>50%	<$(1.4)m	Only if you paid me!

sets. Some have described this process as doing the last experiment first. In general, it is a very good idea.

Another tool in such a risk-reduction approach is leveraging government funding. It can be argued that government funding should be used to reduce the risk of significant commercial opportunities so that the private sector can apply it to create high-valued companies and jobs. Commercial funding necessarily has some relatively immediate market application and introduction. However, there are other sources of "research" funding sometimes available that push forward certain knowledge frontiers that could have as a consequence the development of know-how that supports the subsequent commercial development needed for a specific licensing opportunity.

In addition to reducing risk, one can work to directly enhance value. One tool to accomplish the latter is to form partnering relationships with other R&D organizations that, by pooling technology resources and market awareness, can sometimes significantly increase the NPV perceived by prospective licensees. Even when the NPV is already positive and a prospective licensee is interested in negotiating rights, remember that a licensor always has alternatives. For example, the technology could be pushed closer to market either by internal investment or by partnering with another R&D organization to increase the value. The technology transfer manager should make such investment decisions by calculating the prospective increase in value discounted by the risk of success.

This risk-adjusted hurdle rate approach can be used for exclusive and nonexclusive licenses, as well as for licenses by field (or product) and territory. In each case, the cash-flow projections need to reflect the anticipated commercial outcome given the structure of the agreement. For example, if the licensing strategy is to have two competing licensees in all fields and territories, then the magnitude of the total sales attainable by each licensee is probably less than if there were to be one exclusive licensee. However, the gross margins, or profitability, may remain large, since each licensee will not face a large number of competitors. The net result is likely to be that each licensee will pay less royalty, but together they could (and should be if such an approach is considered) pay more total royalties.[48] More details on DCF models are provided in the Wiley-published book by this author.[49]

5.4.5 *Possible payment structures*

Running royalty structures. There are many possible royalty structures. Because the royalty rate depends upon the economic value associated with specific products, if there are multiple products, then a separate royalty could be established for each product or product area within a single agreement. There is also justification for building up a royalty rate based upon the measure of IP protection obtained. For example, a licensee might pay a royalty of 3% on the basic patent and 1% for the use of the two other patents in the package, or 1% for the use of the unpublished technical information and an additional 3% for the patents, and so forth. Of course, this should only be considered if it relates to an economic benefit (lower k, higher margins, and so on).

Many licensees ask for a declining royalty rate with increasing sales, a so-called staircase or wedding-cake royalty structure. One example would be a royalty of 5% on the first $1 million in sales, 3% for the next $9 million, and 1% for all sales above $10 million, based on annual sales. The underlying theory of this approach appears to be an economy-of-scale argument similar to bulk purchasing. If a company buys one box of paper clips, it might conclude that $5 is reasonable; if it buys 1,000 boxes it may expect to pay only $3 each; and if it commits to buying trainloads per year, it may expect to pay only $1 each. Companies commonly leverage volume purchases when they buy, and apply this same kind of thinking when they sell. However, there is no economy-of-scale principle for IP rights. The licensor's costs of providing the grant to the licensee are not relevant, nor do they decline based on sales volume, as would the costs of a paper-clip supplier. In fact, based upon an economic-return model, it can be argued that the profitability to the licensee *increases* with increasing sales, and so, the royalty rate should actually go *up* with increasing sales. For practical

reasons, the parties may elect to simply compromise and keep the royalty rate fixed regardless of sales volume.

Developing a staircase royalty structure based on *cumulative* sales or on years from first commercial use may have a rational economic basis. Ordinarily, after the initial introduction, the profitability of a product climbs to a peak and then, as the product matures, pricing pressures tend to squeeze margins. A royalty structure that attempts to model this profile makes sense, providing the rate during the high-profit years has been set to correspond with economic benefits. For practical reasons, parties frequently elect a single rate over the life of the patents that balances all these factors. Regardless of the approach, the rate agreed to tends to act as a cap for the reasons discussed in the introduction to this chapter. The licensor does not have a vehicle for increasing the rate, and the licensee can come back to the licensor and threaten to drop the license because of less-than-anticipated margins unless it gets a reduction in the rate.

Licensees sometimes propose capping the total economic return to the licensor. This may be expressed as some multiple of the licensor's costs (You shouldn't expect to get more than ten times what you've invested in this!) or simply as some statement of moral principle ($10 million should be more than enough, after all you are a public, not-for-profit institution!). This is nonsense. A licensor who is the rightful owner of a portfolio of technologies has a stewardship responsibility to return value to the institution for the transfer of such rights. Furthermore, all portfolios exhibit many losers, a few moderate successes, and only a few agreements that perform really well. If the licensor agrees to caps on the total return of all agreements in the portfolio, then the portfolio will produce only losers and moderate returns. Without the occasional big win (at a fair royalty rate), the portfolio will not produce a fair overall return.

What about the approach of a one-time, paid-up license—that is, setting a higher licensing fee with a zero running royalty? Some licensees push hard for this approach—and not always from a pure heart. There are several common arguments in favor of the approach: (1) it eliminates the administrative burdens (quarterly or annual reports and checks) for both the licensor and licensee and (2) basing royalties on sales may divulge highly sensitive licensee business information, which is against company policy or wishes. Recall the earlier discussion about setting the values of future income streams in well-defined situations such as office rent. When a stream of cash payments is well defined and the risk is low or at least well understood, then two parties can readily agree on the conversion value of the future stream into one present payment (which is really just the NPV of the future stream). However, for early-stage technologies, estimates of the range of possible dollar returns from royalties can vary over several orders of magnitude. This is precisely why a royalty *rate* so effectively deals with such uncertainties. When either the licensee or licensor seeks to reduce such uncertainties to a one-time lump sum, there is greater risk involved in making the conversion. One possible motivation for a prospective licensee is simply to see if the license can be acquired cheaply. Every agreement has associated with it a range of expected outcomes. If a licensee can acquire the license by the one-time payment of the NPV associated with the most conservative outcome, then it is in the licensee's interest to do so.

Rest assured, a licensee is unlikely to agree to an NPV associated with the most optimistic outcome. It should be recognized, however, that sustaining ongoing agreements is both a business cost and a risk. An ongoing payment arrangement could possibly lead to a dispute or even litigation. And there may be situations where the licensor's cash needs are such that the institution is willing to forgo the returns associated with more optimistic possible projections. If this becomes the licensor's practice, however, the overall returns on the licensor's portfolio of technologies will be reduced because the licensor will not experience the rare but important higher-than-projected returns from an exceptional license.

Having said all this, sometimes such an arrangement can be in the interests of both parties (beyond the simple example given above). The licensor may wish to take advantage of the high

opportunity value associated with a paid license so that the funds can be used to move further and faster other technology opportunities that will lead to even more substantial returns. Or perhaps the licensees are cash-rich from a current high-outcome year and are simply willing to make a fair and substantial payment to own and control an opportunity because of its perceived strategic importance. Overall, in those cases where the future use and value of an opportunity appears to be reasonably well-bounded, then an NPV calculation can be made that is fair to both parties.

Upfront payments. Upfront payments take many possible forms. As discussed earlier, the extreme case is a one-time payment in lieu of running royalties.[50] A series of payments can also be made, either by calendar (such as annual payments) or by progress (such as upon filing an IND [Investigational New Drug application, a filing with the U.S. Food and Drug Administration], upon first commercial sale or other milestones) in conjunction with or instead of royalties. Or the licensee can commit to R&D to fund certain activities at the licensor's laboratories.

All of these are basically down payments on the NPV opportunity as calculated earlier, and the purpose of any down payment is the same. It combines a form of diligence and commitment, and provides an early return for the original investor, the licensor. In university-industry licensing, the upfront payment will commonly at least exceed the licensee's payment of all the licensor's costs in filing and obtaining a patent or patents incurred to date. If the license corresponded to an NPV of $1.6 million as in the previous example, and the patent costs were $5,000, such an upfront commitment covering only the licensor's costs would be cheap—too cheap.

For well-established transactions such as buying a house or a car, a down payment of 10%, more or less, is common, although for highly motivated sales of, say, certain out-of-popularity automobiles, might be happy with "no money down" deals. For highly speculative opportunities, such as a license to new technology, 10% may be on the high side. Consider in the previous example, that the $1.6 million NPV was computed on the basis of a single, time zero, cash payment of $100,000 and then royalties on sales. Such a figure would then correspond to a down payment of a little more than 6%. This might be quite reasonable. Some negotiators use, as a rule of thumb, one year of projected mature-earned royalties as an appropriate down payment; this is approximately 5%–10% of the NPV.

Minimums. Another form of diligence is the minimum cash payment. Also, agreeing upon such payments increases the likelihood that both parties are looking at the opportunity from similar perspectives. Generally, exclusive licenses contain minimums. Nonexclusive licenses may or may not include minimums. The rule of thumb appears to be an annual payment in the amount of one-fourth to one-half the annual projected reasonable royalty based on sales estimates. Again, the higher the risk and uncertainty of such sales estimates, the lower the minimum royalty, and vice versa.

It is important to realize that the licensee still has significant negotiating leverage on the minimums. If they end up being too high, and it is now five years into the agreement, the licensee can exert a lot of influence on the licensor by threatening to drop the license if the minimums are not reduced in line with the actual sales (assuming the licensee has been diligent in developing the technology and the market). In addition, getting back a five-year-old technology may make it difficult for a licensor to find another party interested in licensing the product. As discussed earlier, the wish, or threat, for better terms, of a licensee in a licensee-initiated negotiation, puts in jeopardy the licensee's investment in the technology (any upfront payments, milestones, annual royalties, and of course its own R&D and market development). So a licensee would have to take a dramatic step to fulfill such a threat and drop its license should the licensor not agree.

Equity consideration. A full treatment of this subject is beyond the scope of this chapter. However, much of what has been discussed above regarding NPV calculations using discounted cash-flow analysis and hurdle rates applies. The reader is referred to the author's Wiley-published books for more information.

5.4.6 *Summary*

Summary observations and valuation principles based on Method IV are given in Box 2 and Box 3.

5.5 *Advanced tools*

Once a DCF model has been established, it is possible to extend such analysis by application of quite complex mathematical modeling tools and gain a better understanding of their economic impact.

The basic tool is sometimes called *probabilistic modeling* and, most commonly, *Monte Carlo analysis*. The complexity of such models used to require mainframe or minicomputers, but at least two such products now run on personal computers. [51]

This tool works by replacing certain cells in a spreadsheet with a probabilistic value rather than a single number as was done in Method IV. Then the model is run over and over again, hundreds of times, to develop a distribution of outcomes. It is much like running the company 1,000 times (or more) and comparing the outcomes. Under the DCF approach, each outcome is the same. However, under a Monte Carlo method, each of the 1,000 runs would produce somewhat different values for those cells that were selected for treatment in this manner. It may sound more complicated, but in many ways it is simpler. In fact, Monte Carlo methods are particularly useful when modeling a start up situation.

Below is an example taken from one of the companies that offers a PC product.[52] This considers a fictitious drug, ClearView, which may be a cure for nearsightedness. The key assumptions are shown in Figure 9.

In this illustration, the impact on profitability will be examined through the probabilistic investigation of five assumptions. These are shown in Figure 10.

First, consider the testing costs. The original model assumed the testing costs would be $4 million. Assume there is an equal probability that the costs will range between $3 million and $5 million but will never be less than $3 million and never more than $5 million. This is shown as the uniform distribution at the top left of Figure 10A.

Next, reconsider the estimate for the number of patients cured: 25 out of 100. Now assume a binomial distribution, a commonly occurring natural distribution, with a mean of 25 as shown in Figure 10B.

Now, adjust the assumption for the marketing costs from simply $16 million to the triangular distribution shown in Figure 10C. The most probable outcome is shown as $16 million, and the minimum and maximum are $12 million and $18 million.

Similarly, the growth rate of the market and the market penetration single values are replaced by the distributions shown in Figure 10D and Figure 10E.

Every simple-value cell in a spreadsheet can be replaced by any of the available probability distributions. As a technology transfer manager gains experience using this tool, it becomes increasingly clear which cells to treat in this manner and which probability distribution makes the most sense. There never is a right answer. In fact, one of the great powers of this methodology is that the model can be run over and over again with changing assumptions to better understand the key assumptions that should be investigated in more detail to reduce overall uncertainty. The result of the Monte Carlo simulation is shown in Figure 11.

This outcome shows what happened when this business venture was run 998 times. The financial outcome ranged from the worst case, when all things broke the wrong way (the highest marketing cost, the fewest number of cured patients, and so on), with a loss of $14.9 million, to the most-favorable outcome (when everything went right) of a net gain of $51.9 million. Half the time, the net gain was less than $9.8 million, and half the time it was more. The big spike to the left on the graph of Figure 11 reflects the severe loss that occurs because the cure rate was so low that U.S. Food and Drug Administration (FDA) approval was never obtained.

Another advanced method of increasing importance is the use of real options (as opposed to financial options). Indeed, an increasing number of books explore the use of real options in business decision making. Their potential application

Box 2: Summary Observations

1. Value is dependent on risk—the risk-adjusted hurdle rate (for the same magnitude and timing of future net cash flows).

2. There is no one right risk model.

3. Price is determined by what a buyer will give for the rights to such cash flows.

4. As a licensor's price aspirations correspond to low (optimistic) values of RAHR, the likelihood of finding such a buyer is reduced (which translates to increased time and resources required to find such a buyer).

5. There is no one right price (providing No. 2 is true).

6. The longer the period of such future cash flows, the wider the risk limits and the greater the uncertainty in price aspiration.

7. For cash streams that meet certain standard categories, such as home mortgages, there are well-established markets that significantly reduce the scatter on risk and price. No such market exists for early-stage technologies.

8. Net-cash-flow models require more work and are subject to significant assumptions about operations and the future (but the licensee is using them to analyze the opportunity and so should the licensor).

Box 3: DCF Valuation Principles

1. Value calculations may have wide limits because of the range of estimates of the magnitude, timing, and risk of future net cash flows.

2. Value is given by a down payment (option/license fee) and a future royalty, which may, in the end, be used to determine the one-time, upfront payment for a fully paid-up license.

3. The down payment for a running royalty license should (normally) be a small fraction of the total estimated value based on one or the other of the following:
   - approximating the higher risk bound (but, nonzero)
   - 5%–10% of the total NPV (best estimate basis)
4. A fair royalty can only be negotiated when reasonable estimates can be made of future net cash flows.

5. The royalty should be uncapped.

6. Royalty scales dependent on total sales, if used, should be based on value not on a quantity discount model.

7. Royalties based on figures below the top line (sales) put the licensor at risk for inefficiency/ineffectiveness of the licensee, which has the effect of double accounting for risk.

to early, high-risk technologies can be useful because real options do not punish substantial but distant future outcomes by high and compounded risk-adjusted hurdle rates. The DCF approach in particular can calculate an almost negligible value to a $1 billion opportunity that occurs, say, 10 years in the future with substantial average risk. Real options can be used to take such risk apart by valuing an opportunity stage by stage, risk by risk, as decisions are reached and investments made. An introduction to such methods is given in the author's Wiley-published books and, in particular, another 2003 Wiley book by the author: *Dealmaking: Business Negotiations Using Monte Carlo and Real Options Analysis*. These resources give a more comprehensive treatment of Monte Carlo and real option methods and negotiation planning and strategy. The 2003 *Valuation and Pricing of Technology-Based IP* also gives a more extensive discussion of various forms of deal structures and financial payments.

5.6 *Auctions*

This analysis of methods and tools began by considering the use of industry standards. In a sense, by considering options it ends there as well. An auction is simply a formalized way of obtaining bids from competitive potential buyers. As a method, it dates from antiquity and is the prevalent form of commodity transactions, ranging from the New York Stock Exchange to commodity markets to estate and sheriff sales caused by owner bankruptcies.

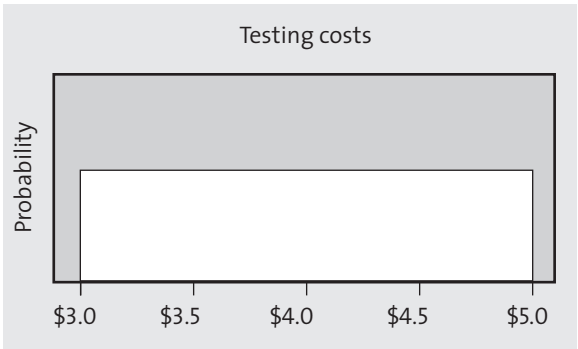
Figure 9: Sample Monte Carlo Method—Basic Assumptions

Fictitious new drug, ClearView, for correcting nearsightedness

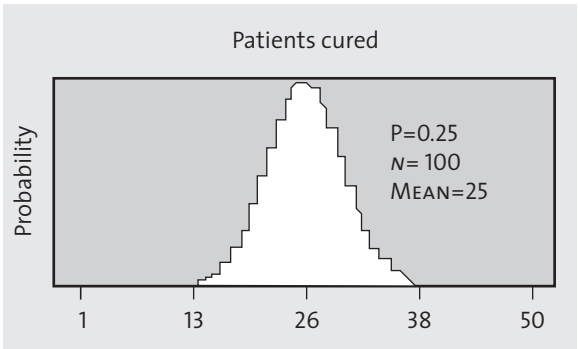
Costs (in millions):	
Development cost of ClearView to date	$10,000
Testing costs	$4,000
Marketing costs	$16,000
Total costs	$30,000
Drug test (sample of 100 patients)	
Patients cured	.0.25
FDA approved if 20 or more patients cured (1 approved, 0= rejected)	
Market study	
Persons in U.S. with nearsightedness today	40,000
Growth rate of nearsightedness	1.00%
Persons with nearsightedness after one year	40,400
Gross profit on dosages sold	
Market penetration	8.00%
Profit per customer in dollars	$12.00
Gross profit, if approved	$38,784
Net profit	($14,000)

Figure 10: Specific Monte Carlo Assumptions for ClearView Example

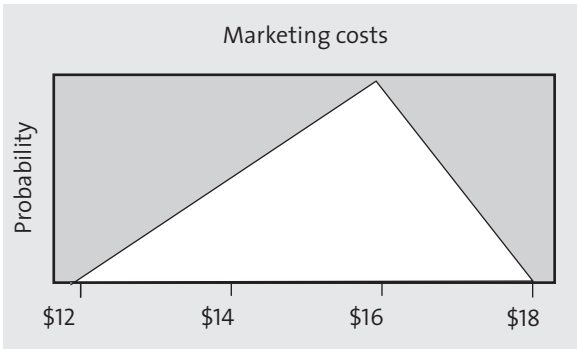
A. UNIFORM DISTRIBUTION



B. BINOMIAL DISTRIBUTION



C. TRIANGULAR DISTRIBUTION



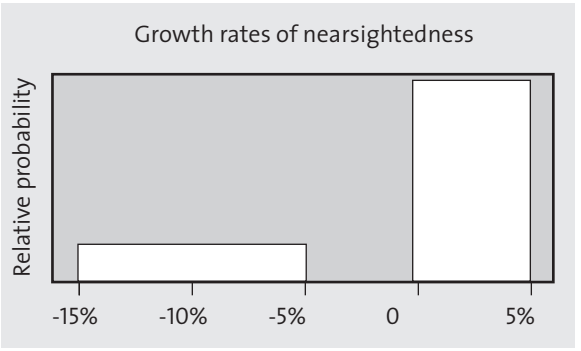
(Continued on Next Page)

Its use in technology licensing contexts, however, has been comparatively rare because of various structural difficulties. One of the most significant barriers is the need for any prospective buyer to perform extensive due diligence and analysis. Imagine the contrast between being on the floor of an exchange and being offered 100 shares of IBM at $100 share or 100 bushels of corn at $3 per bushel. No investigation is needed to determine exactly what is being sold or whether there is a market for it. Contrast this with a vice president of an electronics firm receiving a letter from a university or institute offering to license or sell a portfolio of patents relating to a new approach for making a blue-green laser. For the VP to have any rational idea as to his or her potential interest, he or she will have to substantially invest in learning how this offered technology differs from its own or other published literature, the stage of development, the key benefits, the scope of the intellectual property, and so on.

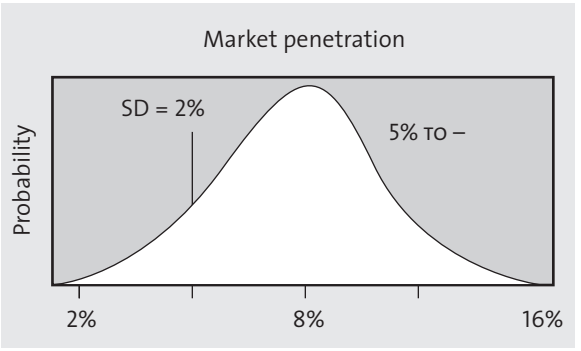
Another barrier to the use of auctions is that the mosaic of the licensing deal is typically much more complicated than a simple cash payment, as in the case of IBM shares or bushels of corn. An upfront payment or payments is to be expected, but so might royalties, additional R&D investments at the discovery institution, and many other deal features. These aspects are not as easily communicated by bidders or compared by sellers.

FIGURE 10 (CONTINUED)

D. CUSTOM DISTRIBUTION



E. NORMAL DISTRIBUTION

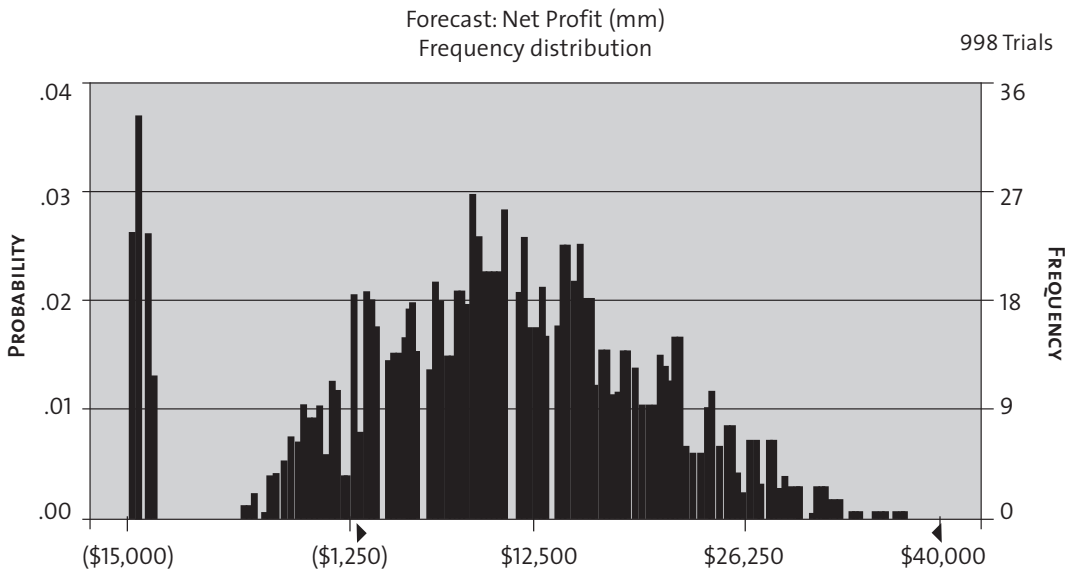


Nonetheless, auctions for intellectual property do occur. Perhaps the most common occurrence is in the context of a shutdown or bankruptcy proceeding, where the investors are seeking to recoup some of the investment and the alternative of continuing as a standalone company no longer exists. All the parties understand that the court has ordered a process, and there will be a sale to the highest bidder.

A famous university example of opportunity licensing is associated with a fat gene discovered at Rockefeller University. According to a *Business Week* article.[53] Rockefeller University and a then recently started biotechnology company initiated discussions; the invention, which has the promise to "cure" obesity by a gene, attracted significant interest by other companies, which led to other, parallel discussions. However, when a large number of companies expressed interest (reportedly more than a dozen), all of them were invited to bid on the opportunity. On 28 February 1995, Rockefeller announced that Amgen had won by agreeing to pay a US$20 million signing fee plus unspecified royalties. According to Rockefeller's vice president for academic affairs, "*Amgen purchased a scientific concept*": a pretty valuable scientific concept.

The very high-perceived potential value of the Rockefeller gene gave the institution enormous bargaining power (some might argue that

Figure 11: Simulation Output (Forecast) for ClearView



Percentile

0%	US$14.939
10%	US$12.933
20%	US$0.617
30%	US$4.166
40%	US$7.402
50%	US$9.770
60%	US$12.110
70%	US$14.968
80%	US$18.341
90%	US$22.612
100%	US$51.917

it created a feeding frenzy). In most licensing circumstances, the seller/licensor is simply not going to be able to attract a sufficient number of simultaneous bidders. This is because the cost of the due diligence, coupled with the reduced likelihood of being the successful acquirer, will encourage already busy companies to do something else with their precious time and energy. Some additional examples of successful and unsuccessful auctions are included in the earlier-cited author's Wiley books.

6. CONCLUSIONS

This chapter started with a letter requesting money for an investment. It will close with another one (again, one actually received by a venture capitalist):[54]

"Hello, How are you doing? My work is necessary for the survival of life of the planet. I need money. Minimum investment $100,000. Profit 25%. Thank you."

This letter has all the basic elements of a good marketing instrument: friendly beginning, statement of mission, expression of need, identification of benefit, friendly close. Now you have the tools to decide whether this is a good deal.

Finally, for those of you whose mind has wandered reading all these pages and looking at all these figures and perhaps now find yourself completely lost, I understand that, you the reader, were hoping that by this time I would lead you to the number. OK, here it is: *3.14156*. It is the best this author can do. Use it with great caution. That is it. That is all you need to know. Happy pricing. ■

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1 The initial version of this chapter was created during the author's tenure with Battelle Memorial Institute, a relationship the author gratefully acknowledges. For more on this topic see Razgaitis R. 1999. *Early Stage Technologies: Valuation and Pricing*, John Wiley & Sons; Razgaitis R. 2002. Technology Valuation. In *The LESI Guide to Licensing Best Practices: Strategic Issues and Contemporary Realities*, chap. 2. John Wiley & Sons, 2002; Razgaitis R. 2003. *Valuation and Pricing of Technology-Based Intellectual Property*. John Wiley & Sons; Razgaitis R. 2003. *Dealmaking: Using Monte Carlo and Real Options Methods*. John Wiley & Sons. For further information about the author, visit www.razgaitis.com.

2 Malone MS. *Upside*. September 1992.

3 See, also in this *Handbook*, chapter 11.11 by D Bobrowicz.

4 *The American Heritage Dictionary*, New Collegiate Edition. 1980.

5 If the licensor has multiple licenses (that is, two for two different applications within the same territory), it is not uncommon to have each licensee pay half the patent costs. When developing the initial agreement with the first licensee, the language can provide that, in the event that there is a second licensee, the cost would be shared.

6 Even for conventional manufacture, this approach to pricing is rapidly being supplanted by value pricing. This is because it has been determined that, in many cases, such pricing shielded manufacturing and overhead inefficiencies that are not being tolerated by a market that can turn to more efficient sellers. In other cases, such a cost-based approach did not capture, for the seller, the high value present in its products.

7 Notice that even in this example there are some important risks and timing issues. The technology, in this example, is in hand, ready, and works. Launching an R&D project always involves risk, no matter how confident anyone may claim to be about the outcome. For example, it may be that no alternative workaround is possible, or that it will take $20 million, or that it will only work 80% as well, or that it will take much longer than anticipated, and so on. Having something in hand today is less risky than attempting an independent solution. On the other hand, there are many examples where a highly sophisticated buyer can invent around an institution's invention cheaply and quickly, even though the institution may have made an enormous investment in developing the invention in the first place.

8 Science & Technology Agency, Japan. Class A Technological Assistance Agreements (1975).

9 Actually, in reviewing the bottom of the table, under electrical, it appears that two agreements had no payments at all. So more than half of the agreements had no upfront fee!

10 McGavock DM, et al. 1992. Factors Affecting Royalty Rates. *les Nouvelles* June 1992. p. 107. The data presented was obtained from the voluntary response to a mailed survey. The authors caution that the number of replies may not be statistically significant. Also, given the nature of voluntary replies, there is no assurance that the survey is not biased.

11 Nelsen L. 1989. University Patents. Presented at the

1989 AUTM Annual Meeting. These rates were not determined by a scientific study; rather, they are typical ranges estimated by Lita Nelsen, Director, Technology Licensing Office, M.I.T, based on extensive experience in this area.

12 Adapted from article published by Corey G and E Kahn. 1991. How to Negotiate Reasonable Royalty Rates for Licensing Novel Biomedical Products. *Genetic Engineering News* July–August 1991. p.4. A related article by the same authors was published in 1990 as Biomedical Royalty Rates: Some Approaches. *Licensing Economics Review* December 1990. p. 13.

13 Adapted from Corey and Kahn (*supra* note 2).

14 Kiley T. 1990. *IPH Newsbrief* April 1990.

15 Ibid.

16 Source: Communication from the seller.

17 Private communication, Emmett Murtha, November 1993.

18 Mike Carpenter presented at workshop given at the 1979 LES Annual Meeting.

19 Ibid.; See also the list of reasonable royalty determinations in Einhorn: *Royalty Patent Licensing Transactions* vol. I, sec 303, pp. 3–11ff; or search DIALOG.

20 There is a widely held perception that royalties determined or negotiated before the mid-1980s, when the Court of Appeals for the Federal Circuit was established, are lower than rates established since.

21 See Einhorn, *supra* note 19.

22 Stevens A. 2000. Finding Comparable Licensing Terms. *AUTM Technology Transfer Practice Manual*. Part VII, Chapter 5. AUTM: Northbrook.

23 Edwards, M. Workshop presented at the AUTM 1993 Annual Meeting. Since these data were published by Mark Edwards there has been an enormous increase in the number of such transactions, especially in the "life sciences/health" area. Examples of such additional data are available at www.recap.com.

24 For more discussion on obtaining copies of comparable agreements see Stevens AJ. 2002. Finding Comparable Licensing Terms. *AUTM Technology Transfer Practice Manual*, Second Edition. part X, chap. 3.

25 Feinber RA. 1982. *APA Proceedings*. Division of Consumer Psychology. p. 28.

26 Ibid.

27 Arnold T and T Headley. 1997. 100 Factors. *les Nouvelles*, March 1987. p. 31.

28 Degnan SA and C Horton. 1997. A Survey of Licensed Royalties. *les Nouvelles*, June 1997. pp. 91–96. Reprinted with permission from *les Nouvelles*.

29 When using a savings approach, the technology transfer manager should build in some inflation factor to avoid collecting 25 cents a unit over a 15-year period when inflation eats into the real value of the royalty. Remember, the $1 savings is $1 in the currency of the year that the royalty is calculated (in this example). Ten years later, with inflation or increasing costs of electricity or a particular raw material, the savings could be $8 in the currency of that tenth year. The agreement should normally have some provision for the calculation of royalty to similarly inflate in dollars so that, as in this example, it would yield $2 in the tenth year.

30 This particular form of the definition is adapted from an article by Sommer EM. 1993. Patent and Technology License Agreements Explained. *The Licensing Journal*, August 1993. p. 3ff. This article and other similar sources also deal with an important but complicated issue of transfer pricing: that is, when a licensee sells or transfers the product made by the practice of the technology to another division or a subsidiary of the licensee.

31 All the materials, labor, electricity, and all other variable costs attributable to the manufacture of the product sold.

32 Because this is a gain in a part of the statement where reductions are applied, it is shown as a negative number; minus a minus means a plus, and so forth.

33 Ibbotson and Associates, Chicago, Ill. www.ibbotson.com.

34 Robert Morris Associates, Philadelphia, Penn.

35 Data from RMA Annual Statement Studies, 1991. published by Robert Morris Assoc.; Philadelphia, Penn.

36 *W.L. Gore and Associates v. International Medical Prosthetics*, 16 USPQ Second. p. 1257.

37 Lee Jr. W. 1992. Determining Reasonable Royalty. *les Nouvelles*, September 1992. p. 24.

38 Duke Leahey has included this point in various talks. The version here was the subject of a private communication in 1993.

39 This is part of a long, impassioned argument between business and science. Science argues that it is unwise to develop and apply technology that is not completely understood. Business says: If we took that view, we would still be sitting on a rock and arguing about the Pythagorean Theorem—so, let's get on with it.

40 Smith and Parr. 1989. Valuation of IP & Intangible Assets. Wiley. p. 125. See also, Razgaitis, *Valuation and Pricing of Technology-Based Intellectual Property* (*supra* note 1); see also, numerous papers and books by Gordon Smith and Russ Parr on DCF methods and ways of separating intangible and tangible values.

41 Some people prefer to use a mid-year convention: that is, the costs and revenues occur on average on one day, halfway through the year. For this convention, it should be 1/2, 3/2, 5/2, and so on, which can be generalized by using a discount factor of $(1+k)^{(2n-1)/2}$.

42 Smith G and R Parr. 1990. Royalty Rate Analysis Techniques. *Licensing Economics Review* November 1990. p. 9ff; also published in the 1991 Supplement to the Razgaitis' *Valuation of Intellectual Property and Intangible Assets* (*supra* note 1). Smith G and R Parr have written extensively on this subject. Their organization publishes the journal *Licensing Economics Review*,

which frequently includes articles on the application of this method, as well as other news and information on valuation, pricing, and other IP matters.

43 This model assumes that the licensor received up-front and minimum payments as part of the $10 million investment by the licensee and a reasonable royalty throughout all the period that the product was in commerce, so that the $126 million cash flow to the licensee was net of all the licensee's expenses, including royalty.

44 Also assumed in this model is that there is no net residual value or cost after the product is withdrawn from the market and the business is exited.

45 A quote heard during a talk by Ray Rogers, finance professor at the University of Michigan Business School.

46 The summary incorporates some of the terms and values by Timmons. (See Timmons JA. 1990. *New Venture Creation)*.

47 Paul Purcell of Battelle, and others, have provided valuable initial insights to negotiating and valuation contexts.

48 Earlier in this chapter, Kiley (see *supra* note 15) proposed nonexclusive royalties as being approximately one-half the royalties paid under an exclusive license. The economic rationale for such a differentiation would need to derive from comparing the NPVs of two DCF scenarios—one as an exclusive license and one as a nonexclusive license. Although it seems obvious that the nonexclusive licensee royalty should be less, it is difficult to generalize what a fair difference should be.

49 Razgaitis R. 1999. *Early-Stage Technologies: Valuation and Pricing*. John Wiley and Sons. Razgaitis R. 2003. *Valuation and Pricing of Technology-Based Intellectual Property*. John Wiley and Sons.

50 However, this author generally recommends that a licensor of early-stage technology not sell out for a one-time, upfront payment. Exceptions to this rule, as to most rules, can be warranted, as discussed in the text.

51 The two products currently available for personal computers are Crystal Ball®, sold by Decisioneering of Denver, Colo., (800/289-2550) and @ Risk®, sold by Palisades, New York (607/277-8000). Both require the use of a spreadsheet program such as Microsoft Excel®.

52 Crystal Ball, sold by Decisioneering of Denver, Colo.

53 *Business Week*, 20 March, 1995.

54 See *supra* note 2.

Valuation of Bioprospecting Samples: Approaches, Calculations, and Implications for Policy-Makers

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ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute; and Adjunct Professor, Cornell University, U.S.A.*

ABSTRACT

In this chapter, the revenue consequences of varying collection fees and royalties with regard to germplasm prospecting contracts are demonstrated. Principal factors are the uncertainty of finding marketable products and the value of these products. Negotiation factors are finding a good balance between collection (initial) fees as opposed to royalty (delayed) payments. Emphasizing collection fees reduces total payments except when national interest rates are very high. Reducing the risk of failure through in-country screening, including the use of indigenous knowledge, is a potentially valuable activity. Issues for contract negotiators are outlined and the implications for biodiversity conservation discussed. Conceptually, the highest valuation approach, royalties, will most encourage conservation, but as the future is typically heavily discounted, collection payments may get more attention and be most effective. Policy considerations for national governments, nongovernmental organization (NGOs), and development agencies are reviewed and it is concluded that grants/loans and training/equipment for in-country screening should be given a high priority as a potentially viable activity in the long term.

It should be noted that the figures and calculations in this chapter are merely for illustration. The valuation of samples, and by extension a country's biodiversity, is a negotiation and will depend on many factors, including alternative investment options by a company, alternative technologies that could be used for lead compounds, interest rates, and a range of risk factors, such as the political situation in a given country surrounding the national debate on bioprospecting. The latter point is a key factor: valuation is always a calculation that has important political consequences. Another complicating factor is the need for confidentiality with which a country and company will hold its overall business estimates. Neither a company nor a country will be likely to share their valuation basis purely for negotiation purposes and because neither want to tip off other entities about the opportunity. It is therefore concluded that, from a practical perspective, the proper valuation is the one that (1) provides the country with compensation and other benefits such that it does not feel taken advantage of and can withstand criticism from its constituents and (2) provides the licensee (typically a company) with a reasonable cost of obtaining the crucial raw or semifinished goods it requires as an input to its business.

1. INTRODUCTION

Since the adoption of the Convention on Biological Diversity (CBD) in 1992, the legal status of traditional knowledge is in the focus of international debate. Concurrent with CBD, Merck & Co. and INBio, the National Biodiversity Institute of Costa Rica, made a deal,

Note: While we have been careful in pointing out throughout this chapter that the monetary figures used in the examples are illustrative, it is important to urge that these figures not be used in actual negotiations. In the authors' opinion, one of the main reasons for the overall low level of interest in bioprospecting deals is that expectations based on the market potential for a blockbuster drug may scuttle a deal on samples to be used for an industrial application with a much lower market potential.

Lesser WH and A Krattiger. 2007. Valuation of Bioprospecting Samples: Approaches, Calculations, and Implications for Policy-Makers. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

which was widely publicized, for the payment of fees and royalties for germplasm collected inside Costa Rican conservation areas. Importantly, the agreement was renewed in 1994, 1996, and 1998 in similar terms and by 2004 has led to the filing of more than 27 patents based on the collaboration. Studies to determine the potential use of a limited number of extracts of plants, insects, and environmental samples have been completed, and the agreement has given INBio access to technology, teams, and training. It marked the first of a series of deals made by INBio (Table 1).

Such collection activities, so-called bioprospecting, have received considerable attention in the literature and have precipitated discussions on payments for collected samples and chemical extracts from samples. But the subject is generally treated in generalities, focusing on research needs, basic rights, and moral obligations. CBD itself is famous for broad language with multiple interpretations possible. On the subject of payments, CBD proposes "*sharing in a fair and equitable way the results of research and development and the benefits arising from commercial and other utilization of genetic resources … upon mutually agreed terms*" (Article 15(7)). There is no attempt to identify appropriate payment approaches or a system for valuing germplasm for specific uses. Even a full decade after the entering into force of CBD, the topic still receives attention, and 15 years since its passing has not been resolved. Evidently, there cannot be resolution on actual terms and payments, since these will be a function of market conditions, alternative technologies (such as recombinatorial chemistry, to name one), and other factors. We hope to shed light on the approaches that could be used to calculate royalty rates and collection fees.

The purpose of this chapter is also the provision of information on the revenue consequences of alternative payment arrangements for collected germplasm. We do not attempt to present actual market values for the material, although approximate figures are used for illustrative purposes. Commonly, germplasm-rich countries charge for samples in the form of a fixed initial payment (collection fee), a delayed payment based on sales of the resultant commercial product (a percent royalty, that is, a form of sharing of benefits), or combination of the two. Here it is demonstrated that when the likelihood of finding a commercializable product is small (the risk of failure great), emphasizing initial payments can be done only at the expense of a significant reduction in the royalty rate and, hence, in the expected overall revenues. The importance of the failure risk is such that reducing it through preliminary in-country screening can improve the revenue prospects greatly. Whether that is a viable approach depends on in-country skills, facilities and costs, which are not evaluated here. Use of indigenous knowledge of plants is another means of reducing the failure rate and can add value to the samples that might be used in determining an appropriate payment to indigenous groups for sharing their knowledge.

The examples used herein apply to pharmaceutical prospecting for medicinal products, the basis of the Merck/INBio agreement. Pharmaceuticals are typically high-value products so the revenue is potentially greatest. The approach developed here, however, is general and can be used as well for other products, such as crop varieties and cosmetics. The variable likelihood of finding useful germplasm and values with respect to the resultant products could lead to somewhat different conclusions. For example, the long standing (but possibly evolving) practice of placing plant varieties in publicly accessible germplasm collections limits the market value of that material.

This chapter does not attempt to identify a specific market value for germplasm. Most efforts to do so, thus far, date back well over a decade and have been conceptually general or relevant only to specific examples from developed countries. It is, nevertheless, well established that biodiversity provides two types of values. These are:

1. **direct value**
   - consumptive-use value (that which derives from such activities as sport fishing, subsistence hunting, gathering)
   - productive-use value (that which derives from such activities as logging)
2. **indirect values**

Table 1: Main Collaborative Research Agreements Signed by INBio from 1991 to 2002

Industrial or academic partner	Natural resources accessed/Objectives	Field of primary application	Research activities in Costa Rica
Cornell University	INBio's capacity building	Chemical prospecting	1990-1992
Merck & Co.	Plants, insects, micro-organisms	Human health and veterinary	1991-1999
British Technology Group	DMDP, compound with nematocidal activity*	Agriculture	1992-present
ECOS	*Lonchocarpus felipei*, source of DMDP*	Agriculture	1993-present
Cornell University and NIH	Insects	Human health	1993-1999
Bristol Myers & Squibb	Insects	Human health	1994-1998
Givaudan Roure	Plants	Fragrances and essences	1995-1998
University of Massachusetts	Plants and insects	Insecticidal components	1995-1998
Diversa	DNA from bacteria	Enzymes of industrial applications	1995-present
INDENA SPA	Plants*	Human health	1996-present
Phytera Inc.	Plants	Human health	1998-2000
Strathclyde University	Plants	Human health	1997-2000
Eli Lilly	Plants	Human health and agriculture	1999-2000
Akkadix Corporation	Bacteria	Nematocidal proteins	1999-2001
Follajes Ticos	Plants	Ornamental applications	2000-present
La Gavilana S.A.	*Trichoderma* spp*	Ecological control of pathogens of *Vanilla*	2000-present
Laboratorios Lisan S.A.	None*	Production of standardized phytopharmaceuticals	2000-present
Bouganvillea S.A.	None*	Production of standardized biopesticide	2000-present
Agrobiot S.A.	Plants*	Ornamental applications	2000-present

(Continued on Next Page)

Table 1 (continued)

Industrial or academic partner	Natural resources accessed/Objectives	Field of primary application	Research activities in Costa Rica
Guelph University	Plants*	Agriculture and conservation purposes	2000-present
Florida Ice & Farm	None*	Technical and scientific support	2001-present
ChagasSpace Program	Plants, fungi*	Chagas disease	2001-present
SACRO	Plants*	Ornamental applications	2002-

* These agreements include a significant component of technical and scientific support from INBio.

Source: Cabrera Medaglia 2004. [1]

- nonconsumptive-use value (that which derives from such activities as tourism)
- option value (that which derives from the delaying of destructive use until the use and value are better understood)
- existence value (bequest value; that which derives from leaving a resource for consumption by future generations)

Valuation is complicated because, with the exception of productive-use value, none of these forms of use involves a marketed product from which value can be ascertained directly. Rather, indirect measures, such as travel expenditures, are used or, in cases of option and existence values, quite esoteric measures, the interpretation of which is not fully clear. Yet valuation is important because it indicates a potential economic justification for preservation or, more precisely, in the case of germplasm prospecting, for substituting sustainable use for destructive uses like logging.

Further complicating valuation is the discussion of appropriateness of adding opportunity cost, the value option foregone when another mutually exclusive use is selected (an opportunity cost of clear cutting is germplasm prospecting, for example). Opportunity costs are sometimes calculated (companies making mutually exclusive investment choices do this routinely) but, traditionally, never are subtracted from the value of the selected use as it is sometimes argued they should be. Conceptually, there is no reason to limit opportunity cost to a single alternative use where many likely exist, nor is there a reason indirect benefits (for instance, those derived from logging open land for farming or grazing) should not be added to the use value. There is the further issue of discount rate for future income—the reduction akin to an interest rate—in the value of delayed consumption compared to present consumption. Typically, private (personal and corporate) discount rates are greater than social rates, although the determination of the social rate is open to different interpretations. Yet, as anyone who has paid off a loan over a ten- or 20-year period recognizes, small changes in the interest rate have major implications on the outcome. Indeed, the use of opportunity cost is a complex matter yet to be resolved.

2. PRICING CHOICES

The Merck/INBio agreement of the early 1990s utilized a combination of the two principal payment alternatives: collection fees and royalties. Merck paid to INBio a fee of US$1.1 million and an undisclosed royalty rate for resulting product sales. A collection payment can be (and in the Merck/INBio case was) paid in total, or in part, in services, such as providing training to national scientists in screening procedures, or as equipment. The purpose here is to demonstrate how total revenues are affected by an emphasis on initial, as opposed to delayed, payments.

Delayed (royalty) payments are preferred by the contracting company, which, for the purposes of this article, we shall assume is a multinational pharmaceutical company. Delaying payments means the company has no interest costs, which are required if payments are made before the product is marketed and revenues flow. Pharmaceutical products can take up to 12 years to bring to the market in the United States, so the

Table 2: Estimates of Variables for the Base Agreement

	Per-sample basis		
Item	Value used in calculations	Range	Comments/Reference
Collection fee	US$50	50–200	Figures are intended to cover actual costs (packaging, transport and related costs) but not return a profit
Royalty payment	5%	1%–5%	Royalty of gross sales
Developing-country interest[a]	15%	10%–25%	Discount rate used by developing countries with hard currency shortages (a likely minimum figure)
Corporate interest rate	7%	5%–9%	Corporate interest rate charged to and by major corporations; lower than developing country rate because of better credit rating and more efficient credit markets in developed countries
Product value	US $500 million	100 million–1 billion +	Total worldwide sales once developed and over the life span of the product. Below an expected market of US$100 million, returns generally do not cover development and regulatory costs
Development delay	10 years	10–12 years	–
Hit rate	1:12,000	1:6,000–1:30,000	Frequency with which collected material will result in a marketable product

a This figure represents interest on a hard currency loan such as one denominated in dollars. It does not reflect the occasionally very high rates - up to and exceeding 100% - for local currency loans during inflationary periods.

interest cost could be considerable. As important, making initial payments shifts the risk of failure to the company, which will have expended the collection and screening costs as well as development charges. With a successful product found in only one of some 12,000 tries and average product development costs of US$230 million including the costs of failures, the risks are indeed large. Because of these risk and interest factors, along with tight budgets and scarce foreign exchange, contracting countries prefer initial payments to subsequent and uncertain royalties. However, the contracting companies will seek compensation in the form of lower overall payments for accepting additional risk. Here we explore how much that compensation is likely to be.

For the purposes of this article a base agreement is computed on a per-sample basis (in U.S. dollars). This agreement is intended to represent the outcome of careful negotiations, with both sides reaching a minimal acceptable position from which they are unwilling to move without concessions from the other party.

Table 2 shows the estimates of the variables required for a bioprospecting agreement. As we are developing different variations, we call this the "base" agreement.

From Table 2, the expected return per sample collected can be computed as shown in Table 3 (figures are rounded for convenience). Total value for a 12,000-sample contract is also included.

Of course, most samples would pay $50 with, on average, the 1/12,000 paying off $25 million. In other words:

5% royalty of $500 million = $25 million

This is a general average with the likelihood of a hit[2] having a wide latitude. Thus, countries selecting this approach would be operating in a "boom or bust" mode. The collection fee covers costs so that no real revenue comes in until and unless a hit is scored. No attempt was made here to determine the range (frequency distribution) with regard to the estimated 1/12,000 hit figure. The present value

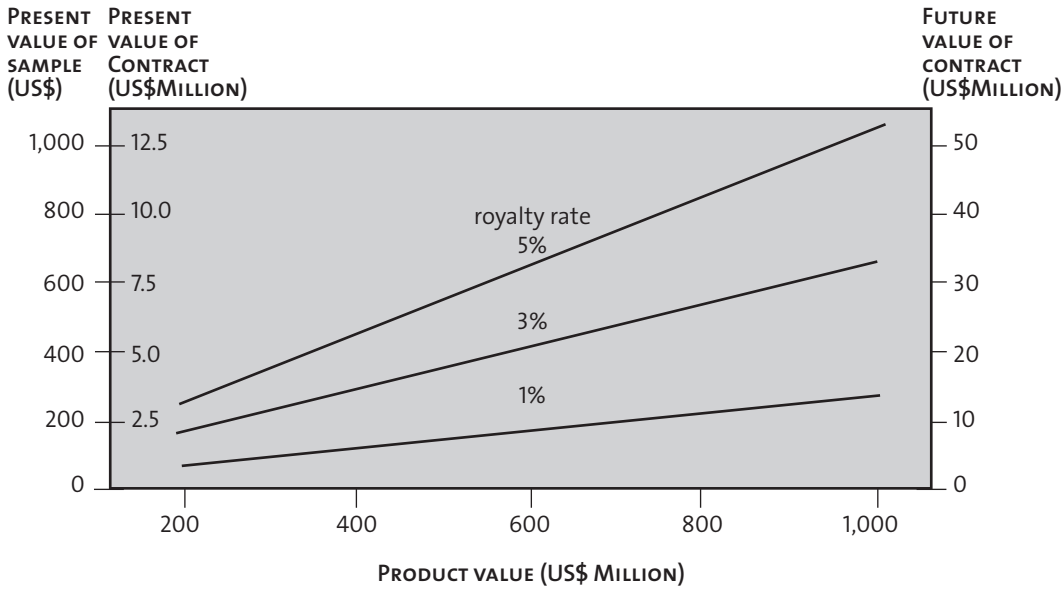
Table 3: Computing Expected Return for the Base Agreement

Item	Per-sample basis			Full contract 12,000 samples
	Calculations	Equation [b]	Return	
Collection fee	_	_	50	0.6 million
Royalty fee paid in year 10	5% x $500 million x $\frac{1}{12{,}000}$	[1]	2000	25.0 million
Present value of royalty fee[a]	$\frac{2{,}000}{(1+i)^n}$	[2]	500	6.0 million
Total present expected value	50 + 500		550	6.6 million

a Where i=15% (developing-country interest level) and n=10 years (development delay).

b Refers to numbered equations in text.

Figure 1: Present and Future Value of Contract as a Function of Product Value and Royalty Rate



Note: Collection fees of $50 per sample are included in the calculations. Other variables are 15% developing country interest rates, 10 years development delay, and 1/12,000 hit rate.

of the $25 million figure is only $6 million because of the high interest rate used (15%) and the ten-year delay involved. Figure 1 gives an indication of how these values are affected by royalty rates and product value.

3. EMPHASIZING COLLECTION FEES OVER ROYALTIES

What would be the ramifications of shifting fees forward, emphasizing current collection payments at the expense of longer term royalties? Suppose for our example the collection fee was increased by $150, to $200 per sample. What would change? We shall assume that the basic revenue situation remains unchanged and that only the schedule is altered. Since there are just two payment parameters (collection fee and royalty rate), increasing one necessitates reducing the other.

The point about raising collection fees necessitating a reduction in the royalty rate has several components. First, there is a direct transfer of dollars. Second, the company, which, in this example, is making payments today instead of ten years in the future, will add an implicit interest charge (technically, a discount) to those payments. The third component, and the most complex to calculate, is the change in the risk undertaken by the company. Under the base agreement, the selling country accepts most of the risk; if no marketable product is forthcoming no royalty payments are made. The 1/12,000 hit-rate figure used here is an average and an approximation. It is possible that 12,000 samples will yield no marketable products or ones with low values. Shifting royalty payments to collection fees means, in effect, that some of the royalty has been "prepaid" so that the failure of a product to materialize is a loss for the company. That is, the company is taking on an additional risk of a loss. In this regard, the contracting company will act like a banker, and indeed like any private corporation, which is a risk/reward managing entity, by demanding to be compensated financially for accepting additional risk. That required compensation can be estimated.

Raising the collection fee by $150 would increase the expected costs for the company by $1.8 million. In other words:

$150 for 12,000=$1.8 million

Moreover, the payments would be made today as opposed to 10 years hence so that the company would have total (including interest) costs of $3.5 million, that is:

From Table 3, Equation [2]: $1.8 million x $(1+ 7\%)^{10}$ = $3.5 million

The company is then willing to pay only $21.5 million (25 - 3.5) in royalties (from Table 3) so that the effective royalty rate becomes:

Equation [3]:

$$\frac{5\%}{\$25 \text{ million}} = \frac{x\,\%}{\$21.5 \text{ million}} \longrightarrow x = \frac{107.5}{25} = 4.3\%$$

But the company accepts additional risk ($1.8 million worth) and will want to be compensated. The amount can be computed using the following the equation:

Equation [4]:

$$\text{size of risk change} = \frac{\text{change in payment}}{\text{payment}} = \frac{\$3.5}{\$21.5 / (1.07)^{10} + \$0.6} = \frac{3.5}{11.5} = 30\%$$

Thus the company is willing to offer a royalty rate 30% lower, that is:

Equation [5]: 4.3% x 0.3 = 1.3%

The new royalty rate is now 3.0%, that is:

Equation [6], from [3]: 4.3% - 1.3% = 3.0%

This is a reduction of 40% of the original value. The new present value of the expected payment per sample can now be computed as:

Equation [7] (from Table 3, Equations [1] and [2]):

$$\$200 \text{ collection fee} + 3.0\% \times \$500 \text{ million} \times \frac{1/12{,}000}{(1.15)^{10}}, \text{ or } \$200 + \frac{\$1{,}250}{4.045} = \$500$$

Hence, the country is giving up $50 ($550 - $500) or 9% per sample to ensure timeliness of the payment.

Table 4: Impact of Country Interest Rate on Total Expected Present Values under Different Interest Rates

Interest Rate	10%	15%	20%	25%
Collection fee	50	50	50	50
Present value of royalty fee[a]	775	495	325	215
Total expected present value/sample	825	545	375	265
Collection fee	200	200	200	200
Present value royalty fee[b]	465	300	195	130
Total expected present value/sample	665	500	395	330
Country loss/gain[c]	-160	-45	+20	+65

a $2,000/(1+i)^10 from Table 3, equation [2] (results rounded)

b $1,250/(1+i)^10 from Table 3, equation [2] (results rounded)

c Total expected value/sample for $200 collection fee - total expected value/sample for $50 collection fee.

An important insight can be derived from this example. The penalty for the germplasm-providing country declines as its interest rate increases, or more correctly, as the gap between its interest rate and the corporate rate of the contracting company (7% in this example) increases. This penalty is shown in Table 4 where, using the figures described above, the penalty declines to zero at a country rate near 20 percent; at higher rates the country is actually better off. The company is borrowing money at a preferential rate and lending it to the country at the same rate, plus risk premium. This approach might be an efficient way for the selling country to finance itself, but several additional factors must be considered.

First, the contracting company must be agreeable to such an arrangement (not all will be). Second, a 15% figure is quite a high discount rate and involves a significant discounting of the future. Note that the country is paying the company 7%, along with discounting the future by 15% for a total discounting of 22%, which reduces any future royalty payment by a factor of 7 that is (from Table 4, Equation [2]):

$$\$25 \text{ million} / (1 + 0.22)^{10} \text{ or } 25/7.3$$

Third and finally, the country is effectively borrowing against the future; should a hit come, less additional revenue will be collected. While that may be undesirable for future generations, this approach does increase the awareness of the value of germplasm resources. Referring again to the Merck/INBio agreement, the more than US$1 million collection fee (a rather insignificant amount) received all the public attention while the level of the royalty figure has never been made

public and potentially could represent a much greater figure.

It should be noted that it is very difficult to come up with an appropriate discount rate without knowing specific country circumstances. It may also not be an objective figure. The concept of personal discount rate, that is, what the person on the other side of the table has internalized about risk, as well as political and economic instability and immediate need for money could all play major roles in the choice between collection payments and royalties.

4. PAYMENT FOR SCREENING

One of the emphases on germplasm prospecting in the CBD, and elsewhere, is the performance of the maximum number of services in country (value added) as opposed to the export of raw germplasm materials. That emphasis not only increases payments but also enhances national scientific expertise while moving away from dependency on commodity-type exports. Here we examine the revenue ramifications of such an approach. No attempt is made to determine the practicality of such a step that depends on the country of origin having adequately trained staff and adequate facilities to be able to complete screenings in an accurate, timely, and cost-efficient manner. Screening near the source of origin has some advantages due to the cost of packaging and transport and the volatility of some compounds. On the other hand, some screening procedures are technically complex or, for infectious diseases, involve high standards for isolation facilities. Those screenings would not be feasible away from a major company's laboratories, at least for the present.

The development of a marketable pharmaceutical product passes through several stages beginning with a primary screening and, if successful, progressing through secondary screening (including isolation and preliminary toxicological evaluations) and proceeding to the several stages of drug development. For purposes here, assume in-country collection with primary screening costs of $200 per sample. Prescreened samples in this example have a 1/3,000 chance of being a hit (four times the unscreened rate) because the least promising samples have been eliminated. The rate depends on several factors, including the stringency of the screens. This rate presumes relatively nonstringent tests that would be most appropriate for a range of developing countries.

Of course, screening does not change the underlying probability of finding a commercializable product. Screening merely increases the value of the retained samples, because they have a higher probability of viability than the collected samples. There is a cost for this: every retained sample represents four screened samples, so the per-sample-retained cost is $800. It is assumed the country will collect the out-of-pocket costs, or $200 per sample, but because these represent actual costs, the country does not make a profit as in the earlier second example. Payments can be computed following the royalty-rate calculation method shown earlier, using the hit rate of 1/3,000 and a collection and screening fee of $800 (figures are rounded):

Equation [8] (from Table 3, Equations [1] and [2]):

Present value of royalty:

$$5.0\% \times \$500 \text{ million} \times \frac{1/3{,}000}{(1+i)^n} = 5.0\% \times \frac{\$167{,}000}{4.04} = \$2{,}100$$

Total expected value per sample: $800 + $2,100 = $2,900

The total expected value per sample is now more than five times the base payment.

It should be noted that both the royalty rate and the risk factor remain unchanged. The additional "collection" fees are merely a transfer of expenses from the company's in-house screening cost to the developing country, and this does not change the basic value of the contract. The calculations assume, however, that the quality of cost screening in the developing country is identical to that of the company. If the quality in the developing country is inferior, the value of the screenings is questionable, and the pharmaceutical company is likely to reject this option. Especially in the case of false negative results (improperly rejecting a potentially viable compound), inaccurate or inconsistent results must be repeated. If the total cost of screening in developing countries is less than that of the pharmaceutical company (a plausible situation due to lower wages and shipping costs), then the selling country can take the difference as profit. For the example just mentioned, imagine further that a screening by the pharmaceutical company costs $150, while in the country of origin it is $100. Total costs including the $50 collection fee are then $200 versus $150. The company should, in theory, be willing to pay the full $200 cost to the developing country, which would yield it a "profit" of $50 per sample ($200 payment - $150 costs). As discussed in the preceding example neither the royalty rate nor the risk factor would change.

Now, however, imagine the costs are reversed, $100 for the pharmaceutical company and $150 for the selling country. This could happen for a number of reasons, such as a high cost of maintaining specialized equipment or simple inexperience and/or inefficiency. If the country still covered costs by negotiating a $200 collection plus screening fee, the company would treat $50 of it ($200 payment - $150 costs) as a higher fee, along the lines of the second example. Rather than repeating those calculations, note that the fee increase here is one-third ($50/$150) of the amount shown in the second example. The royalty-rate reduction would likewise be one-third of that amount, or:

From Equation [6]: 0.33x(5%-3.0%)=0.66

This gives a final rate of:

Equation [9]: 5%-0.66=4.34%

While the amount is not huge, it represents a penalty and would likely not represent a viable option in the long term.

These calculations, of course, are only illustrations and say nothing about the practicality of screening in-country. Actual cost and result figures will be required for such computations. The exercise does suggest that economical in-country screening is a potentially valuable value-added activity. Screenings in countries, following this strategy must, as noted, be less costly than contracting-company screenings, and less accurate. Indeed, to the extent screening in-country is less expensive due to lower salary levels, savings on shipping costs, and other factors, all parties may benefit. However, countries must invest in training and equipment/infrastructure before offering this service. Several sources of funds are possible, including the use of collection fees (as is provided to a small degree in the Merck/INBio agreement) or through a grant or loan from a bilateral or multilateral agency.

5. INDIGENOUS KNOWLEDGE

Indigenous knowledge of plants can be an alternative to preliminary screening. Plants that can be identified as free from insect damage, for example, likely contain potent alkaloids, called the most important group of medical chemicals. If plants identified by indigenous peoples as having particular attributes are collected, the probability of a hit is increased. Here, for simplicity, we will assume the increase is to 1/6,000. Some argue that the success of screening could double or triple if information based on traditional knowledge was utilized. Further, it is assumed that the cost of a single specimen collection is $100 because of the additional difficulty of finding selected plants. Payments are then (again rounded):

Collection fee: $100

Equation [10] (from Table 3, Equations [1] and [2]):

$$\text{Present value of royalties} = 5\% \times \$500 \text{ million} \times \frac{1/6{,}000}{4.04} = 5\% \times \frac{\$8{,}330}{4.04} = \$1000$$

The royalty level in this example is the same as the base situation because:

$$\$50 \times 12{,}000 = \$100 \times 6{,}000$$

So there is no change in the timing of payments. Similarly, the risk factor is unchanged:

Total expected value per sample: $100 + $1,000 = $1,100 (double the base level of $550)

Again, while only hypothetical, this example does indicate the potential value of indigenous knowledge, at least for plants (it is less indicative for microbes and insects with which indigenous cultures are typically less familiar). The additional amount of $500 per sample (Equation [11]), can be paid to indigenous groups for the value of their knowledge, but a suitable transfer mechanism must be developed.

Equation [11] (from Table 3, Equation [2]):

$1,100 - $100 collection fee - $500 present value of royalty = $500

6. CONCLUSIONS

The negotiating of terms for germplasm collection is a complex matter, made more so by the absence of a generally accepted value of the material in its raw form. This article is directed to a related issue: how any payments should be divided between current (collection) fees and future royalties. The two are different because of the ramifications of who accepts the risk of finding a usable product and the capital cost/value of sales to be made ten or more years into the future. The examples shown here suggest, but do not guarantee, that increasing collection rates is costly in terms of overall expected payments. However, for countries short on foreign exchange and, hence, with high interest rates, raising collection fees is an economical means of "borrowing" from the contracting company. Seemingly more favorable is in-country screening, but costs, feasibility, and acceptability of results must be considered carefully before choosing this option. Utilizing indigenous knowledge is, according to the example used here, also remunerative along with the prospect of providing equity payments to numerous groups otherwise far removed from market systems. However, to be utilized by companies, indigenous knowledge must be less costly than mass screening.

Overall, the aggregate payments for collected germplasm, given the current state of knowledge, appear limited. Similarly, the payments to indigenous groups will likely be fairly modest compared

to the needs of those groups. These issues make careful valuation and contractual negotiation all the more critical.

Negotiators need to consider, at least, two additional factors, which have not been discussed here. First is the granting of exclusivity for the samples. Companies, of course, will be hesitant to invest in a product when the possibility exists of a competitor bringing the technology to market first or obtaining the patent. Therefore, companies will seek exclusivity. Countries, however, will wish to find additional markets; certainly, the possibility of multiple products from the samples is there. Thus, countries will opt against exclusivity. As a compromise, countries should (1) charge more for granting exclusivity and (2) set a time limit (it is four years in the Merck/INBio agreement).

Second, negotiators must evaluate their level of trust in the opposite party. One way to consider contracts is as a means of reducing the need for trust by specifying obligations in a way that can be adjudicated. However, it is not feasible to specify all aspects, so some level of trust is required. With germplasm prospecting perhaps the most critical issue is identifying whether the material used in developing a product was derived directly or indirectly from a sample provided under the agreement. Unscreened samples, with the myriad compounds they could provide, and the numerous analogs to them, will be virtually impossible to track thoroughly. Preliminarily screened samples are described in more detail and hence easier to track, but documenting a claim in court could still be difficult and expensive. Thus, considerable trust in the integrity of the contracting company would seem to be critical, but perhaps some checks should be included in the agreement.

In a broader context, this analysis suggests several policy considerations for national governments, nongovernmental organizations (NGOs), and international donors, such as foundations and bilateral and multilateral agencies. These considerations involve both the allocation of payments between collection fees and royalties and in-country screening. If the examples used herein are substantiated at all by actual cost figures, in-country screening is attractive financially as well as for its effects on development and skills improvement. However, considerable investment will be required before such efforts are possible. With adequate in-country funds lacking, international donors should seriously consider loans or grants for training and equipment purchases since in-country screening will be economically rewarding in the long term. Unlike numerous potential projects, there appears to be a ready market for the product, a preliminary-screening service. More, broader conclusions from INBio on their experiences are given in Box 1.

The allocation of funds between collection fees and royalties can affect conservation incentives. While a thorough treatment of that issue is outside of the scope of this article, it does warrant mentioning. Conceptually, the highest valuation approach—payment of royalties—will encourage conservation the most in the long term. However, people typically discount the future heavily so that up-front (collection fee) payments may get more attention and, in the long run, do most to encourage conservation. This is a matter of perception and not of business or economics, which needs exploration through other methodologies. ■

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1 Cabrera Medaglia J. 2004. Bioprospecting Partnerships in Practice: A Decade of Experiences at INBio in Costa Rica. *IP Strategy Today* No. 11-2004. Pp. 27-40. www.bioDevelopments.org/ip.

2 A hit rate is the number of expected lead compounds divided by the number of samples to be screened to obtain the given lead compounds.

Box 1: Lessons Learned from a Decade of Bioprospecting Partnerships at INBio in Costa Rica

A. **There must be a clear institutional policy** for the criteria demanded in prospecting contract negotiations. For INBio, these include the transfer of technology, royalties, limited quantity and time access, limited exclusiveness, no negative impacts on biodiversity, and direct payment for conservation. This policy has led to the stipulation of minimum requirements for initiating negotiations, and these requirements have meant rejecting some requests (e.g., very low royalties, unwillingness to grant training, etc.). This institutional policy also provides greater transparency and certainty for future negotiations. These same policies must also be taken into consideration when local communities and indigenous peoples, such as the Kuna's in Panama, adopt legal outlines in the contractual arrangements entered into by them. They should include other relevant ideas, such as those related to the impossibility of patenting certain elements, licensing instead of a complete transfer, etc.

B. **The existence of national scientific capabilities,** and consequently the possibilities of adding value to biodiversity elements, increases the negotiating strengths and benefit sharing stipulated in contract agreements. As we previously mentioned, the need to grant an aggregated value to material, extracts, etc., is crucial if one wishes to be more that just a simple genetic resource provider. In this regard, the development of important human, technical, and infrastructure capacities through laboratories, equipment, etc., together with the institution's prestige, have permitted better negotiation conditions.

   The existence of relevant traditional knowledge for operations, which INBio has not yet experienced, implies greater scientific capacity and, consequently, should lead to better compensation conditions.

C. **Knowledge of operational norms** and of the changes and transformations taking place in the business sector, as well as the scientific and technological innovations that underlie these transformations, helps to define access and benefit-sharing mechanisms. It is essential to know how different markets operate and what access and benefit-sharing practices already exist in these markets. These vary from sector to sector: the market dynamics for nutraceuticals, ornamental plants, crop protection, cosmetics, and pharmaceuticals are complex and different. This knowledge is needed to correctly negotiate royalties and other payment terms. How can we otherwise know if a percentage is low or high? It is also crucial to be informed about the operational aspects of these markets. When INBio began negotiating new compensation forms, such as advance payments or payments on reaching predefined milestones, with Eli Lilly and Akkaddix, it was vitally important to know the approximate amounts the industry was likely to pay in order to negotiate appropriately. Otherwise, one will likely request terms that are completely off the market or accept terms that are inadequate.

D. **Internal capacity for negotiations**, which includes adequate legal and counseling skills about the main aspects of commercial and environmental law. The Institute now recognizes that negotiations involve a scientific aspect (of crucial importance to define key areas of interest such as a product, etc.), a commercial aspect, a negotiation aspect, and the respective legal aspects. These latter are composed not only of national trade law but also international environment law, conflict resolution, and intellectual property. For these reasons, creating interdisciplinary teams is crucial. At the same time, the need for such a team is one of the most important criticisms of the contractual mechanisms. Solutions such as facilitators or others that pretend to "level the negotiation power" have been proposed by several authors. Unfortunately, until appropriate multilateral mechanisms exist, benefit sharing and contractual systems must go hand in hand. The absence of an interdisciplinary team keeps one of the parties at a disadvantage, particularly given the enormous legal and negotiation capabilities of pharmaceutical companies.

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Box 1 (continued)

E. **Innovative and creative ideas** for obtaining compensation. An ample spectrum of potential benefits exists. In the past, interesting benefit-sharing formulas were developed through appropriate negotiations. Such formulas included, for example, fees for visiting gene banks, collecting material, etc. The contractual path fortunately permits parties to adapt themselves to the unique situation of each concrete case and to proceed from there to stipulate new clauses and dispositions.

F. **Understanding in such key subjects as:** intellectual property rights; the importance of warranties for legality; clauses on ways to estimate benefits (net, gross, etc.); requirements and restrictions on third-party transference of material (including subsidiaries, etc.) and the obligations of such parties; precise definitions of key terms that condition and outline other important obligations (products, extracts, material, chemical entity, etc.); precise determination of property and ownership (IPR and others) of the research results, joint relationships, etc.; confidentiality clauses in the agreements and how to balance them in relation to the need for transparency in the agreement; termination of obligations and the definition of the survivor of some obligations and rights (e.g., royalty, confidentiality, etc.); conflict resolutions.

   As sub-clause D makes very clear, negotiated agreements are complex. For example, the outcomes that give rise to benefit sharing, such as royalties, will depend on the nature of the definitions for "product," "extract," "entity," etc. A more comprehensive definition will lead to a better position. Further examples of aspects that must be specified include delimiting the areas or sectors where samples can be used, the net sales, and what is possible to exclude from them. In addition, the procedures and rights in the case of joint and individual inventions are of interest (preference and acquisition rights, etc.), as are the conditions for the transfer of material to third parties (under the same terms as the main agreement? need for consent or information? transference to third parties so that certain services can be performed? etc.).

G. **Proactive focus according to institutional policies.** There is no need to remain inactive while waiting for companies to knock on the door to negotiate. An active approach to negotiations based on the institution's own policy for understanding national and local requirements has produced important benefits. INBio's Business Development Office and its highly qualified expert staff, the attendance of seminars and activities with industry, the distribution or sharing of information and material, and direct contacts, all of these empower an institution to deal with challenges. The current policy is based on the idea that it is not enough to wait to be contacted or to be available at the behest of a company; instead, one should possess and maintain one's own approach.

H. **Understanding national and local needs** in terms of technology, training, and joint research. International strategic alliances must be struck. Even when an institution or community possesses adequate resources to face a concrete demand, knowing the national situation and the strategic needs will permit it to reach better agreements and fulfill a mission that goes beyond merely satisfying the institution's interests. It will permit the prospecting to benefit society as a whole and demonstrate that it is possible to improve quality of life.

I. **Macro policies and legal, institutional, and political support.** For prospecting to succeed, so-called macro policies have to exist; that is to say, there must be clear rules about the "bioprospecting framework," which requires biodiversity inventories, information systems, business development, and technology access. One reason for Costa Rica's success is that institutions not only have experience in negotiation but also in setting policies and actions in this area overall. This includes, for example, a current biodiversity inventory rated as "successful"

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Box 1 (continued)

that enables us to know what we possess. It is the first step in the quest to use this resource intelligently. Our relevant experience also includes a National Conservation Area System that assures the availability of resources, the possibility of future supplies and provisions, mechanisms that contribute to the conservation of biodiversity as part of the contractual systems, etc. At the same time, the possibility of possessing adequate instruments to manage information, systems of land and property ownership, etc., contribute jointly with the existing scientific capacity to create a favorable environment for bioprospecting and to make possible the negotiation and attraction of joint enterprises. To this should be added other elements, such as the existence of trustworthy partners, which is one of the most relevant aspects in joint undertakings.

Lastly, one crucial topic is the constant denouncement of the business community because of the uncertainty caused by the new access rules (mainly in terms of who is the competent authority, the steps to be taken, how to secure prior informed consent, etc.). The emergence of these new regimes, together with the fact that the intention is to essentially control genetic information, its flow, supply, and reception—a topic where little national, regional, and international experience exists—has caused concern because of the possibility of contravening legal provisions. This has led to the establishment, as a policy, of the inclusion of clauses related to the need to fulfill local regulations, to demonstrate the contracting parties' right to fulfill their obligations pursuant to national laws, to present the appropriate permits and licenses, etc. In some cases, this topic has generated important discussions and analyses in negotiations. At an international level, various bio-prospecting agreements around the world are the target of complaints, claims, and lawsuits precisely due to the lack of legal certainty. This has created problems and discrepancies that hinder activities and joint ventures. A few examples would be complaints about the Agreement between Diversa and the Autonomous University of Mexico (which is still being litigated); or the deal between this company and Yellowstone National Park; or criticisms of the agreement between the Venezuelan Ministry of the Environment and the Federal University of Zurich.

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SECTION 10

Patents and Patenting: Balancing Protection with the Public Domain

Defensive Publishing and the Public Domain

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ABSTRACT

IP (intellectual property) rights can reward innovators and encourage investment in developing new products and services. However, the exclusionary power of IP rights can sometimes have negative effects, making technologies less accessible and, thereby, potentially impeding innovation. To make informed decisions about how to balance access and protection requires an understanding of both the traditional IP rights system (patents, copyrights, trademarks, and trade secrets) and alternative mechanisms for preserving access to technologies. This chapter provides a brief introduction to the public domain and defensive publishing and examines issues concerning the choice behind the choice of whether to publicly disclose or to patent an innovation. Discussing the strategic use of defensive publishing in IP management, the chapter considers both the utility of defensive publishing and its limitations for supporting broad innovation. After an examination of the public domain and how it relates to other open-access concepts, such as open source and the commons, the chapter focuses on the practical considerations involved when using public-domain technologies and defensive publishing to manage intellectual property.

1. INTRODUCTION

A well-functioning innovation system strikes a balance between protecting technologies and preserving access to them. IP (intellectual property) rights can provide incentives that reward innovators and encourage investment in the development of new products and services. However, the exclusionary power of IP rights can also have negative effects. For instance, when research tools or enabling technologies are patented and not available for licensing, the creative and collaborative process of innovation can potentially be impeded. To ensure the balance between access and protection requires an understanding of both the traditional IP rights system (patents, copyrights, trademarks, and trade secrets) and alternative concepts, such as defensive publishing, public domain, and open source.

Debates about IP policy and the need to seek a socially optimal balance between IP rights and the public domain are important for the pursuit of vibrant national and international innovation systems. This chapter's focus, however, is narrower. Rather than examining how policies regarding the public domain might support innovation, we look instead at how, given current IP laws, IP management practitioners can best use the public domain to support particular goals.

The term *public domain* describes a body of work that is freely available, legally unprotected, and not subject to individual ownership. Public domain implies the *absence of individual IP rights.* This definition exemplifies the language associated with the public domain and what remains after all the boundaries of IP rights have been staked. Likewise, we commonly refer to a technology *falling* into the public domain, as if there were never a conscious decision to place something in

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the public domain; instead, the public domain encompasses the residuals of the processes of the IP rights system. This chapter, however, does not view the public domain as simply a default for technologies that are not claimed via IP rights. Instead, the chapter aims to promote a broader appreciation of the public domain as a valuable resource. The authors seek to facilitate the discerning use of the public domain as a tool (among a set of tools that include traditional IP rights and related licensing mechanisms) of prudent IP management.

Section 2 provides background that illustrates the importance of the public domain and how it has changed in recent decades. Section 3 briefly introduces two other open-access concepts—the *commons* and *open source*—in order to distinguish three alternatives from one other and defines their relation to the IP rights system. Section 4 uses a narrower, legalistic definition of the public domain to discuss the practical implications surrounding public domain technologies. That section reviews the patent-law concepts necessary for understanding both the construction of a successful defensive publication, how to ascertain whether a technology is, in a legal sense, part of the public domain. Section 5 introduces the practice of defensive publishing, examining how best to place innovations into the public domain. Section 6 considers potential strategies for the IP manager choosing between patenting and defensive publishing. Section 7 outlines practical issues confronted by users of public domain technologies.

2. INNOVATION AND THE PUBLIC DOMAIN

"There is no area in which public concern about intellectual property and the public domain has been greater than in scientific and technical research. Whether it is the controversy over the patenting of, and access to, the humane genome or pluripotent stem cell lines, the appropriate role of intellectual property in university research, or the use of ethnobotany and traditional herbal knowledge in pharmaceutical patenting, the coexistence of science and property rights has been a fairly constant concern over the last 15 years." –James Boyle[1]

In recent decades, many authors have examined how innovation systems have been changing in response to the expanding system of IP rights. As IP rights have become stronger, broader, and more far-reaching, many technologies that might previously have been freely accessible in the public domain are now proprietarily owned. This phenomenon has been particularly noticeable in the fields of health and agriculture.

In 1980, a landmark U.S. Supreme Court decision (Diamond v. Chakrabarty)[2] set the stage for a burgeoning biotechnology industry and an exponential rise in the number of life-science patents. Allowing for the patenting of human-made microorganisms, the decision clarified the Court's position that patentability did not depend on the distinction between living and inanimate things, but instead between inventions made by "man" and those that exist naturally. Among other influences to increased patenting during this period, the Bayh-Dole Act of 1980 has played a role. It set up new rules for the interface between academia, in which publications are the currency of the trade, and the commercialization of university research through patenting and licensing.[3] The rise in the patenting of life-science technologies and the corresponding reduction in the number of technologies remaining in the public domain has been most remarkable in developed countries. Still, in many developing countries, patenting remains sparse.[4] Indeed, despite the strengthening of IP rights policies worldwide through TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) and TRIPS-plus, international disparities in patenting behavior are likely to persist. Understanding these differences can be important for understanding how best to use the public domain.

Substantial differences in patenting behavior can also be found between the public and private sectors within a country. Public sector patenting behavior and the use of the public domain may be influenced by culture (for example, the land-grant universities in the United States, the centers of the Consultative Group on International Agricultural Research, (CGIAR), and many other public sector agricultural research institutions worldwide have a strong history of contributions

to the public domain), a lack of resources relative to the private sector, and institutional structures that often are designed to accommodate different goals. Although there clearly are exceptions, public sector institutions and individual researchers are generally at a disadvantage when it comes to strategically employing the patent system to achieve their research and development goals. In these instances, the public domain can be a crucial resource.

This chapter does not consider whether the shift in the relative strength of the public domain in the life sciences is disadvantageous, and, if so, to whom. Such complex issues have been considered widely in the literature on IP policy. Instead, the chapter focuses on how to use the public domain to achieve individual IP management goals.

Whether research and development goals involve decisions about how to access technologies, how to preserve widespread access to newly developed technologies, or how to ensure that innovations continue along the research and development path toward commercialization unimpeded by IP issues, a solid understanding of the public domain is paramount. It is essential to know how the public domain interfaces with the IP rights system in order to know when and how to use it.

3. DEFINING OPEN-ACCESS CONCEPTS

In this section we compare the concept of public domain with two other concepts: *open source* and *the commons*. These three terms all relate to open-access alternatives to the traditional IP rights system, but they are very different from one another.

3.1 *Public domain*

In its usage to date, the term public domain *is elastic and inexact. A definition can be but one of many definitions, each surely a function of perspective and agenda ...* [5]

Defining the term *public domain* as the absence of individual property rights creates two mutually exclusive sets of technology: one that is protected by some form (any form) of IP rights and another that has no IP rights. Thus, in patent law, a technology is considered to be in the public domain if one can make, use, offer for sale, sell, or import the invention without infringing an active patent and if there are no other types of IP rights that lay claim to the invention. Technologies in the public domain can be used with impunity because, by definition, there is an absence of ownership and therefore free access. This description of the public domain as a distinct set of technologies with a defined boundary, though, is misleading. In fact, the boundary between the two sets can be difficult to discern, can vary from country to country, and is continually shifting. It is no simple task to ascertain whether or not a technology is in the public domain.

3.2 *Open source*

Like the public domain, open source is characterized by free accessibility. However, with regard to open-source technology, free access derives from a different source. Free access in the public domain is defined by an *absence* of ownership, but free access in open source is dependent upon the *presence* of IP rights that enable the use of open-source licenses.

The concept of open source has its origins in computer software. Once computer code has been *fixed in a tangible means of expression*, it is automatically the subject of copyright protection. This copyright protection allows the owner to license the code. A typical (non-open source) license might, for example, contain terms that restrict the use of the licensed product or stipulate fees to be paid. But the terms of an open source license are seen as an unusual reversal of typical licensing terms (so unusual the license is sometimes called *copyleft*). By signing an open-source license, the licensee agrees to ensure that the software will remain available for public use, modification, and redistribution; the licensee is then in breach if he or she privately appropriates the technology and restricts its public availability.

Such legal protection from private appropriation has been used to generate a self-defending commons of software code that is collaboratively added to and improved upon. A technology licensed under an open-source license, therefore, cannot be in the public domain; otherwise there

would be no license and no way of enforcing the commons.

Several versions of open-source licenses are commonly used, and they vary in the restrictiveness of their terms. For instance, there may be a provision that *any* code that is combined with the licensed code will fall under the ambit of the open-source license. Therefore the entire body of code can only be licensed under the same open-source license terms—it cannot be privately appropriated. This *viral* quality limits the utility of the open-source license in certain commercial contexts but increases the potential for growth of the protected commons of code. Other versions of open-source licenses are less viral and have been tailored to different business needs.

In the fields of health and agriculture, open source has been most easily adopted in areas with similar technology characteristics (for example, genomics). Attempts to apply the open-source model to nondigital technology sectors[6] encounter a range of difficulties. Patent law, not copyright law, protects technologies in these sectors of the life sciences. Applying open-source licensing mechanisms in patent law has its own set of legal challenges. Also, there are differences related to the innovation processes of non-digital technologies. The amounts of time, capital, and risk involved in, for instance, the production process of pharmaceuticals, are vastly different from the production process in software production. In addition, some technologies simply lend themselves less easily to the type of collaborative innovation structures that successful open-source models are based upon. Still, the tenets of open source resonate among communities of innovators in a wide range of technology sectors. The search for new applications of the open-source model is surely a worthwhile pursuit.

3.3 *The Commons*

The term *commons* has been used widely in variety of contexts; its meaning, as applied to IP, is less clear cut than those of either public domain or open source. Outside the field of intellectual property, the commons frequently refers to a commonly managed resource (for example, an *ejido* in Mexico describing commonly managed lands). The collective-management concept translates, albeit loosely, into the term's use in reference to intellectual property.

In addition to describing the management of a body of intellectual property, the term *commons* has also been used in reference to characteristics of ownership and access.[7] Whether a commons is defined by lack of private ownership, open access, or collective management seems to vary according to the context in which it appears and to the author's own interpretation of the word. Depending on the choice of definition, commons can apply to the public domain and to open source.

4. REVIEW OF RELATED LEGAL CONCEPTS

Before discussing the use of the public domain in greater detail, this section briefly reviews the relevant sections of patent law. The legal background presented here is important for defensive publishing, that is, intentionally placing a technology in the public domain through publication and thereby preventing future patenting. In addition, understanding these legal concepts will make clearer the discussion in Section 7 on how to ascertain whether technologies are truly in the public domain. Much of this material will be familiar to the reader who has read in this *Handbook* the chapters on freedom to operate (FTO)[8] and on various aspects of patenting and patenting strategies.[9]

4.1 *Patentability requirements and their importance in defensive publishing*

Defensive publishing seeks to preclude future patenting in a technology area by making it impossible for a potential patentee to satisfy one or more of the statutory patentability requirements.[10] A solid understanding of patentability requirements allows for greater success in defensive publishing. In particular, the patent-law concepts of novelty, nonobviousness, and enablement are key.

4.1.1 *Prior art and the patent application process*

In order to meet patentability standards, the claimed invention must satisfy the statutory

requirements of utility,[11] novelty,[12] and nonobviousness,[13] the latter two of which involve an evaluation of prior art. In addition, the patent must be sufficiently described and enabled in the patent application.[14] If the patent examiner assesses the prior art and deems that the claimed invention is either not new, or is obvious, the patent may be denied, or the claims may need to be narrowed in order to account for the documented prior art. It should be noted that the term prior art encompasses both nonpatented and patented prior art. (This chapter does not consider the latter.)

Citations of prior art can be added by either the applicant or the examiner.[15] U.S. patent law does not require the patent applicant to search for prior art (that duty falls to the patent examiner). However, if the applicant or inventor is aware of prior art, it must be included. The duty to disclose exists under the requirement that applicants act in "candor and good faith" when dealing with the U.S. Patent and Trademark Office (PTO) during the patent-prosecution process. A breach of this duty can be considered inequitable conduct and may result in the patent being unenforceable, but there is nothing to prevent intentional ignorance of prior art on behalf of the applicant. In fact, since 2001, when the PTO began to record which citations were added by the examiner, 40% of U.S. patents have resulted from applications in which the applicant has listed no prior art at all.[16]

It is unclear how thoroughly examiners search for prior art. Patents, both domestic and international, are a kind of prior art that allows for relatively easy and expeditious searching. Defensive publishing, however, depends on the ability of patent examiners to find publications in *nonpatent* prior art searches. Sampat[17] discusses the difficulties patent examiners face in searching for nonpatent prior art and notes the *growing concern that these various constraints on effective prior art searching are increasingly binding, and that the PTO is issuing more and more "low quality" patents, [that is,] patents that would not have been issued had the examiner considered the entire universe of relevant prior art.*

So for those seeking to practice defensive publishing, the skills of crafting a good defensive publication must be matched with attention to its prominence in search engines that patent examiners may be more likely to use. Perhaps more importantly, diligent attention should also be paid to newly published patent applications in the field of interest. As these applications are issued, evidence suggests that the author of a defensive publication may need to make the publication known to the patent examiner in order to be considered as prior art and, therefore, limit the claims of the proposed patent. If defensive publications are brought to light *after* a patent issues, recourse through patent invalidation is possible but may be prohibitively expensive. There are provisions within U.S. patent law for the submission of prior art *during* a patent's application process, and this window of opportunity should be strategically utilized.[18]

4.1.2 *Novelty and nonobviousness*

An invention is ineligible for patent protection if it is either not new or obvious in light of existing prior art. The novelty and nonobviousness requirements for patentability define the parameters within which defensive publishing can be implemented. The parameters define how publicly disclosed inventions, as prior art, can be used to support future patentability rejections.

Disclosure of an invention, and the accompanying bar from future patentability due to lack of novelty, is not limited to publications in printed form. An invention can become ineligible for patenting through any public knowledge of the invention, or though its being used or offered for sale. However, it is important to note that U.S. law limits the use of nonprinted evidence in support of a lack of novelty rejection to that which originates *within* the United States. If the intention is to use evidence from other countries to support a rejection on lack of novelty grounds, the evidence must be either a patent or a printed publication.[19] The section of U.S. patent law relevant to novelty and defensive publishing says that a patent application can be rejected on the basis of lack of novelty if *"the invention was … patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or … more than one*

year prior to the date of the application for patent in the United States."[20] In most other countries, the one-year grace period does not exist; public disclosure of an invention immediately bars patentability in those countries.

In addition to understanding the timing of disclosures, a successful defensive publishing strategy should consider the meaning of the words *printed* and *publication*. For example, is a document posted on the Internet considered *printed*, such that the document constitutes prior art and works to reduce future patenting? Sections 5.1–5.4 discuss best practices in regard to the content of defensively published documents, as well as their date and mode of publication.

The nonobvious requirement in U.S. law states that if the existing prior art is such that a person who is *skilled in the art* would not have difficulty coming up with the invention, the invention is not patentable: "*… if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*"[21]

In comparison to the novelty requirement, the patentability requirement of nonobviousness gives a broader range of possibilities for defensive publishing to prevent future patenting. The key difference is that in order to support a rejection under the novelty requirement, the printed publication must include each and every limitation of the claimed invention, either explicitly or implicitly. A rejection under the nonobvious requirement, however, only requires that the content of the prior art publication can be modified in an obvious way to arrive at the claimed invention. In addition, the patent examiner can use *combinations* of prior art to support a nonobviousness rejection, so even disclosures in defensive publishing that are partially complete may still create difficulties for those wishing to patent in the field.

4.1.3 *Enablement*

Careful defensive publishing anticipates how best to support a patent examiner's rejections under the two patentability requirements described above (novelty and nonobviousness). In order to support rejections under the novelty requirement, the publication, or nonpatent prior art, must be enabled. If the reference is supporting a rejection on grounds of nonobviousness, enablement may not be as critical a factor; a nonenabling publication can still be used to support a rejection on grounds of nonobviousness.[22] This section considers enablement for an author constructing a defensive publication.

Although the legal definitions vary somewhat depending on the country in question, in general the enablement requirement is meant to ensure that the document contains enough detail for a person skilled in the art to be able to make and use the invention after reading the document. A key question is whether it is clear that the public possessed the invention prior to the date the patent applicant claims to have invented it. While the burden of proof of enablement for prior art falls to the patent applicant, who must provide facts supporting a purported lack of enablement (this presumption of enablement in prior art is no different for a nonpatent publication than for a patent), it is still worthwhile considering enablement in a defensive publication.

When plants are the claimed inventions that a defensive publication is seeking to protect from patentability, enablement may require that someone of ordinary skill be able to reproduce the plant. Descriptions of the plant variety, however detailed, may be insufficient. In one case, a reference describing a rose was found not enabled, despite explicit detail and evidence that the author was in possession of the rose.[23] In this case the court ruled that, without information on the grafting process, reproduction of the rose was impossible. In other cases, supporting documentation may be necessary to indicate that seeds were publicly available within the time frame necessary to bar patenting.

4.2 *Overlapping claims and dominant patents*

What are the legal concepts used to ascertain whether a technology is in the public domain and therefore freely available? This question is relevant to both scientists and IP managers who

are considering what technologies to choose for a project. These pesrons must proceed with caution, because the use of a technology in a publication, or the decision to in-license a technology under an active patent, may go only part way to providing the right to practice the technology or pursue a certain research project.

A common misunderstanding in this area stems from a belief that patent claims define mutually exclusive areas of technology. In reality, the patent claims overlap each other: the use of one technology can infringe claims in more than one patent. While the issuance of a patent gives the patentee the right to exclude others from practicing the invention, it does not imply that the patentee can *practice* the invention without, perhaps, infringing existing patents. When the rights to existing patents are needed to practice a technology, those patents are considered *dominant patents*.

The existance of broad, pioneering patents illustrate how dominant patents can affect the rights to use downstream innovations. For example, Monsanto's claim to the plant transformation method using *Agrobacterium* means that all patents in which the claims specifically depend on this transformation method are blocked by a previous patent. U.S. Patent No. 6,369,298 is a patent assigned to Pioneer Hi-Bred International, Inc. (now a subsidiary of DuPont) for transformation of sorghum. In this case, the claimed technology depends on the *Agrobacterium* transformation method. A third party intending to practice this technology would likely not only need a license for U.S. 6,369,298 but also for Monsanto's *Agrobacterium* transformation dominant patent(s).[24]

Pioneering patents like the one described above are relatively uncommon, but overlapping claims and dominant patents exist in all areas of patented technology. Understanding the overlapping nature of patent claims is crucial for those who intend to utilize the public domain, because using a technology that *appears* to be in the public domain may involve infringing one or more patents.

The case study of the E8 fruit promoter provides another example (see the timeline in Figure 1 of the chapter by Fenton et al.[25]) An initial search delivers the documents detailed in this figure: several scientific papers and a group of patents. Once the documents are arranged chronologically, we can see that the E8 promoter's DNA sequence was disclosed early in our chronology in two scientific publications. But ascertaining whether the E8 promoter is still in the public domain and therefore available *freely* involves further investigation. Years after the initial publications, several patents were issued that claimed variations on the sequence and the right to use of the *original* E8 promoter sequence when combined with particular genes. Therefore, while the original sequence itself remains in the public domain, when using the sequence care must be taken to avoid infringing subsequent patent claims.

Published scientific literature, trade journals, conference proceedings, abandoned patents,[26] and expired patents are all good sources for finding public domain technologies. In the case of expired and abandoned patents, the boundaries of the forfeited IP rights have been clearly defined by the claims of the patent: the previous owner of the patent no longer has the legal right to exclude someone from using what is set out in the claims of the patent. But these two areas are especially prone to overlapping claims from other patents that may still be active and affect the freedom to use the technology. Companies often file multiple patents in a technology space, or there may be multiple patents in one family that arose from an initial application. Just because a patent has expired and entered the public domain does not mean the technology is available for use.

When seeking to identify whether a technology is in the public domain, one must be cautious because of overlapping claims. Armed with this knowledge, research into a potential public domain technology begins with publicly available patent databases.[27] These databases provide a great deal of information about the boundaries of the public domain. Nonetheless, it can be difficult to understand the interplay between the published scientific literature and patents, as illustrated in the E8 case study. PIPRA offers technical assistance in this regard, analyzing technologies used

in public sector agricultural research to ascertain with greater accuracy the boundaries of the public domain.[28]

5. WHEN TO USE DEFENSIVE PUBLISHING: THE CHOICE BETWEEN PATENTING AND PUBLISHING

Deciding whether to patent or publish is a strategic decision that must take into account a host of variables: the mission of the institution (and/or the funding agency) involved, the goals of the individual project, the financial resources available to spend on IP protection, the nature of the technology, the functionality of the court system in the countries where the technology will be used, and the strategies being employed by other institutions producing similar technologies. Moreover, defensive publishing and patenting inventions each has its limitations and benefits. Other strategies, such as trade secrecy, trademark protection, and bailment[29] need to be considered as options when formulating an IP management strategy.

Defensive publishing is often associated with promoting access, but there are instances where, perhaps counter-intuitively, defensive publishing may not be the most appropriate choice for getting widespread access to either an end-product or a newly developed technology. There are instances, however, where patenting has limitations and defensive publishing may be the better choice.

5.1 *Can defensive publishing promote access?*

Many institutions and/or sponsors, particularly in the fields of health and agriculture, place a high priority on promoting widespread access to developed technologies. Indeed, publishing continues to play a critical role in universities and at other public sector research institutions. Recent changes in the worldwide use of patenting discussed above, however, are forcing these institutions to reassess whether this IP management strategy is the best way to support their goals. This section focuses on promoting access and highlights some instances where the choice to *patent* a technology may be key to achieving the goals of promoting access, primarily by providing important leverage.

5.1.1 *Will the technology need private-sector resources for further development and distribution?*

IP rights provide private economic incentives that can sometimes be critical to research, development, and distribution processes. As an example, consider the investment needed to bring a drug from discovery through to delivery. Although an accurate estimate of the true cost of drug development is the subject of a lively debate, it is inarguably hundreds of millions of dollars.[30] In most cases it is unreasonable to expect the public sector to take on the levels of investment and risk involved in drug development. A parallel example can be seen in agriculture, where regulatory clearance may be needed for a new product, or seed distribution networks may need to be engaged. It is important, therefore, to assess early whether private capital is likely to be necessary, at some point, for research, development, regulatory clearance, manufacturing, and distribution. IP rights can facilitate the private sector's engagement by providing critical assets for bargaining (for example, in product development partnerships).

5.1.2 *Are there benefits to be gained from segmenting the market?*

One benefit of choosing to patent, rather than publish, is that patenting provides an opportunity to segment the market of technology users or licensees. An IP manager may require different licensing terms, for instance, depending on whether the technology will be used commercially or for humanitarian purposes. Alternatively, the license might contain terms to segment the market geographically or by fields of use. An exclusive license may be implemented, for example, to limit the technology's use to one major crop, reserving all other uses of the technology for widely accessible and nonexclusive licensing. Using such an approach, income generation and access may be complementary goals for the IP provider. Or the rights to a technology in, for instance, developed country markets may be exchanged for contractual obligations to deliver the

product to developing countries for a reasonable price. Choosing to protect the technology with IP rights instead of defensive publishing may provide bargaining leverage that ultimately achieves the institution's goals.

5.1.3 *Is the technology a research tool (enabling technology)?*

A body of evidence indicates that the patenting and access restrictions (through exclusive licensing, for example) of enabling technologies can limit the progress of innovation in health and agriculture.[31] Indeed, the existence and effects of patent thicket– or anticommons-dynamics are now fairly well accepted. The task of this section, however, is not to consider the policy question of whether research tools *should* be patentable, but to examine the choice between patenting (notably in the examples given here with widespread *nonexclusive licensing*) and defensive publishing for the IP manager whose goal is to promote access in a context where research tools, and improvements to them, are widely patented. In other words, how can IP management preserve the right to use an enabling technology?

As a first example, consider plant transformation that confers a new trait. Access to several complementary enabling technologies is required to produce a product. A vector that includes a promoter, selectable marker, a backbone, and a gene of interest must be used, as well as a transformation method and germplasm. Lack of access to any one technology may delay research and development or, in some cases, altogether prevent the progress of the project.

In such a case, the complementary nature of the technologies implies that the decision to patent may confer bargaining leverage. If an IP manager chooses not to patent an enabling technology, for example, a novel selection system with wide applicability in plant transformation, the ability to control the technology's applications is lost. Research projects where the selection system would otherwise have been the limiting factor (where all other technologies are owned or accessible) could progress, without impediment, if the technology were to be published. Alternatively, if the IP manager chooses to patent, the essential nature of the technology may place the owner in a position to demand a wide range of contractual obligations in exchange for the use of the selection system. BiOS, for example, operates on this principle by providing patented enabling technologies under licensing terms that support the organizations open-access goals.[32]

A second scenario concerns improvement patents. Here, as in the previous example, suppose the IP manager chooses not to patent the novel selection system. Improvements to the technology are subsequently invented and patented, restricting the uses of the original technology. Had the IP manager patented the technology, the value of the subsequent improvement patents would depend on access to the underlying dominant patent (see Section 4.2 on dominant patents). The E8 case study provides a concrete example where, had the original sequence been patented instead of published, the use of some of the downstream patents would depend on Agritope, Inc. or Epitope, Inc. licensing the original patent. For technologies that do not lend themselves to subsequent restrictions from improvement patents, this is not a concern. Mouse models are an example of this type of technology. The majority of mouse models used in research, for instance, are licensed and *not* patented.

5.2 *Using defensive publishing as a tool in an IP management strategy*

Clearly, the common perception that publishing inherently promotes access may require reconsideration. Still, what are the merits of defensive publishing for supporting a wide variety of IP management goals? And how does it highlight the limitations of using patents to protect innovations?

5.2.1 *The costs of maintaining a patent portfolio*

Patent portfolios are costly to develop and maintain. Moreover, they sometimes require a lengthy maturation period before reaching a point where they return income. Unless a licensee is found who will underwrite the cost before the prosecution process starts, the initial investment in the cost of prosecuting patents can be large,

particularly where protection is sought in multiple countries. Even where licensees are already in place, it can be many years before a license generates a positive cash flow. In examining U.S. university technology transfer offices (TTOs), Heher notes that 40%–50% operate at a net loss and that profitability often depends on income arising from one or more blockbuster patents.[33] In a cross-country comparison of TTOs, he finds that "*the first and foremost requirement for success from technology transfer is a well-funded high quality research system as the benefits from commercialisation of research are directly proportional to the magnitude of the investment in research.*"[34] While direct and indirect economic impacts provide broad benefits from building an institutional patent portfolio and TTO, the investment is long term and high risk. If resources are particularly constrained, the decision to expend money on patenting deserves careful consideration. Less expensive alternatives to patenting may support IP management goals and allow more resources to be directed toward research.

5.2.2 *Transaction costs of licensing*

The transaction costs of negotiating licenses are substantial and may need to be accounted for in the decision to patent. For instance, if the IP management goal is to promote access to a technology, and the choice is either defensive publishing or nonexclusive licensing, the costs of negotiating multiple nonexclusive licenses, or devising licensing language to segment the market of technology users suitably, may outweigh the benefits. Transaction costs can be somewhat reduced in take-it-or-leave-it nonexclusive licenses, but these tend to be rare.

5.2.3 *Enforcement considerations: costs and legal Infrastructure*

The costs (and feasibility) of enforcing the patent may also need to be considered. Because a patent confers exclusionary rights, it may be worthless without the ability to enforce those rights. Enforcement may require litigation against infringers or using the patent to invalidate subsequent blocking patents. In either case, patent litigation is a game for players with deep pockets. Average costs for patent litigation in the United States exceed $2 million dollars per case. Any decision to patent must include an assessment of whether the patentee can afford to enforce the patent. In addition to the expense, the maturity or efficacy of the patent law system in the countries likely to be involved should be considered. If the technology lends itself to bailment, for example, more control over the use of technologies may be found through contract law, particularly in countries where the patent system is not well developed.

5.2.4 *Defensive publishing as an active strategy*

Defensive publishing is most effective as an active strategy. This is a different use of publishing than that found in many research institutions today. The use of defensive publishing requires carefully constructed disclosures with the greatest possible public exposure and diligent worldwide monitoring of new patent applications as they arise in a particular technology field. When a patent application appears for which the defensive publication has the potential to force a narrowing of the claims or a total rejection, the appropriate channels must be used to alert the patent office of the published prior art.

5.2.5 *Using defensive publishing in combination with patenting*

One of the strongest roles defensive publishing can play is when it is used, not as a substitute for patenting, but in conjunction with it. As an example, consider a strategy where an IP manager patents a core technology and then defensively publishes the surrounding, related innovations, thereby reducing the likelihood that others will be able to obtain dominant patents. Obtaining patents on improvements to a core technology as they are discovered may be a poor use of limited resources. In addition to improvements, new uses of the core technology may be discovered as research and development progress. But defensively publishing these improvements and alternative uses will inexpensively and effectively contribute to preserving the right to a wide field of applications for the core technology.

5.3 *Preserving access: ten questions to consider*

For the IP manager deciding on a strategy for preserving public access, considering the following questions should be helpful:

- What are the IP management goals of the institution or inventor?
- Will the technology need the engagement of private-sector resources for further development and distribution?
- Are there benefits to be gained from segmenting the market?
- Is the technology a research tool (enabling technology)?
- Do the benefits of patenting and licensing outweigh the costs?
- How and where might the patent be enforced?
- Are there other viable options for protection—trade secrecy, bailment, trademarks, and so forth?
- In which territories/countries is the technology likely to be used?
- Can the technology be licensed without patenting?
- Can defensive publishing be used in conjunction with traditional forms of IP protection?

6. USING PUBLIC DOMAIN TECHNOLOGIES

Public domain technologies are valuable inputs to research. Indeed, they are a crucial but commonly underutilized resource for researchers. Using research tools or enabling technologies in the public domain reduces transaction costs and mitigates future potential IP impediments in the research and development process.

In developed countries, many of the standard inputs of science in the fields of health and agriculture have been patented. Scientists, however, continue to use these tools because they have a well-known history, including known levels of efficiency and documented use in specific crops. The use of patented research tools, on the other hand, can open the institution to infringement liability and/or create problems in later stages of commercialization. While the maximum use of public domain technologies may be desirable at the outset of a research project, using better-known tools (which are often proprietary) may be important in the initial proof of concept stages of research. In this case, it is worthwhile to identify whether public domain technologies are available for substitution at a later stage.

The identification and promotion of substitute technologies from the public domain is one of PIPRA's important contributions to the field of agriculture. PIPRA's mandate is to assist public sector researchers worldwide in overcoming IP impediments to the research, development, and distribution of staple crops for developing countries and minor crops in developed countries. Because the commercial market for these crops is too small to attract private-sector investment, the public sector primarily pursues research and development with respect to such crops—often without the resources to successfully address IP issues. Public domain technologies are therefore a critical resource for developing these *orphan* crops.

As PIPRA's library of technical and legal information on public domain and patented, but accessible-enabling technologies (including freedom-to-operate opinions from attorneys) in agriculture grows, so does the demand for knowledge of what technologies *are* in the public domain and how they might be employed in place of currently used patented technologies. Some practical considerations for researchers and IP managers with regard to identifying public-domain technologies are laid out below.

6.1 *Patent databases provide only part of the picture*

As the E8 case study illustrates, an investigation must begin with a search through *both* the published scientific literature and patent databases. It is both the comparison of the content and the timing of the publication of each contributing document that will determine whether the technology in question is in the public domain and its limitations for use. A simple patent search may mislead by returning a bewildering number of related patents. But a comparison of these patents with the published literature can reveal that, for instance, the core technology is in the public

domain and that the patent thicket is made up of improvements, and other patents, limiting the utility of the original technology. If this is the case, knowledge of these limitations may be critical in designing a research plan that invents around existing patents and maximizes the use of the public domain technology.

Sequence comparisons may provide another critical piece of information for the researcher seeking to use a public domain technology. As an example, PIPRA's analysis of the Soybean Heat Shock Promoter found that changing the sequence by one nucleotide allowed researchers to avoid infringing the issued patents.[35] It should be noted, however, that this case is somewhat anomalous. The determination by PIPRA's attorneys that altering a single nucleotide avoided existing patents was reached by carefully considering both prior art and patents. Generalizations cannot be made, because it is only through examining how both sets of specific documents interact that FTO can be evaluated. However, the example illustrates how critical the use of sequence analysis tools such as BLAST can be when analyzing patents. In general, careful attention to the prior art and the use of homology measures in patent claims may be necessary to identify the specific public domain sequence.

6.2 *The landscape is continually changing*

The boundary of the public domain changes as new patents are issued. Periodic updates of the analysis are necessary to check for recently issued patents that may restrict the use of the original technology. Searches can be hindered because patent applications remain unpublished—and therefore invisible in patent search engines—for many months after their initial filing dates.

6.3 *Geographical considerations*

Finding out what is in the public domain is made even more complex by the territorial nature of patents. The analysis for the E8 case study considered only the situation in the United States; any other country would require collecting a different set of documents. Nonetheless, because the boundaries of the public domain are more expansive in some countries than in others, opportunities may exist to design research strategies that take advantage of these differences.

For example, the territorial limits of patents have led to suggestions that developing-country research institutions should use technologies that are not patented domestically but are patented in more-developed countries. Legally, a researcher using a technology in a country where no patent has been filed is not infringing. However, an obvious constraint surfaces when the product of the research is destined for export into a country where there is patent protection. In this case, despite the lack of patent protection domestically, it may be necessary to investigate the patent landscapes of export markets.

There are still further considerations. In order to use a technology that resides in the public domain domestically, but is patented elsewhere, a researcher may require the transfer of materials or know-how from the patentee. These often involve material transfer agreements (MTAs) with restrictive terms and reach-through obligations that may hinder research and interfere with broad access for researchers in developed and developing countries alike. Even where no patent rights are found, this situation may involve negotiating agreements (such as nonasserts) with the technology owner. In addition, even when large companies as patentees are not concerned with infringement issues or losing market share, the companies may be concerned about liability and stewardship issues. Finally, developing country research institutions, or the organizations that sponsor their research, may attach considerable value to the building of relationships with the company that has patented the technology. Therefore, despite the lack of patent protection and the legal freedom to use a technology, there may still be important reasons to negotiate a license.

7. THE MECHANICS OF DEFENSIVE PUBLISHING

This last section focuses on the mechanics of defensive publishing: how to best ensure that a disclosure precludes downstream patenting by others.

Elements to consider in drafting a successful defensive publication include: content, language of choice, publication venue, and publication date. The following sections elaborate on best practices in defensive publishing.

7.1 *Content*

The goal of defensive publishing is to prevent patenting in a particular technology area. Therefore, constructing a disclosure specifically designed to create evidence to prevent patentability will increase the likelihood that fewer patents will issue in this technology space. The disclosure should be as complete and detailed as possible. Where relevant, a publication should include descriptions of all parts of the experiment, experimental conditions, diagrams, formulas, procedures, sequences, materials, and methodologies. We indicated earlier that enablement of the publication may be important; a defensive publication should include evidence illustrating possession of the invention and enable a person skilled in the art to make and/or use the invention.

7.1.1 *Consider disclosing the potential for combining technologies*

In addition to a thorough description, defensive publishing should include potential combinations of the target technology with other technologies. This is true even for combinations for which the author may not have detailed documentation. As the case study of E8 revealed, the inclusion of additional combinations can expand the use of the document to support future nonobviousness rejections. Publishing the sequence of the E8 plant promoter did not prevent the issuance of future patents claiming the use of the promoter *combined* with particular genes. If the authors of the original publication had ended their paper by articulating the likely success of the sequence for promoting the expression of broad classes of genes, there may have been stronger grounds for rejecting subsequent patents. To extend this point, a defensive publication may be even stronger if it anticipates not only the promoter-gene combination, but also its potential use in entire systems, such as the transformation method, selectable marker systems, and other elements of a plant transformation vector, as well as its use in particular crops.

Whether the inclusion of certain language in a publication will prevent future patenting in this case is uncertain, and it should be noted that the combination of prior art references in support of a rejection on nonobviousness grounds comes with several caveats. A successful rejection of a claimed invention due to obviousness must show, not only that someone skilled in the art would have been able to combine the prior art references, but that they *would have been motivated* to do so. Second, there must be a reasonable expectation of success for the purported combination. Third, the references taken together must teach or suggest all the elements of the claimed invention. When drafting the content of a defensive publication, it is impossible to anticipate all the possible combinations of the author's technology with that belonging to others, but by using language that acknowledges the caveats above, the author can broaden the subject matter of the disclosure as much as possible.

7.1.2 *Consider disclosing potential alternative applications*

As with potential combinations, it may be worthwhile to include alternative applications of the technology, even if they are not documented in detail. If the technology is a product, the author may want to consider including the current product, potential uses of the product, and derivative products. While defensive publication can place a product technology in the public domain, processes developed later using that product can still be patented. By anticipating potential applications, the author of the defensive publication may contribute to an obviousness-type rejection in the future. If the technology disclosed is a process, the author might consider including details of products derived from the process. These considerations anticipate the patentability of product and process patents. As an example of product and process patents, consider the famous Cohen-Boyer technology. This was not one patent, but three: (1) a process patent for the construction of molecular chimeras, (2) a product patent for proteins made using recombinant eukaryote DNA,

and (3) a product patent for proteins made using recombinant prokaryote DNA.[36]

7.1.3 *Consider disclosing related alternatives*

One way to design around a defensive publication (or a patent) is to alter, even minimally, the structure of the technology. TGo anticipate this, defensive publication can indicate how the technology may be altered while still maintaining the original disclosed functions and characteristics. This follows common practice in drafting patent claims. For instance, a sequence may be published that includes a percentage homology within which the function of the technology remains the same. In addition, it may be useful to include homologies across different species.

7.1.4 *Consider depositing biological materials*

For some inventions involving biological material, we have established that a written description is insufficient to convey the technology in such a way that a person skilled in the art can practice it. For such inventions, the patent system has come to depend on the deposit of biological materials in recognized, publicly accessible culture collections worldwide. As a rule of thumb, if the biological material can be made, or isolated, without *undue experimentation,* or if the material is otherwise known and readily available, it is not necessary to deposit material. In many cases, however, a defensive publication will be stronger if biological materials are deposited (the deposit accession number should be referenced, where relevant, in the publication and sequence information given).

Patent deposits worldwide have been regulated since 1980 when the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure came into force.[37] The World Intellectual Property Organization[38] provides an updated list of the countries that have ratified the Treaty and the collections that are recognized as international depositary authorities (IDAs).[39]

7.2 *Choice of language*

The choice of language (that is, English, or other) in a defensive publication can also be important. The publication language may need to be, for example, one spoken in the countries in which the patent will be barred. It may be important, however, to write at least the abstract and title in English to maximize the chances that this particular disclosure will be brought to the attention of the patent offices in the United States and Europe during prior art searches. Still, given the limitations of nonpatent prior art searching in patent offices, the best post-publication strategy is to monitor the published application in the technology field and alert the relevant patent office to the defense publication.

7.3 *Where to publish*

As noted previously, U.S. law uses the words "printed publication" in its novelty requirement. U.S. courts have adopted a broad definition of the word *printed*, to include documents stored on electronic media, and on microfilm.[40] Documents posted on the Internet may therefore be used to satisfy the printed aspect of the novelty requirement.

The word *publication* has also been fairly broadly interpreted to mean any printed document that is freely available to the public. Peer-reviewed publications are only one option for defensive publication, and their constraints on content may leave the author with a less than complete defense. Printed materials presented at trade shows, conferences, seminars, or on Web sites are all considered to satisfy the definition of *publication*. Indeed, major corporations have used this kind of defensive publishing as part of their IP management strategy for many decades. IBM provides perhaps the best-known example of the use of a technical journal for defensive publishing. The success of that strategy is illustrated by a 2002 search of the U.S. patent database by Bill Barrett that found almost 10,000 patent citings of IBM's *Technical Disclosure Bulletin*.[41] By publishing technical disclosures without the content restrictions of peer-reviewed publications, IBM wields an inexpensive, flexible tool that complements its overall patenting strategy.

A number of companies specialize in publishing nonpatent prior art. The Web site IP.com, for example, provides expertise in defensive

publishing and offers a search engine to make it easy for a patent examiner to navigate through the site's library of disclosures.[42] Disclosing an invention through such a company will increase the likelihood that a patent examiner will see it. The companies, however, may charge hundreds of dollars for such a disclosure. Another method of disclosure is the use of the statutory invention registration procedure, whereby the PTO allows for the registration of an invention that is unexamined. This method, too, can be expensive. The most cost-effective way to defensively publish is to publish for free on the Internet (but dating material published on the Internet can be problematic; see next section). If the Internet is used to publish defensively, there may be a greater need to monitor recently published patent applications in the field of interest.

7.4 *Timing and date stamping*

The date of a defensive publication is a critical piece of information that must be documented and discernible by the patent office. It helps the patent examiner to determine whether the publication brings into doubt the patentability of the subject matter. The dating of material published on a Web site can be a difficult matter: many documents on the Web are date stamped on the date of *access*, not the date of posting. Obviously, this practice can cause problems for a party those attempting to preclude future patenting in a technology area by using the Internet for defensive publishing. Fortunately, there are solutions. Many companies now offer digital time stamping (DTS) or digital notary services. This technology has become accepted legal proof that the contents of a publication existed at a particular point in time and has not changed since that time.[43] Another readily accessible method of establishing the date of an Internet publication is to scan a document that includes a date and a signature, and post the pdf on the Web.

8. CONCLUSION

This chapter has examined how IP managers and researchers can use the public domain and defensive publishing to their advantage. A strategic IP management plan begins by identifying the inputs and enabling technologies used in research. A strategic IP plan also clearly articulates the intended use of the technologies that are produced. Once this framework is established, IP management tools can be used effectively to support the project's goals.

The public domain is a valuable resource for early-stage thinking about a project's research tools. The above practical considerations will hopefully assist in effectively incorporating public-domain technologies into an IP management plan, thus reducing the need to in-license technologies and freeing up resources for more research. Moreover, when managing the products of a research project, one tool to consider alongside more traditional IP rights is defensive publishing, or placing a technology in the public domain. When considering defensive publishing, however, IP managers should keep in mind both its utility and its limitations. ■

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1 Boyle J. 2003. Foreword: The Opposite of Property? *Law and Contemporary Problems* 66(1-2):25. www.law.duke.edu/shell/cite.pl?66+Law+&+Contemp.+Probs.+1+(WinterSpring+2003).

2 447 US 303 (1980).

3 The Bayh-Dole Act (1980) altered incentive structures surrounding the development of publicly funded research by mandating institutional ownership and the ability to exclusively license these inventions. See, also in this *Handbook*, chapter 3.3 by Gregory Graff and chapter 3.2 by Rachel A Nugent and Gerald T Keusch.

4 Because patents are territorial grants of exclusionary

rights, the patent landscape can vary considerably among countries.

5 Lange D. 2003. Re-imagining the Public Domain. *Law and Contemporary Problems* 66(1-2): 463. www.culturaleconomics.atfreeWeb.com/Anno/Lange%20Reimaging%20the%20Public%20Domain%20LCP%202003.htm

6 For example, the Biological Innovation for Open Society (BiOS, www.bios.net).

7 The discussion of the commons here derives from the excellent compilation of collected papers from the Duke Conference on the Public Domain (www.law.duke.edu/pd/papers.html), in Law and Contemporary Problems, 66, Winter and Spring 2003, where readers will find an in-depth discussion of many facets of the public domain.

8 See, also in this *Handbook*, chapter 14.2 by SP Kowalski; chapter 14.4 by GM Fenton, C Chi-Ham, and S Boettiger; and chapter 14.1 by A Krattiger.

9 See, also in this *Handbook*, chapter 10.5 by O Livne, chapter 10.6 by AS Viksnins and AM McCrackin, and chapter 11.8 by S Shotwell.

10 This section refers in particular to U.S. patent law. However, internationally the requirements for patentability tend to be similar.

11 35 U.S.C. § 101.

12 35 U.S.C. § 102.

13 35 U.S.C. § 103.

14 35 U.S.C. § 112.

15 A member of the public can also add citations. See footnote 14.

16 Alcácer J and M Gittelman. 2004. How Do I Know What You Know? Patent Examiners and the Generation of Patent Citations. Working Paper. www.olin.wustl.edu/cres/research/calendar/files/alcacer_gittelman.pdf#search=%22Alc%C3%A1cer%20and%20Gittelman%20(2004)%22.

17 Sampat BN. Examining Patent Examination: an Analysis of Examiner and Applicant Generated Prior Art. Working Paper. faculty.haas.berkeley.edu/wakeman/ba297tspring05/Sampat.pdf.

18 35 U.S.C. §301. Citation of prior art: *"Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential."*

19 §102(g) allows for proof of prior invention in any country that is a member of the WTO, but this is limited to cases where inventorship is disputed in a formal interference proceeding. Outside the scope of an interference proceeding, proof of lack of novelty is limited to printed documents and patents.

20 The one-year period is based on the *priority* date, which is usually the date on which the patent application is filed. It is possible, however, for a patent to have a priority date that is earlier than the date on which it was filed. Continuation and divisional applications, for instance, may retain the priority date of the "parent" application from which they are derived (in these instances it is even possible for one patent to have more than one priority date, as different content in the claims may have entered the patent application process at different times). In addition, the establishment of a priority date must encompass international applications. If a patent is filed on an invention in Japan, and then later a U.S. application is filed, the U.S. application will retain the priority date of the earlier Japanese application. Patent applications can also have earlier priority dates if a provisional application was filed first.

21 35 U.S.C. 103 Conditions for patentability; nonobvious subject matter.

22 *"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." Beckman Instruments* v. *LKB Produkter AB*, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). *"A non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103." Symbol Technologies Inc.* v. *Opticon Inc.*, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

23 In re LeGrice, 133 USPQ 365 (CCPA 1962).

24 Monsanto's patent application(s) for *Agrobacterium* mediated transformation have not yet issued as patents in the U.S. Until this happens, it is impossible to say with certainty which patents will be blocked by the issued claims. In addition, Monsanto's *Agrobacterium*-mediated transformation patents in other parts of the world have already expired; dominance changes by territory.

25 See *supra* note 8.

26 In addition to patents that have been abandoned due to non-payment of maintenance fees, some abandoned patent applications may also be in the public domain. Under a revised law, U.S. patent applications filed on or after 29 November 2000 are to be published within 18 months. Prior to this change in law, patent applications were not publicly available. The new law still contains an option for secrecy up until the point that the patent issues. If the patentee elects to forego foreign patenting, s/he has the right to request that the application remain unpublished.

27 See, for instance, www.uspto.gov.

28 www.pipra.org.

29 If the technology has an element of tangible property, bailment may be used (for example, material transfer agreements) to protect the technology under contract law instead of patent law—a choice that may be warranted in countries where patents are more difficult or prohibitively expensive to enforce in comparison

with contracts.

30 A report by the Global Alliance on Tuberculosis Drug Development on the economics of tuberculosis drug development estimated the cost of drug development for a tuberculosis indication was US$115-240 million. See *The Economics of TB Drug Development* (October, 2001) at www.tballiance.org. These figures are well below many other cited estimates for drug development cost, such as the well publicized study by DiMasi *et al* (DiMasi AA, RW Hansen and HG Grabowski. 2003. The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 22: 151–185).

31 See, for example, BD Wright and PG Pardey. 2006. The Evolving Rights to Intellectual Property Protection in the Agricultural Biosciences. *Int. J Tech and Globalisation* 2(1/2):12-29. While they articulate the complexity of the issues and admit that *"definitive evidence on the effects of IPR on agricultural research will not be available soon, if ever,"* their paper also includes a catalog of examples where the path of research has been altered because of IP rights. Tomatoes with improved shelf-life characteristics, fungus-resistant strawberries, hypoallergenic wheat, as well as herbicide tolerant barley, turf grass, and lupin are all examples where research and development were suspended due to IP roadblocks.

32 www.bios.net.

33 Heher AD. 2004. Economic Modelling of Institutional Research and Innovation. Unpublished Report for SARIMA. SARIMA Project 3. University of Cape Town: Cape Town.

34 See *supra* note 33, page 3.

35 Contact PIPRA for more information on the written FTO opinion for this technology.

36 Intellectual Property Rights and Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, February 15-16, 1996 (1997), p. 40; www.nap.edu/readingroom/books/property/5.html.

37 The term "microorganism" was appropriate at the time the Treaty was named because the primary uses of biological materials in industry involved bacteria and lower fungi. Today the term is interpreted broadly within the context of the Budapest Treaty to include a wide range of biological materials (for example, bacteria, viruses, isolated DNA, and cell lines, etc. (see Fritz D and V Weihs. 2001. Deposition of Biological Material for Patent Protection in Bio-Technology. *Appl Microbiol Biotechnol* 57:443–450.)

38 www.wipo.int.

39 See www.wipo.int/treaties/en/registration/budapest/pdf/ida.pdf for a current list. Also of relevance is chapter 10.10 by Dennis Harney and Timothy McBride in this *Handbook*.

40 *In re Wyer*, 655 F.2d 221, 226-27 (C.C.P.A. 1981).

41 Barrett B. 2002. Defensive Use of Publications in an Intellectual Property Strategy. *Nature Biotechnology* 20:191-193.

42 www.ip.com.

43 For instance, www.digistamp.com offers non-profit organizations performing medical or environmental public research use of their service at 30 cents per time stamp.

Provisional Patent Applications: Advantages and Limitations

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ABSTRACT

In the United States, provisional patent applications can provide an additional year of patent protection, for a total of 21 years from the initial filing date. With such an extension, a provisional application provides parity with foreign applicants who, pursuant to the Paris Convention, may file for a U.S. patent within 12 months of the foreign filing. Provisional applications have both advantages and disadvantages, so proper management is essential. The advantages include the preservation of a priority date immediately after an invention is conceived, a one-year delay for further developing the invention, an extra year of patent protection, and constructive reduction to practice of the invention. In addition, provisional applications provide an inexpensive way to avoid possible statutory bars and preserve absolute novelty for foreign filing purposes. They also enable the use of the phrase "Patent Pending" to mark products embodying the invention. The disadvantages include a possible increased overall cost of obtaining a patent, potential loss of trade secrets, and a false sense of security. An inventor must also file a nonprovisional application within one year, and the subject matter of a nonprovisional application is limited to subject matter in the provisional application.

1. INTRODUCTION

Beginning in 1995, inventors were able to file provisional patent applications in the United States. This informal type of patent application establishes a priority filing date and provides inventors one additional year to prepare and file a formal utility patent application.

Provisional patent applications were established in the United States to place domestic inventors on an equal footing with foreign inventors. Before the advent of U.S. provisional applications, foreign (Paris Convention signatory) applicants could claim the benefit of a foreign priority date, yet have their U.S. patent term measured from a later U.S. filing date. Foreign inventors were thus granted a term of patent protection that could last for 21 years. U.S. applicants, on the other hand, were disadvantaged: their patent term was measured from their initial U.S. filing date and limited to 20 years. Effective June 8, 1995, domestic applicants were given the opportunity to file provisional applications, thereby establishing U.S. priority dates that would *not* count against any resulting U.S. patent term. Allowing for U.S. patent protection that lasts 21 years from an initial filing date, this change in policy established parity between U.S. and foreign inventors.

As an informal application, a provisional patent application does not require all the formal elements of a utility patent application. For example, provisional applications *are not* required to include formal claims, a declaration of inventorship, or drawings, all of which are required for utility applications. Instead, all that is required is a written description of an invention and a coversheet that, among other things, identifies the document as a provisional patent application.

Cruz RL. 2007. Provisional Patent Applications: Advantages and Limitations. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Unlike utility patent applications, provisional patent applications are not substantively examined by a U.S. Patent and Trademark Office (PTO) examiner. Instead, they are reviewed by the application division of the PTO to ensure that the minimum filing requirements have been met. As a result, the legal cost of *preparing* provisional applications is relatively low compared to utility applications. Similarly, since the PTO does not have to perform a prior art search or analyze provisional patent applications, the cost of *filing* these applications is also quite inexpensive when compared to utility applications.

Aside from costs, several other factors should be considered when determining whether or not to file a provisional patent application. A few of their advantages and limitations associated with provisional applications are outlined below.

2. ADVANTAGES OF A PROVISIONAL APPLICATION

2.1 *Preserve a priority date*

Because they have fewer formal requirements, provisional applications are simpler and generally less expensive to prepare and file. A provisional application may therefore be used to quickly and inexpensively obtain an official filing date for an invention immediately after the invention has been conceived. An official filing date provides unequivocal proof that an invention was conceived at least as early as its filing date.

2.2 *A useful one year delay*

Once a provisional application is filed, an inventor has up to one full year to file a formal utility application. This one-year delay enables an inventor to further develop his or her invention, assess the invention's commercial potential, and seek financial support for further developing and/or patenting the invention. In addition, the one-year delay enables an inventor defer the bulk of the costs associated with preparing and filing a utility patent application until he or she is confident that the invention is commercially viable, and/or until he or she is able to secure financial support for the invention. If the inventor determines during this period that the invention is not commercially feasible, he or she can avoid the substantially higher costs of pursuing a utility application.

2.3 *An extra year of patent protection*

An issued patent gives an inventor the right to exclude others from using, selling, and/or offering to sell the patented invention for twenty years. This twenty-year patent term is calculated from the filing date of the inventor's *utility* patent application. The one-year delay between the filing of a provisional application and the filing of a utility application does *not* count against the twenty-year patent term. As such, filing a provisional application provides up to an extra year of patent protection, effectively extending the patent term to 21 years.

2.4 *Constructively reduce an invention to practice*

An invention is said to be *reduced to practice* when an inventor converts the inventive idea into something that is operable and capable of being reproduced by others. Filing a provisional application has the effect of *constructively* reducing an invention to practice, insofaras the invention is adequately described so as to enable a person skilled in the art to reproduce it. By filing a provisional application, a legal presumption is created that the invention was reduced to practice, albeit constructively, *at least as early as* the filing date of the provisional application. This presumption may be very advantageous to an inventor, particularly if another inventor claims to have invented the same invention first.

In the United States, an inventor is entitled to a patent if he or she is the *first to invent* a particular invention. If a dispute arises over who actually invented the invention first, establishing a reduction to practice date may be paramount to determining which inventor is entitled to the patent. In such disputes, the inventor who establishes the earlier reduction to practice date (for example, by filing the earlier provisional application) will be presumed to be the first to invent. The challenging inventor, i.e., the inventor not deemed the first to invent, may only overcome this presumption by forwarding evidence that establishes that

he or she (the challenging inventor) is entitled to an earlier reduction to practice date. Thus, filing a provisional application not only establishes an early reduction to practice date, but it also shifts the burden to any challenging inventor to prove that she or he invented the invention first.

2.5 *Preserve a non-U.S. priority date*

Most countries outside of the U.S. award patents on a first to file basis. That is, an inventor will be entitled to a patent if he or she is the *first to file* an application for a particular invention, regardless of whether another inventor was the first to actually reduce the invention to practice. As a result, many foreign inventors (and U.S. inventors seeking international patent protection) seek to file patent applications in non-U.S. countries as soon as possible in order to preserve their foreign priority date. It should be noted that under U.S. law, establishing a foreign priority date does *not* necessarily guarantee a specified period of time for filing in the United States. Still, as members of the Paris Convention, patent applicants in Convention member-nations have up to 12 months to apply for patent protection in the United States in order to preserve an international priority date.

2.6 *Avoid statutory bars*

Pursuant to 35 U.S.C. § 102(b), if an invention is published anywhere in the world more than one year before a U.S. patent application for that invention is filed, the publication will act as a statutory bar to obtaining a U.S. patent. This statutory bar is not limited to publications provided by an invention's first inventor. If, for example, a second inventor independently conceives and publishes the invention more than one year before the first inventor files in the United States, the second inventor's publication will bar the first inventor from ever obtaining a U.S. patent on that invention.

To illustrate, suppose inventor X, a German inventor, invents a novel widget on January 1, 2005, and accordingly files a German patent application describing the widget in April 2005. Independently, a French inventor, inventor Y, conceives of the same widget and publishes it on March 1, 2005 in a French publication. Under U.S. law, the German inventor may rely on his or her earlier invention date to predate the French publication date. However, if the German inventor waits until after March 1, 2006 to file a U.S. application, the French publication will be deemed prior art under 35 U.S.C. § 102(b) and will bar the German inventor from obtaining a U.S. patent.

To avoid this 102(b) U.S. statutory bar, the German inventor could file a U.S. utility patent application concurrently with, or even after, filing his or her German application. Pursuant to the Paris Convention, the German inventor would still have a period of one year after filing the German patent application to file a U.S. patent application. However, the utility patent application option could be quite costly, particularly since the German application would have to be translated into English and include U.S.-style claims, drawings, and other formalities.

As an alternative, if the German inventor was not prepared to incur such an expense, or if he or she preferred to further develop the widget before committing to the high costs of filing in the United States, he or she could simply file a U.S. provisional application. Since provisional applications are not required to be written in English or to include claims, drawings, or other formalities, the German inventor could simply file a copy of his or her German application *in German* as a U.S. provisional application. In this manner, the German inventor could preserve a U.S. filing date and avoid a § 102(b) statutory bar, all at a very reasonable cost.

2.7 *Preserve absolute novelty for foreign filings*

Most countries outside of the U.S. require *absolute novelty*, which means that, as a prerequisite to receiving patent protection, a patent application must be filed before *any* public disclosure of that invention. In these *absolute novelty* countries, *any* public disclosure of an invention prior to filing an application for patent acts as a bar to patentability. As such, it is imperative for inventors seeking foreign patent protection to preserve absolute novelty worldwide. Provisional applications may provide an easy, cost effective way to preserve absolute novelty; however, this must be approached with caution, as adequate disclosure is required. There is still a general lack of consensus about

how courts in various foreign jurisdictions will regard a U.S. provisional application as a basis for priority. Even so, if an inventor wished to publicly disclose an invention as part of a presentation, the inventor could preserve absolute novelty by filing a copy of all of the presentation and handout materials as a provisional application. In this manner, the inventor could both preserve a U.S. filing date and preserve absolute novelty in Paris Convention nations, or in nations that have acceded to the WTO (as the TRIPS Agreement [Trade-Related Aspects of Intellectual Property Rights]) incorporates the Paris Convention). This includes the majority of the world's nations.

2.8 *Patent pending*

Once a provisional application is filed, an inventor is permitted to apply the phrase "Patent Pending" to products embodying the invention. Use of this phrase indicates to the public that the marked product or products is or are believed to be inventive and that any and all available patent rights in the invention are being pursued. Application of the phrase also enables the immediate commercial promotion of an invention with less risk of having the invention copied and/or stolen. In addition, a "Patent Pending" notice gives official notice to competitors and potential infringers, which may be particularly useful in establishing a patent infringement claim once the invention is formally patented. It should be noted that the phrase "Patent Pending" does *not* give rise to enforceable patent rights. It is only after a patent is issued that enforceable patent rights attach.

3. LIMITATIONS OF A PROVISIONAL APPLICATION

Aside from the many advantages described above, there are several limitations and disadvantages associated with filing provisional applications.

3.1 *Increased overall cost*

Although provisional applications are typically less expensive to prepare and file than utility patent applications, there are costs associated with the same. Filing a provisional application first, and then filing a corresponding utility application will *always* increase the overall cost of obtaining a patent. This is especially true when multiple provisional applications are filed to cover various aspects of an invention.

3.2 *Disclosure of invention*

Although provisional applications do not have all of the formal requirements of utility patent applications, provisional applications must nonetheless meet the disclosure and enablement requirements of utility patent applications. That is, provisional applications must include a complete, adequate disclosure of an invention, a disclosure of the best mode of the invention, and any drawings necessary for understanding and/or recreating the described invention. If a provisional application cannot adequately support the entirety of a corresponding utility application, then only those aspects that are adequately supported in the provisional application will be entitled to the provisional application's priority date. All other aspects of the utility application will have a priority date corresponding to the filing date of the utility application. In this regard, preparing a provisional application to fully support a later filed utility application may be as time consuming and as costly as preparing a utility application.

3.3 *Potential loss of trade secrets*

Another concern relating to provisional applications is the potential lose of trade secrets. As explained above, although provisional applications do not have all of the formal requirements of utility patent applications, they must nonetheless adequately disclose and enable inventions. In attempting to satisfy these requirements, inventors may disclose too much information, including information they might later wish to retain as a trade secret. Once a provisional application is filed, *all* information disclosed will be incorporated into a later filed corresponding utility application. When the utility application becomes a patent, the entire provisional application will become public, and any potential trade secrets it contains may be lost.

3.4 *One-year filing deadline*

Once a provisional application is filed, an inventor *must* file a utility application claiming

priority to the provisional application within one year. Failure to file a utility application within the one-year period will result in the provisional application automatically being abandoned, which may prevent the inventor from ever patenting the invention.

3.5 *False sense of security*

Filing a provisional application may give an inventor a false sense of security. Although filing a patent application does provide some protections, it does *not* provide any enforceable patent rights. Furthermore, provisional applications *never* mature into patents. If an inventor falsely believes he or she is adequately protected by a provisional application, he or she may delay filing a utility application. And if an inventor fails to file a utility application during the one-year period, the provisional application will automatically be abandoned thereby preventing the inventor from ever patenting the invention.

3.6 *Other potential limitations*

There are other limitations to filing provisional patent applications. For example, since filing a provisional application delays the filing of a utility patent application, any patent that may ultimately issue may also be delayed. Depending on the inventor's (or patent owner's) patent strategy, such a delay may not be desirable.

It is important to note that both provisional and utility patent applications trigger the time line for filing applications under the Patent Cooperation Treaty (PCT) and the Paris Convention. Since international patent applications *must* be filed within one year of a U.S. filing, the high costs of international filing will be incurred within one year of filing a provisional application.

Provisional applications may *not* be amended. If certain aspects of an invention are developed or changed after a provisional application has been filed, an inventor will be required to file another application to reflect these developments or changes.

Similarly, if an inventor accidentally discloses secret information in a provisional application, the inventor will be precluded from going back and amending the provisional application to remove the secret information. In this scenario, the inventor would have the option of abandoning the provisional application and possibly having the option of filing another provisional application that excludes the secret materials. This would, however, reset the priority date.

4. CONCLUSION

Provisional applications provide numerous advantages for both domestic and foreign inventors, which is why they are widely used and are often integral to successful patent strategies. There are also, however, certain risks and limitations associated with provisional applications, so filing provisional applications may not always be desirable or appropriate. Accordingly, before deciding whether to file a provisional application, care must be taken to properly assess:

- the nature of the invention(s)
- the particular needs of the inventor (or company)
- the inventor's (or company's) overall patent strategy ■

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Designing Patent Applications for Possible Field-of-Use Licensing

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ABSTRACT

Patent applications should be organized and drafted with a long-term objective that carefully considers the multiple possibilities, and opportunities, of field-of-use licensing. This is particularly the case in the agricultural, pharmaceutical, biochemical, and chemical disciplines, as inventions can have multiple applications that are sometimes impossible to foresee. Technology managers must, therefore, focus strategically, not only on the basic idea of an invention but broadly, in order to consider the various ways such an invention might be put into more widespread and more profitable use. Therefore, the more details, examples and alternatives that are thought through and then disclosed in the patent application, the greater the opportunity for future divisional or continuation applications, as well as future claims that can be exclusively (field-of-use) licensed. By making all of the institution's licenses, in effect, field-of-use licenses, the technology manager retains the ability to take a possible future use and license it to someone else, maximizing the benefits of the inventions and generating higher royalties for the institution.

1. INTRODUCTION

The life of a technology transfer administrator is not an easy one. With tight budgets, the more that a university can make from its licensing program, the better. One of the great benefits of field-of-use licensing is that it allows a licensor to license the same patent or related patents to different parties in different fields, thereby maximizing the income stream from patent royalties. For example, part of a biotechnology invention could be used to make diagnostic tests for a disease, while another part of the same invention could be used to prepare pharmaceuticals to treat the disease. One company may have expertise in the sale and distribution of diagnostics while another company has all the resources to get U.S. Food and Drug Administration (FDA) approval for human pharmaceuticals. Either of these companies could be licensed to cover both areas, but maximum sales and royalties would be obtained by having each company sell in its area of expertise. This chapter focuses on specific examples of field-of-use licensing and discusses how a manager can aid in the development of well-written patent applications that support this licensing approach.

It might be useful to consider making every license a field-of-use license. Even though a particular invention suggests a single use that appears to perfectly fit a potential licensee, there is simply no way of knowing what other uses may develop over the life of a patent. A piece of control technology developed solely for automobile manufacturing may turn out to be useful for operating a rocket system developed several years

Olson AM. 2007. Designing Patent Applications for Possible Field-of-Use Licensing. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual* (First Edition, Part III: Chapter 3).

thereafter. Rather than simply licensing such a patent exclusively to a particular automaker, an inventor should consider licensing the patent to a particular automaker in the field of automobile manufacturing. When a particular field of use is properly licensed, other fields of use developed in the future would remain the property of the university for later exploitation.

2. THE VALUE OF A QUALITY APPLICATION

There are some basic concepts that can apply to all patent applications, not just those that are appropriate for a potential field-of-use license. First, it is important to have a well-written patent application. Far too many technology managers look at the cost of preparing and filing a patent application as opposed to the *total cost* of obtaining a patent. It is not the cost of filing the application that counts, but the total cost of getting the patent. Although cost alone is not a determining factor of a well-written application, a frugally prepared patent application may contain mistakes or omissions and/or may not be sufficiently thought out to provide broad coverage or ideas for possible future expansion into other opportunities. These initial oversights could lead to expensive amendments, the necessity of filing continuation applications, and even continuation-in-part applications to rewrite the application and thus, raising the overall cost of the application.

2.1 *The patent application as a sales document*

One benefit of a properly written patent application is that it provides a far more useful sales document than one that is poorly prepared. Often, a particularly new and valuable development does not yet have a licensee. Thus, a well-written patent application is important for convincing a potential licensee that the invention is worth licensing. Both the potential licensee and the patent examiner need to be confident of the value of the invention, but for different reasons. The patent examiner will look for "statutory" value—whether the invention sought to be patented is novel, useful, and non-obvious to one skilled in that art. The potential licensee, in addition to statutory value, may seek value based on the potential commercial or humanitarian value of an invention. An application that is poorly constructed and includes typographical errors or scientific inconsistencies will make a negative impression on a potential licensee and on a patent examiner.

2.2 *Allow for future coverage*

A well-written application will reflect considerations of possible areas of future coverage, describing not only the basic idea developed in the lab, but also peripheral ideas and extrapolations. Including such information supports broad and valuable coverage in a patent. It suggests areas for future development that can be covered in more detail in continuation applications. Specifically, if these future ideas are at least sketched out in an application's specification (that is, are adequately disclosed in the original application), there can be a basis upon which to reach back to the earliest filing (priority) date for subsequent claims and related amendments disclosed in the original parent application. Thus, the institution would have the benefit of a filing date that will avoid what otherwise would be prior art.

Coming up with alternative uses of an invention, or other ideas for development, should be a collaborative effort between the patent attorneys, the technology managers, and the inventors. Recognizing that managers often prefer to minimize direct contact between inventors and the attorneys in order to keep costs down, this is one instance where direct communication can prove to be particularly useful and valuable, as even the best patent attorney cannot think of all of the alternative uses of an invention or all the modifications or possible future uses of an invention.

Such contact between the inventor and the attorney is critical for developing examples of adaptations or permutations needed to provide for future field-of-use licensing. Prior to this communication, the technology manager may wish to encourage the inventor to describe additional alternatives or other possible future uses and simply forward these descriptions to the patent attorney. This exercise could begin the creative thought process—the "what if" thinking—needed to come up with other possible future uses. The more the inventor engages in this type of

thinking, the less time it will take for the patent attorney to consider and describe the potential of the invention. A monetary savings can sometimes be realized as well since it will take less time for the patent attorney to prepare the application.

2.3 *Retain control over the patent application*

All too often, a university will turn over the writing of the patent application and the control of the patent prosecution to the licensee. This creates an inherent conflict of interest and a potential for future litigation. (The conflict arises because a licensee may prefer relatively narrow patent protection to minimize the amount of royalties it might have to pay in the future.) In patent prosecution, decisions need to be made as to what level of protection to seek. Relatively narrow patent claims can often be obtained without too much difficulty and expense. Broad coverage, however, may be far more important for a university because it would allow for future licensing and would cover more products to be sold by the licensee. While broad coverage may have been originally sought to cover a licensee's future developments, if, during patent prosecution, the claims are narrowed so that the licensee's future developments are outside of those patent claims, the university could lose significant royalties.

Specific to a potential field-of-use licensing situation, the patent application will have disclosures and possibly claims to uses of the invention that are outside a particular licensee's interest. That licensee would, of course, have no incentive to spend any time or money expanding on the concepts outside of its own interests.

Where the university controls the patent prosecution, it has the ability to determine the breadth of the patent protection it wishes to seek and whether to dedicate resources to expand the patent coverage into other fields of use. When preparing the patent application, one should think of all possible uses of the invention, not just those of a present licensee. These do not have to be worked into all of the claims, but the disclosures should appear in the patent application. At some future time, should another potential licensee show interest in that area, a continuation (or possibly, a continuation-in-part) application can be filed, expanding on that particular aspect of the basic concept. Thus, the institution has the benefit of the earlier filing date, and a new application can expand on and claim the particular new development.

While the university should retain control over the patent application, it is still possible for the license agreement to have the licensee pay for the prosecution of the patent application. In the case of two licensees for the same patent, the patent expenses can be divided equally between the two licensees. This also is discussed in greater detail in the preceding chapter.

3. STRUCTURING THE PATENT APPLICATION

In structuring the patent application, it is best to incorporate as many alternatives as possible for future expansion. Doing so can have two direct effects: (1) the application will support broader claims than might otherwise be possible—this can be particularly important in the biotechnology and chemical areas, where it is often necessary to give more than a simple example to support broad claims in the patent application—and, (2) having ideas for future uses in the application allows for continuation applications to these developments. This is a version of the "throw in the kitchen sink" approach. It is difficult to predict what will have future value, and it may not be worth having claims for ideas for potential uses in the application, but it is worth having at least a sentence or paragraph about a possible alternative. Two or three pages of a patent application can include a great many of these "sleeper" inventions that can remain dormant and be brought to life when they are found to have a particular value.

This is not a new idea. The 1876 Alexander Graham Bell patent titled Telegraphy describes Bell's invention as a multiple telegraph using different frequencies of sound to simultaneously transmit several telegraph messages over the same wire. A reference is made toward the end of the patent that the invention can be used to transmit sounds and, if certain modifications are made, even the human voice. The value of this last extrapolation can be seen by the number

of infringement lawsuits referred to as "The Telephone Cases."

The claims of the patent application can also be structured for field-of-use licensing. There can be broad claims to the general overall concept that are licensed to more than one party on a field-of-use basis; there can also be narrow claims directed to specific fields of use that are licensed only to a particular licensee. The narrow claims can be written to define the field of use, for example, the use of the invention as a diagnostic for a particular disease in farm animals; another narrow claim could define the use as a similar diagnostic for humans. Future continuation or divisional applications could have claims directed to other specific fields of use.

The approach described here has the benefit of providing specific claims or specific patents that can be exclusively licensed to a particular licensee. Generally, licensees prefer to have an exclusive license, even if it is only for a specific claim or a specific patent. In addition, defining specific narrow claims for different licensees can provide a mechanism for allocating the reimbursement cost of prosecuting the patent applications as well as for determining which licensee will be responsible for or involved with suing a potential infringer. For example, the license agreements can be structured such that if a patent claim exclusively licensed to a particular licensee is infringed, then that licensee is required to take part in the infringement litigation. If different claims exclusively licensed to separate licensees are infringed, then both licensees would be involved in the litigation. The idea is that if each licensee's exclusive "turf" is invaded, they would want to be involved. Separate patents for exclusive licensing to different licensees can arise as a result of restriction requirements. This issue is discussed in more detail below.

3.1 *Biotechnology example*

One of the wonders of biotechnology is the discovery that genetic information can be used to code for proteins or parts of proteins. For example, it has been found that relatively short lengths of polypeptides can be used to form vaccines. Prior to this discovery, vaccines had been made from proteins obtained from dead or weakened viruses.

By way of a fictional example, a scientist has discovered the gene coding for one of the envelope proteins of "RBS" virus. Suppose the RBS virus has only recently begun to infect the human population and some of its potential effects include a revival of a previously conquered illness. The scientist has also discovered that a 20-amino acid residue polypeptide which is named "Merkin" and which can serve as a vaccine against the dreaded RBS. In addition, the scientist has found that when the Merkin polypeptide is injected into animals, the animals exhibit an immune response and begin producing harvestable antibodies that react with RBS virus in a sample. The scientist has also recently successfully created a monoclonal cell line that produces antibodies to RBS.

These anti-Merkin antibodies are particularly valuable because they have a high affinity for the RBS virus and, at least in the lab, protect precious bodily fluids from infection. Therefore, a possible use of the antibodies would be to create a direct treatment for an RBS virus infection: the antibody would be collected and then injected into the patient as a form of treatment.

Another use for the Merkin polypeptide is in an assay to detect the presence of anti-RBS antibodies in human blood serum. It was found that using the antibody as a means to detect RBS was not successful because the RBS virus does not generally appear in a high concentration in blood. However, when the Merkin polypeptide was used, it reacted with antibodies in the patient's blood and other precious bodily fluids to indicate whether there had been antibodies produced to fight the RBS virus, now present in the blood. One type of HIV assay system works similarly. It does not detect the presence of HIV itself, but rather it detects the presence of HIV antibodies in the patient's blood. The success of the test depends on the assumption that if HIV antibodies are in the patient's blood, the patient has been exposed to or infected by HIV.

Thus, it appears as though the Merkin polypeptide has at least two immediate uses. The first is as part of an assay system to check for an RBS virus infection, and the second is for future development as a vaccine. The antibodies that have been developed appear to have possible uses for a

future assay as well as possible future therapeutic value.

A potential licensee, Assay Specialists, Inc. (ASI) has shown particular interest in the use of the Merkin polypeptide for conducting diagnostic assays. ASI is a large company that has a great deal of experience in assays of this type, although it has little to no experience in therapeutic treatments and vaccines. Another company, Vaccinia, has indicated an interest in possibly developing a vaccine and therapeutic treatment. At this point, Vaccinia's interest is lukewarm, because preliminary studies of using a vaccine on animals are still being conducted.

Based on this, therefore, a properly prepared patent application could cover the following inventions:

1. The gene used to make the envelope protein.
2. The purified envelope protein.
3. The part of the gene that codes for the Merkin polypeptide.
4. The Merkin polypeptide.
5. A vaccine based on the Merkin polypeptide.
6. Antibodies to the Merkin polypeptide.
7. The monoclonal cell line.
8. Diagnostic products based on the Merkin polypeptide or its antibodies.
9. A therapeutic treatment based on the antibodies.
10. A cure for the recurring illness.

A field-of-use license can be granted now to ASI directed to diagnostic products. This would be a non-exclusive but field-of-use license to the claims directed to the Merkin polypeptide generally (4) and an exclusive license (meaning that ASI will be the only licensee) for those claims that are specifically directed to the use of the Merkin polypeptide for diagnostics (8). There can also be a non-exclusive license for the use of the part of the gene that codes for the Merkin polypeptide (3) so that ASI can also make the polypeptide, using DNA cloning techniques. This results in a licensee signed up in the initial stages and provides a source of revenue to support the patent application(s) and further research.

As matters progress and Vaccinia becomes more interested, a non-exclusive but field-of-use license can be granted to Vaccinia on (3) and (4). Vaccinia would be the only licensee for the vaccine based on Merkin (5). At some future date, if there is a revival of the previously conquered illness in epidemic proportions, there may be another potential licensee and, therefore, justification for a divisional patent application directed to a cure for the recurring illness (10).

3.2 *Chemical example*

Dr. Lovejoy has discovered a highly toxic compound that he has named oxymoronic acid. This compound is very useful in treating certain mental disorders. The only known source of oxymoronic acid is certain mutant desert bushes that grow only in the area surrounding nuclear test sites. The elimination of open air testing of nuclear weapons, however, has put great restrictions on the number of mutant plants available. All attempts to cultivate oxymoronic-producing plants have thus far been unsuccessful, but Dr. Lovejoy has recently found a way of synthesizing a precursor of oxymoronic acid that he has named protomoronic acid that can be manipulated to form oxymoronic acid. Through this synthesis scheme, it is possible to produce oxymoronic acid in the quantities needed for medical treatment purposes.

Through encouragement by the technology manager and the patent attorney, Dr. Lovejoy has worked out alternative synthesis schemes for other possible precursors of oxymoronic acid, one of which is called "AP." While these schemes have not been fully tested, they appear to provide other ways of making oxymoronic acid synthetically and thus may prove to have value in the future. A patent application is prepared having claims in the following areas:

1. Oxymoronic acid in a purified form as a pharmaceutical.
2. The precursor, protomoronic acid.
3. Various alternative precursors, including AP.
4. The methods of making oxymoronic acid using the various precursors.
5. A rat poison based on oxymoronic acid.

The last category listed above was a gratuitous discovery when one of Dr. Lovejoy's graduate students, who had a laboratory in a less than desirable location, dropped some oxymoronic acid on the floor and it was sampled by one of the visiting rodents. It was discovered that it made an extremely effective rat poison.

Because this discovery was fortuitously made and was not considered to have any immediate commercial value, the idea of using oxymoronic acid as a rat poison was put in as a sentence or two in the patent application. This did not cost anything, but it left open the possibility of future options. Some years later, while one of the patent applications was still pending, a major pesticide company came to the university asking for a license to further develop this rat poison. Because a divisional application was still pending, it was possible to file a continuation (or a continuation-in-part) application having claims directed to the use of oxymoronic acid as a rat poison and thereby grant the pesticide company an exclusive license in the field of using oxymoronic acid as a rat poison. In such a case, the graduate student could likely be a co-inventor (as opposed to the rat who actually made the discovery but did not live to tell about it).

An exclusive field-of-use license in the medical area was granted for (1), the pharmaceutical, above. Later it was found that AP had particular usefulness as an adhesive and was licensed to a bumper sticker company because no exclusive license had been granted for (3) above.

4. RESTRICTION REQUIREMENTS AS OPPORTUNITIES

It is quite likely that a patent examiner reviewing a patent application directed to the above examples would take the position that there is more than one invention present in a given application (in some jurisdictions referred to a lack of unity of invention). For example, the examiner may say that the gene is one invention, the polypeptide is a second invention, the diagnostics are a third invention, the vaccine is a fourth invention, etc. When this is the case, the patent application is "restricted" to only one invention, and then one, or possibly more, divisional patent applications are carved out of the original parent patent application.

The typical reaction to this is annoyance. After all, what has been filed as one patent application will now be split up into four and perhaps as many as ten parts. However, one should not necessarily complain, as there might be a silver lining in this gray cloud. This situation, albeit initially annoying, can often be done relatively simply, and present new opportunities.

Since the U.S. Patent and Trademark Office has taken the position that there are separate inventions in the patent application, these inventions can be prosecuted as separate applications. Thus, one can continue to prosecute the claims directed to the diagnostics until those are allowed. The diagnostic patent issues, and that patent can be exclusively licensed to ASI. Meanwhile, a series of other patents may be obtained from the same core invention (the parent application) via a series of divisional patent applications arising out of the restriction requirement. Each patent can be directed to a different field of use and licensed separately. Furthermore, depending on the circumstances of each application, there might be opportunities for patent term extensions due to delays in the patent office, certain administrative proceedings (for example, successful appeals), or for regulated medical products to compensate for regulatory delays. Thus, a restriction requirement, when strategically managed, can become an unexpected series of opportunities.

5. CONCLUSION

The main point presented in this chapter is to encourage creative thinking when preparing patent applications. The technology manager should focus not only on the basic idea, but should also encourage inventors to think broadly regarding all the various ways their invention might be put into use. When the patent application is filed, there is no way of knowing every possible use of the invention. Thus, the more invention ideas that can be put into the patent application, the more support there is for future divisional or continuation applications, or future claims that can

be exclusively licensed. By making all of the institution's licenses, in effect, field-of-use licenses, the technology manager has retained the ability to take one of these possible future uses and license it to someone else, maximizing the benefits of the inventions and generating higher royalties for the institution. ■

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Patenting Strategies: Building an IP Fortress

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ABSTRACT

A comprehensive intellectual property (IP) portfolio can be of substantial value to both private and public sector entities. Patents are a key element of IP portfolios and must be managed according to the mission, objectives, and motivations of the organization that owns them. Large companies can afford an offensive patent strategy, but small companies may not have the resources for this. Therefore, it is extremely important for private sector entities, especially small- and middle-sized companies, to design and implement an effective and cost-efficient strategy for patent management. For public sector entities, patent strategies will focus on advancing social welfare, and the mission of the institution will therefore drive objectives. A key factor to consider is the method of IP protection: patent, trademark, copyright, or trade secret. The costs of maintaining each of these IP categories are different. Although research institutes and companies will likely wish to reduce costs as much as possible, key technologies still need to be protected properly. A company can reduce costs by focusing the patent protection on those geographic areas where it has business. A university can reduce costs by selectively prosecuting patent applications with broad claim structures, strategically licensing technologies, and enforcing patent rights if and when necessary. To build a strong basis of protection, several forms of IP may be used for the same invention or improvement.

1. INTRODUCTION

Historically, a patent was a grant made by a sovereign that would allow for the monopoly of a particular industry, service, or product. Over time, the concept has been refined and now stipulates a contract or compact between the government and the inventor/creator. In return for the right to exclude others from the practice of the invention, the government requests that the inventor fully disclose the enablement of the invention. Additionally, the monopoly is now limited by time and is only applicable in the territory under the jurisdiction of the government that granted the patent.

In the United States, a patent is a fundamental right provided in Article I, Section 8 of the Constitution. Congress is empowered to "*promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.*"

In exchange for a right to exclude others from making, using, or selling the potential invention, the inventor must provide a complete and accurate public description of the invention and the best mode of *practicing* it. This disclosure of information by the inventor allows others to invent further, thus pushing technology forward for the benefit of society.

Congress has given the U.S. Patent and Trademark Office (PTO) the authority to grant an inventor the right to exclude all others from exploiting the invention in the United States for a period of 20 years, or for design patents, up to 14 years, from the date of filing a patent application with the PTO. This right to exclude makes a

Dodds J. 2007. Patenting Strategies: Building an IP Fortress. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

patent a negative right, since a patent holder may only *exclude* others from using, manufacturing, copying, or selling his or her invention.

Patents are territorial. For example, a U.S. patent generally has no force in other countries, just as a patent granted outside the United States has no force in the United States. However, products sold in the United States, even if they are made outside the patent domain, may infringe a U.S. patent. Procedures for filing, regulations for patentability, and patent terms vary considerably from country to country.

The United States is the only country in the world that awards its patents using a *first-to-invent* approach; all other countries have a *first-to-file* approach. The first-to-invent approach has led to the development of patent interference practice, a quasi-litigation conducted within the PTO to determine the issue of *priority*, or who made the invention first.

Another important difference between the U.S. system and the system adopted in many other countries, for example European countries, is the one-year grace period awarded in the United States. This means that an invention is patentable if it has not been published or otherwise brought into public awareness earlier than one year from filing the patent application.

Patents are relatively complex documents to prepare and submit, and the time and expense in obtaining such protection can be substantial. Given the legal complexity and the costs involved, it is important for the inventor to develop a coherent strategy with which to approach the patenting process.

2. DEFINITIONS

- **design patent.** A drawing or depiction of an original plan or conception for a novel pattern, model, shape, or configuration to be used in the manufacturing, textile, or fine arts, and chiefly of a decorative or ornamental character. Design patents are issued for a period of 14 years.
- **monopoly.** A privilege or peculiar advantage vested in one or more persons or companies, consisting of the exclusive right or power to carry on a particular business or trade, to manufacture a particular article, or to control the sale of the whole supply of a particular commodity. Monopoly is a form of market structure in which one or only a few firms dominate the total sales of a product or service.
- **nonprovisional patent application.** A patent that is filed with the PTO includes a written document that comprises a specification (including a description and at least one claim), an oath or declaration, and, when necessary, one or more drawings.
- **patent.** A grant or right to exclude others from making, using, selling, or offering to sell one's invention and a right to license others to sell, make, use, or offer to sell that invention.
- **plant patent.** A patent granted to an inventor who has invented or discovered and asexually reproduced a distinct and new variety of plant. (Plant patents are not issued for tuber-propagated plants or for plants found in an uncultivated state.) Plant patents are issued for 20 years.
- **plant variety protection.** Protection for sexually reproduced (by seeds) or tuber-propagated plants. Registration of Plant Varieties is administered by the U.S. Department of Agriculture.
- **provisional patent application.** An inexpensive first patent application that allows filing without a formal patent claim. It provides means to establish an early filing date. Provisional patent applications expire 12 months after filing. Before this, the inventor has to file a nonprovisional patent application in order to protect his or her invention.

3. TYPES OF PATENTS

There are three types of patents:

1. A *design patent* protects a new, original, and ornamental design for an article of manufacture.
2. A *plant patent* protects a new and distinct, asexually reproduced variety of plant.

Tuber propagated plants are excluded from plant patents.

3. A *utility patent* is granted for any new and useful process, machine, manufacture, or composition of matter or for any new or useful improvement thereof. Most importantly, the invention has to be useful. A utility patent is the type of patent most people are familiar with. An application for a utility patent can be of either the provisional or nonprovisional type.

3.1 *Design patents*

A design patent protects the look of an article. In order to be patentable, the design or the look has to be original. One cannot, for example, get a design patent for a vase that is in the shape of Mickey Mouse, as this image is already patented and not original. A design patent might be granted, however, to a vase having a different mouse-shape.

A design patent application should include the following elements:

- title of the design
- brief description of the nature and intended use of the article in which the design is embodied
- drawings or photographs
- description of the drawings or photographs
- a single claim
- an oath or declaration

A design patent may have only one claim that covers the whole design. The following shows an example of a typical claim: "*The ornamental design for a vase as shown (and described).*"

It is possible to file a utility patent for a new and original way an article is functioning and also file a design patent for the original design of the same article.

3.2 *Plant patents*

A plant patent may be granted on an entire plant if it is a new and distinct variety and it is asexually propagated. Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, or inarching. However, tuber-propagated plants are excluded from plant patents.

An application for a plant patent consists of the following elements:

- title, which must include the name of the claimed plant. The following shows an example of the form of a typical title: *Birch tree named* "*Renci.*"
- specification, which includes a description and one claim
- one or more drawings or photographs
- an oath or declaration

The specification should include a complete detailed description of the plant. Characteristics that distinguish the claimed plant from related, known varieties should be described comprehensively. The specification should also include the origin or parentage of the plant variety and must point out where and how the variety has been asexually reproduced. If the plant variety originated as a newly found seedling, the specification must fully describe the conditions under which the seedling was found growing.

A plant patent is granted on the entire plant. Therefore, only one claim is permitted. The following is an example of a typical plant patent claim: "*A new and distinct cultivar of a birch tree named* '*Renci,*' *as illustrated and described.*"

The drawing must disclose all the distinctive characteristics of the plant capable of visual representation. When color is a distinguishing characteristic of the new variety, the drawing must be in color. As an alternative, a photograph may accompany the application.

If the plant is a newly found plant, the oath or declaration must also state that the plant was found in a cultivated area.

3.3 *Utility patents*

A utility patent can be issued for any new and useful process, machine, manufacture, or composition of matter. In order to be patentable, the invention has to be new, useful, and nonobvious. A patent cannot be obtained for pure ideas or theories, no matter how useful the theory might be. In addition to plant patents, utility patents can be issued for some types of plants, for exam-

ple, transgenic plants. This is because a transgenic plant, if new and useful, may be regarded as a composition of matter or manufacture.

An application for a utility patent requires the same elements as are required for a design patent application.

3.3.1 *Nonprovisional application*

A nonprovisional (utility) patent application has to include the following parts:

- title
- specification, which includes a description and at least one claim
- one or more drawings
- an oath or declaration

The description should be written in such a way that any person skilled in the field to which the invention pertains can make and use the invention.

In a nonprovisional patent application, there must be at least one claim. The scope of the protection of the patent is defined based on the claims. Whether a patent will be granted is also largely decided by the choice of the claim. The optimal claim is one that is wide enough to cover as much as possible without overlapping anything that was already known.

3.3.2 *Provisional application*

A provisional patent application is a lower cost, initial patent application that does not have to include any claims, oaths, or declarations. A provisional patent application has a pendency of 12 months from the date of its filing. A provisional patent application cannot mature to an issued patent, but it gives the inventor an early filing date and use of the term *patent pending*. In order to benefit from the early filing date of the provisional application, a nonprovisional patent application has to be filed before the end of the 12 months pendency of the provisional application.

4. PATENT HARMONIZATION

A patent is valid and effective only in the country in which it is issued. Trade, however, is global, and thus it is important to have patent protection in more than one country. But because every country has its own laws and regulations for patenting, obtaining protection in multiple locations is rarely simple or cheap. To ameliorate this situation, a great deal of effort has been spent, for more than 100 years, to try to harmonize patentability standards across countries.

The Patent Cooperation Treaty (PCT) is an international treaty harmonizing patent application procedures across 117 countries. PCT is administered by the World Intellectual Property Organization (WIPO). With one PCT patent application, an inventor can get a filing date in all member countries. Eighteen months after the filing, the applicant has to decide in which of the member countries he or she actually wants and needs to have a patent. The benefit of a PCT application is that there is no need to file separately in all countries, as the whole procedure can be accomplished in one application. Moreover, the PCT system gives the inventor 18 months time to shop around before deciding in which countries a patent would be most useful.

All PCT applications will be published 18 months from the filing, if not abandoned before that. This practice is generally in line with, although not precisely analogous to, that of the U.S. PTO. In the United States, the inventor may require a U.S. patent application not to be published before issuance if the application is filed only in the United States. Nevertheless, the invention may still be the subject of a PCT application, with similar delay in publication, providing certain provisions are met. Specifically, pursuant to Article 64(3)(b) of the PCT, which articulates the U.S. Reservation, publication can be similarly delayed. According to this article, if only the United States is designated, the international publication is postponed until after the issuance of the U.S. patent. Article 64(3)(b) of the PCT is therefore not inconsistent with the U.S. rule.

5. REGIONAL PATENTS

The creation of regional patent offices has helped to harmonize patent applications in different parts of the world. The European Patent Office (EPO) is the regional patent office serving

countries that are members of European Patent Convention (EPC). By filing a single application in one of the three official languages of the EPC (English, French, German), it is possible to obtain a patent in any or all of the 24 contracting countries. European patent applications can also be extended to some eastern European countries that are not parties to the contract. If a patent is granted by the EPO, then that patent must still be taken to each individual country and *validated* there.

Currently, there is major movement toward developing a community patent for the European Union. Once issued, a community patent would be enforced in all E.U.-counties without any validation requirement. Community patents would, however, require a centralized patent court system, with specialized courts and a centralized appeal court.

Another effort at harmonizing patent applications involves participation by counties of the former Soviet Union in the Eurasian Patent Convention. By filing one application in Russian, a Eurasian patent may be granted in one or all of the contracting countries. Likewise, African countries in which English is spoken have established the African Regional Intellectual Property Organization (ARIPO); African countries in which French is spoken have established the *Organisation Africaine de la Propriete Intellectualle,* or OAPI.

6. FEES

The fees charged by the U.S. PTO include filing fees, publication fees, issuing fees, and maintenance fees. Updated information of the fees is available at the PTO's Web site.[1]

Maintenance fees on utility patents must be paid at 3½, 7½, and 11½ years after the date of issue of the patent, or it will expire. Once a patent expires, the invention is in the public domain and anyone may use it without authorization from the patent holder.

The PTO gives a 50% reduction in most of the fees for organizations designated as "small entities." Independent inventors, not-for-profit organizations, universities, and some small businesses will qualify as small entities.

7. APPEALS, INTERFERENCE, AND OTHER PROCEDURES

The applicant can appeal the decision by a patent examiner to reject a patent application. In the United States, the Board of Appeals within the PTO hears the cases. If the applicant is dissatisfied with the decision of the Board of Appeals, he or she may appeal to the Court of Appeals for the Federal Court.

A unique form of patent dispute is a priority dispute between two or more inventors claiming to be the first to have developed an invention. These disputes are known as interference proceedings.

Two types of post-issuance procedures are available in the United States. If someone believes there is a priority dispute that was not considered when the patent application was examined, that individual can ask for a reexamination of the patent. Anyone, including the patentee, can ask for reexamination. Often times, individuals accused of infringement use the reexamination procedure to question the validity of the patent. If the PTO finds the patent invalid in the reexamination process, there can be no grounds for claiming infringement. Reexamination procedures can be either *ex parte* or *inter partes*. In the ex parte reexamination process, the third party, even if it was the requester, does not have a right to participate in the proceeding after filing the request, nor does the third party have a right to appeal the decision. The inter partes reexamination procedure was created in 1999 and can be applied only to patents issued on or after November 1999. Inter partes reexamination gives the third party a right to provide comments and present arguments during the procedure and a right to appeal to the Patent Office's Board of Appeals.

The second type of post-issuance procedure is a reissue. Only the patentee can seek a reissue and only in the case of an error being made without deceptive intent, in the claims or in disclosure of the original application. If the patentee seeks to broaden the original claims, the reissue has to be

filed no later than two years from the issuance of the patent. However, if the patentee seeks to narrow the claims, a reissue can be filed at any time.

The PTO charges fees for each of these procedures, with reexamination fees being the highest. In addition to these fees, attorney fees will have be paid by the applicant. Attorney fees will probably be significantly higher than PTO fees.

8. OTHER NONPATENT INTELLECTUAL PROPERTY ELEMENTS

Intellectual property (IP), sometimes also called "intangible property," is any product of the human mind or intellect. Thus, IP can be almost anything, including a technical invention or an improvement of an earlier invention. It can also be a unique name or logo, design, method, software, database, domain name, or piece of writing.

The broad area of IP is subdivided into different legal classes that are protected by different means. Patents are not the only way to protect IP. Trademarks, copyrights, and trade secrets are used as well, and very often they form an important part of an overall IP strategy.

8.1 *Trademarks*

A *trademark* is a word, phrase, symbol, design, or combination of these that distinguishes the source of one's goods or services from those of another. A trademark can be valid only when it is used on or in connection with goods or services in commerce. A trademark provides protection to the owner of the mark by ensuring the exclusive right to use it to identify goods or services or to authorize another to use it in return for payment. Trademark protection keeps others from applying similar marks to inferior or different products or services.

Rights to a federally registered trademark can last indefinitely if the owner continues to use the mark on, or in connection with, the goods and/or services stipulated in the registration, as long as the owner renews the mark with the PTO every ten years.

There are various types of marks that can be registered with the PTO. In addition to laying out the provisions for trademarks and service marks, the Trademark Act provides for registration of collective marks, membership marks, and certification marks. A domain name, such as *yahoo.com*, can qualify as a trademark or service mark if it is used in connection with a Web site that offers goods or services to the public.

The basis for filing a trademark can be either actual use or intent to use. If the applicant files a trademark based on intent to use, she or he has to swear to a bona fide intent to use the mark in connection with the proposed products or services. If the mark is not actually used within 30 months of registering the mark, the registration, as related to that specific class,[2] would be considered abandoned.

8.2 *Geographical indications*

A *geographical indication* is a sign used on goods that have a specific geographical origin and possess qualities or a reputation that rely on that place of origin. Geographical indications are defined in the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) as a type of IP. The World Trade Organization (WTO) provides legal means for interested parties to prevent the use of a geographical indication that indicates or suggests that a good originates in a geographical area other than its true place of origin. Geographical indications cannot mislead the public as to the true geographical origin of the good, nor can they constitute an act of unfair competition.

Most commonly, a geographical indication includes the name of the place of origin of the good. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Examples of geographical indications are *Idaho* for potatoes or *Roquefort* for a type of French cheese.

Whether a sign functions as a geographical indication is a matter of national law and consumer perception. The TRIPS Agreement does not require that a WTO member extend protection to a geographical indication if that geographical indication is the generic name of the good in that member country. Therefore, the word "champagne" is not registrable as a geographical indication in the United States because champagne is

a generic term in the United States meaning any light-colored wine with bubbles.

The United States offers robust protection for geographical indications, generally by registering the good with a certification mark, which is a type of trademark.

8.3 *Trade secrets*

Trade secrets are an important and widely used business asset in the United States. Both large and small businesses rely on trade secret protection, often without even realizing it. It has been estimated that 90% of inventions are protected by trade secrets.

There are various kinds of trade secrets. The most famous example of a trade secret is the formula of Coca Cola, which has been kept secret for over 100 years. In addition to chemical formulas or processing methods, trade secrets can consist of software, accounting records, customer lists, and plant designs, among others. Although trade secrets may overlap with patentable subject matter, they go well beyond that. Even failed experiments can qualify as trade secrets; knowledge that a method does not work, in some cases, can give an individual or business a huge competitive edge.

The generally accepted definition of a trade secret appears in the 1939 Restatement of Torts. The subject matter of a trade secret must be secret; as such, matters of public or general knowledge in an industry cannot be appropriated by anyone as a secret. Information that is completely disclosed by the goods that one markets cannot be considered a trade secret. By definition, a trade secret is known only to those in the particular business in which it is used.

8.4 *Copyrights*

A copyright is a type of IP protection for authors of original works. A copyright protects an original work and allows the author an exclusive right to:

- reproduce the work exclusively
- prepare derivative works
- distribute copies or records by sale, lease, or other type of ownership transfer
- perform the work publicly
- display the work

In the Copyright Act there is, however, a fair-use exception that states that the use of an author's original creation is authorized for the purposes of criticism, comment, news reporting, teaching, scholarship, or research. Fair use takes into consideration the purpose and character of the use, the nature of the copyrighted work, the amount and substance of the portion used in relation to copyrighted work as a whole, and the effect of the use upon the potential market.

Generally the categories of works that are protected are:

- literary works
- musical works, including words accompanying music
- dramatic works
- pantomimes and choreographic works
- pictorial graphic and sculptural works
- motion pictures and other audiovisual works
- sound recordings
- architectural works

The work has to be original and in a fixed medium. This means that the work has to be an independent creation of the author and it must exhibit some creativity. Being in a fixed medium means that the creation is in a tangible form: A short story is written down, a song is recorded, and so on. A pure idea or concept cannot be copyrighted without description or illustration.

9. ASSEMBLING A STRATEGY

The development of a coherent IP strategy involves an analysis of three types of IP: self-developed, incoming, and outgoing. In order to develop a strategy to manage IP, an organization generally conducts a freedom-to-operate study or IP audit. Such an analysis inspects all patents, trademarks, copyrights, contracts, material transfer agreements, know-how, and anything else that could be part of the intellectual capital of an organization.

The first step in developing an IP strategy is to document the technologies that already exist in the organization, plus the technologies in development. The existing technology could

consist of trade secrets, know-how, patents, or combinations thereof. The most critical elements of the technologies are placed in a database. The database could, for example, contain the following elements: issued patents, filing and expiration dates of the patents, abstracts of technologies, first claims of patents, current and future potential of IP, existence of licenses, and so on. Each project of the company can be similarly documented. Data of issued and applied patents in each project should be documented; valuable trade secret and contracts should likewise be documented.

When all the IP is documented in a database, consideration should be given to the merits of the documented technologies. Questions to be asked are, for example:

- What stage is the technology in?
- What is the novelty of the technology?
- Is the technology in use?
- Are outside licenses needed to develop the technology further?
- Does a competitive technology exist?
- Is the technology commercially launched?
- Are capital requirements needed to launch the technology?
- Are there environmental or regulatory issues related to the technology?

Depending on the organization, the answers to the above questions will have varying importance. For example, a university technology transfer office might not care too much if the stage of the technology is at a pilot level or whether the patent has been issued. For an organization basing its business on in-house developed technology, however, these issues are crucial.

Patenting is expensive. Therefore, it is important, especially for a small organization, to critically assess which technologies it needs to patent and where. Even if an invention is patentable, it might not always be the best solution to patent it. If, for example, an invention is difficult to reverse engineer, or if it would be easy to invent around a patented technology, then keeping the invention as a trade secret might be more beneficial. Also, patenting might not be an effective tool if it would be difficult to ensure that no one is infringing on the patent. If an organization developed a patentable method for transforming a plant species, for example, it would be very difficult to ensure that no one was infringing on that method, and thus patenting would be largely ineffective.

The organization should also analyze where it will need the protection. There might not be a need to keep a patent valid all over the world if the technology is used only in the United States, or if the only prospective market is in Germany. In these cases, it would be advisable to apply for patents only in the relevant countries.

It is also important to get accurate knowledge of the IP rights of competitors in your field. Knowing the IP rights of other organizations in your field will help you identify where your organization has a distinct competitive advantage, and will enable you to identify and eliminate costs of any out-of-date IP. By knowing your own IP, you can identify under-utilized IP that could potentially be sold or licensed out; knowing other people's IP could help you to avoid costly infringements suits. Finally, knowing your IP gives you a road map to create a successful R&D strategy.

Finally, an organization can choose an offensive or a defensive patent strategy. This depends a great deal on the size of the company, but also on the demands of the particular industry within which the company operates.

9.1 *Offensive patent strategy*

An offensive patent strategy is designed to build barriers to block competitors from gaining entry to your proprietary technologies. Using an offensive patent strategy means filing patents as soon as is practicably possible. Filing a large number of patent applications and later maintaining the issued patents is expensive; on the other hand, an offensive patent strategy may derive large licensing incomes.

Given the expense, an offensive patent strategy is often available only to large organizations, since small companies generally cannot afford the costs of filing and maintaining patents. Beyond size, an offensive patent strategy is more important for companies operating in very competitive fields.

9.2 *Defensive patent strategy*

Using a defensive patent strategy, a company files patents primarily to ensure that innovations can be practically used. With a defensive strategy, filing and maintenance fees will be small, but the company will not gain royalties from licensing patents out.

In addition to these two strategies (offensive and defensive) an organization can adopt something in between, depending on the field and the type of the technology it uses. A defensive patent strategy can be combined with a strong trade-secret portfolio, or a large number of in-licensed technologies. An offensive patent strategy can be used to demonstrate innovations to industries and markets.

9.3 *Public and private sector strategies compared*

The public and private sectors by and large have different missions, objectives, and motivations. These, in turn, drive the overall patent strategies that each employs.

Private sector organizations, primarily corporations, are profit oriented and must aggressively respond to the pressures imposed by the marketplace and shareholders who expect returns on their investments. Therefore, the private sector will use defensive and offensive patenting strategies, often obtaining numerous patents containing narrowly drafted claims. In this way, a series of painstakingly prosecuted patent portfolios is strategically used to build proprietary fortifications. The private sector organization can thereby stake out its territory, protect its interests, and secure its profits. In the expanding world marketplace, this strategy is becoming more and more common; the use of foreign filing and patent families confirms the global strategic perspective of multinational companies.

The public sector, on the other hand, has the very different mission of serving the greater public good. Additionally, for much of the public sector, the perspective is primarily local: either national, or possibly regional. Patenting strategies will focus on more broadly drafted claims that will encompass a technology, or, more often, a key process, method, or technique (for example, a technique of genetic transformation). These types of patents, when strategically licensed, will enable effective development, broad dissemination, and maximum social usefulness of a technological advance. This is precisely in line with the public sector mission of providing for humanitarian interests and the welfare of the general public, in contrast to the much more limited mission of the private sector.

10. THE IP FORTRESS

Building a strong base for IP protection will make it difficult for other people and companies to infringe upon protected rights. One way to secure IP protection is to cover IP with various types of IP rights.

Imagine that the IP of a particular U.S. company is a novel paintbrush. The company can obtain a utility patent in the United States covering the novel paintbrush. If the company has business in Europe, it might be wise to file a PCT as well. It might be beneficial to write a claim, also, for painting with the paintbrush. By doing so, the company would ensure that both people manufacturing the brush, and each small or large painting using the brush, would be guilty of infringement if they were not first granted a license to use the brush in any manner they saw fit. When the company holding the patent improves the tool, it can always file a new patent covering the improvement (continuation-in-part application). Additionally, the design of the paintbrush might be protected by a design patent. Finally, the company might have a unique name for the tool that could be trademarked.

Building such a fortress around the invention makes it difficult for others to use the invention without getting a license. Depending on the policy of the organization and the type of the invention, the organization can then grant either exclusive or nonexclusive licenses to use the product.

There are several ways to protect IP, but one should always remember that protecting IP is expensive. Therefore, an organization needs to think carefully about its competitors, likely infringers, and the geographical area where the invention is to be marketed. Sometimes keeping an invention as a

trade secret might be the cheapest way to protect it. Sometimes patenting, even if more expensive, might give better protection. Finding the best way to build and protect an IP portfolio requires imagination, in addition to a thorough knowledge of the company and its product lines.

11. SUMMARY AND CONCLUSIONS

A comprehensive IP portfolio can be of substantial value to both private and public sector entities. For both sectors, patents are a key element of an IP portfolio. Large companies can afford an offensive patent strategy, but small companies may not have recourses for this. Therefore, especially for small- and middle-sized companies, planning and lateral thinking about how to put in place an effective and cost efficient strategy is extremely important. IP can be protected through patents, trademarks, copyrights, and trade secrets. The costs of maintaining each of these IP categories are different. A company can reduce costs by limiting patent protection to those geographic areas where it has business. But even when a company wishes to reduce costs as much as possible, important technologies need to be protected properly. A strong protection may be built by using several forms of IP for the same invention or improvement.[3] ■

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1 www.uspto.gov/main/howtofees.htm.

2 See also in this *Handbook*, chapter 11.6 by WT Tucker and GS Ross.

3 Recommended reading for further information on this topic:

Field TG, Jr. Avoiding Intellectual Property Problems. www.piercelaw.edu/tfield/avoid.htm.

Field TG, Jr. 1994. Intellectual Property: Some Practical and Legal Fundamentals. *IDEA The Journal of Law and Technology* 4: 79–129.

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Cost-Conscious Strategies for Patent Application Filings

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ABSTRACT

Timing and cost are two key factors involved in patent-filing decisions. This chapter explores mechanisms for delaying the high costs of filing a patent application as long as possible, so that additional information on an invention and evidence of its worthiness can be gathered. The efforts to minimize up-front costs are balanced against the potential need to secure viable patent rights at some point in the future. This chapter begins by walking through the stages of the publication process—from prior to submission, to after publication—and suggests cost-conscious patent-filing strategies that are possible at each stage. The focus is on delaying significant costs until the value of the invention is more certain. The chapter concludes with additional points to consider when making patent-filing decisions.

1. INTRODUCTION

With university inventions, research is often early stage and an invention's worthiness can be uncertain from both a scientific and market perspective. At the same time there is a drive to publish that forces early patenting decisions. Companies have some extra leeway with respect to delaying publication, but are pushed by competitors and a need to demonstrate technical capabilities and, as a result, often face patenting decisions well in advance of a clearly defined product line. Both universities and companies must therefore make decisions on inventions that represent only possibilities—an invention that might end up in a product, an invention for which additional research may demonstrate some significant result, or an invention that may be licensed in the future.[1] The cost-minimizing approach recommended in this chapter is intended for such inventions with questionable or uncertain value. The approach is not recommend for a blockbuster drug or an invention that represents the core of a company's products.

2. DECISIONS, DECISIONS

2.1 *No publications planned*

When the inventors plan no publications and there are no other reasons (such as concerns over competing groups) to secure a priority date, a company or university can enjoy the luxury of time. There is no need to do anything on the patent side so long as the invention will not be suppressed, concealed, or abandoned. Technical research and market evaluation may continue until the invention's value is determined. Then a patent application may be filed, if appropriate.

2.2 *Publication planned for a future date*

If there is significant time before publication submission, technical research and market evaluation may continue in the hopes that additional information will be gathered that can support

Livne O. 2007. Cost-Conscious Strategies for Patent Application Filings. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

the patent filing decision. Often publication submissions are delayed, providing additional time for evaluation. When submission becomes more definite, the steps in the following section may be followed.

2.3 *Publication submission*

Submission of a publication is not necessarily a dire situation. Not all submissions are considered publications. Usually submissions will be maintained in confidence until the publication date (it is advisable to note "CONFIDENTIAL" on the manuscript). If that is the case, several additional months are gained for technical research and market evaluation (again, assuming there are no other reasons to secure an earlier priority date). If the submission will not be maintained in confidence and is considered a publication, then a patent application may need to be filed prior to submission (see section 2.4).

2.4 *Publication imminent*

When publication is imminent, an application needs to be filed only if foreign (non-U.S.) patent rights are desired. If foreign patent rights are not desired, the U.S. patent-application filing does not need to occur until a year after publication. In this case, the steps in section 2.5 "Publication" can be followed (assuming there are no other reasons to secure an earlier priority date).

If foreign patent rights are desired, an application must be filed prior to publication (only a few countries in addition to the United States have grace periods).[2] Figure 1 details the steps that may be taken (see the left-hand "YES" side of the Figure).

There are two main options to choose from. A U.S. provisional application can be filed. Alternatively, if the invention's value is more certain or it has the potential to generate significant revenues, a nonprovisional U.S. application can be filed. By avoiding the provisional stage for more certain inventions, the total patenting cost can be reduced.

2.4.1 *Nonprovisional U.S. application*

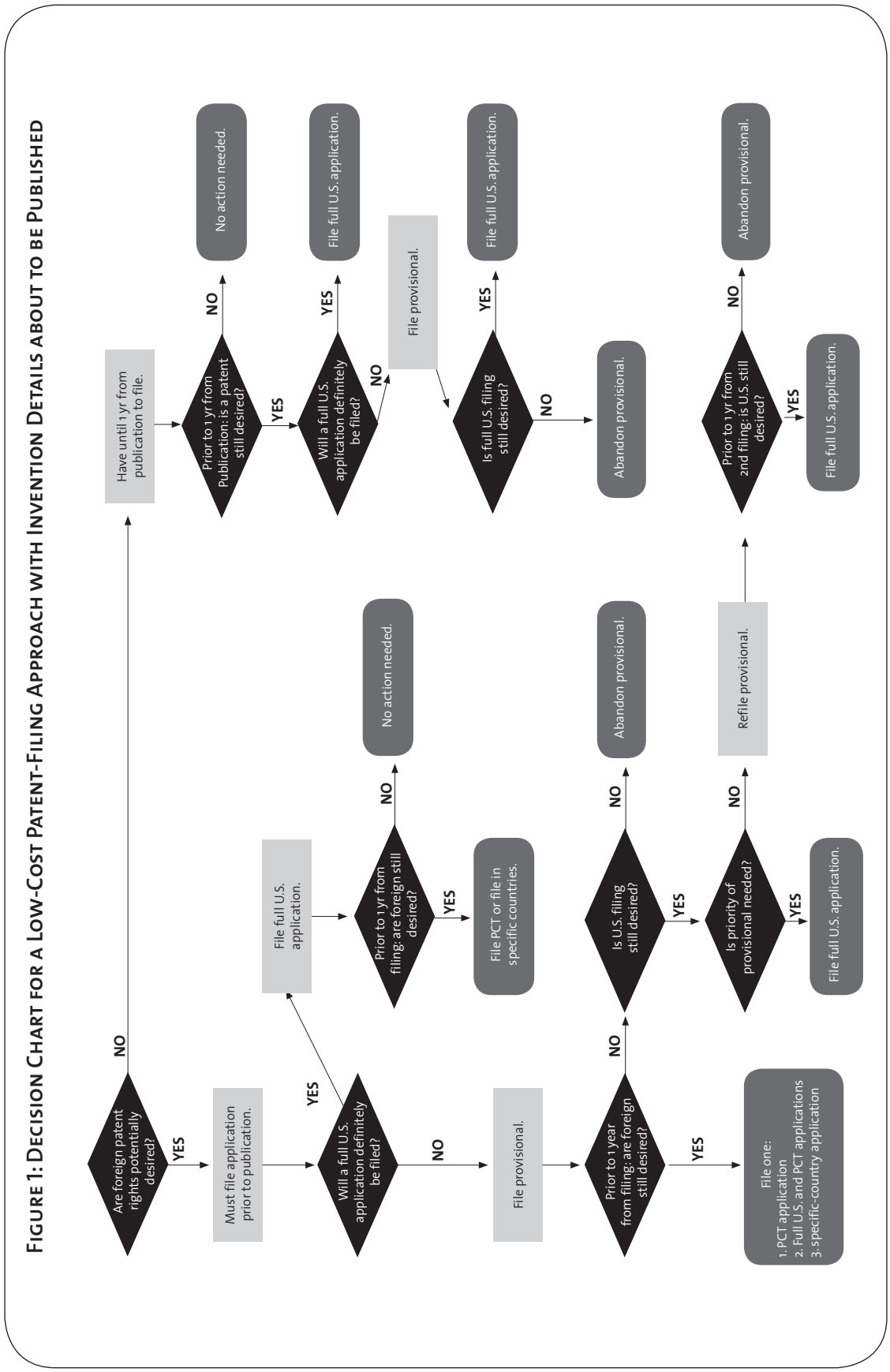
If the nonprovisional application filing route is taken,[3] attorney costs can be reduced by providing a single cohesive document containing all data and information relating to the invention. If possible, this document can be drafted by the inventors and then reviewed by the invention manager. The invention manager can discuss the description with the inventors and work to add any missing information, alternative methods, compositions or devices, and additional breadth to the description. The attorney will then have a more-solid starting point from which to draft the application. Depending on the nature of the invention, costs may be kept below US$10,000.[4]

Once the nonprovisional U.S. application is filed, there is one year during which foreign rights can still be pursued (assuming no prior publication has taken place). If foreign patent rights are no longer desired, no action needs to be taken. If foreign rights are still desired, one of the two following filing approaches can be employed prior to one year from the initial filing:

1. **File a Patent Cooperation Treaty (PCT) application claiming all or specific nations**. Filing a PCT application provides 30 months from the earliest priority date (filing date of the nonprovisional application) before which national-stage patent filings need to occur. Most countries are now members of the PCT (with the Republic of China [Chinese Taipei] one notable exception), so the PCT application is a valuable interim step for maintaining worldwide patent protection.

   The PCT route will reduce initial costs significantly, but total costs will be higher (by the amount of the PCT filing). If the specific countries or regions of interest are not yet known, this is a good route to take (the PCT filing may designate all member nations). Since the U.S. application was already drafted, PCT costs will be limited to governmental fees, and a small amount for attorney time (currently a total of less than US$4,000 for all nations). The U.S. Patent and Trademark Office (PTO) and the World Intellectual Property Organization (WIPO) have extensive Web sites with helpful information on PCT filings.[5]

Figure 1: Decision Chart for a Low-Cost Patent-Filing Approach with Invention Details about to be Published



2. **File national-phase applications in specific countries or regions of interest**. If the desired countries or regions of interest are already known, patent applications may be filed directly in those countries. The cost per country is significant, including translation costs, governmental fees, and attorney time. This route is typically reserved for inventions whose potential has already been demonstrated or whose value, if proven, will be very significant.

2.4.2 *Provisional patent applications*

If the provisional-application filing route is taken, attorney costs can be reduced also by providing a single cohesive document containing all data and information relating to the invention. Like the nonprovisional application discussed above, this can be drafted by the inventors and then reviewed by the invention manager. The invention manager can discuss the description with the inventors and work to add any missing information, alternative approaches, and additional breadth to the description.

This description can then be filed "as is," without claims, at minimal cost (roughly US$300, including attorney time) or, with some sample claims, for a little more. This is a somewhat risky approach, as the attorney will not have reviewed the description to ensure that it provides the information necessary to support desired claims. If it is very uncertain whether or not foreign rights are desired and the added provisional year is likely to provide that information, this may be an appropriate approach. If foreign rights are very likely of interest or the invention has strong potential in foreign markets, it may be preferable to provide the attorney with the single reviewed document and ask that an additional review be conducted and claims added (a total cost of roughly US$1,500–US$2,500, depending on the nature of the invention).

2.4.2.1 *Foreign rights desired*

Once the provisional U.S. application is filed, there is one year during which foreign rights can still be pursued. If foreign rights are desired, one of the three following approaches can be employed up until one year after the initial filing:

1. **File a PCT application claiming all or specific nations**. Filing a PCT application provides 30 months from the priority date (filing date of the provisional application) before which national-stage patent filings need to occur. Most countries are now members of the PCT (with the Republic of China one notable exception) so the PCT application is a valuable interim step for maintaining worldwide patent protection.

   The PCT route provides the lowest upfront costs, but total costs will be higher than the combined costs of filings directly in a few specific countries or regions of interest. If the specific countries or regions of interest are not yet known, a PCT filing is a good route to take (it may designate all member nations). The cost of converting a previously filed provisional application into a full PCT filing can vary significantly depending on how strong the provisional filing was and whether any new information needs to be incorporated (depending on the nature of the invention, costs may be kept below US$10,000)
2. **File a PCT application claiming all or specific nations and file a separate nonprovisional U.S. application**. Filing a U.S. patent application in addition to the PCT at this stage has certain benefits. The U.S. patent application will likely issue sooner. Also, it is possible that the PTO will issue an office action in time to help with the decision on whether or not to go national-phase in other countries. There will be added costs for filing the additional U.S. application, primarily in the form of government fees (roughly US$1,500 to US$2,500 for the filing fee, plus minimal attorney time). If an office action is issued on the U.S. application, there will be additional costs for drafting and filing the response (roughly US$3,000, depending on the nature of the office action).

3. **File applications in specific countries**. If the desired countries or regions of interest are already known, patent applications may be filed directly in those countries. The cost per country is significant, including translation costs, government fees, and attorney time. This route is typically reserved for inventions whose potential has already been demonstrated or whose value, if proven, will be very significant.

2.4.2.2 *Foreign rights not desired*

If foreign rights are not desired but U.S. rights still are, a full U.S. application must be filed within one year of the provisional U.S. filing if the priority date of the provisional is needed.

If priority to the provisional is not needed (for example, if there are no concerns about competing groups), then a full U.S. application does not need to be filed. The provisional application can be refiled within one year of the earliest publication—the cost would be minimal since all the paper work would already be in place (roughly US$300 if an attorney is used). Using this strategy, a company or university would have a year to decide if foreign patent rights were worthwhile (the first provisional) and an additional year to see if a full U.S. patent is desired (the second provisional). If a full U.S. patent is desired, the application must be filed within one year from the filing of the second provisional application.

2.5 *Publication*

If enabling details of the invention have already been published, then non-U.S. rights are generally not attainable.[6] The right hand, "NO," side of Figure 1 outlines the steps that may be taken in such cases. A U.S. patent application does not need to be filed until one year from the publication. During this time additional research and market analysis can occur.

If, toward the end of the one-year time period, the invention's value becomes more certain, a nonprovisional U.S. patent application may be filed.

If the value of the invention is still uncertain but it continues to have potential, a provisional U.S. application may be filed, providing an additional year for evaluation. Filing a provisional application would raise the total costs somewhat, but can dramatically reduce the initial costs. If the evaluation proved positive and a U.S. patent is desired, a nonprovisional application must be filed by one year from the provisional filing date.

3. CONCLUSIONS

This chapter offers ideas for delaying the upfront cost of patent filings in a manner that allows patent rights to be secured in the future. Below are some important points to consider when employing these strategies:

- Before applying the strategies described in this paper, please consult with an attorney to confirm they are appropriate for your specific circumstances.
- There are risks associated with delaying a patent filing. There may be prior art of which you were unaware. Sometimes a paper will be published online prior to print, or a journal will be mailed before its cover date, or conference proceedings sent to attendees prior to the conference. Other groups may publish before you have a chance to file. Foreign countries (and possibly soon, the United States) have a first-to-file system, so delay may result in other groups securing patent rights before you have an opportunity to do so.
- Consider what information will be gained before the next patenting-decision point. If, for example, it will take three years of research to confirm whether an invention is viable, filing a provisional application is not likely to be worthwhile: going straight to a nonprovisional filing will reduce the total costs. On the other hand, if only six months are needed to confirm the value of an invention, a provisional application might be preferable.
- Delaying filings through provisional applications and the other approaches discussed in this paper makes sense only if some applications are abandoned at future decision points. The main benefit of the delay is that

it allows additional time for research and market evaluation so the strong inventions can be separated from the weak. If a patent filing is definitely going to occur, adding the provisional application will increase the total costs.

- Evaluate whether or not foreign (non-U.S.) patent rights are truly desired. Significant flexibility is gained if foreign patent rights are not needed.
- Remember, attorney costs can be reduced by providing a single cohesive document containing all data and information relating to the invention, enhanced by the invention manager who could add any missing information, alternative methods, compositions or devices, and additional breadth to the description. ■

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1 Livne O. 2002. Investigation of At-Risk Patent Filings. *Journal of the Association of University Technology Managers* 14:19-29.

2 See Strauss J. 2000. *Expert Opinion on the Introduction of Grace Period in the European Patent Law.* Max-Planck Institute: Munich. www.european-patent-office.org/news/pressrel/pdf/straus.pdf. Page 44 provides a summary of countries with various types of grace periods ranging from six to 12 months. If detailed information on specific countries is needed, see the WIPO Guide to Intellectual Property Worldwide at www.wipo.int/about-ip/en/ipworldwide/country.htm. WIPO provides a good starting point for information on the patent laws of specific countries.

3 It is also possible to file a Patent Cooperation Treaty (PCT) filing in lieu of, or in conjunction with, the non-provisional U.S. application if the desirability of foreign rights is more certain.

4 All cost estimates in this paper are based on small-entity filing fees. U.S. patent filing fees (effective 1 February 2007) can be viewed at www.uspto.gov/web/offices/ac/qs/ope/.

5 See, also in this *Handbook,* chapter 10.7 by AM Schneiderman.

6 See *supra* note 2 for information on exceptions.

A Guide to International Patent Protection

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ABSTRACT

When approaching the international production, marketing, distribution, and sales of a patented product or process, several key factors must be carefully identified and evaluated. These factors include business and legal issues. Business issues include market location, market size, presence (or absence) of competitors, emerging markets as opportunities, life cycle of the product, and taxes. Legal issues include the presence (or absence) of trade secrets in the patent application, the status of patent applications in foreign countries, the level of patent protection (both law and enforcement) in foreign countries, and statutes, such as novelty requirements, in prospective foreign markets. Having considered a full range of business and legal factors, options for international patent protection can then be evaluated and appropriately selected, according to the business goals and financial resources of the organization. Options include national, regional, and international patent applications, each having its own advantages and disadvantages. This overall strategy can be effectively employed to maximize either business or humanitarian objectives.

1. BASICS OF INTERNATIONAL FILING STRATEGIES

You have a researcher who has developed an exciting invention, and you have already decided to file a patent application in the United States. Now you need to decide if you should also file patent applications abroad, and if so, where. The cost of filing patent applications in every country in the world can add up quickly, as there are about 200 countries where some degree of patent rights are available. Therefore, you will need to be selective as to where you will file patent applications.

Many factors need to be considered when deciding where to file foreign patent applications. Some factors relate to the business development or marketing of the invention, and other factors relate to the legal status of the invention. For example, will the invention be considered "novel" in the countries where you want to file? Do the countries permit patenting the type of technology your inventor has developed? Some countries do not offer patent protection for computer software, for instance. Another factor to consider is whether you will be able to enforce your patent once you receive it. The degree of judicial respect that patents are given in different countries varies considerably. Some countries have laws that allow a party to obtain a patent but have almost no enforcement mechanisms. International treaties such as the North American Free Trade Agreement (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should help to make enforcement easier and remedies for infringement more adequate.

Viksnins AS and AM McCrackin. 2007. A Guide to International Patent Protection. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this *Handbook*. The original paper was published in the *AUTM Technology Transfer Practice Manual Second Edition* (Part IV: Chapter 2.2).

Specifically, here are some of the business and legal questions to consider when planning a foreign patent filing strategy:

- **How big is the market for your invention in a particular country?** If the market for the invention is a relatively small one, it may not be worth the expense of filing an application in that particular country. A benchmark that some companies use is US$5 million in revenue per year for the invention.
- **How big is the market for your invention in a particular region?** Many inventions are region-specific. For example, if your invention is a transgenic blueberry plant, you likely do not need to consider filing in the region of Equatorial Africa, since blueberry plants do not grow there. Also, it may be that a patented product has a major market in a handful of countries and only a minor amount of interest elsewhere. Further, covering the major markets may provide an advantage in economies of scale. If most of your potential customers are in countries where you have patent protection, you may have such strong manufacturing and cost advantages that you do not need to have patent coverage in less-important countries.
- **Where are the major manufacturing centers for you and for your competitors?** Certain regions of the world are centers of manufacturing for different industries. For example, the Far East economies of Singapore, Hong Kong, Korea, Indonesia, Thailand, the Republic of China, China (People's Republic of China), and Japan are important manufacturing countries for the computer and semiconductor industries.
- **Where are the emerging markets?** Developing countries may be strengthening their patent laws and therefore make patents more valuable in the near future. For example, China has recently revised its patent laws and should be considered for certain inventions. There are still many problems in enforcing patents in China, but in the long run, the size of the market could make up for the short-term difficulties. As another example, Vietnam's recent accession to the World Trade Organization (WTO) will necessitate tangible progress towards TRIPS provisions implementation.[1] An important aspect of this will be strengthening patent laws and their enforcement.
- **Would a defensive patent be valuable?** It can be worthwhile filing in a particular country, even if a market is small, if you know that a major competitor is doing business or has a manufacturing plant in that country. You can possibly get the competitor to license the new technology from you or at least prevent the competitor from commercializing your invention in that country.
- **Do you have limited time?** Some technologies only have a life span of a few years, and you can expect to get income from licensing fees only in the early years of a patent. Other technologies are in development for a long period of time and are only economically valuable in the last years of the patent. It can take ten years to get a Japanese patent application issued. Even though you might be able to successfully sue an infringer and get retroactive royalties back to your filing date, by then the competitor will already be in the market. Also, you often cannot get a restraining order to make the competitor stop infringing until after the patent has actually issued.
- **Do you have limited funds to spend on foreign patent protection?** It may be more worthwhile to carefully pick just a few countries and spend all your money on getting well-prosecuted, broad patents in those countries rather than getting narrow patents in a lot of countries. Another strategy would be to concentrate all your efforts on the key features of your technology that competitors will need in order to be competitive.
- **What is the status of a patent application in the foreign country of interest?** In some countries, such as Japan, published applications are respected almost as though they

were already-issued patents and can provide licensing opportunities. This local custom can make an unissued patent application valuable even if the national patent office has a reputation for letting patent applications pend for a long time.

- **Would your invention be considered novel in your country of interest?** Most countries require that an invention be undisclosed, or *novel*, as of the effective filing date of the application. Novelty requirements vary considerably from country to country. Some countries require *absolute novelty* (which, in practical terms, means that a patent application must be filed before *any* public disclosure), while other countries give inventors or applicants grace periods, following disclosure, for filing patent applications.
- **Where are your competitors filing their patent applications?** Place of filing can be indicative of future business plans. You may want to file in the same countries your competitors are filing in, even if you do not initially plan to manufacture or sell your invention in those countries.
- **Are there trade secrets in your application?** Most foreign applications (and most U.S. patent applications filed on or after 29 November 2000) are published about 18 months after their priority date. The invention may be of more value when kept as a trade secret for a potentially unlimited time than when disclosed in a patent, which has a limited life span.
- **Can holders of patent rights realize tax advantages in foreign countries?** Patents can be bundled with a technology transfer license to transfer the situs of taxation, allowing expatriation of funds with less tax impact.

2. OPTIONS FOR FILING INTERNATIONAL PATENT APPLICATIONS

2.1 *Overview*

Once a decision has been made to file a patent application, there are three choices for filing in a foreign country: (1) file directly in the patent office of the country of interest, (2) file in a regional patent office, or (3) file using the procedures set forth in the Patent Cooperation Treaty (PCT).[2] These filing options are discussed below. Unlike in the United States, applications in most other countries are filed in the name of the assignee(s), not the inventor(s).

2.1.1 *National applications*

Prior to 1 June 1978, directly filing a patent application in a foreign country's patent office was the primary way to obtain foreign patent protection. Applicants often would rely on the rights granted under the Paris Union Convention (that is, for member nations of the Paris Convention) for a right of priority.[3] This right of priority allows a resident of a country that is a member of the Paris Convention to first file a patent application in any member country, and then, within 12 months of the original filing date, to file patent applications for the same invention in any of the other member countries. By treaty, the later applications receive effective filing dates that are the same as the original filing date. In other words, they would be treated as though they had been filed on the same day as the first application, so long as they were filed within the 12-month period.

Applicants who file a subsequent application in a country that is a member of the Paris Convention will not be given the priority of their original application. If possible, applicants should consider filing any applications in nonmember countries on the same day as their first Paris Convention application.

It should be noted that even though the Republic of China is not a member of the Paris Convention, patent applications filed in the United States may have priority over applications filed in the Republic of China because of a bilateral agreement between the two countries (effective 10 April 1996). The priority period is 12 months for inventions and new utility model applications; the period is six months for new design applications. Various requirements must be met in order for priority to be granted. For example, priority must be claimed on the filing date of the application filed in the Republic of China,

the applicant of that country's application must be the same as the applicant on the U.S. application, and the invention disclosed in the Republic of China application must be the same as that of the corresponding U.S. application.

A major disadvantage of filing directly in individual countries is that such a strategy can be very expensive, as applicants must pay the individual national government filing fees, patent attorney fees, foreign associate fees, and potential translation costs early in the patent program.

2.1.2 *Regional applications*

A potential alternative to filing directly in each country of interest is to file in a regional patent office. These patent offices have come into existence through international treaties. Examples of regional patent offices are the European Patent Office (EPO),[4] the African Regional Industrial Property Organization (ARIPO),[5] the African Intellectual Property Organization (OAPI),[6] and the Eurasian Patent Convention (EA).[7]

Often, the EPO is the most commercially important of the regional patent offices, so its procedures will be discussed in more detail. Use of the EPO allows for a uniform procedural system for filing a patent application in member European countries. The cost of filing a patent application in the EPO is about US$10,000. This figure includes the EPO filing fees, the U.S. attorney fees, and the fees charged by the EPO associate. The EPO does not allow U.S. patent attorneys to communicate directly with it, so a European patent attorney, or agent qualified to practice in the EPO, must be hired for certain aspects of the filing and prosecution process.

The application is reviewed by an EPO examiner based on the investigation of the prior art in light of the claims. The examiner must consider a PCT Chapter II examination report, if applicable. (The PCT procedure is discussed in further detail below). The EPO issues an *official action* statement. The U.S. patent attorneys respond to the official action through their European associates. After successful examination, the application is granted as a European patent. It should be noted that interim protection can be available during pendency by filing a translation of claims in each designated country.

An applicant, however, does not gain any enforceable patent rights until the European patent is registered, or "validated," in each of the countries in which protection is sought. Registration can be expensive because in addition to government issue fees and translation fees, further fees for the European associate and local agents in each country will be incurred. Once the European patent is validated, annual maintenance fees, or *annuities*, will be due periodically in each of the countries. Maintenance fees vary considerably from country to country. For example, annuities in the United Kingdom and France can total about US$7,000, whereas in Germany they can total about US$18,000, over the life of the patent. Of course, these are estimates and are subject to change.

2.1.3 *PCT applications*

The Patent Cooperation Treaty (PCT) is an international agreement that provides a unified and simplified procedure for filing multiple foreign patent applications via a single initial application. Most industrialized countries are members of the PCT, including many countries that are also members of different regional patent offices. Please note that this list is constantly changing as new countries join the PCT. All PCT member countries are bound by the Paris Convention; however, not all Paris Convention member states are PCT member countries.[8] If you have questions as to whether certain countries are PCT member countries, you may check the most recent PCT newsletter, on the Web, or contact the PCT Help Desk.[9]

PCT Rule 4.10 enables applicants to claim priority of an earlier-filed application in, or for, a member country of the WTO[10] that is not party to the Paris Convention.

The procedures set forth in the PCT allow applicants to obtain and/or preserve the priority date of the first-filed application in any of the PCT member countries, including the United States. An applicant files a copy of the application in a PCT office and pays the PCT filing fee. This filing of the patent application may be the

first time it has been filed anywhere, or it can be an application that claims priority over an earlier-filed application, so long as it is filed within 12 months of the initial filing date.

Along with a copy of the application, the applicant files a *PCT request*. When the request is filed, the presumption is that the applicant would like to designate all available countries or regional offices, thereby reserving the right to, at a later time, file national (or regional) applications claiming priority to the first-filed application. In Box No. V of the PCT request form, it is stated that "*The filing of this request constitutes, under Rule 4.9(a), the* ***designation of all Contracting States*** [emphasis added] *bound by the PCT on the international filing date, for the grant of every kind of protection available, and, where applicable, for the grant of both regional and national patents.*" In other words, priority to the first-filed application is automatic and all-inclusive, with all possible designations. The PCT request form, however, provides for the "de-designation" of Germany, Korea, Russia, and Japan (for example, if applications have already been filed in these countries). It is critical to keep in mind that if patent protection is desired in a non-PCT country, an applicant must file directly in that country.

When filing an international application that relies on the Paris Convention one-year grace period for a priority date, the time period for filing the foreign application is calculated from the date of the *first-filed national application*. For most U.S. applicants, the first-filed national application is a regular nonprovisional U.S. application. It is important to note, however, that if a U.S. provisional application is filed as the first-filed application, the one-year grace period begins with the filing of this provisional application and not with the filing of the "conversion" regular nonprovisional U.S. application that claims priority over the provisional application. Thus, if a provisional application is filed, the conversion date for the nonprovisional U.S. application and the Paris Convention bar date for the filing of international applications fall *on the same day*. Therefore, the international application *and* the U.S. regular application need to be filed on the same date. The applicant does not get an additional year beyond the regular U.S. application in which to file its international applications.

Prosecution of a PCT application has two parts. Chapter I involves the initial processing of the application, a search of the prior art, and publication of the application and search results. Chapter II involves an optional international preliminary examination. (Figures 1 and 2)

Once an applicant decides to file a PCT application, the applicant enters Chapter I by filing a PCT *office request*, a copy of the application, and the PCT filing fee. Application in most countries is made in the name of the owner of the invention, not of the inventor, as in the United States. The PCT filing of the patent application may be the first filing, or a PCT application that claims priority to an earlier-filed application can be filed, so long as it is filed within 12 months of the priority date. Either the U.S. Patent and Trademark Office (PTO) or the International Bureau of the World Intellectual Property Organization (WIPO) can act as PCT receiving offices for applications on inventions by applicants who are either nationals or residents of the United States. Either the PTO or the European Patent Office can be designated as the searching authority.

The application is then reviewed by an authorized examiner, and a prior art search is performed. The examiner reviews patents and publications from around the world and lists those that are determined to be relevant prior art, with respect to the claims of the application. Within 16 months of the priority date, a *preliminary search report* is issued. The applicant then has an opportunity to amend the claims in the application. After 18 months from the priority date, the application is published.

Under previous PCT procedure, within 19 months of the priority date, applicants were required to choose to enter PCT Chapter II, enter the national stage (that is, file the application in at least some of the countries or regional offices designated), or abandon the application. If the applicant decided to enter PCT Chapter II, the filing of a *demand* for a preliminary examination was required and a Chapter II filing fee would be assessed. However, the Article 22(1) *time limit* for filing national-stage applications *without the*

need to file a demand has been changed from 20 or 21 months to 30 or 31 months. This change went into force on 1 April 2002. Applicants should recognize, however, that some PCT member countries maintain reservations regarding this new timing rule and should remain cautious.[11]

Applicants may file a preliminary amendment with the demand. When that has been done, the PCT examiner prepares a written opinion that should be received by the applicant within 22 months of the priority date. The applicant has an opportunity to amend the claims and respond to the examiner's opinion during the period between 22 and 28 months following the priority date. A final PCT international preliminary examination report is published approximately 28 months from the priority date. PCT Chapter II is closed at 30 or 31 months from the priority date.

Normally, just before the 30- or 31-month mark, the applicant again must decide whether to file applications in at least some of the designated countries, or regional offices, or to abandon the application. The applicant can choose to file the application in some or all of the countries originally designated. The applicant, however, cannot add to the list of countries originally designated. Because the PCT application does not, in itself, result in the granting of any national patent rights, the applicant must initiate the national stage in each of the national offices where patent protection is desired. At this point, the applicant, via a local attorney or agent, files a copy of the international application, a translation of the application (if necessary), the national fee, and any other documentation required by the national office. The remainder of the prosecution is similar to that discussed above, when an application is filed directly in a national office. The national offices, however, do give deference to the PCT international preliminary examination report and may not conduct a further search.

It should be noted that it is possible at any time during the PCT process to file one or more national-stage applications. It is not necessary to wait until the end of Chapter I or Chapter II to file a national or a regional application.

For U.S. applicants using the PCT procedure and wanting to select the EPO to perform the prior art search, the EPO has limited the categories it will search and/or examine. The EPO will not search *or* examine applications in the areas of business methods and related inventions. "*[T]he EPO is no longer a competent [International Preliminary Examining Authority], within the meaning of PCT Article 32(3), for international applications filed by U.S. residents or nationals in the* [U.S. Patent and Trademark Office] *or [International Bureau] as a Receiving Office where the corresponding demand is filed with the EPO on or after 01 March 2002, and where the application contains one or more claims directed to the fields of business methods.*"[12]

In the 1990s, the EPO had indicated that it would search inventions in the area of telecommunications, but would not examine these applications. This meant that U.S. applicants needed to have all telecommunications inventions examined by the U.S. Patent Office, even if the EPO had performed the search. The EPO, however, resumed its competence as an international preliminary examining authority, effective 1 July 2004, for demands filed by U.S. residents or nationals on or after 1 July 2004, for international applications filed by nationals or residents of the United States, where the application contains one or more claims relating to the field of telecommunications.[13]

Similarly, in the field of biotechnology, although the EPO had earlier announced that it would neither search nor examine applications in that area, and that such applications were required to designate the U.S. Patent Office as the searching and examining authority, the EPO resumed its competence as an international searching authority and international preliminary examining authority, effective 1 January 2004, for international applications filed by nationals or residents of the United States, where the application contains one or more claims relating to the field of biotechnology.[14]

2.2 *Advantages and disadvantages of different application strategies*

2.2.1 *Direct national filings*

If an applicant has only a small number of countries where she or he wants to file and chooses to

actively pursue prosecution in only those countries, the applicant can avoid the costs associated with the intermediate steps of filing in the PCT or regional patent office prior to filing nationally. Some countries conduct no, or limited, examination.

Disadvantages to direct national filing are that (1) each application will be independently examined (no deference given to a prior favorable review in a different country), and (2) government filing fees and translation costs will be due early in the patenting process.

2.2.2 *Direct regional filings*

With direct regional filings, applicants may be able to avoid some translation costs (for example, the Eurasian Patent Convention requires applications to be filed in Russian, but no translations into different languages will be required by the various countries after grant of a Eurasian patent). Another advantage to direct filings is that substantive examination of the regional patent in each of the designated countries is no longer necessary. This makes direct regional filing especially cost-effective if protection is desired in a number of member countries, since the single regional examination replaces national examinations performed by each member country.

If obtaining protection in only a few member countries is desired, it may be less expensive to file applications in each country individually, thus avoiding costs associated with the intermediate steps of first filing in the regional patent office.

2.2.3 *PCT filings*

PCT filings preserve future foreign patent rights and permit an applicant to delay national entry into PCT member countries for up to 30 or 31 months from the priority date. This delay period may provide opportunities for further market analysis, obtaining a licensee or business partner for the invention, and obtaining a preliminary examination report regarding the issues of novelty, inventive step, and industrial applicability of the claimed invention.

Ultimately, the same costs for national filing or registration (and possible further national prosecution), patent attorney fees, local associate fees, and translation costs, if appropriate, will be incurred just as they would if the national stage was entered directly. Also, the additional intermediate costs associated with the filing and prosecution of the PCT application will be incurred. Further, the countries of interest must be members of the PCT.

3. POSSIBLE INTERNATIONAL FILING PLANS

The selected international filing strategy will depend on the potential importance of the invention and other business and legal considerations. The following are examples of filing strategies in a variety of circumstances.

3.1 *Invention has immediate international market potential*

1. File application in the United States; expedite obtaining a foreign filing license from the U.S. Patent Office.
2. After receipt of a foreign filing license, file in countries of interest that are not members of the Paris Convention.
3. File a PCT application designating all PCT countries within three months after the U.S. filing.
4. Within 12 months after the U.S. filing date, pay designation fees for desired countries, and proceed with the PCT prosecution.
5. Within 12 months after the U.S. filing date, file national applications in non-PCT countries that are Paris Convention countries.

3.2 *Invention has international, but not global, market potential*

1. If it is known ahead of time which countries have market potential, one could:
   a. File a PCT application designating countries of interest, including the United States. If filing in any Paris Convention nonmember countries is desired, obtain a foreign filing license, and file applications upon receipt of the foreign filing license.
   b. Within 12 months after the PCT filing date, pay designation fees, and proceed with the PCT prosecution.

c. Within 12 months after the PCT filing date, file national applications in non-PCT countries that are Paris Convention countries.

2. If it is not known which countries may be of interest at the initial filing date, one could:
   a. File a U.S. application (and obtain a foreign filing license if interested in any countries that are not members of the Paris Convention).
   b. Within 12 months after the U.S. filing date, file a PCT application designating EPO, Japan, Canada, and any other PCT countries of possible interest.
   c. Within 12 months after the U.S. filing date, file national applications in non-PCT countries that are Paris Convention countries.

3.3 *Applicant is interested only in NAFTA countries*

1. File a U.S. application.
2. Within a one-year grace period, file an application in Canada and Mexico. (File in Canada within one year from any disclosure by the inventor.)

3.4 *Bars to patentability in foreign countries*

Most countries require that an invention be "new or novel" in order for the inventor or applicant to obtain a patent for the invention. The definition of *novelty* varies considerably among the different countries of the world. Some countries have a requirement of absolute novelty, that is, the invention cannot have been described orally or in writing, anywhere in the world, or have been sold, used, and so forth, prior to the filing or priority date. Other countries have a requirement of relative novelty. For example, relative novelty can mean that the invention must not be known in the particular country or described in a written document anywhere in the world (but foreign oral disclosures may not destroy novelty). Also, a country might give inventors or applicants a grace period in which to file their patent application after they, or a third party, disclose the invention.

Under Chapter II of the PCT, a claim not disclosed by prior art is considered to be novel. The relevant prior art is anything made available to the public, anywhere in the world, by means of a written disclosure, drawings, or other illustrations, prior to the relevant date (filing date of the first-filed patent application or the filing date of the PCT application).

The European Patent Convention (EPC) has a more-restrictive view of what is new. Under the EPC, an invention is considered to be new if it does not form a part of the *state of the art*. The state of the art includes everything made available to the public by means of written or oral description, by use, or in any other way, before the effective date of filing of the European patent application or a patent application from which the European application claims priority. Additionally, the content of European patent applications that were filed prior to the priority application, but published after the priority date, are also part of the prior art for novelty purposes.

There are many variations as to what constitutes novelty in a particular country, and these national definitions can change. Therefore, it is highly advisable to inquire of a local patent attorney or agent as to the current novelty requirements for a given country.

4. CONCLUSIONS

When properly managed, international patent protection can afford many strategic and economic advantages for an organization, as it seeks to optimize value in its inventions. However, implementation of such a patent-portfolio-management strategy requires careful planning, coherent organization, and a thorough knowledge of an invention's potential. For example, critical considerations include market potential (both in terms of monetary and geographical factors), the presence or absence of competitors, and the overall patent protection regime (in terms of laws and enforcement) in the various nations or regions where the invention might be used, sold, produced, or marketed. Having carefully weighed these considerations, options for patent protection can then be evaluated. For example, patent

applications can be filed within national (for example the U.S. Patent Office), regional (for example, the EPO), or international systems (for example the PCT), each with advantages and disadvantages, depending on the objectives and resources of the organization. Whatever course is taken, coherent planning is essential, and a thorough knowledge of all relevant parameters is fundamental. Finally, it is important to remember that such an overall strategy can be effectively employed to maximize either business or humanitarian objectives. ■

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1 Vietnam became the WTO's 150th member following a decision by the General Council, on 7 November 2006, to approve the southeast Asian country's membership agreement. More information is available at www.wto.org/english/thewto_e/acc_e/a1_vietnam_e.htm.

2 www.uspto.gov/web/offices/pac/dapp/pctstate.html. See, also in this *Handbook*, chapter 10.7 by AM Schneiderman.

3 Listings of states party to the PCT and the Paris Convention and Members of the World Trade Organization can be found at www.wipo.int/pct/en/texts/pdf/pct_paris_wto.pdf.

4 A listing of European Patent Organisation (EPO) member states can be found at www.european-patent-office.org/epo/members.htm.

5 A listing of members of the African Regional Intellectual Property Organization (ARIPO) can be found at www.aripo.org/articles.php?lng=en&pg=14.

6 A listing of members of the African organization of the Intellectual Property (OAPI) can be found at www.oapi.wipo.net/en/OAPI/historique.htm.

7 Web site of the Eurasian Patent Organization Office (EAPO): www.eapo.org/index_eng.htm.

8 See *supra* note 3.

9 The newsletter is available at www.wipo.int/patentscope; to reach the help desk, call +1-703-305 3257 (United States) or +41-22-338 8338 (Switzerland).

10 See *supra* note 3.

11 Time Limits for Entering National/Regional Phase under PCT Chapters I and II can be found at www.wipo.int/pct/en/texts/pdf/time_limits.pdf.

12 Patent Cooperation Treaty (PCT) Information. European Patent Office as Searching and Examining Authority. www.uspto.gov/web/offices/com/sol/og/patpcti.htm.

13 Ibid.

14 Ibid.

Figure 1: Overview of International Patent-Protection Procedures

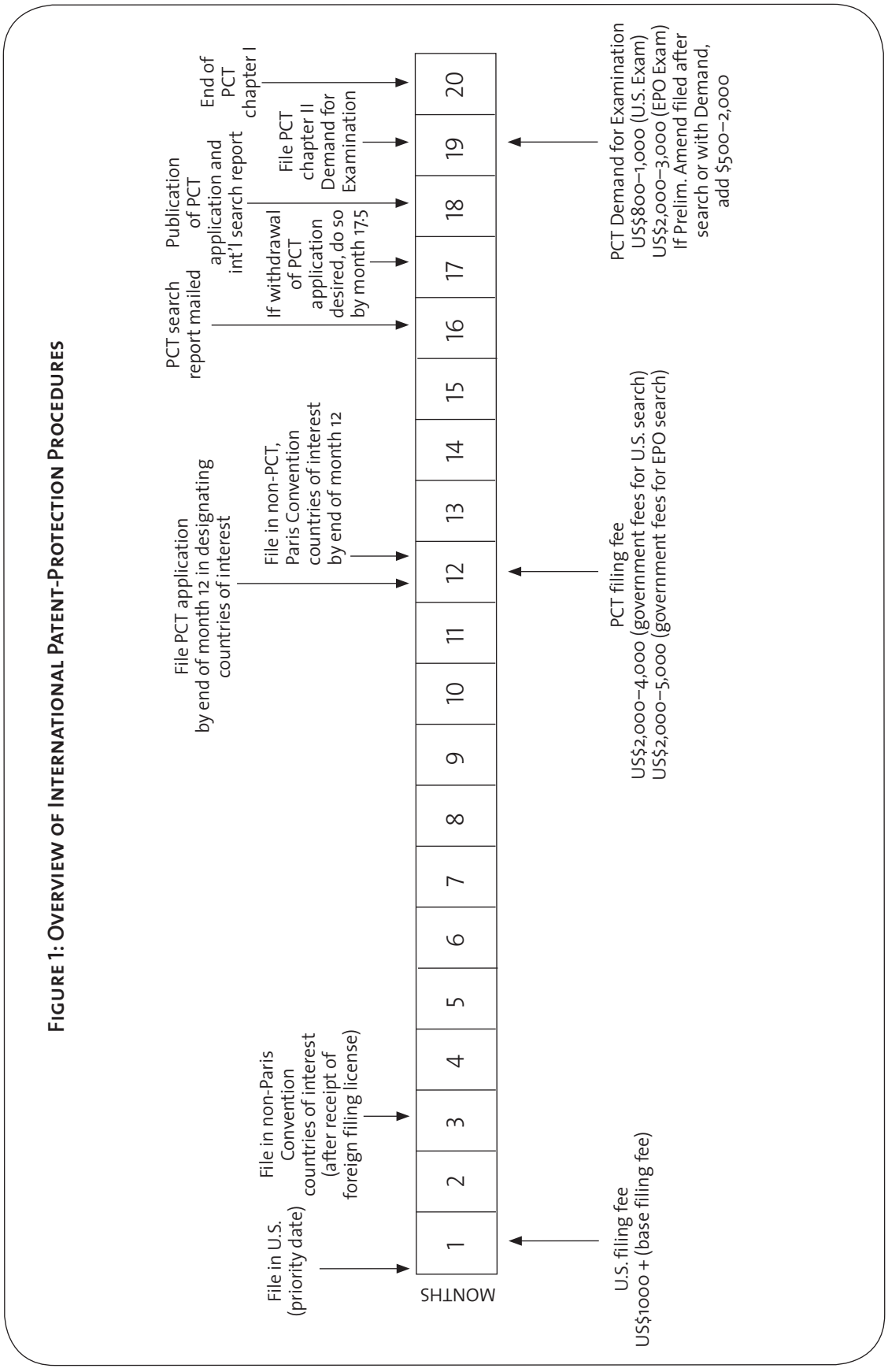


Figure 1 (continued)

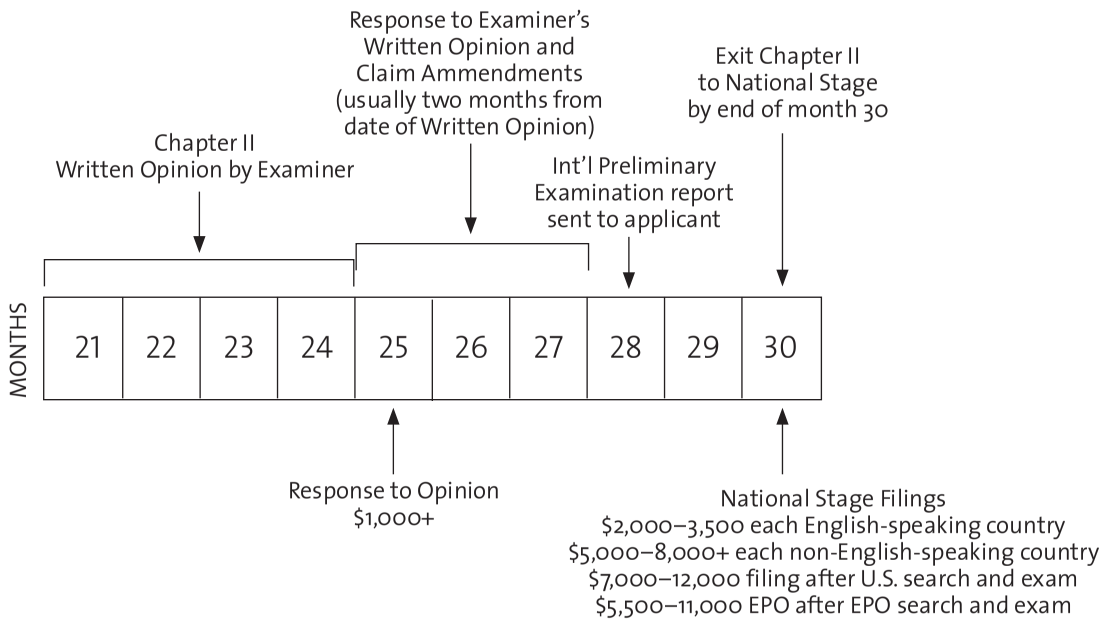


FIGURE 1 (CONTINUED)

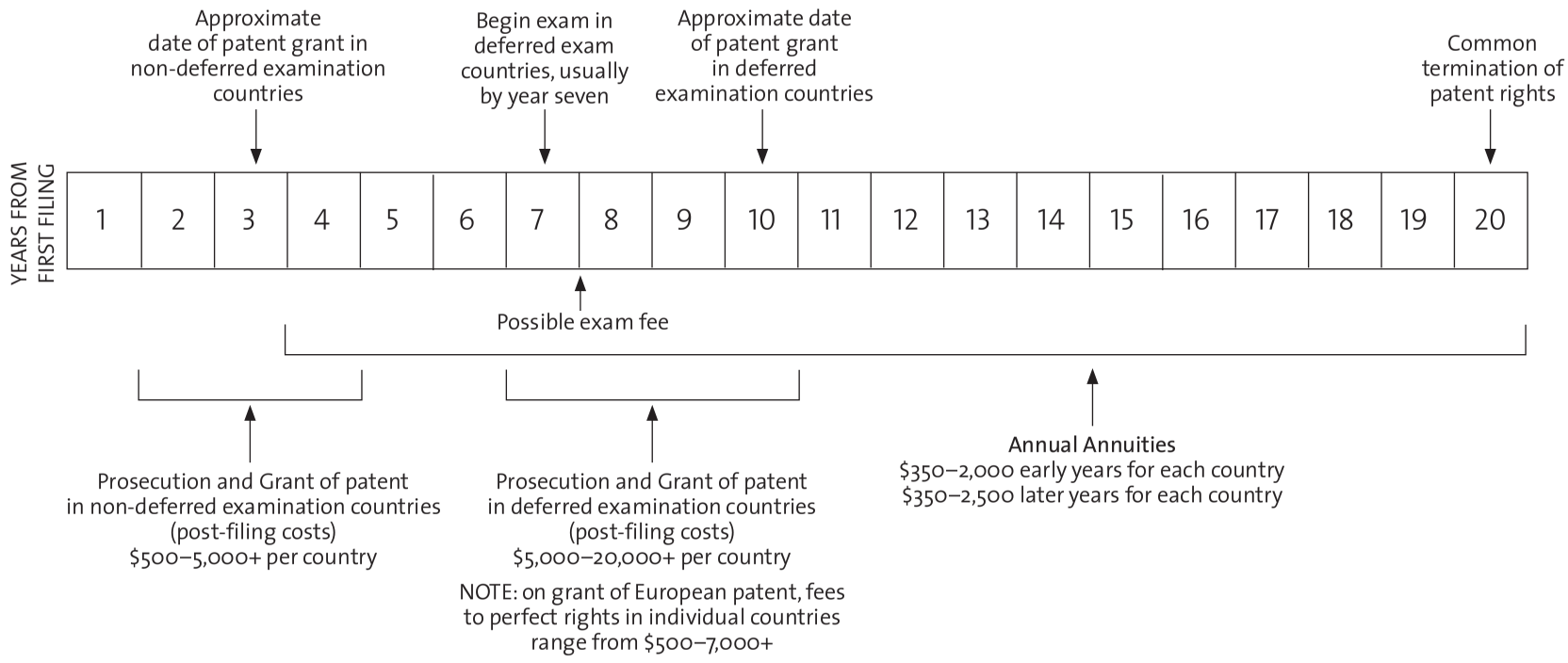
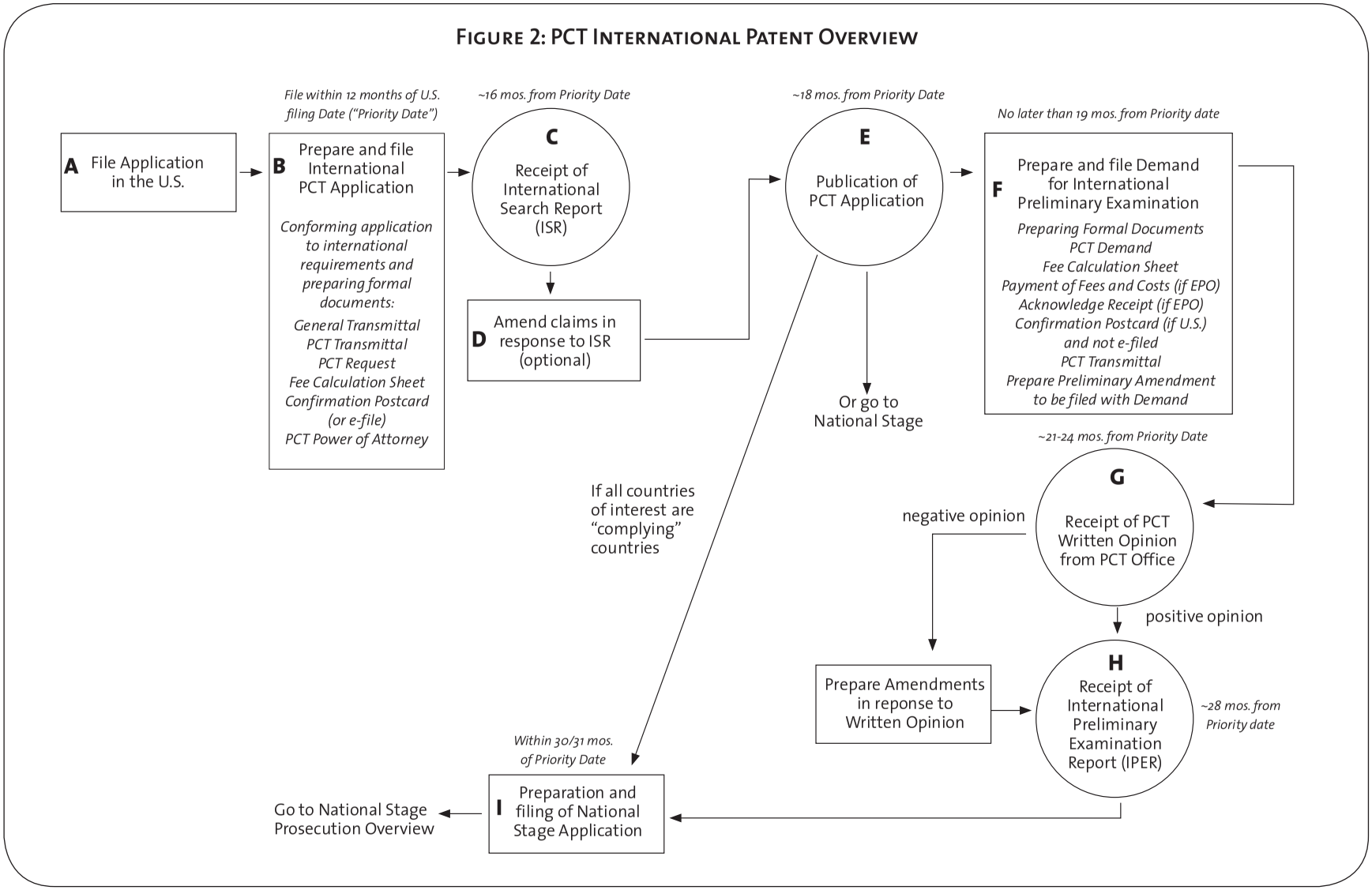


Figure 2: PCT International Patent Overview



Filing International Patent Applications under the Patent Cooperation Treaty (PCT): Strategies for Delaying Costs and Maximizing the Value of Your Intellectual Property Worldwide

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ABSTRACT

Obtaining international patent protection for an invention can present a significant financial commitment for an early-stage company, entrepreneurial venture or not-for-profit organization with a limited budget for intellectual property management. This chapter examines the use of patent application filings under the Patent Cooperation Treaty (PCT) to delay, consolidate, or minimize the costs of patenting overseas. Using the PCT to file internationally enables a patent applicant to delay, generally for up to 30 months after the first (priority) filing date, strategic decisions about the countries in which to pursue patent protection. The delay offers a significant advantage, since it allows the applicant more time in which to evaluate commercial demand for the invention, the likelihood of its success in overseas marketplaces, and the likelihood of obtaining a patent grant in a particular country, prior to filing national-phase patent applications in the countries in which patent protection is sought.

1. INTRODUCTION

Obtaining international patent protection for an invention can present a significant financial commitment, especially for small or early-stage companies, entrepreneurial ventures, not-for-profit organizations (such as universities and charitable organizations), and independent inventors. Such entities usually have to conserve their financial resources while striving to build, maintain, protect, and expand their intellectual property (IP). The cost of procuring a national or regional patent, from the initial drafting of the application through prosecution of the patent application, allowance, issuance, and post-issuance maintenance of the patent, can easily run from US$30,000 to US$50,000 in legal and patent-office fees. Should patent protection for an invention be sought in more than one country, the costs of international patent procurement can multiply accordingly. Since the costs associated with obtaining patent protection are so significant, IP protection strategies that delay, consolidate, or minimize costs are advantageous.

The Patent Cooperation Treaty (PCT) is an important IP protection tool that can be used to confront the financial challenges associated with international patent protection. By facilitating the filing in any number of PCT member countries of parallel patent applications, a PCT patent application offers a valuable means of managing, delaying, or consolidating the costs of international patent protection for a given invention. The PCT can buy time to strategically evaluate the overall potential value of an invention, that is, provide time within which to make an informed decision as to how to best proceed.[1]

The challenge of managing the costs of protecting IP so that the IP becomes a commercial asset—and not a financial liability—is one that is faced universally by technology managers. An enterprise that has developed (or acquired) IP must

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decide at the outset whether that IP is worth protecting with a patent. The costs and benefits of patent protection must be carefully analyzed. Although a discussion of such a cost-benefit analysis is beyond the scope of this chapter, it is worth noting here that a granted patent generally "protects" the subject IP only to the extent that it confers to the patent owner the right to enforce the patent, that is, to exclude others from making the invention, using it, importing it, and so forth. In conducting a cost-benefit analysis, an enterprise may decide that the total expected value of a particular piece of IP simply does not merit the expense of obtaining a patent and enforcing the rights the patent confers.

The patent applicant (or IP owner) must determine the merits of the invention, the commercial demand for the product or process provided by the invention, the likelihood of its success in the marketplace, and whether protection should be sought in a particular country.[2] The applicant must also determine, preferably with the advice of a patent attorney, patent agent, or other professional with expertise in patent law, the likelihood that the patent application would succeed in the patent office of a particular country or region and whether that national patent office would decide that the invention meets its requirements for patentability and, thereby, grant a patent.

Ideally, these analyses are conducted prior to selecting specific countries in which to file patent applications. Thus, any strategy that extends the time limit for filing a patent application in a country, while preserving the priority (first filing) date for the application, potentially gives the patent owner more time for analysis and decision-making before making the financial commitment to seek patent protection abroad.

For patent owners and other entities with a proprietary interest in the subject matter to be patented, but without large budgets for patent portfolio development (for example, not-for-profit organizations, universities, regional technology incubators, and agricultural cooperatives), extending the time limit for filing a patent application can provide a much-needed opportunity to stimulate investment and technology transfer. The extended time period afforded by filing an international PCT application, as described below, is increasingly recognized by developing countries as an opportunity to publicly promulgate an invention with "patent pending" status, to identify and negotiate with potential corporate sponsors, investors, licensees, and others involved in technology development and commercialization and to stimulate further domestic inventive and related technological activities.

2. APPROACHES TO INTERNATIONAL PATENT PROTECTION

There are three basic approaches to procuring international patent protection on an invention.[3] The first approach, and the most expensive, is to file (usually on the same day) separate patent applications in the national patent office of each country or region[4] in which protection is sought.[5] The drawback of this approach is that legal and filing fees for each country begin to accrue as soon as the application is filed.

The second approach for filing internationally is to file a patent application in accordance with the Paris Convention for the Protection of Industrial Property.[6] Taking this route, the applicant files a patent application in a single Paris Convention member country[7] (usually required to be the country of residence of at least one of the inventors), which establishes a first or *priority filing date* for the application. The applicant can then delay filing in other Paris Convention countries for up to 12 months after the priority filing date. Member countries of the Paris Convention agree to recognize the priority date of a patent application filed in one member country and to give the benefit of that priority date to corresponding applications in all member countries. This approach delays the costs associated with international patent procurement for one year. Procurement costs initially accrue in the country of first filing, and then, up to one year later, the costs associated with filing applications in the other Paris Convention countries begin to accrue (Figure 1).

The third and least-expensive approach, which is the primary focus of this chapter, is to file a single "international" application under the

auspices of the PCT. Of the three approaches, filing a PCT patent application is, financially and strategically, the most advantageous for managing, delaying, or consolidating the costs of international patent procurement. Filing a PCT patent application allows the applicant to delay, for up to 18 months after the filing the application or in most cases, for up to 30 months after the filing of the first (priority) application, strategic decisions about which countries to pursue patent protection in. The delay provides a significant advantage, since it allows the applicant more time to evaluate the commercial strength and viability of the invention prior to filing national-phase patent applications in the countries in which patent protection is sought.

3. THE PATENT COOPERATION TREATY (PCT)

The Patent Cooperation Treaty (PCT) is a cooperative agreement entered into by more than 130 countries (called PCT contracting states) with the purpose of bringing international conformity to the filing and preliminary evaluation of patent applications,[8] both simplifying and making more economical the process of seeking patent protection in other countries. An applicant does not apply for an "international" patent by filing an application under the PCT. The World Intellectual Property Organization (WIPO), which administers the processing of PCT applications, does not grant international patents. Instead, the PCT filing process produces a single patent application that has been vetted for compliance with filing formalities and that has undergone a preliminary search and evaluation. This single application can then be transmitted to the national patent offices of as many PCT member countries as the applicant chooses, for filing as a *national-phase* application in that country. The PCT thus streamlines and consolidates the process of seeking patent protection in more than one country into a single series of steps and a single set of preliminary requirements (see Section 4).

Filing international applications with the PCT is becoming increasingly popular. In January 2005, the one millionth PCT application was

Figure 1: Traditional Filing Route under Paris Convention

Local first-filed patent application followed within 12 months by multiple foreign applications claiming priority under the Paris Convention:

- multiple formality requirements
- multiple searches
- multiple publications
- multiple examinations and prosecutions of applications
- translations and fees required at 12 months

Some rationalization because of regional arrangements: ARIPO, EAPO, EPO, and OAPI†

† African Regional Intellectual Property Organization, European Patent Office, Eurasian Patent Organization, Organisation Africaine de la Propriété Intellectuelle.

Source: Courtesy TDR Patents: T. David Reed LLC.

filed, with the doubling time for numbers of applications filed having gone from 22 years (for the first half million applications) to just 4 years (for the next half million applications).[9]

3.1 *Non-PCT member countries*

More than one hundred countries, however, are *not* members of the PCT, including a number of countries in Asia (for example, Cambodia, Nepal, Pakistan, Thailand), South America (for example, Bolivia, Chile, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela), Central America (for example, Panama), the Middle East (for example, Iran, Iraq, Jordan, Kuwait, Lebanon, Saudi Arabia, Yemen), and Africa (for example, Ethiopia, Rwanda, Somalia). To obtain patent protection in nonmember countries, a patent application must generally be filed directly with the national (or regional) patent office.[10] Since patent protection involves complex questions of law, the applicant is well-advised to consult with patent counsel familiar with local patent law, international Paris Convention patent practice, and international PCT patent practice *before* filing a patent application, especially if applicants are either residents of non-PCT contracting states or inventions were made in non-PCT contracting states. For example, if all of the applicants on a patent application are residents or nationals of non-PCT countries, then an application filed with the PCT is generally denied an international PCT filing date.

In general, if the application is first filed in a country that is not a member of the PCT but *is* a member of the Paris Convention,[11] then the applicant will be *ineligible* to file a PCT application but may choose to file additional applications in the national patent offices of other Paris Convention member countries within 12 months of the filing (priority) date of the first application (Section 2, second approach, above).

If the application is first filed in a country that is not a member of the PCT or the Paris Convention, then the applicant will be *ineligible* to file a PCT application, or an application under the Paris Convention in Paris Convention member countries, within 12 months of the filing (priority) date of the first application. The applicant will be obliged to file a separate patent application (usually on the same day) in the national patent office of each country or region in which protection is sought (Section 2, first approach, above).

3.2 *Costs associated with filing a PCT patent application*

Filing a PCT patent application entails paying a single set of filing fees, as opposed to multiple filing fees for each country in which patent protection is sought. Currently, PCT filing fees are approximately US$1100 for filing an application (with a fee reduction for filing electronically online or via other electronic media), from US$200 to US$2100 for a search of prior art publications (depending on which international searching authority performs the search), and a nominal transmittal fee (around US$300) charged by the PCT receiving office. The applicant can also elect to file a *demand* (request) for international preliminary examination of the application, which entails an additional fee of approximately US$600 to US$750.

3.3 *PCT filing consolidates and delays patent prosecution costs*

Filing a patent application under the PCT consolidates or eliminates the duplication of costs associated with multiple filings in multiple countries and enables the applicant to submit a single patent application in a single language and in a format that conforms to the requirements of all the national patent (or regional) offices of PCT contracting states. The added burden and expense of translating the application and of filing it in a particular format for a particular national patent office is thus avoided.

During the *international phase* of its pendency, a PCT application undergoes a preliminary evaluation that comprises an international search for prior art publications, a written opinion and a preliminary report on patentability, and optionally, a preliminary examination and a second, more detailed, report on patentability. The applicant can then choose to transmit the uniform application and accompanying evaluation documents to the national patent offices of as many PCT contracting states as desired, in which the application enters the national phase of the patent procurement process.

By far, the most expensive aspect of international patent procurement is the national-phase cost, which includes the fees paid to each national patent office for entrance into the national phase and during the patent prosecution process, the legal fees of local attorneys or agents to obtain a national patent, and the fees to the national patent office to maintain the granted patent in force. Filing under the PCT enables costs associated with the national phase to be deferred, in most cases for up to 30 months from the priority (first filing) date, while an international patent-protection strategy is formulated and decisions are made about which countries to seek protection in.

3.4 *The role of WIPO in the Patent Cooperation Treaty*

WIPO, an international organization based in Geneva, Switzerland, is the administrative body that oversees the filing of international applications under the PCT. The International Bureau of WIPO administers the international phase of the PCT application process, prior to entrance into the national phase of countries in which patent protection is sought. WIPO receives and stores PCT applications, along with their associated files of patent search and examination documents and correspondence. WIPO examines each application for its adherence to filing formalities (such as the required format for the patent application, accompanying administrative filing papers, and fees paid). Based on this initial examination, the applicant may be required to correct any formal defects to bring the application into conformity with the PCT format accepted by patent offices in the member states. The carrying out of these procedures reduces the costs of patent procurement at an early stage. Formalities defects in the PCT application that are identified during the international phase can be rectified before the application reaches the national patent offices and enters the national phase of the patent examination and procurement process. Thus, separate formalities rejections by national patent offices in which patent protection is sought can be avoided.

WIPO is responsible for publishing PCT applications[12] and accompanying information about them, which can be accessed worldwide via the Internet at the WIPO Web site. WIPO oversees translation of portions of the PCT application and associated documents into English or French, also available on the Internet, and can provide the national patent offices of contracting states with application documents.

4. OPTIONS AND STEPS FOR FILING UNDER THE PCT

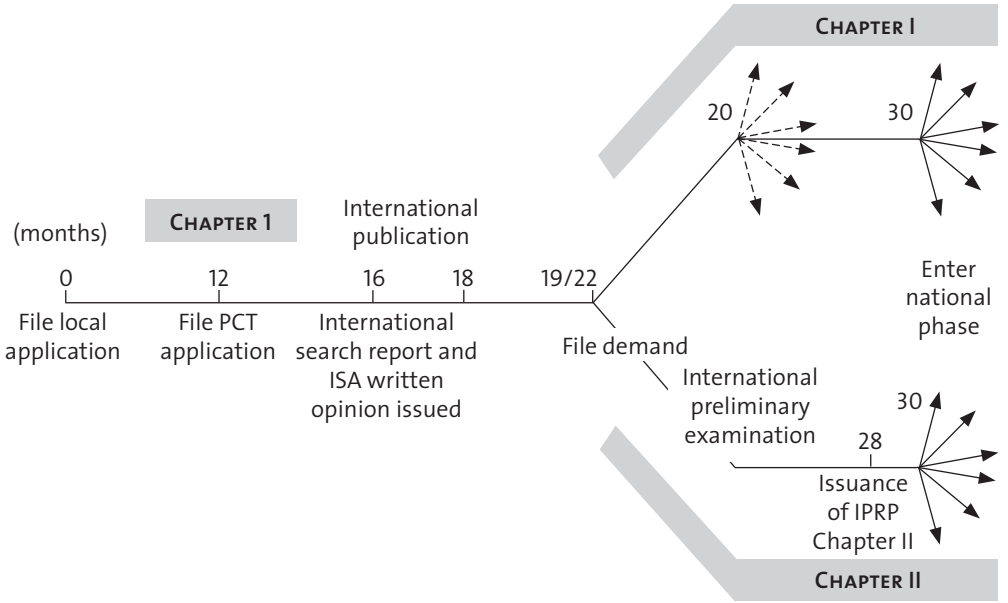
4.1 *Alternative 1: File an international PCT application that complies with PCT formality requirements and pay one set of fees.*

An international patent application can be filed under the PCT if at least one of the inventors of the invention is a resident of a PCT contracting state. Applicants can generally file an international PCT application with the national patent office of their country of residence, with the national office acting as a receiving office for the PCT. Under some circumstances, the PCT application can be filed directly with WIPO in Geneva.

The WIPO Web site provides detailed guides to PCT filing requirements,[13] as well as a guide to PCT time limits[14] and a PCT time-limit calculator[15] to assist applicants in computation of essential time limits for filing applications and for submissions of other required documents. Time limits under the PCT are measured from the priority date of the application (Figure 2). The priority date is defined in PCT Article 2(xi) as follows:

> *(xi) "priority date," for the purposes of computing time limits, means:*
>
> *(a) where the international application contains a priority claim under Article 8 [of the PCT], the filing date of the application whose priority is so claimed;*
>
> *(b) where the international application contains several priority claims under Article 8, the filing date of the earliest application whose priority is so claimed;*
>
> *(c) where the international application does not contain any priority claim under*

Figure 2: PCT Time Limits



Time limits for international PCT applications filed on or after 1 January 2004.

- "Month 0" corresponds to the priority date, the date of earliest filing of a local, regional or national application. An international PCT application claiming priority to the priority date must be filed prior to the expiration of *12 months* from the priority date.
- Approximately *16 months* after the priority date, the international search report and the written opinion are issued by the international searching authority (ISA).
- Approximately *18 months* after the priority date, the application is published.
- In countries that have *not* withdrawn their notifications of the incompatibility of the time limit under PCT Article 22(1) with applicable national law, a *demand* for international preliminary examination should be filed prior to the expiration of *19 months* from the priority date, if the applicant wishes to postpone entry into the national phase. Otherwise, a demand may be filed for up to three months from the date of transmittal of the international search report and written opinion of the ISA, or *22 months* from the priority date, whichever expires later.
- The international preliminary report on patentability (Chapter II) is issued by the international preliminary examining authority (IPEA), approximately *28 months* from the priority date. Unless an international preliminary examination report is established under Chapter II, the International Bureau of WIPO issues a report on behalf of the ISA that has the same contents as the written opinion. This report, the international preliminary report on patentability (Chapter I), is communicated to each designated national-phase office not before the expiration of 30 months from the priority date.
- The national phase usually must be entered prior to the expiration of *30 months* from the priority date. Some countries make provisions for entering the national phase later than the PCT 30-month time limit (see endnote 15). As with all deadlines mentioned in this chapter, the PCT articles, rules, applicant's guides, and the PCT time-limit calculator should be consulted, and deadlines should be confirmed by a qualified patent attorney or agent.
- For all designated states to which new Article 22(1) of the PCT does not yet apply, the applicant must decide whether to file demand by 19 months or to enter national phase by 20 months. As of 26 June 2006, these countries maintain reservations to the new Article 22(1) timing: Switzerland, Lithuania, Sweden, Tanzania, and Uganda.

Source: Modified after the U.S. Patent and Trademark Office.[17]

Article 8, the international filing date of such application[.][16]

The time limits are based on the earliest priority date of the PCT application and include:

- time limit for submission of the priority document on which the priority date of the PCT application is based
- earliest potential date for international publication of the PCT application, which is usually 18 months after the priority date
- time limit for a demand for international preliminary examination
- time limit for entry of the application into the national/regional phase

4.2 *Alternative 2: File a national application first and then a PCT application within 12 months*

Once a PCT application is filed, the applicant has up to 18 months to delay before deciding to enter the national phase and file national applications in one or more PCT contracting states (Figure 2). To delay even further the time between the first filing (priority) date of an application and entry into the national phase, the applicant has the option of filing a national application first, and then, up to 12 months later, filing a PCT application claiming priority to the national application. Laws of individual PCT contracting states generally require that if an applicant desires to file a patent application and the invention was made in a particular state, then either a national patent application must be filed in that state (and generally, a foreign filing license obtained) before the application is filed as a national application in other states, or an international PCT application must be filed directly with a PCT receiving office.

During the 12-month period following the filing of the priority application, the applicant can choose to file one or more additional national applications, as new refinements or embodiments of the invention are developed. A PCT application must be filed no later than 12 months after the filing date of the first application, however, to claim benefit of that earliest application's priority date.

The PCT application, however, can incorporate the disclosures of, and claim priority to, all the national applications directed to that invention that were filed during the previous 12-month period. The disclosure and claims of the PCT application may therefore differ from those of the priority application(s) preceding it in the *patent family*.[18] The PCT application can also include new disclosure pertaining to the invention (for example, a description of new embodiments of the invention) or new claims that were not set forth in any of the priority applications. However, to obtain benefit of an earlier priority date, a new claim included in the PCT application must be supported by the disclosure of the priority application filed on that date.

After filing the PCT application, the applicant has, as described above, up to 18 months to delay before deciding to enter the national phase and to file national-phase applications in separate PCT member countries. Hence, the applicant can delay for 12 months plus 18 months, or in most cases up to 30 months, after the filing of the initial priority application before entering the national phase in a desired PCT contracting state.[19] In the meantime, the applicant can use this delay to advantage, and take the time to evaluate the merits of seeking protection in specific countries and to delay the assessment and accrual of patent prosecution fees in multiple countries.

Hence, with this approach:

- A *national* patent application is filed in the patent office of a PCT contracting state (member country), establishing the priority (first filing) date. This national application is sometimes referred to the *priority application*.
- Within 12 months after the priority date, a PCT application is filed and enters the *international phase*.
- Within 18 months of PCT filing, or within 30 months of the priority date, the PCT application enters the *national phase* of selected PCT member countries.[20]

4.3 *Designating countries in which to file a national-phase application*

When a PCT application is filed, all contracting states that are bound by the PCT to the

international filing date are designated, by default, as potential venues for filing subsequent national-phase applications.[21] Before the expiration of the 30-month time limit after the priority date, the applicant can select a specific subset of the designated states for actual filing of national-phase applications with national patent offices. The transmittal to, and filing of, the international PCT application with the national patent office of a contracting state is known as entering the national phase of international patent prosecution (Figure 2). By filing under the PCT just before the expiration of the 30-month time limit, the applicant delays examination of the application for patentability by a national patent office significantly past the point at which national examination would normally occur had application been filed directly with the national patent office.

The prosecution phase of a national-phase patent application can become very expensive. It can take several years of interaction between the patent attorney and the patent examiner during the examination proceedings and cost tens of thousands of dollars (US$) in attorney costs and national-patent-office prosecution fees, before patent claims are possibly allowed and the application issues as a patent. If patent prosecution is undertaken in more than one country, then the costs of obtaining patent protection multiply accordingly. Thus, one of the chief advantages of filing under the PCT is the permitted delay of up to 30 months after the priority date to enter the national phase.

4.4 *PCT international search report and written opinion*

Prior to publication of the PCT application 18 months after the priority date, and during the international phase, a PCT international searching authority (ISA) conducts a search of the international technical literature to identify patent publications, technical publications, and other prior art references that are material to patentability of the claimed invention. Current ISA's are the European Patent Office and the national patent offices of Australia, Austria, Canada, China, Finland, Japan, the Republic of Korea, the Russian Federation, Spain, Sweden and the United States. The ISA conducts the search according to search standards set by the PCT and compiles an international search report containing a list of references that are deemed material to patentability. For each reference, the search report states the patentability criteria (for example, novelty, nonobviousness or inventive step, and industrial applicability) for which the reference is considered material. The ISA issues a written opinion that accompanies the search report and that states whether the invention appears to be patentable based on the results of the search.

The international search report and the written opinion provide the applicant with an early indication of the likelihood of success in obtaining a patent based on the claims as filed. This early indication is another significant advantage of filing under the PCT. In view of the search report and the written opinion, the patent claims can be amended by the applicant to better distinguish the invention from the prior art before the application enters the national phase. Thus, the possibility of having the same claims rejected by multiple national patent offices for the same (or similar) reasons can be minimized or avoided. The added legal and administrative expense of filing separate claim amendments in each national patent office can also be avoided.

Another distinct advantage is that the applicant may submit to WIPO informal written comments addressing, and possibly rebutting, the reasoning and conclusions set forth in the written opinion. This enables the applicant to begin creation of a prosecution record for the application that sets forth reasons for patentability of the claims, and that accompanies the application as it enters the national phase in each country and is examined by each national patent office.

The applicant (as explained in Section 4.5) also has the option to file a demand and to pay for an international preliminary examination (a *Chapter II examination*), which is a more detailed evaluation of the patentability of the claims that results in the issuance of an international preliminary report on patentability (IPRP Chapter II). The time limit for filing a demand is three months from the date of transmittal of the international search report and the written

opinion, or 22 months from the priority date, whichever comes last.[22]

If the applicant does *not* file a demand for international preliminary examination, the ISA's written opinion will be subsequently converted into an international preliminary report on patentability (IPRP Chapter I), which is sent, along with the applicant's informal comments responding to the written opinion, to each of the patent offices selected for national-phase entry, not before the expiration of 30 months from the priority date.

Thus, when the national phase is entered in each country, each national-phase patent application is accompanied by the same search and international preliminary report(s) on patentability (a Chapter I report, and optionally, a Chapter II report, depending on whether international preliminary examination has been elected or not). This significantly reduces the search and examination effort required for each separate national patent office.

4.5 *International preliminary examination*

If an applicant requests and pays the additional fee for international preliminary examination, then a second, more-detailed evaluation of the patentability of the claims is conducted by a PCT examiner associated with one of the international preliminary examining authorities (IPEAs), which are the same as the international searching authorities (ISAs) described above. A demand (request) for international preliminary examination may be made at any time prior to (a) three months from the date of transmittal to the applicant of the international search report and the written opinion or (b) 22 months from the earliest priority date (whichever is later).

The international preliminary examination provides a formal opportunity for the applicant to respond to the reasoning and conclusions of the PCT examiner, as set forth in the written report or the international preliminary report on patentability (Chapter I), regarding patentability of the claims, and to set forth on the record amended claims and arguments for patentability. The international preliminary examination concludes with the issuance, by the PCT examiner, of a second or international preliminary report on patentability (Chapter II), which is transmitted to the national patent offices. The international preliminary report on patentability (Chapter II) will be issued by the IPEA, in general, at around 28 months from the priority date (see Figure 2).

This creation of a formal-patent prosecution record prior to national-phase entry further reduces the duplication of efforts of each separate national office in performing a separate preliminary examination and the expense incurred by the applicant in responding to the results of each such national examination. The international preliminary report on patentability (Chapter II) accompanies the patent application as it enters the national phase, which can further reduce the duplication of examination efforts in each national patent office. It also can serve to consolidate and focus the prosecution strategy for the application and avoid the duplication of efforts by patent attorneys or agents prosecuting the application in each country.

Although national patent offices have no legal obligation to consider the reasoning and conclusions of the international preliminary reports on patentability (Chapters I and II), they will frequently do so. Thus, international preliminary examination is a means to reduce the effort expended on separate examination of the same application in various national patent offices, and hence to reduce the applicant's legal fees associated with separate examinations. For example, examiners in several national patent offices may have the same basis for objection to (or rejection of) the same group of claims in the application, and the applicant may choose to submit similar arguments to each examiner to overcome the objection. The examiner in each country, however, may respond very differently to these arguments, taking into account the differences in national or regional patent law. Thus, although a national-phase application may elicit similar objections in the initial office actions issued by examiners in different national or regional patent offices, there may be much less conformity in the subsequent prosecution history of the application as the application progresses through the various patent offices. In patent offices of countries that have less

capacity or resources for patent examination, however, patent examiners may rely on IPRPs more extensively. Thus, the IPRPs can have a greater influence on the patent claims that eventually are granted in those countries, thus promoting some similarity or uniformity in the claims granted in various countries.

Furthermore, the PCT examiner who issues the written report or the international preliminary report on patentability (Chapter I), and who performs the optional international preliminary examination and issues the more-detailed international preliminary report on patentability (Chapter II), may be the same person and be assigned to examine the application during the national phase. For example, the examiner who examines a PCT application submitted to the U.S. receiving office may be the same person who examines the corresponding application filed with the United States Patent and Trademark Office (PTO). This also avoids duplication of efforts and can result in a more thorough and informed evaluation by the patent examiner, who has previous experience with the application during the international phase.

4.5 *National-phase entry*

National-phase entry of a PCT application requires, by the end of the 30th month after the first priority date of the application, that the applicant selects the PCT contracting states in which to file a national phase application, files an application with each national-patent office, pays the associated national filing fees, and, under certain circumstances, furnishes a translation of the application.[23]

An advantage of filing a national-phase application, as opposed to filing a national application directly with a patent office, is that the applicant can use information acquired during the PCT international phase to strengthen the application upon entry into the national phase. The applicant can use information derived from the written opinion and the international preliminary report(s) on patentability to plan which claims to amend or eliminate prior to entry into the national phase. In countries that charge filing surcharges for claims in excess of a prescribed number, such surcharges can be reduced or avoided.[24] For example, the United States charges significant surcharges for independent claims in excess of three or total claims in excess of 20 in an application. Under the PCT, there is no claim limit or charge for excess claims. Hence, an applicant planning a subsequent U.S. national-phase entry can choose to include a large number of contemplated claims in the PCT application and then consider the results of the PCT evaluation from the international phase and amend or eliminate claims accordingly.

5. SUMMARY AND CONCLUSIONS

Filing a patent application under the PCT enables the applicant to delay strategic decisions about where to pursue patent protection by:

- consolidating patent prosecution costs: single-application format, language, and set of fees
- providing the applicant with preliminary feedback regarding patentability of the invention
- providing the applicant with the opportunity to present arguments for patentability, to amend claims, and to strengthen the application prior to filing with national patent offices
- enabling the applicant to delay filing the application in individual national patent offices for up to 30 months after the first (priority) filing date
- delaying prosecution costs of filing applications in multiple countries
- streamlining the process of filing applications in multiple countries

Delaying international patent prosecution provides more time to determine:

- the value of IP to applicant or owner
- the strength of commercial demand abroad
- which claims in a patent application are likely to be patentable
- which countries are most attractive for pursuing patent protection
- the likelihood of obtaining a patent grant in target countries. ■

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1 This chapter reflects the present considerations and views of the author and provides information for educational purposes only. It is not intended to constitute legal advice or to substitute for obtaining legal advice from a lawyer about a particular legal issue. Legal advice needs to be tailored to specific circumstances, and readers are therefore urged to consult directly with a lawyer for assistance regarding their particular legal issues.

2 See also Radack DV. 1992. Patents Outside of the U.S.: A Cost-Effective Approach. *JOM* 44(4): 62. www.tms.org/pubs/journals/JOM/matters/matters-9204.html.

3 World Intellectual Property Organization (WIPO). 2006. WIPO Publication, No. 433(E): Protecting Your Inventions Abroad: Frequently Asked Questions about the Patent Cooperation Treaty (PCT). WIPO: Geneva, Switzerland. www.wipo.org/pct/en/basic_facts/faqs_about_the_pct.pdf.

4 Examples of regional patent offices include African Regional Industrial Property Organization www.aripo.wipo.net/index.html; Eurasian Patent Organization www.eapo.org/index_eng.html; and the Gulf Cooperation Council www.gulf-patent-office.org.sa.

5 Since patentability is based, in part, on novelty and nonobviousness of an invention, patent applications on the same invention should be filed on the same day and should not be spaced out (filed in different countries at different times).

6 Articles of the Paris Convention for the Protection of Industrial Property can be viewed online at www.wipo.int/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf.

7 Many, but not all, members of the Paris Convention are also members of the PCT (and vice versa). List of Paris Convention contracting parties (currently 170) can be viewed online at www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2.

8 Articles of the Patent Cooperation Treaty (PCT) can be viewed online at www.wipo.int/pct/en/texts/pdf/pct.pdf. PCT Regulations, including rules and requirements for filing applications, time limits, and so on, can be viewed online at www.wipo.int/pct/en/texts/pdf/pct_regs.pdf. A list of PCT contracting states (currently 134 contracting states) can be viewed online at www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=6.

9 World Intellectual Property Organization (WIPO). 14 January 2005. Press Release 401: WIPO Marks Filing of One Millionth PCT Application. WIPO: Geneva, Switzerland. www.wipo.int/edocs/prdocs/en/2005/wipo_pr_2005_401.html.

10 See also World Intellectual Property Organization (WIPO). No stated date. *WIPO Publication No. 849(E): A Brochure on Intellectual Property Rights For Universities and R&D Institutions in African Countries*. WIPO: Geneva, Switzerland. ISBN 92-805-1097-7. www.wipo.int/freepublications/en/intproperty/849/wipo_pub_849.pdf.

11 See *supra* note 7.

12 Languages of international publication: Arabic, Chinese, English, French, German, Japanese, Russian, and Spanish.

13 WIPO provides detailed guides online to filing under the PCT: World Intellectual Property Organization (WIPO). *PCT Applicant's Guide (Volumes 1 and II)*. WIPO: Geneva, Switzerland. Volume I is available at www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf and Volume II at www.wipo.int/pct/guide/en/gdvol2/pdf/gdvol2.pdf.

14 World Intellectual Property Organization (WIPO). PCT Timelines and Time Limits. WIPO: Geneva, Switzerland. www.wipo.int/pct/en/seminar/basic_1/timeline.pdf.

15 PCT time limit calculator. www.wipo.int/pct/en/calculator/pct-calculator.html.

16 PCT Article 2. www.wipo.int/pct/en/texts/articles/a2.htm#_2.

17 www.uspto.gov/web/offices/pac/mpep/documents/1800_1842.htm.

18 The term *patent family* is used to designate a relationship between a patent application and its priority application(s) or other patent priority document(s). At least three descriptions are commonly used in patent practice to characterize a patent family:

(1) The applications or documents are directly or indirectly linked to a specific priority application or document.
(2) All applications or documents have at least one priority application or document in common.
(3) All documents have exactly the same priority or priorities in combination.

See also European Patent Office (EPO). About: Patent Families at gb.espacenet.com/espacenet/gb/en/help/161.htm.

19 There are a few instances in which the national law of a contracting state is incompatible with the PCT 30-month time limit-rule and in which the national patent offices of these countries still adhere to the old 20-month time limit for entering the national phase (This older rule was replaced on 1 April 2002 with the new time limit). In countries with a 20-month time limit for entry into the national phase, the limit can be extended to 30 months if a demand for international preliminary examination is made. Some countries make provisions for entering the national phase later than the PCT 30-month time limit. In these cases, if the applicant fails to meet the time limit to nationalize their PCT application within 30 months, the time limit can be extended upon petition and payment of extension fees. As with all deadlines mentioned in this chapter, the PCT Articles, Rules, Applicant's Guides,

and the PCT Time Limit Calculator (available online at www.wipo.int) should be consulted in determining time limits and the deadlines confirmed by a qualified patent attorney or agent.

20 If the country in which the *national* (priority) application was filed is also selected as a country into which the PCT application enters the *national phase*, this essentially creates a continuation application in that country.

21 The PCT request form, which is one of the administrative forms filed with a PCT application, sets forth this default designation. Certain exclusion provisions can be selected, using the request form, to exclude a country from designation.

22 A demand should be filed prior to the expiration of 19 months from the priority date if the applicant wishes to postpone entry into the national phase in countries that have not withdrawn their notifications of the incompatibility of the time limit under PCT Article 22(1) with applicable national law (see Figure 1 and World Intellectual Property Organization). *PCT Practical Advice 2003*. www.wipo.int/pct/en/newslett/practical_advice/pa_122003.htm.

23 The general national-phase entry requirements and the specific requirements for each PCT contracting state are described in detail in: World Intellectual Property Organization (WIPO). *PCT Applicant's Guide Volume II*. WIPO: Geneva, Switzerland. www.wipo.int/pct/guide/en/gdvol2/pdf/gdvol2.pdf.

24 See also Austin CB. 2005. Leveraging PCT Patent Applications to Gain Advantages in Patent Prosecution. www.michaelbest.com/articles.cfm?action=view&publication_id=1648.

Filing and Defending Patents in Different Jurisdictions

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ABSTRACT

In order to build an effective patent portfolio, an organization must (1) understand the dynamics of the international patent landscape: how to establish foreign priority, where to file patent applications, and the advantages and disadvantages of pursuing various filing options; (2) determine in which countries and/or jurisdictions the organization should seek patent protection based on its objectives (whether commercial or humanitarian access); and (3) anticipate the possibility of litigation and know what its options for litigation are.

1. INTRODUCTION

In February 2006, the U.S. Patent and Trademark Office (PTO) issued its seven millionth patent. It took 75 years for the PTO to issue its one-millionth patent (in the year 1911), but in less than a tenth of that time the office issued its last million.[1] Inventors in the United States and abroad are seeking to obtain patents at a pace unparalleled in history, and revenue from patent licensing is at an all-time high.

A company must ask itself several key questions before assembling a patent portfolio (or portfolios). What do we plan to do with our patents once we have them? Do we intend to assert our patents *offensively* (that is, with the aim of protecting market share), either as part of a licensing strategy or in litigation if companies are unwilling to license? Or do we plan to use our patents *defensively*, as leverage in licensing negotiations or in order to ward off litigation by others? If a portfolio is to be used offensively, where are our potential targets located and/or doing the most business? If a portfolio is to be primarily defensive, in what location is our company most at risk from licensing approaches or litigation offensives?

2. OVERVIEW OF PATENTING PROCEDURES

To obtain a patent for an invention, the inventor (often called the applicant) must file an application for a patent at one or more national or regional patent offices. Once the necessary documents are filed and any fees paid, the patent office will examine the patent and decide whether or not to grant the applicant patent rights for the claimed invention. A patent's first application date is commonly called its "priority date."

In most instances, an applicant will file a patent application in a national patent office in the country where he or she is located (such as the U.S. Patent Office [PTO], the Japanese Patent Office [JPO] or the European Patent Office [EPO]), in order to protect the invention for domestic markets; later, he or she can file patent applications in other countries or file an international application under the Patent Cooperation Treaty (PCT) procedure (see Section 3) in order to protect the invention in foreign markets. Importantly, patent

Yin R and S Cunningham. 2007. Filing and Defending Patents in Different Jurisdictions. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

rights awarded by a patent office protect the invention only within the jurisdiction of that particular patent office, and not in other parts of the world.

3. OVERVIEW OF THE PARIS CONVENTION TREATY

The Paris Convention, formally known as the Paris Convention for the Protection of Industrial Property, established the system of priority rights that is now internationally accepted. The United States and 171 other countries are signatories to the Paris Convention Treaty, and the signatories are sometimes collectively referred to as the "Paris Union."[2]

Under the Paris Convention Treaty, if an inventor files a patent or trademark application in another Paris Convention member nation within 12 months of the priority date, he or she is granted the *right of priority*: in other words, his or her patent or trademark application will take precedence over that of any identical patent or trademark application filed in the second country. Therefore, an inventor will not lose patent rights even if it takes him or her a long time to transfer the application to another country and have it translated into that country's language. Since the Paris Convention Treaty is reciprocal (in other words, country A must accord to the inventors of country B the same right of priority as country B accords to the inventors of country A), no member has an advantage over any other.

Not every country is a member of the Paris Union. However, some countries that are not signatories of the Paris Convention Treaty, such as Thailand, have entered into bilateral treaties with the United States that grant inventors rights similar to the right of priority.

4. FILING A PATENT APPLICATION IN DIFFERENT TERRITORIES

Significant differences exist between patent offices. Table 1 provides the main differences between the three major patent offices, and the following text describes them in more detail.

Table 1: Significant Differences between the Three Main Patent Offices[3]

Issue	EPO	JPO	U.S. PTO
Status of successful patent applicant	First to file	First to file	First to invent
Patent duration	20 years	20 years	20 years
Application language	English, French, or German	Japanese	English
Area in which the patent is valid	Designated EPC[a] member and extension countries	Japan	United States
Request for re-examination of the patent	Yes, within 6 months	Yes, within 3 years	No provision
Time of publication of application	18 months from priority date	18 months from priority date	18 months from priority date[4]

a European patent convention

4.1 *Filing with the U.S. Patent and Trademark Office*

When an application is filed at the U.S. Patent Office [PTO], it is assigned to a patent examiner. On the date 18 months from the priority date, the application is published (that is, information about the application is made available to the general public). It is possible for an applicant to request that the application not be published, but this request will be considered only if a patent for the invention has not been, and will not be, filed in a foreign country. The patent examiner searches through U.S. and foreign patent documents and published patent applications dated prior to the priority date in order to determine whether or not the claimed invention fulfills the requirements of being new, useful, and nonobvious.

If a patent application is rejected, the applicant is notified in writing and given the opportunity to challenge the rejection. At any time during the lifetime of a patent, any person may file a request for the PTO to conduct a second examination of any claim of the patent on the basis of prior art patents or printed publications. In order to keep the patent in force (that is, to keep the invention protected by the patent), the applicant must pay maintenance fees within certain time periods.

In the calendar year 2005, the PTO granted a total of 157,740 patents: 143,806 utility patents, 12,950 design patents, 716 plant patents, 245 reissue patents, and 23 statutory invention registrations.[5] The total number of patents issued in 2005 was 13% less than the number issued in 2004 and 8.7% less than the number issued in 2000; the number of utility patent grants issued in 2005 was 12.5% less than the number issued in 2004 and 10.4% less than the number issued in 2000.[6]

In 2005, U.S.-resident inventors were granted 52.4% of all U.S. patents—a half-percent increase over 2004—and foreign-resident inventors were granted the remaining 47.6%.[7]

4.2 *Filing with the JPO*

The patent application process of the JPO is similar to that of U.S. PTO, although there are some important differences. Patent applications filed with the JPO are not automatically examined by patent examiners. Instead, the applicant has to file a request for examination within three years (reduced from seven years in 2001) of the application date. If the applicant fails to file a request for examination within the time limit, the application is withdrawn. All applications pending examination are published in an official Patent and Utility Model Gazette 18 months after the priority date. If the patent examination process does not turn up any reasons for refusal, the patent is granted and published in the gazette. After the patent is granted, anyone can request an appeal examination of the patent on the basis of lacking novelty or an inventive step (obviousness).[8]

4.3 *Filing with the EPO*

By filing a single patent application with the EPO in one of the three official languages (English, French, or German), an applicant can obtain the patent rights to an invention in one or more countries that are signatories of the European Patent Convention Treaty (EPC Treaty). Currently, 31 countries have signed the treaty, and five additional countries are covered by an extension agreement. At the time of filing, the applicant has to specify the EPC countries and "extension" countries in which he or she wishes to seek protection. If the applicant pays designation fees for seven countries, then the patent will automatically be granted in all EPC member states. Consequently, each patent application to the EPO is usually a bundle of patents, one for each country in which the applicant is seeking protection.

There are three different ways to file EPO patent applications:

1. Direct filing with the EPO; filing date becomes the priority date
2. National patent application extended to the EPO application within 12 months of the priority date, that is, the EPO application is filed after first application
3. International application filed under EPC Treaty

Once an application is filed with the EPO, it is subjected to a two-phase examination procedure. First, the patent examiner will search for pri-

or art relevant to the invention; this search report, along with the patent application, is published 18 months after the priority date. The applicant then has six months to file a request for a further examination. If he or she files such a request, the EPO will conduct a substantive examination to decide whether or not to grant the patent. If the applicant does not file a request within that time period, the application is deemed to have withdrawn. Within nine months of a successful EPO patent grant, anyone can file an opposition to the patent.[9]

In 2002, more than 110,000 patent applications were filed at the EPO. This represented an 84% increase from 1991. In 2002, residents of the European Union were granted the largest share of EPO patent applications (44.7%), a share that far exceeded that of U.S. residents (27.3%) and Japanese residents (17.4%). The share of biotechnology patents filed with the EPO grew by 8.3% a year between 1991 and 2002, while total EPO patent applications grew by 5.7%. In 2002, more than 5,800 biotechnology patents were filed at the EPO, with 39.9% coming from the United States, 34.5% from the European Union, and 14% from Japan. The proportion of residents of European Union being granted EPO patents is consistent with the proportion of U.S. residents being granted U.S. patents, suggesting that, overall, U.S. residents and E.U. residents must "share" their home market with residents from other jurisdictions. However, the growth of biotech patents has exceeded the growth of nonbiotech patents, and U.S. residents have filed proportionally more patents in this area than E.U. residents, suggesting the lead U.S. residents have in this area of technology.

4.4 *Filing international applications under the PCT*

On January 24, 1978, the United States became a signatory to a multijurisdiction treaty, the PCT. The PCT allows an applicant to seek patent rights in a large number of countries by filing a single international application with a single patent office. The PCT is not a single patent filing effective in many jurisdictions. Instead, an applicant who files a PCT application is allowed to prolong his or her right to file patent applications in the national or regional jurisdictions designated in the PCT application for up to 30 months from the priority date.

During the 1990s, the average annual growth rate for PCT filings was 17%. More recently, the growth rate has slowed, but there were still 135,602 PCT applications filed in 2005, a 10.6% increase over the previous year and a more than 45% increase over the number of applications filed in 2000 (93,237). These figures demonstrate the increasing importance of PCT filings.

5. A GLOBAL PATENT-FILING PROGRAM

For several reasons, a global patent-filing program can quickly become prohibitively expensive if it is not managed properly. Patents are only enforceable within certain geographical regions. Patent prosecution (that is, the process of obtaining the patent) can be costly and time consuming. In many countries, the applicant must pay regular post-issuance fees ("maintenance fees" or "annuities") in order to keep the patent in force. Finally, patent applications must be filed before the invention is disclosed—in other words, when its commercial merits are uncertain. Global patent filing is a high-stakes gamble.

Nevertheless, the risk can be reduced somewhat by considering the following questions:

- **Does the invention have global market potential?** If the invention has only regional application, then it does not merit global patents.
- **Will the invention still be useful 15 or 20 years from the date of filing?** In many countries, the typical lifespan of a patent is 15 to 20 years from the date of filing. If the invention will quickly become obsolete, then a global filing program may not be economical. Furthermore, it often takes two to three years from the date of filing for a patent to issue. Until a patent is issued, the invention will not have any enforceable legal protection. In that case, it may not be worth applying for patent protection at all: it may be more cost-effective to cash in on

the advantages of being the first to bring the invention to market.

- **Are the rights accorded to the patent owner *separable*?** That is, has the owner the right to exclude another from selling the invention *or* the right to exclude another from manufacturing the invention? Countries can be divided into two categories: those where the invention can be manufactured and those where the invention can be sold. Of course, some of these countries may overlap. Nevertheless, it is not necessary to file patent applications in both countries where the invention can be made *and* in countries where the invention can be sold. Protection in only the countries where the invention can be sold effectively controls the world. Even though a would-be infringer/competitor can make the product in a country not protected by any patent, the product cannot be sold in other countries. Furthermore, during the time a patent offers protection, capital markets and labor markets change—thus changing the situs of manufacturing over the life of an issued patent. In general, therefore, filing patent applications in the countries where the invention can be sold offers sufficient protection.
- **Is it necessary to file for patent protection in every country in which the invention might be marketed?** This may not be necessary. If patents are filed in 80%–90% of the countries where the invention can be marketed, no competitor could capture more than 10%–20% of the worldwide market. If the cost of producing the product can be brought low enough, there may be no would-be competitors at all.

6. LITIGATION CONSIDERATIONS

Patents often lead to litigation, both at home and abroad. This is not, however, all bad. Patents can be used prospectively—by threatening or initiating litigation to help preserve market share. Patent rights can, of course, be used by a company to protect itself from other companies that would accuse it of patent infringement. Parties seeking to initiate patent litigation in the United States can do so in various federal district courts or before the U.S. International Trade Commission (ITC).

6.1 *Filing in a federal district court*

When filing a patent lawsuit in a federal district court in the United States, a litigant must first identify which courts would be proper venues. Then it must consider which of the permissible district courts would best suit its litigation goals.

6.1.1 *Finding the proper venue for litigation*[10]

For a court to be a proper venue for patent litigation, the court must have jurisdiction with regard to the subject matter of the dispute and the persons or entities involved. *Jurisdiction* is the power of a court to adjudicate a dispute.

A corporation is considered to "reside" in any judicial district in which it is subject to *personal jurisdiction* at the time an action is commenced.[11] According to the U.S. Court of Appeals for the Federal Circuit, personal jurisdiction exists in a patent infringement case in which a defendant deliberately places infringing products in the stream of commerce with the expectation of exploiting business in the *forum state*. Accordingly, an action for patent infringement may be brought against a corporation in any district where the corporation is subject to personal jurisdiction at the time the suit is commenced. An action for patent infringement may be brought in any judicial district where the defendant resides.[12]

U.S. district courts that hear patent litigation cases are located in various states. Each district court in a state (the forum state), may properly exercise personal jurisdiction over a party outside the forum state if: (1) the party is amenable to service of process under the long-arm statute of the forum state; and (2) the party's activities in the forum state satisfy the minimum contacts requirement of the Due Process Clause.[13] With regard to the first requirement of long-arm statute, various states have enacted legislation permitting its courts (including the federal district courts in that state) to exercise personal jurisdiction over nonresidents of the forum state, under certain

conditions. As for the second requirement of due process, the Supreme Court of the United States has decided that the Constitution permits a nonresident of a forum state to be subject to the jurisdiction of the courts in the forum state, if the nonresident had certain minimum activities with the forum state, thereby satisfying due process. Because several state long-arm statutes, including those of Texas and California, are coextensive with the Due Process Clause, the questions of personal jurisdiction often collapse into a constitutional due process inquiry.

Even if a court is chosen for litigation proceedings, the case will not necessarily be held in that court. Patentee plaintiffs are often subject to venue challenges in the form of (1) a motion to dismiss for lack of personal jurisdiction,[14] (2) a motion to dismiss for *forum non conveniens*, which is to say, the forum is inconvenient for witnesses, experts, documents, and so forth, or (3) a motion to transfer to an alternate venue. When the original venue is improper, and not merely inconvenient, the defendant can file a motion to dismiss for improper venue. If a plaintiff files a lawsuit in a district of proper venue that is inconvenient for the defendant or the witnesses, and if there is a more convenient federal court where the lawsuit could have been brought, the defendant may file a motion to transfer venue under 28 U.S.C. § 1404(a). When the more convenient forum is abroad, the defendant can file a motion to dismiss for *forum non conveniens*.[15] A defendant should request a transfer of venue in a separate motion filed either at or near the time the defendant files its answer.

6.1.2 *Evaluating the proper venues*

Next, the patent applicant must decide which federal district courts and divisions are most favorable. This decision will likely depend on the average time to resolution, the cost of litigation, and the likelihood of litigation success. Other factors, such as potential for a retaliatory suit, may also need to be taken into account, but they are not within the scope of this article.

Time to resolution is a critically important consideration. Some district courts are known for prompt resolution; others are not. Some are known for being especially fast and are familiarly known as "rocket dockets": the Eastern District of Texas, the Eastern District of Virginia, and others who have adopted specific local patent rules that require expedited disclosures and trial time lines.

Federal Court Management Statistics for 2005[16] reveal that the median time from filing to trial in civil cases during the twelve-month period ending September 30, 2005, was approximately 22.5 months. During this period, an estimated 253,273 civil cases came before federal courts, of which approximately 12,184 were classified as intellectual property cases involving copyrights, patents, and/or trademarks (Table 2).

Rocket dockets may become more common. In September 2006, the U.S. House of Representatives passed a bill to create a pilot program designed to encourage and develop the expertise of district judges in patent cases. Should the bill become law, it would establish a ten-year pilot program in at least five federal district courts and grant US$5 million each year to educate judges and hire additional staff with expertise in patent matters. The five courts will be chosen from the 15 district courts with the largest number of patent cases in the previous year and only those that (1) are authorized to have at least ten district judges and (2) have at least three judges who have requested to hear patent cases. According to a study recently performed by the law firm of Fulbright & Jaworski LLP, if the pilot program were to become law this year, the five participating district courts would likely be chosen from among the following fourteen candidate districts:[17]

- Central District of California
- Southern District of New York
- Northern District of California
- District of New Jersey
- Southern District of California
- District of Massachusetts
- Middle District of Florida
- Eastern District of Michigan
- Southern District of Florida
- Eastern District of Pennsylvania
- Northern District of Georgia
- Northern District of Texas

- Northern District of Illinois
- Southern District of Texas

The cost of litigation (see Table 3) should also be considered by plaintiffs when choosing where to initiate patent litigation. According to a 2005 study of the American Intellectual Property Trial Lawyers Association, the location of patent litigation can greatly influence litigation costs.[18]

Finally, although the likelihood of success is difficult to predict, George Mason University School of Law Professor Kimberly A. Moore says that "choice of forum plays a critical role in the outcome of patent litigation."[19] Ms. Moore conducted an empirical analysis of the ten most frequently selected district courts for patent litigation between 1983 and 1999. She concludes that, overall, patentees won 58% of all patent suits but that the win rate varies by region (Table 4).

6.2 *Filing in the U.S. ITC*

Although federal district courts are the customary venues for patent litigation, plaintiffs can also file a complaint in the U.S. ITC under certain circumstances. Under the Tariff Act of 1930 (19

Table 2: Median Time from Filing to Trial for Civil Cases in 2005 in 20 Districts[20]

District court	Months from filing to trial	Number of IP cases
Eastern District of Virginia	9.4	182
Western District of Wisconsin	11.3	51
District of Maine[21]	13.0	17
Southern District of Texas	15.3	366
Eastern District of Texas	15.9	193
Southern District of Florida	16.7	332
Middle District of Florida	20.0	280
Eastern District of Wisconsin	20.3	76
Central District of California	20.5	1427
Northern District of Texas	20.7	279
Eastern District of Pennsylvania	20.8	1005
Southern District of New York	22.0	876
Eastern District of Michigan	22.0	208
District of Minnesota	23.0	201
District of Delaware	23.5	149
Southern District of California	25.4	162
Northern District of Georgia	27.0	273
Northern District of Illinois	27.0	462
Northern District of California	28.0	467
District of Massachusetts	31.0	221

U.S.C. § 1337), the ITC conducts investigations into allegations of certain unfair practices in import trade, including patent infringement, via the importation of infringing products. In 2003, the ITC initiated 18 patent investigations; in 2004, it initiated 28; and in the first half of 2005, it initiated 21.

Plaintiffs are required to provide more evidence to the ITC than they are to federal courts. In patent cases, for example, the Commission requires the following documents in order to initiate a "Section 1337 investigation": claim charts that purport to show infringement, copies of license agreements pertaining to each asserted patent, copies of certified prosecution histories for each asserted patent, and copies of the technical references cited in the prosecution histories for each asserted patent.[22]

After a complaint is filed with the Commission, the Office of Unfair Import Investigations (OUII) examines the complaint and determines whether or not to initiate a Section 1337 investigation, usually within 30 calendar days of the filing of the complaint. In the event the Commission opts to institute such an investigation, the Commission serves all respondents named in the investigation, as well as the U.S. embassy for the country in which they are located, with a copy of the complaint and a notice of investigation. A notice of investigation is also published in the Federal Register. The OUII only rarely decides not to initiate an investigation.[23]

Table 3: All-Inclusive Cost of Patent Litigation in 2005

Geographic region	Average cost of patent litigation for cases valued from US$1 to US$25 million (in US$)	Average cost of patent litigation for cases valued above US$25 million (in US$)
Boston	2,638,889	4,107,143
New York City	3,667,308	6,190,000
Philadelphia	3,287,500	4,712,500
Washington, DC	3,167,742	6,947,917
Other East	2,468,750	3,076,923
Metro Southeast	3,285,294	9,440,909
Other Southeast	1,662,500	3,342,857
Chicago	2,133,000	4,404,412
Minneapolis-St. Paul	1,567,500	3,688,889
Other Central	1,686,098	3,258,571
Texas	2,847,826	4,993,750
Los Angeles	3,015,000	4,866,667
San Francisco	2,823,529	7,985,714
Other West	2,279,630	5,283,333

Once an investigation is instituted, the Commission assigns an investigative attorney from the OUII to function as an independent litigant representing the public interest in the investigation.

A Section 1337 investigation is conducted in accordance with procedural rules unique to the ITC, although these rules have some similarities with the Federal Rules of Civil Procedure. The Federal Rules of Civil Procedure are the rules by which litigation is conducted before all U.S. District Courts. However, for example, during a Section 1337 Investigation, it is the administrative law judge who issues subpoenas[24] with nationwide jurisdiction. Another important distinction is timing. Typically, a Section 1337 investigation moves quickly, with quick deadlines for discovery responses and briefing (usually ten days, rather than 30 days) and statutory target dates that require completion of the Commission's proceedings "*at the earliest practical time.*" This often occurs within 15 months, depending on the complexity of the case. As a result, parties initiating ITC investigations can reasonably expect a trial within nine or ten months from filing.

A Section 1337 investigation often leads to a formal evidentiary hearing before the presiding administrative law judge. At the conclusion of this hearing, the administrative law judge issues an initial determination that serves as an initial decision of the merits of the case. The initial determination may then be subject to a review by the full Commission of the ITC (if the parties so choose) before it becomes the final determination of the ITC Commission. The initial determination often issues at least three months prior to the 15-month target date for the investigation's completion. At the request of one of the parties for a review of the initial determination, the Commission may review and adopt, modify, or reverse the initial determination or it may decide not to review it at all. If the Commission declines to review the initial determination, it becomes the final determination of the Commission by default.[25]

Table 4: Win Rate Distribution Among Some Prolific District Courts (1983-1999)

District court	Patentee wins (percent of total cases)	Infringer wins (percent of total cases)
Northern District of California	68	32
District of Minnesota	67	33
Central District of California	63	37
Southern District of New York	63	37
Southern District of Florida	63	37
District of New Jersey	61	39
Eastern District of Virginia	58	42
Northern District of Illinois	48	52
District of Delaware	46	54
District of Massachusetts	30	70

Source: The Federal Judiciary[26]

In the event that the Commission determines that Section 1337 has been violated, the commission may issue a *cease-and-desist order,* directing the violating parties to cease their illegal activities, as well as one of two types of *exclusion orders*: general (applying to all infringing articles, regardless of source) or limited (applying to those infringing articles imported by a respondent to the investigation) barring certain products from entry into the United States.[27] The Commission cannot assess monetary damages. The Commission's exclusion orders are enforced by the U.S. Customs Service, although the Commission enforces its own cease-and-desist orders.

The president has 60 days to review Commission orders before they become effective. During this period, infringing articles may enter the United States if the importer posts a bond with the Customs Service for an amount determined by the Commission. Similarly, activities prohibited by a Commission cease-and-desist order may also continue during the Presidential review period if the respondent posts a bond with the Customs Service. Appeals of Commission orders pursuant to Section 1337 investigations are heard by the U.S. Court of Appeals for the Federal Circuit.

There are advantages and disadvantages to using the International Trade Commission as a forum for patent litigation (see Table 5). Perhaps the greatest advantage is that the win rate of plaintiffs in ITC investigations is approximately 70%, as opposed to 58% in federal district courts.

7. CONCLUSIONS

A global patent filing program is an essential component of an integrated system of IP management. It maximizes value and protects the integrity of an organization's patent portfolio. Such a program requires knowledge, organization, and planning. The dynamics of the international patent landscape must be understood (for example, issues relating to establishing foreign priority, where to file patent applications, and the advantages and disadvantages of the various filing options). Organizational efforts will focus on arranging the patent portfolio to achieve strategic global objectives (for example, determining in which countries and/or jurisdictions to seek patent protection according to (in the case of private sector) commercial objectives, or, (in the case of the public sector) humanitarian access objectives. Planning requires foresight. For example, one must anticipate the possibility of litigation and know what the venue options are based on the cost, speed, and likelihood of success in litigation. With such a comprehensive program in place, both public and private sector organizations will be positioned to anticipate, manage, and overcome the uncertainties and challenges that characterize the international technology marketplace in agricultural and health innovations. ■

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1 PTO Press Release (February 14, 2006) titled United States Patent and Trademark Office Issues 7 Millionth Patent.

2 For a current listing of members of the Paris Union: www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2.

3 A patent application filed with the EPO may be submitted in the official language of any EPC member state (including the extension states), but a translation must be submitted in one of the three official EPO languages (English, French, or German) within three months of filing the application and no more than 13 months after the earliest requested priority date. The date of application is the actual filing date. If a request for priority is also filed, that is, the application was initially filed in a foreign jurisdiction, then the "requested priority date" is the priority date that the applicant requests the EPC application be accorded. A patent application filed with the JPO must be written in Japanese, but the specification, claims, drawings, and abstract can be written in English, as long as a Japanese translation of the English documents is filed within two months of the initial filing date. It is possible to file a patent with the U.S. Patent Office in any language, as long as an English translation is submitted within two months.

4 The application for an invention that has not and

will not be patented in foreign countries will not be published if the applicant so requests.

5 A Statutory Invention Registration is authorized by law: 35 U.S.C. § 157. It permits a party to publish an invention, but without all the attributes of a patent, that is, the published invention can be used defensively, as a publication, but not offensively to assert infringement against others.

6 U.S. Patent and Trademark Office. 2006. Calendar Years 1790 to the Present. Table of Annual U.S. Patent Activity Since 1790. www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.pdf.

7 U.S. Patent and Trademark Office. 8 February 2006. Patent Trends Calendar Year 2005.

8 OECD. 2005. Compendium of Patent Statistics. Organisation for Economic Co-Operation and Development: Paris. p. 55.

9 OECD. 2005. Compendium of Patent Statistics. Organisation for Economic Co-Operation and Development: Paris. pp. 55–56.

10 Subject matter jurisdiction (that is, the power of the district court to hear the subject matter of the controversy) is not an issue for patent cases because

Table 5: Advantages and Disadvantages to Initiating ITC Investigations

Advantages	Disadvantages
Broad injunctive remedies exclude importations or order infringing parties to cease and desist from particular activities.	Section 1337 refers only to imported goods; ITC does not award monetary damages. (However, filing a case with the ITC does not prohibit one from filing a parallel case in federal court.)
Investigations are usually completed in 15 months or less, faster than most district courts.	The discovery and motion practice is fast, permitting little time to search for prior art that might invalidate a patent or other evidence to render a patent unenforceable. Responses are often due within 10 calendar days. Furthermore, because in an ITC investigation the OUII is another party, discovery and response briefing are served/filed not only by the opposing party, but also by the OUII.
Broad *(in rem)* jurisdiction means jurisdiction is derived from the imported articles, as opposed to the presence of particular parties or acts in and around Washington, DC. Thus, goods of a downstream importer who is not named in the ITC, and who normally might not be subject to the jurisdiction of the courts (such as a foreign resident), may be excluded.	The domestic industry requirement mandates that the complainant demonstrate that: • there exists a domestic industry protected by the patent right that the plaintiff seeks to enforce • the defendant has performed an unfair act • the defendant's act has a detrimental effect or tendency (above and beyond mere legal infringement).
No counter-claims are permitted.	The plaintiff must provide detailed factual allegations for each element of each claim.
The trier of fact is an administrative law judge with experience in patent lawsuits.	There is no possible recourse to trial by jury.
The administrative law judges are rotated on a regular basis. Thus, assignment of a case to an administrative judge might be predicted.	In recent months, the rotation of judges has become less predictable

federal courts have exclusive jurisdiction over patent issues. See 28 U.S.C. § 1338. However, if the litigation involves other claims, those other claims might be permissible in federal court.

11 28 U.S.C. § 1391(c).

12 See 28 U.S.C. § 1400(b).

13 See Hildebrand v. Steck Mfg. Co., Inc., 279 F.3d 1351, 1354 (Fed. Cir. 2002).

14 Unlike challenges to subject matter jurisdiction, the defense of lack of personal jurisdiction must be raised at the outset of litigation or else the defense is deemed waived. See Fed. R. Civ. P. 12.

15 Quackenbush v. Allstate Ins. Co. (517 U.S. 706, 722 [1996]).

16 www.uscourts.gov/fcmstat/index.html.

17 Anonymous. 2006. Patent Rocket Dockets? House Approves Bill for Pilot Program to Enhance Patent Expertise in Certain Federal District Courts. Fulbright & Jaworski LLP Client Alert (October 2006). www.fulbright.com/images/publications/FulbrightClientAlertPatentRocketDockets1.pdf.

18 American Intellectual Property Lawyers Association. 2005. AIPLA Report of the Economic Survey 2005. pp. 109–10.

19 Moore KA. 2001. Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation? *N.C. L. Rev.* 79: 889.

20 The median time was calculated using the date a case was filed and the date the trial began. In the case of reopened cases that resulted in a second completed trial, the median time was calculated using the original filing date and the date the second trial was completed.

21 Statistics for the District of Maine were not available for 2005. These statistics are for 2004.

22 See Rule 210.12(c–g), 19 C.F.R. § 210.12(c–g).

23 See U.S. International Trade Commission. 2004. Section 1337 Investigation: Answers to Frequently Asked Questions. Publication No. 3708. p. 21.

24 See Rule 210.32, 19 C.F.R. § 1337. Investigation: Answers to Frequently Asked Questions 210.32. The Federal Rules of Civil Procedure limit the scope of any subpoena to command a person within 100 miles where the court sits if the rules of state statute permit issuance of state -wide subpoena.

25 Ibid.

26 See supra note 21 at page 916.

27 The remedy of an exclusion order has become a more powerful tool (and threat) after eBay v. MercExchange (126 S.Ct. 1837 [U.S. 2006]). In the wake of the eBay decision, patent owners can no longer assume that injunctions will issue if infringement is found in a case brought in federal district court.

The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry

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ABSTRACT

All biotechnology and pharmaceutical products must be approved by both the U.S. Patent and Trademark Office (PTO) and the U.S. Food and Drug Administration (FDA). To maximize the impact of a product's market exclusivity, the time spent on getting approval should be minimized. This chapter discusses how the interplay between PTO and FDA applications affect the patent approval process, and by extension the patent term, and how these impact the commercial life of a product.

1. INTRODUCTION

The goals of the public and private sectors of the drug industry are often different. The public sector's main goal is to provide drugs to the public for the lowest possible price, while the private sector is most interested in achieving the greatest possible profit. Many private company tactics are employed for maximizing revenue are important to understand as they can also help the public sector to achieve its goals. For example, price discrimination—the practice of selling health products at different prices to different customers in various markets—is commonly used by private corporations to increase their profit margins. This practice, however, can also be used by nonprofit organizations: if they were to sell their products to developed countries at higher prices—or to license them to manufacturers in developed countries—the organizations would be better able to subsidize drug prices in poorer countries.

There are other ways that companies can maximize their revenue. For instance, companies in the biotechnology and pharmaceutical area must apply for approval from the U.S. Patent and Trademark Office (PTO) and Food and Drug Administration (FDA). Both of these applications are necessary: the PTO approves patents that protect a company's inventions, and FDA approval of a product is necessary before a new product can be marketed. These approval processes are lengthy, and companies should minimize the time spent on the process as part of a profit-maximizing strategy. This chapter outlines various ways to extend a patent's effective life through the strategic management of these approval processes.

2. PTO AND FDA APPROVAL PROCESSES

2.1 *Patent applications*

The PTO grants patents to inventions that are novel, useful, and nonobvious.[1] The *novelty* requirement

Fernandez DS, J Huie and J Hsu. 2007. The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Editors Note: This chapter is included in this Handbook to show the important interface of patents and the regulatory drug approval process and how this interplay affects market entry. It is not intended as an endorsement of effective patent life extensions to delay the market entry of generic drugs.

prevents anyone from patenting an invention that is already available to the public. The *usefulness*, or *utility*, requirement states that one skilled in the art must be able to utilize the invention in a manner that provides immediate benefit to the public. The *obviousness* requirement prevents applicants from patenting products or processes that are insignificant modifications of already existing products or processes.

The inventor of a patented invention has the right to exclude others from making, using, offering for sale, or selling the invention in the United States or in U.S. territories or possessions. A limited 20-year monopoly[2] is granted to the inventor in exchange for public disclosure of the invention.[3] In the United States, the average time between filing of the application and approval of the patent is 3 ½ years, while the average time for a biotechnology patent is nearly 4 ½ years.

2.2 *Discovery phase and preclinical studies*

Simply put, in the discovery phase of research, scientists identify specific chemical or biochemical entities that are worth testing further. Next, preclinical studies are undertaken comprising in vitro studies and animal testing, pharmacodynamic responses, metabolic profiling, cellular receptor interaction, and/or physiology that is generally analogous to humans. Preclinical studies take an average of five years, but the precise length of time depends on the complexity of the study and the success achieved by initial research.

2.3 *FDA approval process*

The FDA approval process usually requires ten to 12 years and US$100 to US$500 million. The process is accomplished in two phases: clinical trials and new drug application (NDA) approval.

The FDA approval process begins when a manufacturer requests permission, by submitting an investigational new drug (IND) application, to begin human testing. The IND application must provide preclinical data of high quality to justify the testing of the drug in humans. Once the IND application is filed, the manufacturer must allow the FDA 30 days to review the prospective study before clinical trials can begin. IND applications must be re-filed annually until clinical testing is completed. Approximately 85% of all drugs for which IND applications are filed are subjected to clinical trials.

The next stage is Phase I clinical trials, which use human subjects. Phase I trials focus on establishing a drug's safety profile and examining how the drug is absorbed, distributed in the body, metabolized, and finally excreted. Phase I trials usually do not use more than 100 healthy volunteers, and the trials last, on average, from one to three years.

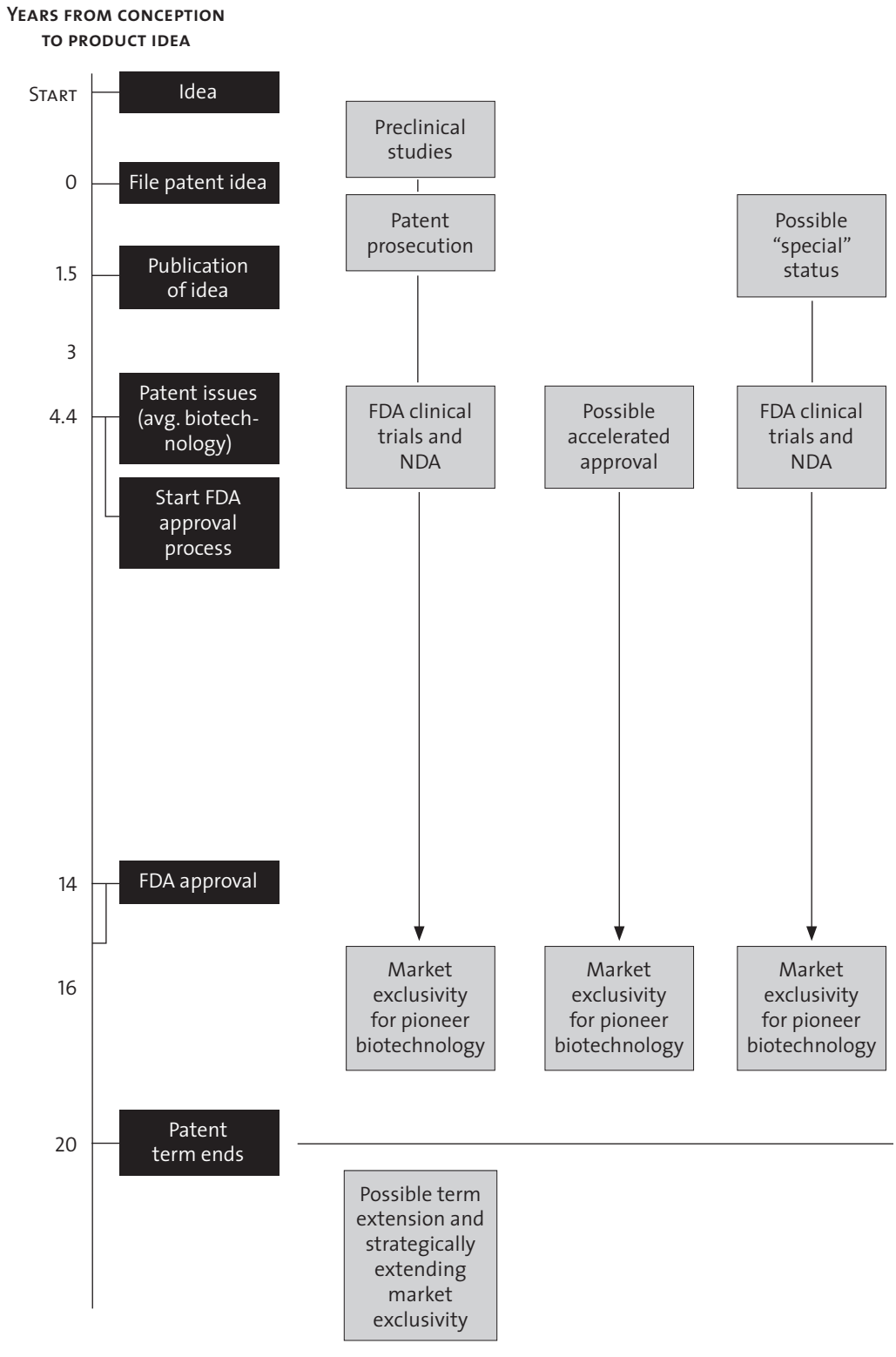
If the drug successfully passes Phase I, it is submitted to Phase II trials, which evaluate dosage, broad efficacy and additional safety. In this phase, volunteers who suffer from the targeted disease are given the drug. Phase II lasts two years, on average.

Phase III trials attempt to verify the effectiveness of the drug with double-blind studies that involve at least 1,000 patients. (A double-blind study is a stringent way of conducting clinical trials whereby subjective bias is eliminated by neither doctors/nurses nor patients knowing whether they administer/receive a placebo or experimental drug.) This phase continues to build the drug's safety profile by monitoring any side effects that result from long-term use of the drug. This phase lasts, on average, between three and four years.

If the drug successfully passes the first three phases of clinical trials, researchers can then file a new drug application (NDA) that includes the drug's proposed labeling. A team of physicians, statisticians, chemists, pharmacologists, and other scientists at the Center for Drug Evaluation and Research review the company's NDA by examining the preclinical and clinical reports and using risk-benefit analysis to determine whether or not the product's beneficial effects outweigh its possible harmful effects. Approval of an NDA can take from two months to several years, but, on average, approval is granted within two years. Once the NDA is approved, the innovating company is allowed to distribute and market the drug.

Once the drug is distributed in the public market, it is considered to be in Phase IV trials. The manufacturer must continue to monitor and

Figure 1: Timeline for Patent/Product Approval and Profit-Maximizing Options



evaluate the drug's safety during routine use (see Figure 1 for a timeline of the above process).

2.4 *Filing PTO and FDA applications*

The "effective life" of a patent is defined as the period of time between a product's introduction to the market and the patent's expiration date. The manufacturer of a product with a long effective life will enjoy extended market exclusivity and thereby recover research and development costs. When the patent expires, the manufacturer will be at a real disadvantage: on average, generic drug companies capture 57.6% of the market for drugs with expired patents. Obviously, the faster the drug is approved and thus comes to market, the longer the marketing period and thus the generation of revenues and profits.

Preclinical studies are the rate-limiting step in the FDA approval process because clinical trials cannot begin until there is sufficient data to justify human testing. Therefore, as many preclinical studies should be performed as early as possible and preferably before a patent application is filed, as the results of such studies also help support claims for the utility of an invention.

There are several reasons why innovating companies should file patents for their products before seeking FDA approval for them. In the first place, the PTO has lower safety standards than the FDA;[4] although a patent application must demonstrate that a drug has a "sufficient probability" of safety in humans, the applicant is not required to provide any clinical evidence of its safety.[5]

Next, patents are important IP (intellectual property) safeguards. If an innovating company were to begin the FDA process before filing a PTO application, another company could patent the invention before them. The innovating company would either have to license the biopharmaceutical from the other company (losing royalties, market exclusivity, and company value in the process) or abandon the FDA process altogether and forfeit millions spent in research and development.[6] Even if another company does not patent the product, the innovating company must be careful not to disclose the invention, otherwise the innovating company would have one year to file the patent before the patent enters the public domain (internationally, the patent application must be filed before disclosure).

There are two other reasons to file patents before beginning an FDA application: (1) FDA approval is accelerated for patented compounds, and (2) patents attract the notice of potential investors who can provide the capital to fund FDA clinical trials. Ideally, preclinical studies should end before, or concurrently with, patent issuance, and FDA clinical trials should begin immediately thereafter. But before clinical trials can begin, the manufacturer must turn over several documents justifying the conduct of the trial, verifying the quality of the data produced, and demonstrating the compliance of the investigator with all regulatory requirements. These documents include: scientific journal publications, in vitro and animal data, trial subject information, financial analysis, and laboratory protocol. The FDA must review and approve these documents before clinical trials can begin. As mentioned above, the filing of the patent should be done first, or the drug manufacturer runs the risk of missing the one-year deadline for establishing priority of invention.

Once the FDA has approved the drug for U.S. consumers, the innovating company will enjoy market exclusivity for the patent's effective life. A strategically written patent will effectively and efficiently protect against product infringement by other companies. The innovating company should take pains to develop brand recognition and build consumer reliance on its products in order to retain the largest possible market share once the patent term ends.

3. EXTENDING A PATENT TERM

Once the patent term ends, the innovating company need not lose its market exclusivity immediately. Various tactics can be used to extend a patent term and delay generic market entry.

Assuming a patent satisfies certain basic criteria,[7] the PTO will grant patent extensions when its approval process takes longer than three years. If, for example, a patent took four years to issue, the patent term may be extended by an additional year.[8]

Two laws also allow for patent terms to be extended: the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) and the Generic Animal Drug and Patent Term Restoration Act of 1988. Title II of the Hatch-Waxman Act (the "patent term restoration" or "extension" clause) gives certain patent holders the opportunity to extend patent terms for human drug products, including antibiotics and biologics, medical devices, food additives, and color additives. The Generic Animal Drug and Patent Term Restoration Act provides a similar opportunity to holders of patents for animal drug products (excluding those derived from recombinant DNA technology). These laws were designed to stimulate innovation by domestic drug companies. Both acts allow a patent term to be extended by up to five years. However, the total effective patent life cannot exceed 14 years from the date of FDA approval.[9]

In order for an innovating company to obtain a patent term extension, certain criteria must be met:

1. The patent has not expired.
2. The patent has not previously been extended.
3. The patent owner or its agent submits the application.
4. The product has been subjected to a regulatory review period with the FDA or the U.S. Department of Agriculture (USDA) before its commercial marketing or use.
5. The permission for commercial marketing or use represents the first permitted commercial marketing or use of the product for which the regulatory review occurred (see below). For products produced using recombinant DNA technology, excluding animal drug products, the product must be the first produced using that technology.
6. The patent restoration application must be submitted within 60 days of the product's initial FDA approval.[10]

The regulatory review period is composed of a testing phase and an approval phase. The testing phase is the period between the effective date of an investigational product exemption (for example, an IND application) and the initial submission of a marketing application (for example, an NDA). The approval phase is the period between the submission and the approval of the marketing application.[11] The PTO calculates the length of the extension by considering both the lengths of the aforementioned testing and approval phases. It is important to note that the PTO does not consider times the applicant did not exercise due diligence[12] during the regulatory review period.

After the innovating company's patent term expires, generic companies may enter the market with generic drug equivalents. Whereas the initial FDA approval process may have taken ten to 12 years, the Hatch-Waxman Act allows generic companies to use the abbreviated new drug approval (ANDA) process to gain approval for generic equivalents within six months. There are three requirements for filing an ANDA application:

1. The company must show that the proposed generic drug is the same as, or bioequivalent to, an FDA-approved drug.
2. The company must certify that a patent protected the approved drug.
3. The company must not use a production method that has been patented by the innovating company (a so-called *production method patent*).

Because of the third stipulation, it is wise to file the drug production method patent a few years after filing the original patent (generally focusing on the composition of the drug). This will ensure that even when the drug composition enters the public domain, the production method will continue to be protected. This strategy is even more effective for biopharmaceuticals than for traditional chemical pharmaceuticals because it is so difficult to create production methods using complex microbiological systems.

Another strategy is known as the *metabolite*[13] *defense* involves filing patents for useful drug metabolites in years subsequent to the filing date of the main patent. Once the generic version of the drug is marketed, the innovating company can bring a patent infringement claim against the

generic company, since the company will inevitably be manufacturing infringing products via its customers' metabolic processes.[14] While the effectiveness in court of the metabolite defense may be debatable,[15] litigation can delay market entry of generics.

Finally, an innovating company can file a citizen petition with the FDA, citing safety concerns regarding a generic biopharmaceutical. Although the majority of citizen petitions are eventually rejected by the FDA or withdrawn by innovating companies, filing such a petition can delay generic market entry for six months or more.

4. ACCELERATING MARKET ENTRY

There are essentially five ways in which companies may accelerate the introduction to market of a new drug:

- *PTO special status:* The PTO awards special status to certain biotechnology inventions, processing them ahead of all others. To qualify for a special status the company must be a small entity (a company with fewer than 50 employees) or a nonprofit organization. The petition must state that the patent applicant's technology will be significantly impaired if a patent examination is delayed.
- *FDA well-characterized status:* The FDA can designate a biopharmaceutical as a well characterized biotechnology product if its identity, purity, potency, and quality can be substantially determined and controlled. As long as the manufacturer is able to produce the same product, the manufacturing technologies of a well-characterized pharmaceutical can be altered without having to repeat clinical trials. If a company develops a well-characterized biotechnology product, it can begin FDA clinical trials immediately and improve the manufacturing process at a later date.
- *FDA expanded access exception:* This exception allows manufacturers to market the product before completing clinical trials (before completing the approval process). Expanded access is available for a very limited number of new drugs that are pending final FDA approval. This program allows drugs to be used and marketed before the FDA approval process is completed. The manufacturer must apply for a drug to be made available through an expanded access program. To acquire such status, the company must provide sufficient evidence that the drug will be effective against a given disease and that the drug has not been linked to unreasonable health risks. The provision is somewhat uncommon because the FDA generally allows expanded access only if there are no other satisfactory treatments available for the given disease.
- *FDA accelerated approval process:* The FDA may accelerate approval of a biopharmaceutical if adequate and well-controlled clinical trials indicate that it will provide considerable therapeutic benefit over existing therapies, particularly in cases of serious or life-threatening diseases.

5. CONCLUSION

The PTO and FDA approval processes are expensive and time-consuming. By the time a drug can be marketed to the public, part of its patent term will have already expired. In order to maximize profits, FDA processing time should be minimized as far as possible. In addition, patent terms can sometimes be extended, and various strategies can be used to prevent generic companies from taking too much of market share. Nonprofit organizations in particular may benefit from the strategies outlined in this chapter, especially if they are used in conjunction with price discrimination. ■

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1 35 U.S.C. § 102; 35 U.S.C. § 103.

2 On December 8, 1994, President Clinton signed the Uruguay Round Agreements Act into U.S. law. The Uruguay Round Agreements Act gives all patents that were in force or filed as of 8 June, 1995 an effective term of 17 years from the date the patent was granted or 20 years from the date of the first filing of the patent application. All patents filed after 8 June, 1995 have a patent expiration date of 20 years from the date of the first filing of the patent application.

3 *Nelson v. Bowler* 626 F.2d 853 Cust. & Pat. App., 1980 (C.C.P.A. 1980), *"Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility."*

4 35 § U.S.C. 102; 35 U.S.C. 103.

5 See *In re Hartop*, 311 F.2d 249 (C.C.P.A. 1962).

6 The Federal Circuit recognized such concerns of pharmaceutical companies in In re Brana, 51 F.3d 1560 (Fed. Cir. 1995): *"FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. . . . Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer."*

7 21 C.F.R. Part 60.

8 35 U.S.C. § 155; 35 U.S.C. § 156.

9 If the patent was issued before 24 September, 1984 and the product's regulatory review period began before that date, then the limit is two years. For animal drug products whose regulatory review periods began before 16 November, 1988 the limit is three years. In all cases, the total patent life for the product cannot exceed 14 years from the product's approval date.

10 The FDA defines product approval as the date the FDA sends a letter notifying the marketing applicant that (1) the FDA approved the marketing application, (2) the product development protocol was completed, or (3) the listing of used food or color additives. The 60-day term begins on the day after approval; the PTO must receive the application for patent extension on the 60th day (or the next business day after the 60th day if this day falls on a weekday or holiday).

11 The FDA has 30 days by law to determine the regulatory review period for a product. After this period, there is a 60-day comment period during which parties can request revisions to the regulatory review period determination. The end of the 60-day comment period marks the end of the regulatory-review period stage.

12 Due diligence is defined as *"that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."* 35 U.S.C. § 156(d)(3).

13 Metabolites are the metabolized derivatives of a drug.

14 In *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 759 (Fed. Cir. 1997), the court *"recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite."* See also *Zenith Labs., Inc. v. Bristol-Meyers Squibb Co.*, 19 F.3d 1418 (Fed. Cir. 1994) (stating that a compound claim could cover a compound formed upon ingestion).

15 In *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), a Federal Circuit panel recognized that patent protection is available for metabolites of known drugs: *"[A] patentee may obtain patent protection for an inherently anticipated compound through proper claiming."*

Deposit of Biological Materials in Support of a U.S. Patent Application

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ABSTRACT

The deposit of biological material in support of a U.S. patent application is a mechanism by which an applicant can cure what might otherwise be potentially fatal defects in a patent application and even an issued patent. A biological deposit can, in some cases, satisfy the requirements of enablement, written description, and best mode, and potentially broaden the scope of claims in the event of litigation. This chapter briefly explores the relationship between biological deposits and patentability requirements, what can be deposited, where and when a deposit can be made, and who has access to the deposit.

1. WHAT DOES A DEPOSIT ACCOMPLISH?

Referencing deposited biological material in the specification of a U.S. patent application provides the advantage of the deposited material being incorporated into that patent's disclosure.[3] As part of the disclosure, the deposited material may be employed to augment or correct deficiencies in the specification of the application, specifically, as to enablement, written description, and best mode requirements.

1.1 Deposit and the enablement requirement

While not always required, a deposit of biological material is one way to satisfy the *enablement requirement* of 35 U.S.C. § 112. The specification of a patent must enable a person *skilled in the art* to make and use the invention claimed, aided only by his or her ordinary skill and the state of the art.[4] The enablement requirement is typically accomplished through a written description of the invention within the specification. But inventions not easily or reasonably described by the written word alone may be "*described in surrogate form by a deposit that is incorporated by reference into the specification.*"[5] By providing access to biological material that is difficult to describe, an applicant enables the public to make and use the claimed invention.

A deposit of biological material also can reduce the amount of disclosure required in the application to enable the claimed invention. For example, in *In Ex parte C*, by describing the parental varieties and the selection process in conjunction with a seed deposit, applicants successfully enabled a novel variety of soybean plant, seeds from the plant, and a method of producing seeds by self-pollination.[6] Notably, the Board of Patent Appeals and Interferences (BPAI) did not require an exacting description of breeding, selection, and testing since the invention, a disease-resistant soybean plant, was placed in deposit.

A deposit of biological material may enable more than just the species so deposited. For example, in *Ajinomoto v. Archer-Daniels-Midland*, the Federal Circuit held that a method for producing an amino acid from a genetically engineered bacterium was enabled, despite the fact that only one altered strain of bacteria that produced threonine

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was disclosed and deposited.[7] However, the BPAI was not quite so generous in several previous cases. For example, in *Ex parte Hata*, the BPAI affirmed the rejection of claims directed to treatment of infectious disease by administering specific strains of *Lactobacillus* on the grounds that the select strains deposited were narrower than the broader class of all strains and that undue experimentation would be required to locate new microorganisms covered by the claim.[8]

1.2 *Deposit and the written description requirement*

While not always required, a deposit of biological material is one way of satisfying the written description requirement of 35 U.S.C. § 112. This requirement is met if the specification describes the claimed invention in sufficient detail, such that one skilled in the art would reasonably conclude that the applicant was in *possession* of the claimed invention at the time of filing. This can be achieved by describing the invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[9] Put simply, the specification must describe the invention such that it is distinguishable.

Until 2002, it was somewhat uncertain whether a deposit of a biological sample could satisfy the written description requirement. But in that year, the Federal Circuit, in *Enzo v. Gen-Probe*, held that deposit of a biological sample in a public repository could fulfill the requirement.[10] The specification of the Enzo patent provided a functional description (hybridization characteristics) and referenced a biological deposit, but disclosed no sequences or structural descriptions of any of the claimed nucleic acids. Thus, under *Enzo*, a reference to a deposit coupled with a functional description meets the written description requirement so long as a known correlation exists between the described function and a deposited or described structure. The generic scope of claims supported would be that which a person of skill would deem the patentee to possess based upon the disclosure, which includes information obtainable from the deposits.[11]

The information obtainable from deposits in support of a patent can potentially broaden interpretation of the claims. For example, in *Schering v. Amgen*, the patent owner could have used deposited biological material to show that the claims to leukocyte interferon encompassed the subtype IFN-alpha14, despite that the specification disclosed only two other subtypes.[12] In *Schering*, the patent owner provided evidence that the deposit coded for IFN-alpha14, but only to the appellate court and not to the trial court. The court held that, although a deposit could satisfy the enablement requirement, the deposit must be part of the record before it is used to provide support for a particular claim construction. Because the patent owners in *Schering* presented the evidence too late, the deposit could not influence claim construction. However, the lesson remains that deposited biological material incorporated into the disclosure may be used to support a claim interpretation more broadly than that explicitly disclosed in the specification.

1.3 *Deposit and the best mode requirement*

A deposit of biological material may also satisfy the *best mode requirement* under 35 U.S.C. § 112, ¶ 1,[13] but a deposit is not strictly necessary.[14] The best mode of carrying out an invention must be disclosed in sufficient detail at the time of filing the application to allow one of ordinary skill to practice it. To satisfy the best mode requirement, there must be no concealment of a mode of practice known by the inventor at the time of filing to be better than that disclosed.[15]

In *Amgen v. Chugai Pharmaceutical*, the defendants argued that, in the field of living materials, a biological deposit should be required so that the public has access to exactly what the patent applicant contemplates as the best mode.[16] The Federal Circuit held that a deposit was not necessary where the best mode of preparing a cell line necessary to practice the invention was disclosed and enabled in the specification.[17]

Similarly, in *Scripps v. Genetech*, where a patent specification described the process for producing, screening, and evaluating monoclonal antibodies, the Federal Circuit held that applicants had not concealed the best mode for

practicing the invention of protein purification using antibodies, despite not having deposited successfully isolated antibodies.[18] In *Scripps*, the court specifically rejected the argument that the "*laborious nature of the process of screening the monoclonal antibodies*" required deposit of the antibodies representing the best mode.

2. WHAT CAN BE DEPOSITED?

Biological material eligible for deposit are those materials capable of direct or indirect self-replication.[19] Representative examples include bacteria, fungi, yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. Furthermore, the deposit rules provide that viruses, vectors, cell organelles, and other nonliving material existing in, and reproducible from, a living cell may be deposited by means of a deposit of the host cell capable of reproducing the nonliving material.

Generally, for each deposit, the specification of the patent must contain the accession number for the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination, and the name and address of the depository.[20]

3. IS A DEPOSIT REQUIRED?

The biological deposit "requirement" is not a requirement per se. Rather, the deposit rules provide a mechanism by which an applicant can overcome what would otherwise be a deficiency in the patent application. It is important to note that a biological deposit may be referenced in a specification even when not required. Moreover, referencing a biological deposit in the specification does not give rise to a presumption that the deposit was necessary under 35 U.S.C. § 112.

A biological deposit may be necessary where biological material is required to practice an invention and "*words alone cannot sufficiently describe how to make and use the invention in a reproducible manner.*"[21] For example, a deposit could be required where an invention cannot be practiced without access to an organism only obtainable from nature.[22] In the words of the Federal Circuit:

> *When an invention relates to new biological material, the material may not be reproducible even when detailed procedures and complete taxonomic description are included in the specification. It is then a condition of the patent grant that physical samples of such materials be deposited and made available to the public, under procedures established by the [U.S. Patent and Trademark Office] and international treaty.*[23]

Even so, if "*words alone cannot sufficiently describe*" the invention such that a biological deposit would normally be required, such a deposit would still not be necessary if the biological material necessary to the invention is (1) known and readily available to the public or (2) derived from readily available starting materials through routine screening that does not require undue experimentation.[24]

3.1 *Known and readily available*

Biological material need not be deposited unless access to the material is required under 35 U.S.C. § 112 and the material is not otherwise known *and* not readily available to the public. Indications that biological material is known and available include:

- commercial availability
- references to biological material in printed publications
- declarations of accessibility by those working in the field
- evidence of predictable isolation techniques
- an existing deposit

Thus a patentee may forgo a deposit in favor of assuming an obligation to make the necessary biological material publicly available.

While the U.S. Patent and Trademark Office (PTO) will accept a showing of current availability, the patentee takes the risk that the biological material will cease to be known and readily available.[25] The rules do not provide for post-issuance original deposits. But the PTO will accept a replacement deposit when a patent owner has diligently provided the replacement deposit after receiving notification that the depository can no

longer furnish samples of the original deposit, or that the deposit has become contaminated or lost its capability to function.[26] Failure to diligently make a replacement deposit will preclude grant of a certificate of correction.[27] A replacement deposit subsequently made will not be recognized by the PTO, and a request for a certificate of correction, even if made promptly thereafter, will not be granted.[28] Furthermore, the failure to make a replacement deposit where a deposit is considered to be necessary to satisfy the requirements of 35 U.S.C. § 112, will cause a patent involved in a reissue or reexamination proceeding to be treated by the PTO as if no deposit had been made.[29]

As such, unavailability of biological material necessary to practice the invention is a defect that cannot be cured after the grant of a patent and can result in unenforceability. This risk is reflected in advice from the PTO:

[Where] an applicant for patent has any doubt as to whether access to a biological material specifically identified in the specification is necessary to satisfy 35 U.S.C. § 112 or whether such a material, while currently freely available, may become unavailable in the future, the applicant would be well-advised to make a deposit thereof before any patent issues.[30]

3.2 *Derived without undue experimentation*

If only starting materials are readily available, the specification must provide sufficient guidance on making or isolating the biological material necessary to the invention without undue experimentation, or else a deposit of the material will be required.[31] Undue experimentation is decided under a standard of reasonableness; it is not merely a quantitative determination. Generally, there is no undue experimentation where time-consuming experiments are merely routine, such as a reliable screening test performed on a large number of samples.[32]

4. WHEN CAN BIOLOGICAL MATERIAL BE DEPOSITED?

Under current U.S. patent laws and practice, biological material may be deposited at any time prior to the issue of the patent the deposit supports. This includes deposits made during the pendency of the application. But deposit after application can seriously compromise international rights.

In the United States, biological material specifically identified in the patent application may be deposited during the pendency of the application (*i.e.*, before issuance of the application as a patent).[33] A reference to a deposit in the specification provides a basis for making a deposit after the filing date of the application. The applicant must merely provide a corroborating statement that the deposited biological material is that specifically identified in the application as filed. If the requirements are met, the post-filing addition to the application of a deposit date and accession number at an independent depository will not be considered new matter prohibited by 35 U.S.C. § 132.[34]

As such, a U.S. patent applicant could privately deposit a biological sample on or before the patent application date, identify the deposited material in the disclosure, and then later transfer the sample to a recognized public depository and add the depository data at any time prior to the issuance of the patent. Such a private deposit may be in the inventor's own laboratory or in the laboratory of a colleague, so long as the PTO has access to the samples during pendency and the samples are transferred to a public depository before the patent issues.

For example, in *In re Lundak*, the inventor deposited a biological sample necessary to his invention in the laboratory of a colleague.[35] After filing a patent application that identified the privately held sample, the inventor transferred the sample to the American Type Culture Collection (ATCC) and amended his application with the accession number and deposit date. The Federal Circuit held that for the purposes of 35 U.S.C. § 112, it was "*not material whether a [biological] sample … resided in the [inventor's] hands or the hands of an independent depository as of filing date.*" [36]

As another example, in *In re Argoudelis*, Argoudelis deposited biological material with a depository prior to filing the patent application but restricted access to the deposit during the pendency to persons authorized by the patent

applicant.[37] The court found the deposit met the requirements of 35 U.S.C. § 112 despite the restriction on public access, because access would be unrestricted after patent issuance.[38] Similarly, in *Feldman v. Aunstrup*, Aunstrup deposited biological samples at a recognized depository in the Netherlands before his filing date, but restricted deposit availability to his designees.[39] These restrictions were removed before the patent issued. The court found the deposit sufficient because the PTO could access the deposit through Aunstrup during application pendency, and the public was assured access upon issuance.[40]

To the contrary, many foreign jurisdictions require a deposit to be made before the filing date of the priority application to obtain foreign priority rights. For example, an applicant who deposits biological material after filing a U.S. provisional application but before filing a PCT application will be unable to benefit from the U.S. provisional application priority date to the extent it is dependent on the deposit. As such, to fully preserve foreign rights, an applicant should make any deposit of biological samples before the priority application is filed.[41]

Examples of jurisdictions that require deposits to be made before the filing date of the priority application include Australia, Canada, China, and the European countries that are members of the European Patent Organization (as established by the European Patent Convention). While certain of these jurisdictions provide means of correcting for a late deposit, such remedies often require that (1) the failure to deposit be the result of an error in judgment or an omission that led to the failure to deposit (such error not being the failure to deposit itself and not including intentional delay, for example, for strategic or financial reasons) or (2) the applicant be able to declare that, although a deposit was not made, the biological sample was nevertheless available to the public on the filing date of the application. Because the successful use of such remedies is not a foregone conclusion, it is highly encouraged that any deposit be made prior to the filing of an application that may be called to serve as a priority document for an international application.

Again, while a post-filing, pre-issuance deposit is sufficient for the purposes of a U.S. patent application, this approach may not fully preserve foreign patent rights.

5. WHERE IS BIOLOGICAL MATERIAL DEPOSITED?

A U.S. applicant may deposit biological materials in any of the 35 International Depositary Authorities (IDA) recognized by the World Intellectual Property Organization (WIPO) under the Budapest Treaty.[42] Signatory countries (64, as of 2006),[43] including the United States, are required to recognize a biological deposit made in any depository institution approved by WIPO, no matter the location. Under the Budapest Treaty, storage time is required to be at least 30 years, and after the applicant has made the deposit, it cannot be reclaimed. Furthermore, the depository has a duty of secrecy concerning the fact of a deposit and the nature of the deposited material.

Only two of the 37 IDAs recognized by WIPO are in the United States—the American Type Culture Collection (ATCC) in Manassas, Virginia, and the Agricultural Research Service Culture Collection (NRRL, acronym based on former name) in Peoria, Illinois. But as of 1999, these two U.S. depositories held 51.6% (or 20,461 deposits) of the world's total patent-related biological deposits.[44] As an example of applicable fees, the ATCC charges US$2,500 for a patent-related deposit. This fee includes viability testing, a deposit certificate, 30 years of storage, release of samples according to deposit rules, quarterly informing report of distribution of released materials, and regulatory compliance reviews.[45]

A recent report from the U.S. Government Accounting Office (GAO) compiled empirical data regarding the deposit practice in the United States.[46] The GAO reported that about 0.6% of U.S. patents (308 out of 52,841) granted during the final three months of 1999 were supported by biological deposits in the two IDAs in the United States. Of these, only 53 patents (about 0.1%) were supported by biological deposits of seeds. The ATCC, one of only four IDAs accepting seed

deposits, estimated that less than 8% of its total deposits were for seeds.

An applicant should also maintain his or her own samples of the biological material during the term of deposit. As discussed above, unavailability of biological material necessary to practicing the invention is a defect that cannot be cured after the grant of a patent and can result in unenforceability. The applicant's practice of maintaining his or her own samples for the duration of the patent protects against any circumstances wherein samples would no longer be available from the depository.

6. WHO IS ENTITLED TO SAMPLES OF DEPOSITED BIOLOGICAL MATERIAL?

During pendency of an application, a deposit incorporated into a patent application specification need not be available to the public, but must be available to the PTO.[47]

After issuance of a patent, deposited biological material that is incorporated into the specification by accession number must be freely available to the public.[48] That is to say, all restrictions on availability of the deposit to the public must be irrevocably removed upon granting of the patent, unless the request is not made according to proper procedures. As a small measure of protection, a depositor can contract with the depository to require that samples of a deposited biological material will only be furnished if the request is in a dated writing that contains the name and address of the requesting party and the accession number of the deposit, and the depositor is notified in writing of such a request.[49]

The deposit of biological material in a recognized depository is not a grant of a license, either express or implied, to infringe the patent. Furthermore, the release of deposited material from the depository to others does not grant them a license, either express or implied, to infringe the patent. The ATCC, for example, provides a standard disclaimer in its catalogs, reference guides, and to recipients of cultures: "*This material is cited in a United States and/or other Patent and may not be used to infringe the patent claims.*" [50] Regardless, a depositor should supplement this disclaimer with a letter tailored to each notification of request for samples, making it clear there is no implied or express license covering the biological materials received from the depository.

The number of samples estimated to have been released worldwide to legally entitled parties in 1999 was estimated at 7,400. In that year, the ATCC released about 7,000 samples, or 95% of the worldwide total. In comparison, NRRL (the other recognized U.S. depository) released 123 samples, European IDAs released 190 samples, and a Japanese IDA released 63 samples.

In its recent report to Congress, the GAO was unable to identify a single documented case in which a person or organization had gained access to a biological deposit and then used it to infringe the underlying patent.[51] This lack of findings was based on court cases, representatives from the biotechnology industry, and officials from PTO, ATCC, NRRL, and WIPO.

7. CONCLUSION

The rules governing biological deposits in support of a patent application provide a means of curing potentially fatal patent defects, as well as flexibility in the preparation of the application. As discussed above, a biological deposit can in some cases satisfy the requirements of enablement, written description, and best mode, and potentially broaden the scope of claims in the event of litigation. A deposit will usually be necessary only when words fail to explain how to make and use the invention, but an applicant may reference a deposit even when not required. While a deposit can be made at any time during pendency of a U.S. application, those seeking foreign rights are advised to deposit before the filing of any priority application. A U.S. applicant can deposit in any of the 35 IDAs recognized by WIPO, with two of these in the United States The public will have free access to biological materials deposited in support of an issued patent, but the patent owner is somewhat protected by receiving information regarding who receives such deposits. ■

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1 The views expressed in this article are those of the authors alone, and should not otherwise be attributed to the firm or its clients. The author's law practice is concentrated in biotechnology, biochemical, and pharmaceutical patent preparation and prosecution, as well as validity/invalidity and infringement opinions and counseling related to patentability and freedom to operate.

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3 *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992).

4 35 U.S.C. § 112, ¶ 1.

5 *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1326 (Fed. Cir. 2002); See *In re Wands*, 858 F.2d 731; 8 USPQ2d 1400, 1403 (Fed. Cir. 1998).

6 27 USPQ2d 1492 (BPAI 1993).

7 228 F.3d 1338 (BPAI 1987), 56 USPQ2d 1332 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1957 (2001).

8 6 USPQ2d 1652 (BPAI 1987). See *Ex parte Jackson*, 217 USPQ 804 (BPAI 1982); *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) (limiting enablement of generic claims covering bacterial vaccine of hybrid *S. typhi* bacterial species to the extent of deposited species where there were no working examples outside of deposited species and unpredictability in the hyperconjugation procedure used to produce the strains).

9 MPEP § 2163 (2003) (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997)).

10 See *supra* note 5, at 1325.

11 See *supra* note 5, at 1327.

12 222 F.3d 1347, 55 USPQ2d 1650 (Fed. Cir. 2000).

13 *Wands*, 858 F.2d, at 736.

14 *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991).

15 *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987).

16 *Amgen*, 927 F.2d 1200.

17 See *supra* note 16.

18 *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

19 37 C.F.R. § 1.801.

20 37 C.F.R. § 1.809(d).

21 MPEP § 2402.

22 See *Amgen*, 927 F.2d, at 1211.

23 *Ajinomoto*, 228 F.3d, at 1345, 56 USPQ2d at 1337–1338.

24 *Wands*, 858 F.2d, at 735–736.

25 Compare *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969).

26 37 C.F.R. § 1.805(a). During a PTO proceeding (such as, for example, the prosecution of a patent application, the reissue or reexamination of a patent, or an interferences proceeding), the PTO will not recognize a replacement deposit by the patent owner if the depository could still provide samples of the original deposit. MPEP § 2407.06.

27 MPEP § 2411.04. A replacement deposit made in connection with a reissue or reexamination shall not be accepted unless a certificate of correction is requested. MPEP § 2407.02.

28 MPEP § 2411.04.

29 MPEP § 2407.03.

30 MPEP § 2411.04.

31 See 37 C.F.R. § 1.802; *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 7 USPQ2d 1191 (Fed. Cir. 1988); *Amgen*, 927 F.2d, at 1211; *Wands*, 858 F.2d, at 735.

32 Compare *Jackson*, 217 USPQ 804 (isolation procedure required undue experimentation so deposit was required) *with Hata*, 6 USPQ2d 1652 (biological materials obtainable through routine experimentation and a reliable screening test did not require deposit).

33 37 C.F.R. 1.804; MPEP § 2406.

34 *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985).

35 See *supra* note 36.

36 *Lundak*, 227 USPQ, at 93–94.

37 434 F.2d 1390, 168 USPQ 99 (CCPA 1970).

38 *Id.,* at 1393 ("It is not necessary that the general public have access to the culture prior to the issuance of the patent").

39 517 F.2d 1351, 186 USPQ 108 (CCPA 1975).

40 See *supra* note 39, at 1355.

41 See MPEP § 2406.03.

42 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, 32 U.S.T. 1241 (April 28, 1977) www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html. A listing of the IDAs as of May 17, 2006 www.wipo.int/treaties/en/registration/budapest/pdf/idalist.pdf.

43 WIPO, Budapest Treaty Contracting Parties, Status as of May 17, 2006 www.wipo.int/treaties/en/documents/pdf/budapest.pdf.

44 U.S. General Accounting Office, Report to Congressional Committees GAO-01-49, *Intellectual Property: Deposits of Biological Materials in Support of Certain Patent Applications*, at 9 (Oct. 2000) www.gao.gov/new.items/d0149.pdf.

45 ATCC. 2004. *Patent Depository Expanded Services and Fee Changes for 2004* www.atcc.org/Services/PatentFees.cfm.

46 See *supra* note 44, at 9.

47 *Lundak*, 227 USPQ at 93–94.

48 37 C.F.R. § 1.808 (a)(2).

49 37 C.F.R. § 1.808.

50 ATCC. 2004. *Use of Patent Cultures*, www.atcc.org/Services/PatentMore.cfm.

51 See *supra* note 44.

Protecting New Plant Varieties through PVP: Practical Suggestions from a Plant Breeder for Plant Breeders

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ABSTRACT

A plant variety protection (PVP) certificate preserves a plant variety owner's exclusive rights to sell, reproduce, import, and export a plant variety and its seed. In addition, a PVP certificate prevents others from claiming PVP or utility patent rights. This chapter walks the reader through the process of applying for a PVP certificate and describes other ways to prevent the unauthorized use or sale of protected plant varieties.

1. INTRODUCTION

A plant variety protection (PVP) certificate preserves a plant variety owner's exclusive rights to sell, reproduce, import, and export the plant variety and its seed; In addition, a PVP certificate can also prevent others from claiming PVP or utility patent rights. The duration of a PVP certificate is 20 years (25 years for a tree or vine). A PVP certificate can, when combined with licensing, develop future funds for a breeding program. It also can preserve the financial and other interests of participants in a program, who may have provided upfront funds.

To be eligible for PVP, a variety must be:

- new and distinct from other varieties (novel)
- genetically uniform
- stable through successive generations

This chapter discusses the rules governing the U.S. PVP application procedure, which is administered by the U.S. Department of Agriculture (USDA).[1] The U.S. PVP Act is very similar to the provisions developed by the Convention of the International Union for the Protection of New Plant Varieties (UPOV), which have been, or are being, adopted in many nations around the world. Of course, anyone considering applying for a PVP certificate must thoroughly familiarize him- or herself with local laws and application procedures.

The U.S. PVP Office (PVPO) considers a variety to be new, and therefore eligible for PVP certification, only if propagating or harvested material of the variety has not been sold, or otherwise disposed of to other persons, for the purpose of exploiting the variety for more than one year, in the United States, or four years outside of the United States.

2. THE COUNTDOWN TO PVP CERTIFICATION

The breeder should be the person to complete the PVP certificate application because only he or she will possess the required information and be able to answer follow-up questions from the examiners. It is important to maintain good breeding records, because they are invaluable in case of an infringement challenge.

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2.1 *Two years in advance*

Obtain from the U.S. PVPO the instructions for application as well as the proper (species-specific) Exhibit C form (see Section 3.4 below for more details). Start conducting any tests that will be required to fill out Exhibit C (such as those for disease and pest resistance); such tests may take one or two years to complete.

2.2 *One year in advance*

Verify that the crop variety is worth protecting and that the potential returns on the sale of the crop justify the expense of the PVP certificate. The plant breeder should consult with his or her seed project leader (if he or she works for a national research center or a university) or his or her supervisor or sales manager (if he or she works in the private sector). The decision of whether or not to apply for a PVP certificate and subsequent commercialization must be driven by objective analysis, not emotion. It is easy to form an emotional attachment to a project that has required a great deal of time, effort, or money. Seek advice and suggestions from seed growers, advisory committees, company sales representatives, and, most critically, the farmers who will ultimately be growing the crops.

The following questions are important to consider:

- Is it likely that royalties or other returns on the variety will repay the cost of PVP certificate application?
- Does the variety have sufficient advantages over standard varieties? Is it likely to attract the interest of seed companies, seed growers, and (most importantly) farmers?
- How large are the new variety's seed volumes likely to become?
- How broad will the variety's geographical area of adaptation be?
- How large will the variety's potential market be?
- Do any seed companies or seed growers have a particular interest in the variety?

Depending on the answers to these questions, you will want to consider whether the variety is appropriate for general release (that is, release to all interested companies or growers) or exclusive/limited release (that is, to one or a limited group of companies and/or growers). PVP is most useful when the release is exclusive.

If there were several contributors to the breeding project, you would need to decide whether or not to pursue an application for a joint PVP certificate with them. Consider the following questions:

- What entities (companies, associations, and so on) contributed to the development of the new variety?
- Do these entities wish to seek a license for the new variety?
- Will these entities help to cover the application costs for a PVP certificate and certification?
- Do these entities have first refusal rights for licensing?

3. PREPARING THE PVP CERTIFICATE APPLICATION

The U.S. PVPO provides detailed instructions for how to fill out and submit application forms for PVP certification. All documents can be accessed online.[2]

3.1 *General application requirements and procedure*

A PVP application consists of:

1) A completed and signed Form S&T-470 (Application for Plant Variety Protection Certificate). The applicant must provide his or her name, address, and representative, and the variety's genus, species, and variety name (a temporary variety name will suffice until the PVP certificate is issued). The proposed variety name or experimental number must be cleared with the Seed Regulatory and Testing Branch of the USDA.[3]
2) the following "exhibits," all of which will be discussed in detail in the following sections:

- Exhibit A: Breeding History, consisting of the variety's genealogy, the methods used to develop the variety, a statement of the level of variability in any variety characteristics, a

statement of genetic stability, and the type and frequency of variants
- Exhibit B: Statement of Distinctness Guidelines, stating how the variety may be distinguished from all other varieties in the same crop
- Exhibit C: Objective Description of Variety, a crop-specific form
- Exhibit D: Optional Supporting Information
- Exhibit E: Statement of the Basis of Ownership, stating who owns the variety and verifying that the applicant is eligible to file for PVP in the United States
- Exhibit F: Declaration Regarding Deposit, stating that the applicant will submit a certain amount of propagation material to a seed depository

Included with the forms must be a check drawn on a U.S. bank (as of 6 October 2006, the fee for filing and examination was US$4,382), payable to "Treasury of the United States." Since fees are subject to change periodically, always check current schedules at the U.S. PVPO Web site.[4] Issue fees will also be charged when the certificate is issued.

The U.S. PVPO office maintains databases of known varieties of most U.S. crops (including those originating in the United States and in some foreign countries). The PVP examiner will compare the information given in the application with the database for that crop. The examiner may request additional data if he or she finds one or more varieties in the database with essentially similar descriptions (which often happens). Please note that if all other traits seem similar to another variety, then DNA profiling may be useful, at the discretion of the PVP examiner.

Remember, that the U.S. PVPO does not conduct actual field/greenhouse evaluation (so-called growing out) or other tests on varieties that are described in PVP applications. The applicant must provide all data. Diligence in this regard will be well worth the effort.

3.2 *Exhibit A: Breeding History*

3.2.1 *Parentage and breeding methods*

Exhibit A describes a number of different aspects of the variety's breeding history. First, it describes the pedigree of the new variety, including both the parents used in each cross and the source and pedigree of each parent. The PVP office specifies that:

Obtaining intellectual property rights requires disclosure. As part of this disclosure the applicant is to provide the public with information about his/her invention in exchange for protection of the variety. For Plant Variety Protection, this includes a full disclosure of the parentage and breeding methodology in the Exhibit A, Origin and Breeding History. This information would specify the plant material the applicant started from, i.e., the parentage. All material in the parentage must be traceable back to varieties, lines, or clones, etc. that are publicly known or a matter of common knowledge.[5]

Exhibit A also describes the breeding methods used in creating the new variety, including any specific selection criteria that were used. Keep it simple to avoid confusing the examiner. There is no need to say *why* certain selections were carried out, merely *what* was accomplished and *when* it took place.

3.2.2 *Uniformity and stability*

This statement declares that the variety has been observed to be uniform and stable for all characteristics over a certain number of generations. The words "uniform" and "stable" must be used in the statement.

The statement specifies the number of cycles of seed reproduction through which the variety has remained unchanged for all distinguishing characteristics. It is likely that stability dates from when you initiated increase of the line that became this variety. Remember that variation is acceptable, as long as it is predictable and the variants are describable and commercially acceptable. Many modern varieties include a low level of one or more variants.

A *variant* is a predictable phenotype that differs in one or more ways from the main phenotype of the variety. The applicant must identify the variant as typical of the variety and provide data on the percentage and frequency distribu-

tion of variant plants. It is permissible to have more than one variant, so long as each one is accounted for. However, the total frequency of all variants in the population cannot exceed 5%; a variety that is composed of more than 5% variants will be deemed a *mixture* (and thus not eligible for PVP).

An *off-type* is a phenotype that is not specified as an expected variant. If you find that you cannot remove a certain phenotype from your variety, consider describing it as a variant. If you do not describe it as a variant, the variant will be considered an off-type by certification inspectors or seed analysts.

3.3 *Exhibit B: Statement of Distinctness*

In order to demonstrate distinctiveness, the variety must be shown to be distinct in one or more traits from either:

(1) the variety that is most similar to it
(2) several similar varieties
(3) all other varieties of the species

When measuring quantitative traits, describe your statistical design and provide statistical references such as F values, least significant differences (LSD's), standard deviations (SD's), range, or other references, that may indicate the degree of variability in the tests; this provides an indication of just how distinct the variety really is, that is, if it can be distinguished from similar varieties. Include data taken from at least two locations (preferably from two different states) or over two years, but *do not pool data* across years or locations. The more data, the better. Sources of data may include trials at state agricultural colleges, cooperative tests performed by breeders in several states, or industry tests. However, be aware that the PVP office also has access to results from most of these tests and will likely use these to evaluate the distinctiveness of your variety. For many crops, the PVP office requests that several standard varieties be included in comparative tests against the variety submitted in the PVP application in order to provide a point of reference to evaluate distinctness.

The U.S. PVP application instructions indicate that:

- Differences in quantitative characters such as plant size, seed size, and maturity, that are not obvious and detectable without a direct comparison, must be supported by evidence provided by the applicant. The evidence must be given as numerical data obtained from at least two trials.
- Distinction based on differences in color needs to be referenced with a standard such as the Royal Horticultural Society Colour Chart or the Munsell Book of Color, unless dramatic (i.e., red versus green). Color chart measurements must be conducted in two or more localities or growing seasons.[6]

It is sometimes helpful to submit photos to demonstrate color differences.

Distinctions in disease reaction between the new variety and other varieties must be supported with data or results from at least two trials conducted in two or more localities or growing seasons, unless the distinction is dramatic (for example, other varieties are highly susceptible to disease, while the new variety is disease-resistant). Remember to include the following: the disease reaction to the causal agent or organism; the causal agent or source of the disease (if it has been demonstrated or identified); and the race, strain, or pathotype of the disease, where appropriate.

It is important to note that yield is not accepted by the PVP office as a basis for distinctness because it is not a sufficiently stable trait. Yields depend largely on environmental factors.

3.4 *Exhibit C: Objective Description of Variety*

As in Exhibit B, numerical data must be provided to support certain elements of the variety description: performance characteristics, pest resistance, quality, or other traits. Data should be gathered in at least two locations or over two years. Describe the statistical methods used, plus coefficient of variance (CV), SD, LSD, range, or other estimates of test variability.

3.4.1 *Essentially derived varieties*

An *essentially derived variety* is usually developed when one or a few genes or traits are added to a preexisting variety, resulting in a phenotypic change or changes. The change may be cosmetic (for example, a change in flower color) or economic (for example, the addition of a value-added, genetically engineered trait, such as an insect-resistance gene, into an existing variety).

The U.S. PVPO will approve an essentially derived variety if it shows one or more distinguishing characteristics *and* if the original variety has a PVP certificate issued after 1994. The U.S. PVPO will not protect an essentially derived variety if the original variety was not protected, or was protected only with pre-1994 criteria. PVP protection may not protect the owner of the variety from infringement liability if the original variety's germplasm comprises the majority of the essentially derived variety. For that reason, it is sensible to make arrangements to compensate the owner of the original variety for the use of the germplasm. At the time of this writing, there was no absolute rule regarding which varieties are essentially derived and which are not, though seed committees and organizations are working to develop criteria. Disagreements must be worked out between variety owners, or if this is not successful, by the courts.

3.5 *Exhibit D: Optional Supporting Information*

Exhibit D is required for wheat (milling and baking quality must be described), but it is optional for other crops. This exhibit describes quality factors of the crop and/or offers other information pertaining to variety uniqueness that is not included in the other exhibits.

3.6 *Exhibit E: Statement of Ownership*

Exhibit E is a statement of who developed the variety, who owns it, and who or what entity, if any, has rights to it. A single paragraph will suffice.

3.7 *Exhibit F: Declaration Regarding Deposit*

In Exhibit F, the applicant declares that he or she has included with the application a "voucher sample" of at least 3,000 untreated, viable seeds capable of propagating the application variety (minimum germination rate 85%). In the case of vegetative and clonal crops, the applicant declares that he or she will deposit a viable cell culture in a public depository, where it will be maintained for the duration of the certificate.

The U.S. PVPO may use a small subsample of the submitted seed (no more than 25 seeds) in the process of examining the application. The rest of the seed sample will be deposited by the U.S. PVPO in the National Seed Depository Laboratory (NSDL) at Fort Collins, Colorado. The NSDL keeps PVP seeds separate from their normal collections and only the applicant and the U.S. PVPO will have access to the seed for the duration of the certificate. These deposited seeds will be used in case of an identity challenge. The NSDL will return any remaining seed to the applicant after the PVP certificate has expired or is no longer in force.

4. OTHER CONSIDERATIONS

4.1 *Critical dates to keep in mind*

1. *Date of first sale*. You must apply for a PVP certificate within one year after the date of the first commercial sale of seed or planting stock of your variety. (Sales of experimental seed for further testing only are exempt.) You have four years from the date of the first commercial sale (six years for a tree or vine) to apply for a PVP certificate for foreign varieties. Keep evidence of the date of first sale in the form of an invoice or receipt.
2. *Date application is received in the U.S. PVPO*. The date the original application was received is considered to be the date of application, though requests for additional information may take months or years to satisfy. The variety can be sold while a PVP certificate is being sought for it.

4.2 *When to apply*

Apply for PVP certificate as soon as you decide to protect the variety and can assemble the necessary information (which should be before the date of

first sale). The amount of time it takes to get a PVP certificate application approved is highly variable. It depends on the current workload at the U.S. PVPO and can be lengthened by requests for additional information. Figure on at least a year or possibly two years.

4.3 *After filing*

Be prepared to respond to questions and requests from the PVP examiner; few applications are accepted as originally submitted. Some of these questions may be answerable with existing data; for others, more data may need to be collected.

5. FURTHER PROTECTION FOR PLANT VARIETIES

Although a PVP certificate gives you or your agent the sole right to sell the plant variety in question and protects the variety name from infringement, it is sensible to take additional precautions:

- Control all breeder seed that you or your organization grow, harvest, and maintain.
- Control all foundation seed production by producing it only within your organization or granting tight licenses or contracts to trusted seed producers.
- Control who gets foundation seed, through licenses or sales, with tight contracts.

5.1 *Enforce protection*

Stay alert for unauthorized sales of your PVP seed: such things as advertisements in local newspapers are giveaways of illegal activity. Tell any individuals, companies, or other organizations that sell or distribute your variety to be alert to illegal sales and to notify you immediately if they detect them.

It is important to realize that the unauthorized seller may very well not realize that the variety is protected. Notify the offender that he or she is selling a PVP-protected variety. A warning is often sufficient to stop the problem. If the offender persists in making illegal sales, threaten to cut him or her off from future releases. Sue only as a last resort, and consider whether a court battle is worth the cost in money and public relations.

5.2 *Bag-tag warning*

Before the PVP certificate is awarded, label all seed containers of the variety as follows:

> *Unauthorized Propagation Prohibited*
> *U.S. Variety Protection PVPA 1994*
> *Applied For*

After the PVP certificate is awarded, label seed containers as follows:

> *U.S. Protected Variety PVPA 1994*
> *Unauthorized Sales for Reproductive Purposes Prohibited*

5.3 *Brown-bag sales*

Under the *farmer exemption*, farmers are permitted to grow and save enough seed of a PVP variety to plant their own acreage.[7] If they decide not to plant the seed, they are allowed to sell it. However, some farmers produce and sell large volumes of seed, far more than they would be able to plant on their own farms. In the United States, this practice is unfortunately common in the Midwest and South, particularly with soybeans, cotton, and peanuts. Because the illegal seed is often sold in unmarked brown bags, this practice is popularly called "brown bagging." A recent Supreme Court decision that upholds the rights of PVP certificate owners may discourage, but will not stop, brown-bag sales.

Title V of the U.S. Federal Seed Act makes it unlawful to sell uncertified seed of a PVP variety by the variety name. Many state seed laws include similar provisos. On page one of the PVP application, you can state your intention to also apply for Title V protection. Of course, brown bagging can still occur even if Title V is in force. In such cases, you will need to seek help from the appropriate state, federal, or state seed-law enforcement agency. Seed-law enforcers can issue orders that prohibit offenders from further action, and may

issue a stop-sales order or fines to a persistent offender.

6. CONCLUSION

Assembling and submitting a PVP application for your variety can be either a nearly unbearable aggravation or a very easy task. It all depends on how organized, diligent, and proactive you are. The key elements are to plan well ahead, keep careful records, know what you need to do, know when you need to do it, and know what the PVP offices needs (not less and not more) to process your application. From a practical standpoint, this means keeping good breeding records, being familiar with the PVP Web site, knowing what the forms and exhibit schedules are, and keeping track of time. If you are organized, the application process will likely go smoothly. And remember, after your PVP certificate is issued, be diligent and watch for infringers. PVP can provide your variety, and your breeding program or business, with a foundation for realizing returns on your investments, which can then be used to develop the next round of improved varieties from your breeding program, for which you will then seek PVP. ■

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1 Pursuant to the PVP Act of 1970, 7 U.S.C. § 2321–2583.

2 www.ams.usda.gov/science/pvpo/apply.htm.

3 They may be contacted at: U.S. Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Programs, Seed Regulatory and Testing Branch, 801 Summit Crossing, Place, Suite C, Gastonia, North Carolina, 28054-2193 (Phone: 704-810-8870). www.ams.usda.gov/lsg/seed.htm.

4 See *supra* note 2.

5 www.ams.usda.gov/science/PVPO/Forms/GuidelinesA.htm.

6 www.ams.usda.gov/Science/PVPO/Forms/GuidelinesB.htm.

7 McCarthy JT, RE Schechter and DJ Franklyn. 2004. *McCarthy's Desk Encyclopedia of Intellectual Property, Third Edition*. The Bureau of National Affairs, Inc.: Washington, DC.

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