A Brief History of the Canadian Patent System

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and the
Patenting of Higher Life Forms

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A BRIEF HISTORY OF THE CANADIAN PATENT SYSTEM

EXECUTIVE SUMMARY

PURPOSE OF PATENTS

Governments provide patent rights to promote economic growth by promoting innovation and the advancement of scientific and technical knowledge. By granting rights, governments aim to create a business climate that will encourage research and development and attract trade and investment. Statutory patent rights serve as an incentive to invent, and patentees use these rights to prevent others from practicing their inventions.

WHAT IS A PATENT

In order to obtain a patent, applicants must submit a formal application to the Patent Office. The application, which contains both a description of the invention and claims that define the scope of protection being sought, is examined by technically qualified patent examiners in order to ensure compliance with the *Patent Act*. To be patentable, the claimed invention must be new, non-obvious, and useful, and must be directed toward subject matter that is patentable under the Act. A refusal of the application by the Commissioner of Patents can be appealed to the Federal Court of Canada.

RIGHTS AND ENFORCEMENT

Patent rights allow a patentee to exclude other from making using or selling the claimed invention without the patentee’s permission, during the term of the patent. A patentee can enforce these rights by suing an infringer for monetary compensation.

Early Patent Systems

Before Confederation, the four existing provinces in what is now Canada had already enacted their own patent legislation. Patents were granted only to residents, and patentees were obligated by statute to manufacture patented inventions locally, and importation of patented products was prohibited. The early patent systems were designed to encourage the establishment of local industry, even to the extent of granting patents to residents who imported technology invented abroad by others.

At Confederation, authority for patents was assigned to the federal Government under the then *British North America Act, 1867*, and Canada's first federal *Patent Act* came into force in 1869.

International Influence

Many of the provisions in the first federal *Patent Act*, as well as in the earlier provincial Acts, were modeled on the first *United States Patent Act* of 1790. In particular, Canada

adopted the first-to-invent principle used by the United States whereby a patent is granted to the inventor with the earliest invention date in cases where two or more inventors claim the same invention. Subsequent amendments were influenced by practise in both Great Britain and United States, while more recent amendments have been influenced by the European Patent Convention (EPC).

In the second half of the 19th Century, an international debate on the value of patents existed between pro- and anti-patent forces. However, near the end of the Century, international discussions had reached a sufficiently strong consensus to conclude the first patent treaty in 1883, the *Paris Convention for the Protection of Industrial Property*. Two key provisions of the Treaty were national treatment that obligated member states not to discriminate against foreigners, and recognition by member states of foreign patent application filing dates, known as convention priority rights. A Secretariat originally formed to administer the *Paris Convention* was absorbed in 1970 by the creation of the *World Intellectual Property Organization (WIPO)*, which shortly thereafter became one of the specialized agencies of the United Nations.

Canada first harmonized its patent legislation with international practice in 1923, two years before joining the *Paris Convention.* Over the past ten years, Canada has joined four patent-related treaties concerning: the classification of patents; the international recognition of microorganism deposits; international norms for the protection of new plant varieties; and, an international procedure that facilitates the obtaining of patent protection in more than 100 member countries, namely the *Patent Cooperation Treaty (PCT).*

Compulsory Licensing for Foods and Medicine

The 1923 Canadian *Patent Act* introduced the first compulsory licensing scheme for patented foods and medicines. It provided for the granting, virtually as a right, of licenses to manufacture patented foods and medicines in Canada, without having to prove abuse of the rights under a patent.

In the 1960s, several government studies were conducted to address the high costs of consumer drugs. Based on recommendations contained in the studies, the compulsory licensing provisions of the *Patent Act* were amended in 1969 to allow licenses to be issued for the importation of patented medicines. This had the desired effect of increasing competition in Canada's pharmaceutical manufacturing industry, and helped to establish the generic drug manufacturers sector.

In the 1980s, the Government sought to increase pharmaceutical research and development in Canada by improving protection for patented medicines. The compulsory licensing regime was amended in 1987 by Bill C-22 to significantly increase patent protection for medicines. At the same time, the Patented

Medicine Prices Review Board (PMPRB) was established, with a mandate to monitor consumer drug prices, and authority to impose sanctions against undue price increases. In 1993, a second amendment completely eliminated the compulsory licensing scheme for patented foods and medicines, a scheme that had existed in Canada for some seventy years. The amendment also strengthened the remedial powers of the PMPRB.

General Patent Procedure

Over a period of some 20 years, three major patent studies were initiated by the Government to determine how best to amend the patent system to enhance its effectiveness in encouraging industrial growth. The *Royal Commission on Patents, Copyright and Industrial Design* was appointed in 1954, followed in 1966 by the *Economic Council of Canada Study*, and in 1976 a comprehensive *Working Paper on Patent Law Revision* was published. Even though there was common ground in the recommendations of the three reports, particularly in regard to amendments to the general procedure for obtaining and maintaining a patent, no legislative action was taken at the time.

An opportunity to amend the general patenting provisions of the *Patent Act* arose during the drafting of the above-mentioned Bill C-22, and a number of procedural amendments were included in the Bill. These amendments brought in a series of fundamental changes to the general procedure for obtaining and maintaining a patent in Canada, including the adoption of a European-style first-to-file patent system, thereby severing a century old similarity with the first-to-invent principle, which is still in use in the United States.

Trade-Related Agreements

The conclusion of three trade-related agreements in less than ten years caused a series of changes to Canada's intellectual property laws. Although the *Free Trade Agreement (FTA)* with the United States did not result in any changes to the *Patent Act*, the *North American Free Trade Agreement (NAFTA)* and the *World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS)* introduced several significant international obligations. Under the Agreements, patents had to be made available for all fields of technology, and patent rights could not be restricted based on the place of invention or whether a patented product was imported or manufactured locally. A dispute resolution procedure was put in place that allows member states to challenge domestic laws for non-compliance with the agreements.

Patentability of Life Forms

Patents on microorganisms have been allowed in Canada since 1982, when a decision by the Commissioner of Patents granted a patent for a yeast culture. Protection has not been available

for plants and animals other than the protection provided for new plant varieties under the 1990 *Plant Breeders' Rights Act*.

However, a 2000 Federal Court of Appeal decision, gave a broad interpretation to the *Patent Act* definition of invention and ruled that it included genetically-modified, non-human mammals. This overturned a decision by the Commissioner of Patents, affirmed by the Federal Court Trial Division, refusing claims to a genetically-engineered mouse. The Government has sought leave to appeal the decision to the Supreme Court of Canada. Both the European and United States Patent Offices, as well as patent offices in other industrialized countries, have granted a patent to what has become known as the "Harvard mouse".

The European Patent Office (EPO) decision to grant a patent on the Harvard mouse was not without controversy as more than 300 organizations protested the decision on ethical and environmental grounds. In reaching its decision, the EPO concluded that the patent was not contrary to the public order and morality provisions of the *EPC*.

The National Biotechnology Advisory Committee's 1998 Report entitled, *Leading in the Next Millennium*, contains five recommendations on patent changes that should be made to enhance Canada's competitiveness by bringing the patent system in line with its major trading partners. Most of the patent recommendations have been either partially implemented or are under consideration.

CANADIAN PATENT OFFICE ADMINISTRATION

The Canadian Patent Office was established by statute in 1906. It currently forms part of the Canadian Intellectual Property Office (CIPO), which is responsible for the administration of intellectual property laws on patents, trade-marks, copyright, industrial designs, and integrated circuit topography.

In order to enhance the effectiveness and use of the patent system, the Patent Office has implemented a number of measures to modernize its operations and improve service to the public including: a proactive information initiative to disseminate patent information and promote the use of the patent system in Canada's regions; a major ten- year project to automate the internal operations of the Office and to make patent information available online from Industry Canada's Strategis Web site, at a cost of $76 million; and, obtaining approval to become a self-funding, Special Operating Agency, which provides CIPO with increased flexibilities in administrative and financial matters.

ROLE OF THE COURTS

Patents are presumed valid when granted but their validity can

be challenged in court, and the onus is generally on the party attacking the validity to prove otherwise. Patentees can use either the Federal Court of Canada or provincial courts to enforce their patent rights.

Conclusion

From a broad perspective, the basic steps of obtaining a patent have changed very little over the past century, and the statutory definition of invention and the patentability criteria of novelty, non-obviousness and utility are virtually the same as they were some 100 years ago. Legislative provisions have, however, evolved from early government policies that favoured residents over foreigners and focused on the establishment of local manufacturing, to today's policies that tend to emphasize international trade and investment.

Efforts continue, under the aegis of WIPO, to obtain international agreement on substantive patent matters. The conclusion of the 1970 Patent Cooperation Treaty was a success, but the Treaty is largely procedural in nature. With the notable exception of the 1973 EPC and the subsequent establishment of the European Patent Office, harmonization of substantive matters has otherwise been elusive.

Acceptance of significant international norms was, however, more quickly accomplished under the recently concluded trade agreements namely the *North American Free Trade Agreement (NAFTA)* and *TRIPS*. The *TRIPS* dispute settlement procedure has already been used to challenge Canadian patent legislation. Complaints have been filed by the United States and the European Community against Canadian implementation of its obligations under *TRIPS*, and the WTO has ruled that Canada has not lived up to its obligations.

Historically, the concept of what subject matters can be patented has expanded as new technologies are invented. The patentability of biotechnology inventions has attracted global attention. But, ethical and environmental concerns are being debated and as a result discussion on patentability, normally limited to the patent community, have taken on a new dimension and have moved to other sectors of society.

A BRIEF HISTORY OF THE CANADIAN PATENT SYSTEM

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A BRIEF HISTORY OF THE CANADIAN PATENT SYSTEM

1. INTRODUCTION

The practice of granting patents for inventions dates back to ancient times, but patents were not granted based on legislation until the Middle Ages.[1] While originally patents were granted as forms of privilege, favour or royal patronage, it is generally believed that patents based on legislation were granted by governments to promote their national interests. However, some have argued that the notion of patent rights is not solely derived from a legislated right, but also from an inherent right of creators and inventors, and that statutes do not create these rights as much as develop and limit them.[2] The former view, that patents are granted to promote national interests, is generally accepted in Canada and many other countries.

The first patent allowed in what is now Canada was granted in 1791 under an ordinance from the Governor and Legislative Council of Quebec, but the first patent legislation was not enacted until some thirty years later by both Lower and Upper Canada.[3]

Canada is a large net importer of technology, and patent policies adopted by the Canadian government over the years must therefore be read in context of Canada's patent ownership profile. More than 90 percent of Canadian patents are owned by foreigners, with roughly half owned by United States patentees. Even in the early years of the 20th Century, some 80 percent of patents belonged to foreigners.[4] The challenge for the Canadian government has been to devise ways to encourage invention and innovation in Canada via the patent system while recognizing the fact that patent ownership rests mainly in the hands of foreign patentees.

The paper has been prepared at the request of the Canadian Biotechnology Advisory Committee (CBAC) to provide a historical perspective on Canada's patent system, and to provide background information for the Committee's deliberations on the patentability of biotechnology inventions. The paper traces the development of the Canadian patent system in the 20th Century. It is not, however, intended to provide a comprehensive review, but only highlights significant events and issues, with greater emphasis on the latter half of the century. Recent events that are relevant to the patenting of higher life forms are noted. Where relevant, the paper will follow the development of Canada's patent system in four main areas, namely: (1) first inventorship, (2) what can be patented, (3) procedure for obtaining a patent, and (4) patent rights and enforcement.

Patent terminology, as is the case with most specialized disciplines, is replete with technical and legal jargon whose meanings are not commonly understood. As far as possible, the paper strives to limit the use of technical words so as to make

it more readable by the non-patent community.

2. PURPOSE OF PATENTS

Starting with the earliest patent legislation, nations have used the patent system to improve their economies by encouraging specific kinds of behaviour by the business community.

Patents can be viewed from several points of view. First, from a government's point of view since it develops and implements policies on the granting of patent rights. Second, from a patentee's and owner's point of view since they are the direct beneficiaries of the rights.

From a government's perspective, the patent system is a key tool for encouraging economic growth by promoting innovation and the advancement of scientific and technical knowledge. Its policy initiatives aim to create a business climate that encourages research and development, the commercialization of new technologies, and the promotion of trade and investment.

From a patentee's perspective, the rights act as a strong incentive to invent and also provide certain market advantages. By being able to prevent others from practising the invention patentees gain a head start in the market place, as well as the financial advantages of a sole supplier.

In addition, a patent can be viewed as a contract or bargain between the inventor on the one hand and the government representing the interests of the public on the other. This theory, which is commonly held view in Canada, was developed in England as far back as the 1800s.[5] For its part, the government agrees to provide an exclusive right, and in return, inventors agree to publicly and fully disclose technical information concerning their inventions.

Also, patent rights have been characterized by some as a monopoly, albeit limited in length and nature. Because of the economic costs and benefits traditionally associated with monopolies, patent legislation strives to obtain a fair balance between at times competing interests from various sectors of the business community. For example, patentees, inventors, the research and development sector, and potential users of patented technology do not always agree on the kind of patent policies that should be implemented. The Government's goal is to provide an appropriate level of protection so as to fairly balance the interests of the various groups.

Inventors are a critical component of the patent system, since they are the creators of patented technologies. However, the great majority of patents are granted not to inventors but to their employers who normally own the patent rights to their

employees' inventions.

Instead of applying for patent protection, owners of proprietary technology can alternatively opt to keep their technology confidential and rely on trade secret law and confidentially agreements for protection. This approach is generally more effective with respect to technologies related to processes, rather than products or articles, since the latter are more difficult to keep secret as they normally become available to the public. Trade secrets differ from patents in an important manner in that trade secret technologies are not publicly disclosed.

An important advantage to trade secret protection is that the period of protection is unlimited, and lasts for as long as the technology stays secret, or until another person, independently, or through permissible reverse-engineering, acquires or publicizes it. Furthermore, protection is not limited to patentable inventions, and is therefore applicable to a broader range of technologies.

3. WHAT IS A PATENT

Patents belong to the field of intellectual property, which mainly includes copyright, trade-marks, and industrial designs. In addition, patents also belong to the narrower field known as industrial property, which includes the above, except for copyright.

Unlike, for example, copyright, where protection is automatic upon the creation of a work, an inventor must request a patent by filing a formal patent application with the Patent Office. The technological content accompanying an application, called a specification, consists of two parts: (a) a disclosure including drawings, where applicable, that describes the invention, and (b) claims that define the scope of protection sought for the invention. In the disclosure, the applicant must provide a clear and complete description of the invention such that it will allow others to construct and use the invention once the patent has expired. Basic information on Canadian patents is found in a Guide published by the Canadian Intellectual Property Office (CIPO).[6]

First Inventorship

Two basic approaches are used to decide the question of first inventorship in cases where two or more independent inventors file an application for the same invention. Under the first-to-invent principle used by the United States, and formerly used by Canada, the patent is granted to the inventor with the earliest invention date. Under the first-to-file principle used by virtually every country except the United States, and recently adopted by Canada, a patent is granted to the inventor

with the earliest filing date.

What Can Be Patented

The globally accepted criteria for an invention to be patentable are that it must be new, non-obvious, and useful. The definition of invention, which has remained virtually unchanged since Confederation, is found in Section 2 of the *Patent Act*[7] as follows:

> "any new and useful art, process, machine, manufacture or composition of matter, or any useful improvement in any art, process, machine, manufacture or composition of matter".

The non-obvious requirement, which has only recently been added to the Act, is found in a later section of the *Act*. Prior to this addition, Canadian courts considered the non-obvious requirement as implicit in the word “invention”, even though it was not directly expressed in the Act. To be patentable, an invention must not be obvious to a person skilled in the art or technology to which the invention pertains.

A patentable technology must be new in that it was not made public before the patent application was filed. In Canada, inventors have a one-year period of grace during which they may publicly disclose the invention and still obtain a valid patent, but this grace period does not necessarily apply in other countries.

Not all subject matter is patentable under the Act. Two statutory exceptions from patentability are scientific principles and abstract theorems. Also, new technologies do not always clearly fall within the above definition, and the Commissioner of Patents and the courts must decide their patentability by interpreting the terms of the definition. Recent examples where the patentability question has been under consideration include computer programs, higher life forms, methods of medical treatment, and methods of doing business using computer or Internet technology.

Procedure for Obtaining a Patent

Patent applications are examined by technically qualified patent examiners for statutory compliance, particularly the patentability criteria of novelty, non-obviousness and usefulness. To decide the novelty and obviousness issues, examiners conduct a search of existing patents and other published documents, known as the “prior art”, and review any prior art cited by other patent offices against corresponding foreign applications. If all statutory requirements are satisfied, the patent is granted. In the event that an application is rejected by an examiner for non-compliance, the applicant can request a review by the Commissioner of Patents.

The review is conducted by the Patent Appeal Board, which is composed of senior examiners who prepare a reasoned recommendation to the Commissioner. If the examiner's rejection is upheld by the Commissioner, the Commissioner's refusal to grant a patent can be appealed to the Federal Court of Canada.

Under Canada's deferred examination system, patent applications are not automatically examined upon filing. To initiate examination, an applicant must formally request examination within five years from the filing date, otherwise the application becomes abandoned. The five-year period allows applicants time to assess the commercial value of their inventions and to decide whether or not to continue with the patent process.

In Canada, it normally takes between two to three years from the filing of the request for examination to the issuance of a patent. Even though Canadian applications are made public 18 months after their filing date, the invention claimed in a pending application that has been made public cannot be freely used by others during its pendency, since once a patent is granted, the patentee can sue for payment of reasonable compensation. Making patent applications public makes knowledge of the technology described in the application publicly available at an early date, i.e., before the grant of the patent.

Canadian Patent Agents

A patent specification must be clearly and correctly worded in order to withstand careful scrutiny by Patent Office examiners and, if necessary, by the courts. In particular, the claims of an application, which define the scope of protection of inventions, must be precisely drafted to ensure that the scope is not so broad as to jeopardize their validity or so narrow as to inadequately protect the invention. In addition, filing and prosecuting an application before the Patent Office requires a good knowledge of patent law and Patent Office practice. For these reasons, most inventors hire registered patent agents to prepare, file and prosecute their applications before the Patent Office. Virtually all registered agents are members of the Intellectual Property Institute of Canada(IPIC), formerly known as the Patent and Trade Mark Institute of Canada(PTIC), an organization of intellectual property professionals. The history of the patent profession and of the Institute, established in 1926, is well documented in its 1985 publication.[8]

Rights and Enforcement

A Canadian patent gives the patentee the statutory right to exclude others from making, using or selling the invention for a term of twenty years from the filing date of the application.

In the event that someone practices a patented invention in Canada without the patentee's permission, i.e., infringes the patent, the patentee can sue the infringer for monetary compensation in the appropriate court.

Patent rights are not absolute and are subject to legislative restrictions that have varied over time. In Canada, the most controversial of these has been the compulsory licencing of patents. When patentees voluntarily license others to practice their patented inventions, the terms and conditions of the licence, including the payment of royalties, are negotiated and decided between the patentee and the licensee. Compulsory licences, on the other hand, are granted under the Act to third parties by the Commissioner of Patents who determines the terms and conditions of the licence and sets the royalty. Patentees have argued that the royalties set by the Commissioner are lower than what could privately be negotiated.

Compulsory licences have also been authorized for the domestic manufacture of patented inventions in the event of abuse of the rights under a patent. The most common abuse alleged by persons applying for a licence has been a failure by the patentee to work the patented invention in Canada on a commercial scale. In addition, compulsory licences have been available, virtually as a matter of right, for the local manufacture or importation of patented foods or medicines. Protection for inventions relating to foods or medicines was further limited in that patent claims were restricted to the process by which an invention was made, such that a food or medicine could not be claimed *per se,* independent of the process. As discussed below, the compulsory licencing provisions and claiming restrictions for foods and medicines have now been deleted, and the conditions under which the infrequently used abuse-based compulsory licencing provisions are permitted have been restricted.

Other restrictions have included provisions: (a) that allow governments to use patented inventions, (b) for the handling of applications relating to nuclear energy and military weapons or equipment, and (c) that allow manufacturers of generic medicines to stockpile or to seek regulatory market approval for patented medicines, prior to the expiry of a relevant patent. As mentioned below, the government use provisions have recently been amended, and the stockpiling feature is under revision.

4. UNITED STATES AND EUROPEAN INFLUENCE

Historically, Canadian patent practice has been largely influenced by developments in Great Britain and the United States. It is therefore useful to briefly note the early beginnings of the patent system in those jurisdictions.

Two milestones that are most frequently used to mark the beginning of law-based patent systems are the provisions enacted in Venice in 1474, and the passing of the Statute of Monopolies in England in 1624. The sovereign's power to grant monopolies was substantially limited by the statute. It has been called the Magna Carta of the rights of inventors, since it outlawed monopolies in general, but spared patent monopolies granted to the first and true inventor of any manner of new manufacture.[9] Great Britain first codified its patent provisions in the *Patent Act* of 1852.[10]

United States

Shortly after the passing of the United States Constitution, the U.S. Congress enacted its first Patent Act in 1790 which implemented the following wording in the 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".[11] The United States Patent Office and the position of Commissioner of Patents was established by the 1836 Act, which also introduced examination of patent applications and authority to refuse the grant of a patent.

Europe

Efforts to unify patent practice among European countries and create a single European patent date back to the beginning of the 20th Century when several proposals were put forward. Moreover, an initiative to establish a single British Empire patent was also discussed. However, none of the proposals were adopted.

The signing of the Treaty of Rome in 1957, which created the European Economic Community, spurred discussions among European countries on the creation of a single European patent system and a single Patent Office. The discussions, which included countries that were not members of the Community, led to the conclusion of the *European Patent Convention (EPC)* in 1973 and the subsequent establishment of the European Patent Office (EPO) in 1978.[12] Neither the EPC nor the EPO are part of the formal European Community (EU) structure, and consequently membership is not limited to EU states.

The European patent law created by the Convention exists side-by-side with the national patent systems of member states. By filing a single application with the EPO, a bundle of European patents can be obtained, one patent for each country in which protection is sought. However, even though the EPO allows the patents, they come into effect and are issued as national patents by each of the twenty member states, and any patent disputes are litigated before the respective national courts. Discussions are once again under way in Europe to establish a

single European Community patent that would be effective throughout the EU.[13] In November 2000, the European Patent Organization held a Diplomatic Conference to revise the 1973 EPC. The Conference dealt with a large number of reforms at the substantive, institutional and procedural level, including reducing patenting costs and setting up a European central court system for the enforcement of European patents.

The pre-confederation provincial Patent Acts in what is now Canada, as well as the ensuing federal Acts, were largely modeled on United States legislation, and were based on the first-to-invent principle. However, compulsory licencing provisions based on abuse of the rights under a patent, and for patented foods or medicines, were largely derived from British practice.[14] Some of the more recent amendments to the Canadian *Patent Act* have been inspired by European practice, rather than that of the United States.

5. THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

Increased trade in the middle of the 19th Century led patentees to seek protection for their technologies abroad. Despite differences of opinion that existed at the time on the value of patents, a degree of international consensus was reached near the end of the century when the first international treaty on patents, the 1883 *Paris Convention for the Protection of Industrial Property*, was concluded.[15] It included two key provisions: recognition of foreign patent application filing dates, known as convention priority, and national treatment under which member states were obliged to provide the same protection for foreigners as for their nationals.[16] The Treaty, which Canada joined in 1925, has since been amended several times and currently has a membership of some 160 states.[17]

In 1970, the secretariat responsible for the administration of the Paris Convention was replaced by the *World Intellectual Property Organization* (WIPO). Its broad objectives are to promote the protection of intellectual property and to ensure administrative cooperation among its member states. WIPO became one of the specialized agencies of the United Nations in 1974, and thus undertook the added responsibility of promoting creativity in and facilitating the transfer of technology to developing countries.[18]

Since its inception WIPO has worked towards the global harmonization of patent practice. While efforts to obtain agreement on substantive changes to the Paris Convention have not been successful, treaties on an international patent classification system, the international deposit of microorganisms, and an international procedure to facilitate the obtaining of patents in a number of countries have been

concluded. Canada became a member of WIPO in 1970, and is a member of the above treaties, as well as the International Convention for the Protection of New Varieties of Plants (UPOV) (the acronym UPOV stems from the French title: Union Internationale pour la Protection des Obtentions Végétales).[19] The Convention is not a WIPO Treaty, but is administered by the WIPO secretariat. Basic information on these treaties is provided in Table 1.

In June 2000, WIPO concluded a Patent Law Treaty (PLT) to harmonize formality requirements for the filing of patent applications and the maintenance of patents.[20] It is expected that the Treaty will come into force within the next several years. Initial work towards the harmonization of substantial patent issues is also planned.

6. THE CANADIAN PATENT ACT: HISTORICAL HIGHLIGHTS

While this paper is primarily concerned with events during the 20th Century, it is useful to briefly note the early legislative activities in what is now Canada. Prior to Confederation, several of the provinces had already enacted their own patent legislation. Early legislation favoured local residents and did not allow foreigners to obtain patents. Laws were designed to encourage the establishment of local industry, and patents could even be obtained by importing foreign technology without actually having invented it.[21]

At Confederation, the federal Government was assigned exclusive legislative authority by section 91(22) of the then *British North America Act, 1867,* [22] for "Patents of Invention and Discovery".[23] The first federal Patent Act came into effect in 1869 and before the end of the nineteenth century foreigners had become eligible to obtain patents. As well, statutory authority was enacted to allow patent examiners to be hired to conduct a thorough and reliable examination of patent applications.[24] Table 2. highlights some of the legislative patent activities from 1824 to the end of the 19th Century.

At the beginning of the 20th Century, several amendments were enacted including a provision making applications secret during their pendency. The first major revision of the 20th Century occurred in 1923 when measures were passed to allow Canada to join the Paris Convention. The 1923 amendments provided priority rights for corresponding foreign applications, introduced restrictive claiming provisions for foods or medicines, and provided compulsory licensing, virtually as a right, for the local manufacture of foods or medicines.[25]

The 1935 *Patent Act* lowered the term of a patent from eighteen to seventeen years. In 1947 the Act was amended to protect the rights of inventors who were unable to meet statutory time

limits during World War II, and to provide a procedure for the handling of applications relating to national defence and atomic energy. When Newfoundland entered Confederation in 1949, the Act was further amended to extend its provisions to the new province.[26] Table 3 highlights some of the legislative changes to the *Patent Act* from 1900 to the 1950s.

From the 1950s to the end of the century, the *Patent Act* was amended numerous times to: (a) implement recommendations in a Government Study, (b) comply with international obligations arising from trade-related agreements, and (c) improve the administration of the Act via technical and non-controversial amendments. Amendments with respect to parts (a) and (b) are discussed below under headings 7 and 8 respectively. In regard to part (c), the 1992 *Miscellaneous Statute Law Amendment Act* made editorial changes to the *Patent Act*, and the 1993 *Intellectual Property Law Improvement Act* added the previously judicially applied non-obviousness criterion to the statute, and allowed a deposit of biological material, referred to in the disclosure of a patent application, to be considered part of the application. Table 4 highlights some of the legislative changes to the *Patent Act* from 1960 to 1999.

7. GOVERNMENT PATENT STUDIES

For almost thirty years, starting in the late 1950s, the benefits and costs of having a patent system came under frequent scrutiny as the Government examined the patent system with a view to enhancing its contribution to the Canadian economy. Several studies were conducted to determine how best to promote Canada's technological development and strengthen its international competitiveness. The effects of the patent system were reviewed to determine a fair balance between the benefits that accrue from the incentives provided by a patent system and the economic costs arising from the grant of exclusive rights.

Royal Commission on Patents, Copyright and Industrial Design
The first of these studies produced a 1959 Report by the *Royal Commission on Patents, Copyright and Industrial Design*, chaired by Justice J.L. Ilsley[27]. With respect to patents, the Commission's mandate was, *inter alia*, to determine if the existing legislation provided a reasonable incentive to invention, research and creativity, and made scientific and technical creations publicly available.

In its Report, the Commission proposed several fundamental patent changes as follows: (a) adopt a first-to-file patent system, (b) publish patent applications before the grant date, (c) delete the claiming restriction for food or medicine that were introduced in 1923, (d) change the prohibition on the granting of patents for illicit subject matter to instead

prohibit patents that would be offensive under the Criminal Code, e) start the patent term from the date of filing instead of from the date of grant. f) introduce patent maintenance fees, and, g) make the non-obviousness requirement statutory.

None of the Royal Commission's recommendations that required legislative action were implemented by the government of the day.

Patents and the Cost of Drugs

The above-mentioned Ilsley Commission stated in its Report that few matters connected with patents had been more extensively studied than the working of patented inventions, and the compulsory licensing of patents.[28] This statement turned out to be prophetic for Canada over approximately the next three decades.

In the 1960s, consumers believed that prices for medicines were too high compared to other countries. In response, both the federal and provincial governments commissioned several studies to examine the question. The following three federal studies are of particular relevance to the patent system: (a) a 1963 Report by the *Restrictive Trade Practices Commission Concerning the Manufacture, Distribution and Sale of Drugs*,[29] (b) a 1964 Report by the *Royal Commission on Health Services*: *Recommendations with Respect to Drugs*[30] *9*, (the Hall Commission) and, (c) a 1966 *Report of the Special Committee of the House of Commons on Drug Costs and Prices* (the Harley Committee).[31]

The three reports concluded that consumer prices for drugs were too high. The above-mentioned first report proposed the abolition of patent protection for medicines, while the Hall and Harley reports recommended that compulsory licensing for medicines be extended to include importation. The Government adopted the latter approach and amended the compulsory licensing provisions in 1969. This led to a proliferation of compulsory licences, increased competition in the manufacture of drugs, and helped to establish the generic drug manufacturing industry in Canada.

The Economic Council of Canada

In order to move patent discussions and debate into the mainstream of economic policy decision-making, the Government requested the Economic Council of Canada in 1966 to study and provide advice on patents in light of the country's long-term economic objectives.

In its 1971 *Report on Intellectual and Industrial Property*, the Council stressed the need to use Canadian economic resources as productively as possible and stated that the transfer of the manufacturing of patented technology into Canada should only occur where it could be economically justified.[32] Characterizing

information as a commodity, it recommended that the patent system should encourage the rapid and effective dissemination of technical information.[33]

As can be seen from Table 5, the Council Report agreed with several of the Ilsley Commission recommendations. In addition, it recommended that compulsory licences for manufacture in Canada become available after five years, and in order to prevent price discrimination, importation of a patented product should be allowed from countries where the product enjoys patent protection.[34]

Working Paper on Patent Law Revision

Within five years of the Report of the Economic Council, the government continued its efforts to modernize the patent system by publishing a Working Paper on Patent Law Revision in 1976.[35] The purpose of the paper was to prepare a set of detailed proposals for public debate in anticipation of the drafting of new legislation.

The Report included several contentious proposals that generated a great deal of public response. Among the most controversial proposals were: (a) a split patent term of nine years plus five years if the patent was commercially worked in Canada, (b) compulsory licences to manufacture after seven years if the patent was not worked in Canada, and (c) a restriction on patent rights which would allow third party importation of a patented product.[36]

From 1959 to 1976 the reports of the Ilsley Commission, the Economic Council and the Working Paper recommended a series of basic changes to the procedure for obtaining a patent. Although none of the proposals were immediately implemented, many of them were eventually enacted into law. Table 5 lists the main common proposals contained in the three reports which were later enacted.

The Eastman Commission of Inquiry

To assess the prospects for a significant expansion of the innovative sector of the Canadian pharmaceutical industry, the Government appointed a Commission of Inquiry, the Eastman Commission, to identify proposals that could lead to a consensus on a licensing policy for patented medicines. The 1969 compulsory licensing regime had produced a vigorous generic sector, but it was argued that the existing patent incentives were not sufficient to encourage an optimal level of investment in Canadian research and development.

In its 1984 Report, the Commission recommended that (a) the claiming restrictions for medicines be removed to allow drugs *per se* to be patented, and (b) that a compulsory licence should not be available until after the expiry of a four-year period

of exclusivity.[37] This was intended to encourage the early introduction of new drugs by raising the profitability of research and development in Canada.

Bill C-22

Following the release of the Eastman Report, the Government introduced Bill C-22 in 1986 to amend the compulsory licensing provisions of the *Patent Act*. The Bill was duly passed by Parliament in 1987 after a prolonged struggle between the House of Commons and the Senate over the impact of the changes on the consumer cost of drugs in Canada. The Bill, which represented a major shift in government policy with respect to the protection of patented medicines, deleted the claiming restrictions for medicines and introduced a period of market exclusivity of seven to ten years. This partly dismantled the 1969 compulsory licensing regime and significantly increased the protection for patented medicines in Canada. As a result of the new provisions, compulsory licences only became effective once the market exclusivity period had expired. At the same time, the Pharmaceutical Manufacturers Association of Canada (PMAC) publicly agreed to increase their R&D expenditures in Canada as a percentage of their sales. To protect consumers, the Government established the Patented Medicine Prices Review Board (PMPRB) with authority to monitor drug prices and order sanctions in the event of undue price increases for patented drugs.

In addition to the above amendments to the compulsory licensing regime, the Bill contained a series of fundamental changes to the procedure for obtaining and maintaining a patent. The amendments were designed to simplify the patent system, and make patented technology available to the public at an earlier date. The most significant change was the adoption of the European first-to-file principle, which moved Canadian practice away from its historical similarity with the United States. Other European style procedures that were adopted included: early publication and deferred examination of patent applications, a 20 year patent term starting at the filing rather than at the grant date, and the introduction of patent maintenance fees. Table 5 highlights the main features introduced by the Bill.

The Bill included a further provision that allowed Canada to become a member of the 1970 Patent Cooperation Treaty (PCT). The Treaty, which Canada joined in 1990, sets out a uniform international procedure designed to eliminate duplication among member states. It is designed to benefit those applicants who seek to patent an invention in a number of countries by, among other advantages, reducing patenting costs.

The Treaty provides for the filing of an international application with one of a number of PCT Receiving Offices,

including the Canadian Patent Office. The application is searched by one of several PCT International Searching Authorities, and published by WIPO. Applicants may request a non-binding, preliminary examination, which is conducted by PCT International Preliminary Searching Authorities. The Treaty, however, has no provisions for the granting of a patent. The authority to grant remains with each member state, and following completion of the PCT procedure, applicants must request a patent from each country in which protection is sought. The Treaty, which has a membership of 110 states, has become widely used with the number of international patent applications filed under the Treaty continuing to increase annually.

The Science Council of Canada

During its existence, the Science Council of Canada produced several papers that touch on or deal directly with intellectual property.

Concerns about the impact of trade-related intellectual property issues on industrial competitiveness, caused the Science Council to publish a Discussion Paper in 1990.[38] The paper was based on a major Canadian survey of high-technology and top R&D companies together with interviews with industry associations and research institutes.

With respect to top R&D firms, the paper revealed strong evidence of the importance of intellectual property, with more than 80 percent of firms reporting intellectual property activity over a three-year period. However in the field of biotechnology, 67 percent of the top R&D firms and 39 percent of high technology firms were dissatisfied with the available intellectual property protection and laws. Biotechnology firms were also the most likely to indicate that Canadian intellectual property laws discourage their local R&D efforts. However, it should be noted that the survey was conducted before the enactment of Canada’s Plant Breeders’ Rights Act (PBR) in 1990, discussed below.

Patents and Competition Law

Competition law is designed to prevent companies from inappropriately creating, enhancing or maintaining market power that undermines competition without providing offsetting benefits. Patent and competition law are complementary in that they both promote efficient operation of the market place.

To clarify the treatment of intellectual property, including patents, under the *Competition Act*, the Competition Bureau in 2000 published Guidelines that set out how the Bureau views the interface between intellectual property and competition law. The Bureau's intention is to promote transparency in the enforcement of the Competition Act and to apply it to conduct

involving intellectual property in generally the same manner as it is applied to other forms of property.

The Guidelines state that anti-competitive conduct involving intellectual property falls into two broad categories: conduct that is "something more" than the mere exercise of an intellectual property right, and conduct that is the mere exercise of a right and nothing else. The general provisions of the Competition Act will apply to the former, and the special remedies part of the Act to the latter.[39]

8. TRADE-RELATED AGREEMENTS

In less than a decade from the late 1980s to the early 1990s, Canada negotiated and ratified three trade-related agreements, all of which created obligations that required amendments to Canada's intellectual property legislation.

The Free Trade Agreement
The 1988 *Free Trade Agreement (FTA)* with the United States did not include a chapter on intellectual property, and while it required changes to the *Copyright Act* relating to the dissemination of cross-border broadcast programming, no amendments to the *Patent Act* were needed. The parties merely agreed to work towards improving intellectual property protection internationally.

Bill C-91
In anticipation of upcoming international obligations, Parliament enacted legislation in 1993 that eliminated the compulsory licensing regime for drugs and foods. The market exclusivity periods for patented medicines enacted by Bill C-22 were repealed, and market competition was now delayed until after the patent expiry date. This amendment increased patent protection for medicines in Canada to a level enjoyed by other technologies, and for the first time since 1923 patented medicines were no longer subject to a specific compulsory licensing scheme. Following passage of the Bill, multi-national pharmaceutical companies, as they had done in 1987 with respect to the compulsory licensing amendments enacted by Bill C-22, undertook further commitments to increase their research and development expenditures in Canada.

At the same time, the Bill: (a) strengthened the remedial powers of the Patented Medicine Prices Review Board established in 1987, and (b) introduced restrictions on the rights of patent holders to allow, before the expiry of a patent, early working of an invention for the purpose of seeking regulatory approval, and development and stockpiling of copies of drugs. As discussed below, the stockpiling and early working provisions were subsequently challenged by Canada's trading

partners for non-compliance with its international obligations.

The North American Free Trade Agreement

The *North American Free Trade Agreement (NAFTA)* with the United States and Mexico came into effect in 1994 and resulted in several amendments to the Patent Act. Under the pre-NAFTA Patent Act, the Government of Canada had the right to use any patented invention provided that it paid the patentee reasonable compensation. The 1993 *NAFTA Free Trade Agreement Implementation Act* extended this provision to include provincial governments, but substantially limited the conditions under which either the federal or provincial governments could use a patented invention without prior negotiation with the patentee. The NAFTA Act also deleted the granting of abuse-based compulsory licenses on the grounds of not working an invention in Canada.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The World Trade Organization (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),* which came into effect in 1996, resulted in only minimal changes to the Patent Act including restrictions on government use of semiconductor technology. However, many amendments had already been made since negotiations of the intellectual property chapter of NAFTA were concluded at about the same time that the TRIPS discussions were nearing completion. This overlap resulted in a substantial similarity between NAFTA and TRIPS on patent matters, particularly in relation to patentable subject matter, exclusions from patentability, and exceptions to the exclusive rights of patentees.[40]

A key item is that patents must be available for all fields of technology. However, exceptions exist for certain methods, i.e., diagnostic, therapeutic and surgical, for treating humans and animals, and to protect *ordre public* or morality. Countries can also exclude plants and animals other than microorganisms from patentability, as well as essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. Countries are not obliged to adopt these exclusions, but if they do, they must make patentability of these technologies available to all WTO members. With respect to the enjoyment of patent rights, member states must make patent rights available without discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. These provisions will restrict the development of future government patent policies on these matters.

WTO Dispute Settlement

WIPO intellectual property treaties lack effective dispute settlement procedures. In contrast, WTO members can challenge

domestic laws for non-compliance with WTO obligations. If rulings of a trade panel or the WTO appellate body, confirmed by the WTO Dispute Settlement Body (DSB), are not implemented, they become subject to trade sanctions.

Any doubts as to the willingness of WTO member states to use this procedure with respect to patent matters have been dispelled. Canada has recently been the subject of two separate complaints launched by the European Community in relation to early working and stockpiling of pharmaceuticals, and by the United States in relation to the length of the term of a Canadian patent.

In April 2000, the DSB endorsed Canada's early working regime, but found the stockpiling provisions inconsistent with Canada's TRIPS obligations. Canada has indicated that it will comply with the ruling by amending its provisions that currently allow companies to manufacture and stockpile a patented medicine in the six-month period prior to the expiry date of the patent.[41]

In May 2000, a WTO panel found that Canada failed to make a minimum of 20 years of protection available for patents filed before October 1, 1989. The Canadian Government appealed, but the WTO Appellate Body upheld the panel decision. Canada is reviewing the ruling before deciding on how to implement the decision.[42]

9. PATENTABILITY OF LIFE FORMS

Decisions on the patentability of life forms have evolved largely as a result of court or patent office rulings, rather than by specific legislative amendments. This is true with respect to Canada as well as most other industrialized countries. In tracing Canada's policy development it is useful to briefly refer to events in the United States and Europe, since changes to Canadian practice on the patentability of new technologies are frequently influenced by international developments.

Canadian Protection

It is worth noting that submissions were received by the Ilsley Commission in the 1950s urging Canada to provide legislation to protect plants, modeled on the 1930 United States *Plant Patent Act*.[43] The Commission was not, however, convinced that it was in the best interests of Canada to provide plant protection.

Processes of using microorganisms for commercial purposes have been considered patentable by both the Patent Office and the Courts dating back to at least the 1960s. However, claims to a microorganism *per se* were not deemed patentable until two 1982 decision by the Commissioner of Patents. The Commisioner ruled

that claims in an application by Abitibi Co.[44] for a yeast culture and claims to a cell line in an application by Connaught Laboratories[45] were patentable. The Abitibi application contained claims directed to a microbial culture system, used to purify effluent from the manufacture of wood-pulp. The Commissioner held that microorganisms that are produced *en masse* in such large numbers, as chemical compounds are prepared, that any measurable quantity will possesses uniform characteristics and properties, are patentable. The Connaught Laboratories application contained claims to a cell culture of a bovine cell line useful for the production of insulin.

An application by Pioneer Hi-Bred for a patent on a new cross-bred variety of soybean was the first plant patent case to reach the Supreme Court of Canada.[46] The Commissioner of Patents had refused the claims for the soybean on the grounds of non-statutory subject matter. The applicant appealed, but the Federal Court of Appeal upheld the Commissioner's view that the claims did not fall within the statutory definition of invention. In 1989, the Supreme Court affirmed on the basis that the application did not meet the statutory description requirements. The Court was not convinced that a person skilled in the art of cross-breeding could arrive at the same result as the inventor by following the instructions in the application. Even though the applicant had deposited seeds of the soybean in both Canada and the United States, the Court held that the deposits did not meet the description requirements of the Act. The Court failed, however, to rule directly on the patentability of higher life forms, i.e., whether claims to the soybean constituted an invention under the *Patent Act*.

In 1990 Canada enacted the *Plant Breeders' Rights Act (PBR)* and one year later joined the 1978 text of the UPOV Convention. The 1961 Convention sets out a regime designed to permit the breeder of a new plant variety to obtain protection for the reproductive material of the protected variety. The PBR, administered by the Canadian Food Inspection Agency of Agriculture and Agri-Food Canada, was designed to stimulate the Canadian plant breeding industry and provide wider access to foreign varieties. It provides protection for new varieties of plants, either sexually or asexually bred. The UPOV Convention was amended in 1991 to increase the protection provided under the Treaty. Bill C-80,[47] tabled in the House Of Commons in 1999, contained amendments to the *Plant Breeders' Rights Act* which would have allowed Canada to join the 1991 UPOV text. The Bill, however, died on the Order Paper.

In addition to the question of patentability, a key issue relating to biological inventions has been how to satisfy the disclosure requirements of the Patent Act. An amendment to the *Patent Act,* discussed above, allows for a deposit of biological

material referred to in a patent application to be considered as part of the disclosure. Applications that involve or relate to the use of biological material can therefore refer to a deposit of the biological material in order to comply with the statutory disclosure requirements. This amendment addressed the issue identified by the Supreme Court in the above 1989 Pioneer Hi-Bred case. Canada joined the Budapest Treaty on the *International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedures* in 1996. The fundamental principle of the Treaty, administered by WIPO, is that all member states recognize a single deposit made by a patent applicant in one of the more than 30 recognized "international depositary authorities", as sufficient for their own national procedures.

A decision on August 3, 2000 by the Federal Court of Appeal of Canada held that a genetically-modified, non-human mammal, qualified as a patentable invention under the *Patent Act*.[48] The Court, in a 2-1 split decision, arrived at its ruling by assigning a broad interpretation to the statutory definition of invention. Previous interpretations have given the statutory definition of invention a narrow interpretation with respect to the patentability of higher life forms.

The application filed in Canada in 1985 by the President and Fellows of Harvard College was directed towards a genetically-modified mammal that was prone to developing cancer. The Harvard application included claims to (a) a genetically-engineered non-human mammal, (b) an oncogene, and (c) a process for isolating and inserting the oncogene into the embryo of a mammal. The process and oncogene claims were not rejected, but the Commissioner refused to allow the claims to the mammal *per se* on the grounds that higher life forms constituted non-statutory subject matter. The Federal Court Trial Division upheld the Commissioner's refusal, but the applicant appealed, and the Federal Court of Appeal overturned the decision and held that claims to the genetically-modified mammal were patentable. On October 4, 2000, the Government sought leave to appeal the decision to the Supreme Court of Canada.[49] Corresponding patents on what has become known as the "Harvard mouse", have already been granted by countries around the world, including the United States and Japan, and by the European Patent Office.

United States Protection

The United States has provided patent-like protection for asexually propagated plants since 1930 when it passed its *Plant Patent Act*.[50] More recently, a series of decisions over a period of several years has produced the current policy of allowing higher life forms to be patented. Four key decisions are briefly noted below.

- In 1980, the United States Supreme Court in *Diamond v. Chakrabarty*[51] stated that "anything under the sun that is made by man" was patentable, and ruled that a novel genetically-altered bacterium, useful in cleaning up oil spills, constituted statutory subject matter.

- In 1985, the United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interferences allowed claims to maize plants and seeds;[52] and in 1987 the Board held that claims to a genetically-altered oyster were patentable subject matter. [53]

- In 1988, the USPTO granted a patent to Harvard University for a genetically-engineered mouse.[54] This patent corresponds to the pending Canadian application on the "Harvard mouse", discussed above.

The latest "life form" issue confronting the USPTO concerns the patentability of gene-based inventions.[55] New USPTO guidelines for patent examiners were published in this regard in January 2001 to clarify the written description needed for a patent application to comply with the statutory utility requirement. Briefly, the guidelines state that an applicant must assert a specific and substantial utility that would be considered credible by a person of ordinary skill in the art to which the invention pertains.[56]

European Protection

The 1992 grant by the European Patent Office of a patent for the Harvard mouse was not without controversy. More than 300 non-governmental organizations and Green political parties mounted a joint campaign to revoke the patent, arguing that it violated the European Patent Convention. The challenges were largely based on environmental concerns and ethical grounds, alleging, *inter alia*, that the mouse posed unacceptable risks to the environment, and that the patent violated public order since genetically engineering an animal that is predisposed to suffer is contrary to morality.[57]

In 1998, the European Parliament concluded ten years of debate by approving a European Community Directive on the Legal Protection of Biotechnology Inventions.[58] The Directive defines what is deemed to be patentable, and provides a non-exhaustive list of non-patentable subject matter. The list is based on the EPC prohibition against the patenting of inventions whose commercial exploitation is contrary to "ordre public" or morality.

10. CANADIAN PATENT OFFICE ADMINISTRATION

At Confederation the Patent Act was administered by the Department of Agriculture, with the Minister of Agriculture as

the Commissioner of Patents. The Patent Office was established by statute in 1906, and the first non-ministerial Commissioner of Patents was appointed in 1919.

In recent years, the administrative measures noted below have modernized office operations and improved service to the public in order to enhance the effectiveness of Canada's patent system.

- The Patent Office added a new dimension to its operations in the 1970s by implementing a proactive program to disseminate patent information. The goal was to make patent information, particularly the technical information contained in patent documents, more accessible to the business and R&D community, as well as to the general public. To make the information more equitably available across the country, patent experts were located in Canada's regions to provide clients with advisory and educational services, and generally promote the use of the patent system. This initiative has recently been strengthened through the use of computer technology, noted below.

- To improve efficiency, the administration of intellectual property statutes, consisting of patents, trade-marks, copyright, industrial designs, and integrated circuit topography, was consolidated under a newly created Canadian Intellectual Property Office (CIPO) in 1991.

- A ten-year $76 million major project, *TechSource*, to automate the internal operations of the Patent Office and to convert the paper-based patent search file into electronic form was completed in 1997. Scanned images and text of more than 1.4 million Canadian patent documents dating back to 1920, and text-searchable documents dating back to 1978 are now available online from Industry Canada's Web site.[59]

- CIPO became a Special Operating Agency (SOA) in 1993 to take advantage of the administrative and financial flexibilities offered by SOA status, followed by the establishment of a revolving fund. As a result, CIPO was mandated to place much greater emphasis on improving service to its clients. The revolving fund made the office a self-funding body, and allowed it to use the statutory fees it receives from intellectual property applicants and owners to fund its operations.

- To keep the pendency period of patent applications that are subject to examination as short as possible, the Patent Office has, over the last few years, hired and is

continuing to hire a substantial number of new patent examiners.

11. ROLE OF THE COURTS

Both the provincial courts and the Federal Court of Canada have authority to enforce the rights of patentees and to decide patent disputes. The Federal Court of Canada has exclusive jurisdiction to hear appeals from decisions of the Commissioner of Patents, and in the impeachment of patents. Nevertheless, provincial courts can deal with objections of patent invalidity, but any decision on that issue applies only narrowly between the parties.

Under the *Patent Act*, patents are presumed valid when granted, and the onus is generally on the party attacking the validity of the patent to prove otherwise. An analysis of recent patent decisions by Federal Court Trial Division over an almost thirty year period reveals that in 67 percent of cases the court held at least one of the claims in a patent valid. In 59 percent of the cases the patentee was least partly successful with respect to infringement.[60]

A 1990 study published by the Science Council of Canada found that 17 percent of surveyed Canadian firms and 45 percent of top R&D performers were involved in court proceedings relating to intellectual property during a three-year period. Furthermore, some 40 percent of firms surveyed were involved with, threatened with, or considered intellectual property-related legal action. A common complaint throughout the survey was the cost of applying and enforcing intellectual property rights, with the cost of litigation, for the top R&D firms who reported their expenses, averaging $370,000 per case.[61]

It is worth noting that the linkage between the regulatory approval process for obtaining a Notice of Compliance from Health Canada and the patent regulations brought in under Bill C-91 has resulted in a large number of cases being heard by the Federal Court of Canada.[62]

A 1991 study addressed concerns about many aspects of Canada’s intellectual property litigation, legislation and education system.[63] The study examined court procedures and intellectual property actions. It identified varies difficulties and developed recommendations to make the judicial system more expeditious and cost-effective, some of which have been adopted.

Interlocutory Injunctions

In patent cases, interlocutory injunctions are at times requested by patentees during a court action to prohibit a defendant from infringing the patent until the action is

finally heard and determined. Patentees argue that their inability to obtain an injunction is effectively equal to allowing the defendant to practise the patented invention, without royalty payments, until the trial is heard. Defendants, on the other hand argue that, if they are successful at trial, the granting of a pretrial injunction unjustly bars them from using the technology and causes monetary losses.[64]

Even though the threshold for one of the criteria for obtaining an interlocutory injunction was lowered in 1975, the number granted by the Federal Court has recently declined, with the major stumbling block being the "irreparable harm" criterion.[65] The Court's position is that harm suffered by the patentee due to infringement is normally "repairable" by monetary compensation.[66]

12. THE NATIONAL BIOTECHNOLOGY ADVISORY COMMITTEE (NBAC)

The 1998 Report of the National Biotechnology Advisory Committee (NBAC)[67] contains recommendations to improve protection for biotechnology inventions. The recommendations together with an indication on what action has so far been taken are set out below.

1. Ratify the 1991 UPOV Convention and amend Canadian legislation to strengthen protection of plant varieties in compliance with the Convention.

> **Action:** PBR Regulations were amended in 1998 to extend protection to all varieties of plants. As indicated earlier, Bill C-80 that included amendments to the Plant Breeders' Rights Act that would have allowed Canada to join the 1991 Text of the Convention, died on the Order Paper.

2. Work towards bringing Canada's patent practice into closer alignment with other industrialized member countries of the WTO to: (a) strengthen patent protection for multi-cellular life forms, (b) introduce patent term restoration, and (c) adopt a patent opposition procedure.

> **Action:** The question on the patentability of higher life forms is currently focused on the Federal Court of Appeal Harvard Mouse case, discussed above.
>
> Patent term restoration allows patentees to have the length of a patent term extended to compensate for delays in obtaining required government approval to market a product.[68] There is no indication that patent term restoration is under consideration.

The Canadian Patent Act currently allows anyone to protest the patentability of any claim during the pendency of a patent application, or request re-examination of any claim in a patent, on the basis of prior art submitted to the Patent Office. However, these are not formal inter partes procedures. The adoption of a formal opposition procedure is currently under discussion.

3. Ensure that applications for gene sequences are not allowed without a known specific utility.

Action: Current Patent Office practice requires that the disclosure include a utility that is real and can be demonstrated.

4. Adopt a fast-track procedure for the granting of applications with claims that are co-extensive with those granted by Canada's major trading partners.

Action: Applicants can currently obtain early examination of an application by means of a special order request. There is, however, no indication that the adoption of a formal fast-track procedure is under consideration.

13. CONCLUSION

Looking back from a broad perspective, the basic procedural steps of obtaining a patent, i.e., an application is filed, examined for compliance with the Patent Act, and granted or refused, have remained the same over the past century. Also, the statutory definition of invention, and the patentability criteria of novelty, non-obviousness and utility have, remained virtually the same since Confederation. Today’s legislative provisions have, however, evolved from a strong focus on residency requirements and local manufacturing to today’s policies, influenced by the global economy’s emphasis on trade and investment.

Canada first became bound by international patent obligations when it joined the 1883 Paris Convention for the Protection of Industrial Property in 1925. Even though the Convention has been amended several times since then, progress on the harmonization of substantive patent issues has been largely elusive. The conclusion, after almost ten years of deliberation, of the 1970 PCT was a success, but the Treaty is largely procedural in nature, and was not able to address substantive matters. WIPO continues its efforts in this regard, but the only recent international harmonization of substantive matters has been the EPC and the establishment of the EPO. Recent trade-related agreements have, however, established significant international patent norms, coupled with an effective dispute resolution procedure.

Looking ahead, the boundaries that define what subject matter can be patented will, if the past is any indication, continue to expand to accommodate new inventions. In this context, debate concerning the patentability of biotechnology-related inventions will likely differ from, for example, questions concerning computer or Internet-related inventions. Policy decisions with respect to biotechnology may have to take ethical and environmental concerns into consideration in order to gain general societal acceptance.

The patent norms negotiated under trade-related agreements are such as to restrict future government attempts to develop Canadian policy initiatives designed to benefit primarily local innovation. In order to encourage domestic innovation via the patent system, the government may have to develop administrative or other measures that do not violate international obligations. Nevertheless, compliance with these norms by Canada’s trading partners should provide more uniform protection for Canadian products abroad.

As the Canadian economy becomes more dependent on global trade and investment, other trade-related issues could arise that establish links with various patent issues, and thereby shift policy discussions on these matters to the international level.

TABLE 1
CANADIAN MEMBERSHIP IN WIPO PATENT-RELATED TREATIES

NAME AND YEAR OF TREATY	YEAR CANADA JOINED; NUMBER OF MEMBERS[1]	BASIC DESCRIPTION
Paris Convention for the Protection of Industrial Property (1883)	Joined: 1925; Members: 160.	Contains basic norms such as national treatment and convention priority rights for foreign applications.
Patent Cooperation Treaty (PCT) (1970)	Joined: 1990; Members: 109.	Establishes a procedure for the international filing, publication, search, and preliminary examination of international applications. The Treaty does not have authority to grant patents, which remains with national offices.
Strasbourg Agreement Concerning the International Patent Classification (IPC) (1971)	Joined: 1996; Members: 47.	Administers and updates the International Patent Classification (IPC), used by virtually all countries.
Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patents (1977)	Joined: 1996; Members: 49.	Governs procedure for the deposit of a sample microorganism, described in a patent application, with an International Depositary Authority (IDA). A single deposit with one IDA is recognized by all member states.
Union Internationale pour la Protection des Obtentions Végétales (UPOV) (1961)	Joined: 1991; Members: 46.[2]	Provides international norms for the protection of new plant varieties. (Not a WIPO Treaty, but administered by WIPO secretariat.)

[1] WIPO Web site: www.wipo.org/treaties (Info. as of Jan. 30/01)

[2] See UPOV Website, www.upov.int. (Info. as of Jan. 30 01).

TABLE 2

CANADIAN PATENT LEGISLATIVE HIGHLIGHTS
1824 to 1899

PERIOD	EVENTS	HIGHLIGHTS
1820s	First Patent Acts in Lower and Upper Canada.	First-to-invent patent system; Patents for residents only; Patents granted for imported technology invented by others; Patent term of 14 years.
1830s to 1850s	First Patent Acts in Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland, and the Province of Canada.	Patent term of 14 years, extendable to 21 years for insufficient remuneration.
1860s	First federal Patent Act (1869).	Government can use patented inventions; Patent applications are open to the public; Patent term of 15 years (three 5 year periods); Patents could be impeached for non-working in Canada; Minister of Agriculture is Commissioner of Patents.
1870s	Federal Act extended to the new provinces of Manitoba, British Columbia and Prince Edward Island. Second federal Patent Act (1872)	Foreigners can obtain patents.
1880s and 1890s	Federal Act extended to North West Territories.	Patent term of 18 years (three 6 year periods); Statutory authority to employ examiners; Federal Exchequer Court to hear (a) conflict proceedings to determine first inventor, and (b) impeachment proceedings.

TABLE 3

CANADIAN PATENT LEGISLATIVE HIGHLIGHTS 1900 TO 1959

PERIOD	EVENTS	HIGHLIGHTS
1900 to 1919	Patent Act extended to new provinces of Alberta and Saskatchewan.	Patent Office established by statute; Patent applications made secret; Exchequer Court to hear appeals from refusals by Commissioner of Patents to grant a patent; Compulsory licenses for not working; First appointed Commissioner of Patents; Patent Office transferred to Department of Trade and Commerce.
1920s	Third federal Patent Act (1923).	Claiming restrictions and compulsory licensing for the manufacture of patented foods and medicines; Provisions for inventions made by public servants; Convention priority rights for foreign applications; Patent term of 18 years.
1930 to 1959	Fourth federal Patent Act (1935). Patent Act extended to the new province of Newfoundland (1949).	Mutual recognition of Canadian and Newfoundland patents; Procedure for handling national defence and atomic energy applications; Provisions on public servant inventions transferred to separate Act.

TABLE 4
CANADIAN PATENT LEGISLATIVE HIGHLIGHTS
1960 TO 1999

PERIOD OR DATE	EVENT	MAIN AMENDMENTS
1960s	Compulsory licensing amendments (1969)	Introduced compulsory licences to import patented medicines.
1970s and 1980s	Bill C-22 Compulsory licensing, and general patent amendments. (Royal Assent 1987)	**Compulsory Licensing:** Deleted claiming restrictions for foods and medicines, and introduced periods of market exclusivity for patented medicines of 7 to 10 years. **General Amendments:** First-to-file patent system; Early publication of applications; Introduced maintenance fees; Term of patent starts from filing date; Grace period for acts by inventor; Authority to join and implement Patent Cooperation Treaty (PCT).
1990	Plant Breeders' Rights	First Plant Breeders' Right Act: provides protection for plant varieties; Administered by Agriculture Canada.
1992	MSLA[1]	Editorial amendments.
1993	Bill S-17, IP[2] Improvement Act	Added patentability requirement of non-obviousness; Deposits of biological material to be treated as part of a patent application.
1993	Bill C-91, Compulsory licensing amendments	Repealed compulsory licensing provisions for foods and medicines; Provided exceptions for early working and stockpiling of patented medicines before patent expiry date.
1994	NAFTA Implemen-tation Act	Extended Government use of patented inventions to provinces; Deleted compulsory licences for non-working.
1996	WTO/TRIPS Implemen-tation Act	Restrictions on government use of semiconductor technology.

[1] Miscellaneous Statute Law Amendment Act.
[2] Intellectual Property.

TABLE 5
COMMON ELEMENTS OF PATENT PROCEDURE RECOMMENDATIONS
(RE: GOVERNMENT STUDIES: 1950s to 1970s)

RECOMMENDATIONS	1959 ILSLEY COMMISSION REPORT	1971 ECONOMIC COUNCIL REPORT	1976 WORKING PAPER ON PATENT LAW REFORM	ENACTED IN 1980s AND 1990s.
Convert to first-to-file patent System.	Yes	Yes	Yes	First-to-file system adopted
Early publication of applications.	12 months after filing	12 months after filing	Yes (Time to be prescribed)	18 months after filing
Patentability prohibition for illicit subject matter.	If offence under Criminal Code	No proposal	Adopt EPC[3] provisions	Prohibition deleted.
Delete claim restrictions for foods or medicines.	Yes.	No proposal.	Yes.	Restriction deleted.
Introduce maintenance fees.	Yes.	Yes	Yes.	Yes.
Change start of patent term.	17 years from filing date.	17 years from filing date.	9 years from filing date, plus five more years if worked in Canada.	20 years from filing date.
Provide protection for plants.	Not in favour of plant protection.	No proposal.	Exclude plant varieties, per EPC[1]	Plant Breeders' Rights Act enacted.
Add non-obviousness requirement to	Yes.	No proposal.	Yes.	Yes.

[1] European Patent Convention.

ENDNOTES

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21. Gordon Asher, supra at Note 3, pp. 60-70.

22. In 1982, The British North America Act, 1867 was renamed the Constitution Act, 1867.

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24. Gordon Asher, supra at note 3, pp. 65-70.

25. Gordon Asher, supra at Note 3, p.7.

26. Gordon Asher, supra at Note 3, pp. 72-74.

27. Report on Patents of Inventions, supra at Note 9.

28. Report on Patents of Invention, supra at Note 9, p. 77.

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