MEDICON VALLEY ACADEMY

medicon valley patent guide

HOW TO PATENT BIOTECH & MEDICOTECH INVENTIONS
WHERE TO FIND EXPERT ASSISTANCE

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Communications

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BENT CHRISTENSEN NIELS GERNER LARSEN

Introduction

BY BENT CHRISTENSEN, MANAGING DIRECTOR AND NIELS GERNER LARSEN, PROJECT MANAGER, MEDICON VALLEY ACADEMY

Research-based inventions are a prerequisite for the development of new pharmaceuticals, methods for medical treatment, and medicotech devices.

Patents are essential for protecting the development and commercialisation of these new products and methods.

The aim of this guide is to provide you with insight into the possibilities of patenting an invention. The guide offers advice on how best to protect an invention, and where to seek further information on patenting. Such insight is a prerequisite for being able to make proper use of experts in the patenting field. The guide is mainly aimed at scientists and entrepreneurs, as well as small and medium-sized research-based companies in Medicon Valley.

The guide provides answers to questions such as what protection does a patent provide, where to apply for a patent, and how to commercially exploit a patented invention. The guide also contains a summary of the prosecution of a patent application and the associated costs.

In addition, the guide provides advice on how to administer patents effectively.

A number of articles written by people with different backgrounds and experiences are included in the guide. From their various points of view, these contributors write about the significance of patents.

Also included in the guide is a list of the experts in Medicon Valley, who will be able to assist you protecting your invention in the best possible way.

Finally, at the end of the guide is a glossary explaining patent-related terms and expressions.

With this guide, Medicon Valley Academy believes that the knowledge that is being created in Medicon Valley will come to be utilised even better. It is this knowledge that makes Medicon Valley one of the world's most attractive bio-regions.

MEDICON VALLEY ACADEMY

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Articles

Patent links: www.mva.org/patentguide

1. Why patent?

Patents are of great importance in the knowledge society, as they enable inventions to be exploited via the development of a product or a method. The utilisation of patented inventions can be of benefit both to the individual and to the society. At the individual level, both the scientists and the companies concerned can satisfy their professional and economic interests, while at the societal level, patented inventions in the life science can lead to better public health, more efficient medical treatments, and also contribute to improving regional and national competitiveness.

Having obtained patent protection of an invention, profitable commercial operation of the invention provides a basis for sustained growth and profitability, and ensures that an attractive return on investment can be devoted to the development and commercial exploitation of further inventions.

In Medicon Valley, excellent research results have led to the development of Turbuhaler, Cipramil and the NovoPen by AstraZeneca, Lundbeck and Novo Nordisk, respectively. The development and commercial exploitation of these products were not, however, exclusively based on excellent research, but also on intelligent use of patents.

The protection of inventions is particularly important in highly competitive industrial fields, and hence patents represent a major commercial asset for innovative companies in the fields of biotech and medicotech.

If you as an inventor wish to build up your own company on the basis of your invention, and thereby become an entrepreneur, a patent is essential. "No patent, no money", the investors say.

If you prefer to concentrate on research, and do not wish to build up your own company, you can allow others to utilise your invention. In this case, you can secure yourself a share in the income derived from your patented invention.

If you are employed by an established company, an invention capable of being exploited commercially should be patented to protect the invention and to secure a return on investments.

Patents are granted for novel and innovative products or methods, and confer a monopoly of up to 20 years, by means of the right to exclude others from exercising the invention claimed in the patent.

A patent can be used to protect an invention, but it can also be transferred between parties, licensed to other parties, or even be used as collateral.

A patent may thus be regarded as a strategic asset aimed at improving the competitive advantages and the earning capacity of a company, for example by:

- securing a technological platform for a future development
- preventing competitors from gaining access to emerging markets
- creating retaliatory power against competitors
- preventing innovative products from being plagiarised
- increasing the goodwill of the company and its products or services
- making it possible to participate in technology transfer agreements
- securing a revenue from the licensing of patented technology

The strategic challenges involved in patenting are discussed in chapter 10.

Patents are more than just important

BY MADS ØVLISEN, CHAIRMAN OF THE BOARD OF DIRECTORS, NOVO NORDISK

Anyone, I would imagine, who has tried to create a biotech company knows just how important patents are. You learn this when you're studying, and again at your first job, and if you haven't done so before, you realise it the first time you meet potential investors.

But patents are more than just important. They are crucial in deciding whether your invention has a commercial future. Have you managed to avoid the pitfalls created by other patents or publications, or will they cut you off from patenting your product or limit its use? Can you be sure that your application will result in a patent, and if it does, can you just go ahead, or will you need to negotiate with others who feel they have better rights than you? And how will all this influence the way you formulate your application?

These are just a few of the things you have to consider, and it can be hard to do when you're working hard – especially if you are just a few people, and under the kind of pressure of time that characterises biotechnical research and development.

And it's one thing to consider these factors, but how can you get a clear impression of the minefield and chart a path through it? You need expert advice. Remember that when you're putting together your board and recruiting people to your team: make sure, first and foremost, that you have expert, professional (even in your own field), highly skilled patent advisors. Otherwise, you'll be like a tightrope walker without a net.

A lot of people question the ethics of patenting. But our society demands renewal, and it is reasonable and necessary to protect the time and effort that lies behind innovation.

If you succeed in getting your patent, then you need to be concerned about the way you exploit it, but this is another, equally important, story.

2. What protection does a patent provide?

A patent right constitutes a sole and exclusive right as well as a prohibition right.

PATENTING A PRODUCT

When a patent is directed to a product, the protection conferred by the patent prevents third parties from:

- producing
- using
- offering for sale
- selling
- importing

the product for commercial purposes.

A patent granted for a product protects all kinds of use of the patent, irrespective of whether such uses are listed in the patent.

Prior art citable against a product claim includes all products which would achieve the same technical effects as those claimed for the product of the invention, e.g. prior art products suitable for carrying out the claimed invention and achieving the same technical effects.

Prior art: Everything made available to the public before a patent application is filed.

Prior art citable (material): Material believed to be of relevance for an evaluation of an invention is identified by the patent authorities and listed e.g. in a novelty search report as references relevant for an evaluation of the novelty or the inventive step associated with the invention.

Products not suitable for solving the same technical problem as that solved by the product of the claimed invention do not constitute prior art with respect to a claim directed to a product.

PATENTING A METHOD

When a patent is directed to a method for producing a product, the protection conferred by the patent prevents third parties from:

- carrying out the method
- using
- offering for sale
- selling
- importing

a product directly obtained by the method.

The indirect protection of products directly obtained from patented methods is an important form of protection.

Prior art citable against a method is limited to methods for the same stated purpose. It is therefore important to consider the wording of a method claim as well as the technical problems solved by the method, in order to influence the prior art which will be citable against the method claim.

A combination of method claims and product claims is often desirable in order to ensure an efficient protection of an invention.

GERTRUD BOHLIN OTTOSSON JAN TROFAST

Patents – a prerequisite for a successful project

BY GERTRUD BOHLIN OTTOSSON, MANAGING DIRECTOR, IDEON SCIENCE PARK AND JAN TROFAST, PRINCIPAL SCIENTIST, ASTRAZENECA R&D LUND

The structural change of the industry to a more knowledge based activity and the expected lack of trained working power in the future will increase the demands on a flexible and interdisciplinary education. The pharmaceutical industry competes in a world of increasing costs, new groups of customers and constantly increasing competition. At the same time it has become more difficult to make new innovations. A well organised and effective research is fundamental in a competitive international environment. However it is the creativity of the individual scientist who creates the innovations.

Research is an activity, where standard measures of efficiency are difficult to use. A fundamental prerequisite in this activity is that the innovations could be protected in a proper way. A patent should not only be regarded as a temporary right for the inventor but could also give the research society access to invaluable knowledge similar to any scientific literature. Protected intellectual property is critical to new innovations. A strong patent portfolio does not only consist of a large number of recently filed patent applications – the intellectual property of the business should be looked upon as a whole. Multiple intellectual property protection must be used for each business segment in order to strengthen the overall protection. Research is nowadays very interdisciplinary in character creating even greater problem to be fully aware of existing prior art. The scientists are – from patent perspectives – often limited in the ways they analyse their results. Continuous support and cooperation between the scientist (inventor), his/her scientific environment as well as other disciplines such as a patent department/legal department will be of utmost importance for the development and strengthening of the IP portfolio and in order to be fully prepared for future oppositions/appeals and perhaps also litigations.

Each project must have a carefully elaborated strategy for intellectual property. Here we must include factors like e.g. speed of obtaining patents, length of patent protection, effectiveness of patent protection, insufficiencies eliminated by clarity and careful evaluation of the scope of the claims (also for the prior art). The patent claims define the invention, but do not conclusively define the cope of protection. Continuous work is necessary in order to foresee

… to be continued

3. Criteria for patentability

… continued

future infringing products and to have as efficient control of prior art as possible to get a valid patent. An IP strategy has to be elaborated from the start of a project and should be kept alive throughout the whole project.

Each branch of industry exists under certain conditions – the pharmaceutical industry having long developing time for an innovation but at the same time having often rather long duration of time for a product on the market compared to the electronic industry. It is important to have an IP strategy for each case, but the strategy may look different. A strong and carefully elaborated patent portfolio is a prerequisite for a successful research project.

One of the most important issue's for any organisation working with inventors, scientists or entrepreneurs in order to turn ideas into prosperous businesses is to stress the necessity of how to co-ordinate patent portfolio with new innovations, capital and time. The strength of the patent strategy is often the key to the financing of the project.

There are three basic criteria for patentability. The invention must be:

- novel
- associated with an inventive step
- subject to industrial applicability

Additional criteria for patentability are that the invention is not exempted in general from patentability, e.g. for moral reasons, or specifically excluded from patentability, e.g. a method for cloning human beings.

NOVELTY

A product is novel if the identical combination of physical and functional features has not previously been disclosed.

A product can be protected by claiming its physical features, or its functional features, or a combination of both. It is often desirable to claim a product by a combination of physical and functional features, as functional features confer a broader protection of the product than the protection which would have been conferred by claiming physical features only.

When evaluating the novelty of methods, it is necessary to consider more than just the method steps carried out when the method is exercised. Methods for producing a product can disclose:

- a starting material
- one or more method steps for processing the starting material
- the result of the method, in the form of the end product

A method for producing a product is novel when either the starting material is novel, or when the combination of processing steps is novel, or when the product resulting from the method is novel. A novel product always results in a novel method for producing the product.

A method for using a product and achieving a technical result can disclose:

- the product to be used for carrying out the method
- the method steps carried out when performing the method
- the technical results obtained from carrying out the method

A method for using a product is novel when either the product is novel, or when the method steps are novel, or when the technical result is novel.

ASSESSMENT OF NOVELTY

When performing an assessment of the novelty of an invention, one key question is whether the claimed subject matter is derivable directly and unambiguously from the prior art, including any features "implicit" in what is expressly mentioned in the art. If this is the case, then no novelty exists.

An evaluation of the novelty of an invention must clarify what has been made available to the public.

It is essential that a conclusion of "lack of novelty" is not reached unless a prior art document contains a clear and unmistakable disclosure of subject matter pertaining to a later invention. A clear distinction must be made between the information that is unquestionably derivable from the prior art document, and the information that may be imagined or considered obvious.

Read the related sections:

Explicit and implicit disclosure
When is a species really novel?
Novelty and implicit prior description

at www.mva.org/patentguide

INVENTIVE STEP

In contrast to the determination of novelty, an inventive step must be evaluated as it would have been evaluated on the date of filing (see chapter 6 and 7) of the claimed subject matter, and not on the date of publication of the relevant prior art document. No inventive step is associated with an invention if the result of actions leading to the invention is clearly predictable, or if there is a reasonable expectation of success in arriving at the invention.

ASSESSMENT OF INVENTIVE STEP

When evaluating an inventive step, the relevant question to ask is not whether a skilled person from a relevant technical area could have carried out the invention, but whether he would have done so in the hope of solving the underlying technical problem or in the expectation of some improvement or advantage. The point is not whether a skilled person could have arrived at the invention by modifying the prior art, but whether he would have done so in the light of the enablement of the invention being disclosed by the prior art.

… to be continued

4. What can be patented?

… continued

Read also the related sections:

Assessment of inventive step (part 2)
Obvious to try versus reasonable expectation of success
Problem and solution approach
Hindsight knowledge

at www.mva.org/patentguide

INDUSTRIAL APPLICABILITY

Industrial applicability should be understood in the broad sense, as including any activity that can achieve a technical result in any industrial field, but not in the private sphere of an individual. As such, most inventions will be regarded as industrially applicable. In Europe, inventions are not regarded as having industrial applicability if they are directed to methods for medical treatment of a human or animal, including methods for therapy and surgery, as well as diagnostic methods.

Most inventions in the fields of medicotech and biotech can in fact be patented. Below, we introduce some examples.

MEDICOTECH

In the field of medicotech many inventions are claimed as a device, or as a combination of a device and a biological entity. Functional features can also be used for protecting inventions in the area of medicotech. Examples of medicotech inventions include products such as e.g. insulin pens, surgical equipment such as lasers, fluid handling devices exploiting e.g. robot technology for carrying out e.g. diagnostic assays, immunoblotting devices, microfluid devices, polymer chips suitable for contacting biological material, hybridisation arrays, and the like.

BIOTECH

Within biotech, it is possible to patent living organisms, such as microbes and transgenic multi-cellular organisms. Examples of other biotechnological inventions that may be patented include vectors, cell lines, artificially generated tissues and - in isolated form - plant cells, proteins (including antibodies), genes, partial gene sequences, cDNAs and SNPs.

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IPR is vital for survival - also within medical devices

BY LARS RASMUSSEN, GROUP CEO, COLOPLAST

It has become quite a tradition to protect new inventions as well as trade marks within the medical device business. As an example, Coloplast submitted no less than 23 patent applications last year. In a business such as Coloplast where 20-30% of the total turnover arises from products introduced within the last 4 years, the objective of IPR activities is first of all to optimise protection of products and processes in the first critical couple of years in order to obtain a competitive advantage.

An intelligently composed patent portfolio is not only a must for protecting the knowledge invested in the inventions of the company; it is also a potential business opportunity in case one or more of the patents can be sold on a royalty basis to interested and non-competing parties.

Patent strategy for medical devices

BY THOMAS GRÖNBERG, PHD AND NIELS MENGEL, MBA, PARTNERS AND FOUNDERS OF ØRESUND–HEALTHCARE CAPITAL

A robust patent situation and/or patent portfolio strategy is often one of the most important elements that determines whether a venture capital company will say yes or no to an investment opportunity. A patent has value only if it can be applied to a product, and if the application can be sold in a marketplace. However, the right wording and the right coverage – market and sector wise – and the way the patent portfolio is structured, often makes the difference – the difference between a break-even and a real bonanza.

Consequently, we work closely with companies in order to optimise the patent situation.

The patent strategy is, as already stated, a very important part of the overall business approach; in many cases the different parts in the approach are interdependent in a rather complex pattern.

For this reason, we have developed a short and rather general guide or checklist for a patent portfolio strategy.

The elements are:

1. **Choose the right patent agency**
   Make sure that the communication with your patent agency is optimal. If not, it might be a good idea to change agency.
2. **Compile an inventory of interesting marketplaces**
   The EU, USA, Canada and Japan are obvious places to list, but many other areas in the world could be of interest, too.
3. **Analyse the current patent situation**
   Approved patents, applications, objections from patent offices or infringement disputes.

4. **Strengthen protection in those market segments where you would like to operate, but realise that you are weak**
   In the medical device business, there can be many market segments. The product may be used in close proximity to the patient – in vivo or in vitro – or it may be used in a laboratory. It may be used as a research tool in hospitals, or in the pharmaceutical industry. It may also, of course, be suitable for veterinary applications.
5. **Make a decision on patent design policy**
   Several narrow patents, or one or more broad patents? It all depends on your level of financing, and what your competitors do.
6. **If other patent holders obstruct you in market segments where you would like to operate, then try to negotiate a license**
   This action is of course highly dependent on your overall business strategy and your financial strength, especially if you are an unknown company. It's a good idea to take this situation into consideration if you invite a venture capitalist into your company. Will he be able to support you in these negotiations? Does he have the right skills, network and capabilities in the medical sector to be able to help?
7. **Make sure that your trademark and design registration is optimal**
   Trademarks and design registration are protective measures which are sometimes forgotten.
8. **Introduce laboratory bookkeeping**
   Keep a thorough record of every step in your development department. This could be useful when it comes to discussing priority dates – especially in the US.
9. **If possible, protect the consumables**
   Opportunities for add-on sales and/or sales of consumables are often present in the medical device business.
10. **Continually check what your competitors are doing in the field of patent protection**
    Evaluate whether there is a risk of potential infringement.
11. **Continually stimulate and follow up partners who may create new patent ideas**
    Where are new ideas created? By partners, in-house, or maybe by groups in other organisations?
12. **Allocate finances for the plan**
    The implementation of an active professional patent strategy costs money, so you should optimise your plan, not maximise it.
13. **Go through the patent portfolio from time to time**
    Maybe not everything is necessary. Maybe some of your IPR could be closed, or even sold off.
14. **Financing**
    Allocate money for the implementation of your plan.

This plan should be documented and approved by the board of directors. It should also be an active document, adjusted in accordance with changes in the surrounding world.

A final word of advice: If you are looking for funding for your innovation, the best advice is to talk to venture capitalists before implementing your chosen patent strategy. Bringing a venture capital investor into your company often means a change in strategy – including the patent strategy.

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Examples of patentable inventions in the area of recombinant gene technology include one or more of the following claims directed to:

- a gene comprising a nucleotide sequence
- a fragment of the nucleotide sequence and a nucleotide sequence complementary thereto
- a nucleotide sequence capable of hybridising to the gene, or a fragment thereof, under stringent conditions
- a cloning vector comprising the gene
- a polypeptide encoded by any of the above nucleotide sequences
- a pharmaceutical composition comprising the gene or the polypeptide
- an isolated biological cell comprising the gene or the vector
- a transgenic organism comprising the biological cell
- an antibody having an affinity for the polypeptide
- any polypeptide - characterised by at least one physical feature - capable of being recognised by the antibody
- a method for constructing the biological cell comprising the gene or the polypeptide
- a method for identifying binding partners for the polypeptide
- a method for identifying agonists or antagonists for the polypeptide
- a method for therapy or surgery using the gene, or the polypeptide, or the antibody
- a method for therapy or surgery using the agonist, or the antagonist, of the polypeptide
- a diagnostic method using the gene, or the polypeptide, or the antibody
- use of the biological cell or the transgenic organism
- use of the gene or the polypeptide or the antibody
- medical uses of the gene or the polypeptide or the antibody
- use of the gene, or the polypeptide, or the antibody, in the manufacture of a medicament for treatment of a clinical condition in an individual in need of the treatment

INVENTIONS EXEMPTED FROM PATENTABILITY

Biotechnological inventions at present excluded from patentability according to e.g. Rule 23d of the European Patent Convention include methods for cloning human beings, methods for modifying the germ line genetic identity of human beings, and the use of human embryos for industrial or commercial purposes.

In addition, the European Patent Convention also excludes from protection processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes.

ØRESUND SCIENCE REGION

ØRESUND SCIENCE REGION

Øresund Science Region is an alliance between four regional and bi-national network organisations:

- Medicon Valley Academy
- Øresund IT Academy
- Øresund Food Network
- Øresund Environment

The main purpose of ØSR is to promote innovation and growth through co-operation.

Øresund Science Region has a solid base for development and unique possibilities globally speaking for success. We have 140.000 students and 10.000 researchers at the twelve Øresund University institutions; a large number of successful high-tech companies, small start-ups as well as major international companies; a number of science parks and an innovation oriented public sector.

OVERALL AIMS

- Establishing state of the art scientific clusters and networks.
- Stimulating new knowledge within areas where ØSR is competitive on a global scale.
- Developing and securing an innovative environment and an efficient commercialisation structure.
- Global branding of Øresund as a high-tech region with a human touch.
- Promoting integration across borders in the region; disciplines, academia/industry/public sector, Denmark/Sweden, Øresund/The world.
- Organising conferences and symposia.
- Promoting and initiating PhD programmes, summer universities and life long learning.

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The Active Biotech Q platform
– a second and third generation patent approach

BY TOMAS LEANDERSON, VICE PRESIDENT, R&D, ACTIVE BIOTECH

The immunomodulatory small molecule Roquinimex was discovered about 25 years ago. It modulates immune responses, inflammatory responses and angiogenesis, and was included in a clinical development programme for the treatment of multiple sclerosis (MS). The Roquinimex MS clinical phase II studies showed proof of principle. However, the following phase III programme had to be terminated because of unacceptable toxicity, including rare cardiovascular events. In addition, Roquinimex also showed proof of principle in a phase II study for Type I diabetes, and prevented development of disease in experimental autoimmunity, as well as in experimental tumour models. U.S. Pat. No. 4,547,511, issued on 15 October, 1985, covers Roquinimex, a 3-quinolinecarboxamide derivative, as well as a broad range of quinoline (Q) derivatives.

In 1998, Active Biotech acquired a research facility in Lund and projects from Pharmacia & Upjohn, including the Roquinimex patent. Within the Lund research unit was also considerable competence concerning the chemistry, pharmacology, pharmacokinetics and clinical behaviour of this substance. At the present time, there are very few effective drugs available for the treatment of chronic inflammatory/autoimmune diseases such as MS, and even fewer that are orally active. The molecular target and mechanism of action of Roquinimex are unknown, but given the broad reactivity of the substance and its true immunomodulatory ability – i.e. it is not an immune suppressor – we concluded that it targets a pivotal pathway in the pathogenesis of inflammatory/autoimmune diseases. Needless to say, such a pathway would be of considerable commercial interest , and we consequently launched a search for a second-generation orally active quinoline derivative.

In this type of effort, the intellectual property strategy is of vital importance. Initially, a far-reaching structure-activity relationship (SAR) project with Roquinimex as the lead was launched, aiming at compounds with significantly improved risk/benefit ratios. Since the target structure was unknown, a ligand-based drug design approach was used.

Hundreds of compounds were synthesised and screened using various animal models of autoimmune inflammatory disease. Compounds thought to hold promise were brought for preliminary safety evaluation. The project resulted in the discovery of new quinoline derivatives with unexpected and superior effect profiles over the closest prior art and, consequently, in the filing of patent applications. Several patents have been issued in, amongst other countries, the U.S., where product and method-of-treatment claims related to diseases caused by autoimmunity and pathological inflammation were allowed. As a follow-up, the antitumour effect observed for Roquinimex led us to explore the new quinoline derivatives in the oncological field, and new compounds with interesting antiangiogenic/antitumour properties were found. This led to the filing of a "second medical use" patent application, which has now been issued in the U.S.

The manufacture of the drug substance and product is an important part of the drug development process, and presents further opportunities to strengthen an intellectual property portfolio. Consequently, scale-up chemistry activities on the new quinoline derivatives have led to the establishment of a new synthetic route and a recent filing of a patent application.

Finally, an extensive target identification/validation project has been launched, with all the necessary qualities, in a structure-based drug design programme. Having identified the target structure, and with knowledge of the mechanism of action, the search focus has now shifted to novel chemical classes, i.e. third-generation quinoline compounds. These will form the basis of novel and more selective compounds, and will give rise to new patent applications, extending the life time of the Q platform intellectual property portfolio and strengthening the existing intellectual property portfolio of Active Biotech.

5. How the invention can be exploited commercially

The ownership of an invention can reside; in the company where the invention was created, with the person who created the invention, or in the public institution (hospital, university, or public research institution) at which the invention was produced. Beyond this, the ownership may be divided among several actors in the form of strategic alliances, which are common in the biotech and medicotech fields.

Legislation pertaining to the ownership of inventions may be viewed at

Denmark: www.folketinget.dk and www.dkpto.dk
Sweden: www.riksdagen.se and www.prv.se

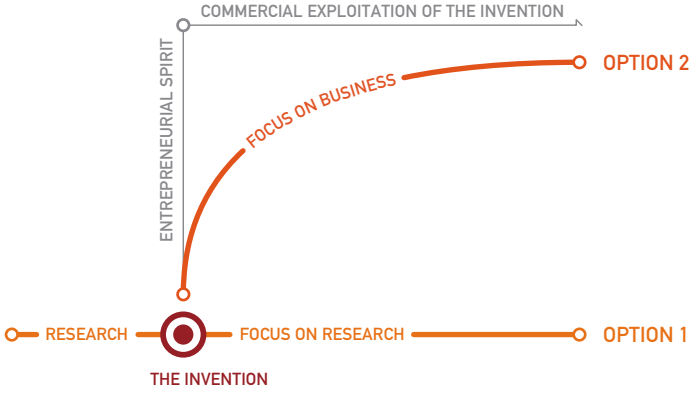

FIGURE Options for scientists who hold the rights to their own inventions

In many instances, patentable inventions will have been developed within a company. In this case, it is the responsibility of the company to determine how to exploit the invention. These aspects are discussed in chapter 10.

But there are also many examples of inventions with good commercial possibilities in which the scientist holds the patent rights. If this is the case, there are various possible options for making commercial use of the invention. Two options are outlined below.

OPTION 1 - THE INVENTOR

The scientist focuses on his or her own research and leaves the development of the commercial possibilities/interests of the invention (and those of the scientist) to others.

If the scientist do not wish to utilise an invention to build up a company, it is possible to license a patent to another company. This will allow the scientist to concentrate on research while still earning an income from the invention, but without having to work on it commercially. It is also a possibility to turn to innovation environments, which have the ability to develop the invention further. Thereby, the scientist will not need to be directly involved.

OPTION 2 - THE ENTREPRENEUR

The scientist follows up his or hers invention commercially via a company, often a start-up. In this case, the scientist plays the role of an entrepreneur.

If the scientist wish to start a company on the basis of an invention, a patent is a prerequisite for attracting investors to the company.

… to be continued on page 23

Make full-time use of your talents

BY STEN TROLLE, MANAGING DIRECTOR, FORSKARPATENT I SYD AB

One of the things that characterises mankind is its ability to create. Human beings have made tools from earliest times, and we also know that they created art, for example in their cave paintings. This talent has later developed to create specialists, such as craftsmen, painters or sculptors. The greater the talent involved, the greater the level of specialisation, and the greater the specialisation, the more you can produce of whatever it is that you specialise in.

One of the foremost examples of this is the work of the architect. The architect designs a building that has never existed before, and has a vision of what it will look like. To help him construct it, he makes use of engineers, construction workers, pipe-layers, and other experts.

As far back as the 15th and 16th centuries, there were great artists who employed a whole battery of other painters to perform work for them, before Rembrandt, for example, wrote his signature on the finished creation. Today, we know that a large part of the work was done by his students, while he himself directed the process and told them what to paint.

… to be continued

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In modern times, it is not just architects who employ others to complete their works, but also anyone who designs or who has a vision of what a creation or a service should look like.

The classic inventor used to first think up a device, and then construct it. This was a technique that worked just fine in its day. The really great inventors like Edison and Henry Ford, however, did not just have laboratories, but also teams of specialists to carry out experiments and evaluate the potential of an idea.

Many inventors still believe that they have to turn their own visions into reality. But with today's ever more complex systems, far less is accomplished by a creative mind if the person with the idea has to do it all. It is no accident that inventors now work in teams, whether in laboratories or in industry. Today, inventors working at a university are able to see their research discoveries turned into patent applications and be patented, whereupon they have a choice of:

- realising the idea themselves via their own companies,
- acting as an expert consultant to a licensee, or
- continuing with their own research and letting others

exploit the discovery.

All three methods are fine, but not all are equally fine for everyone.

It is said that the expression "the cobbler should stick to his last" has its origin in a story about one of the great painters, who had just completed a portrait. A cobbler happened to come by and remarked that the shoes were incorrectly painted. The artist then altered the shoes according to the cobbler's instructions, but when the cobbler continued to criticise the painting, the artist replied "cobbler, no higher than the sandal" (ne sutor supra crepidam) – for that was his own area of expertise.

In the same way, modern inventors must make use of other experts – cobblers – and must realise that they are themselves cobblers in the great painting. For those inventors whose appropriate last is the research laboratory, and who wish to exploit their creativity to the maximum, it is important to leave the realisation of their visions and ideas to others, who may be able to do so with greater efficiency and skill than them. Only then will research be both efficient for society and enjoyable for the scientist.

Today, when risk capital ventures have fewer and fewer free resources, it has also become more difficult to attract capital for new and brilliant ideas. The alternative is either to seek a patent and realise your ideas using your own resources, or to ally yourself with a large company that possesses the resources and the interest. The difficulty here for the inventor is to negotiate conditions with a large company which will not encroach upon the research, but will nonetheless provide a high probability of progress and a good economic return.

Like many other players in the market, we at Forskarpatent in Syd AB (Lund University Technology Group) work according to the principle that "a cobbler should stick to his last". We ensure that other craftsmen are made available, who will complete the work of art according to the vision of its inventor.

… continued from page 20

PROFESSIONAL ASSISTANCE

As the patent is the central strategic hub in the commercial exploitation of an invention, it is recommended to ally with experts from the patents field. There are several different possibilities available during the start-up phase. You can inquire at a patent agency, find other professional patent consultancy assistance, or make use of the innovation environments, which, like the other patent professionals, can help to provide relevant knowledge and networks.

For profiles and contact information of the experts in Medicon Valley, see the presentations later in this guide.

FINANCIAL SUPPORT

Scientists in both Denmark and Sweden can seek financial support towards the cost of patenting their own inventions.

In Denmark, the innovation environments can set aside funds for the preliminary examination of research-based inventions with commercial possibilities. Around DKK 20,000 will normally be required for a novelty investigation and the submission of a priority patent application. If the preliminary examination indicates that the project built up around the invention could be a commercial success, the innovation environments can invest a further DKK 862,500, of which it is not unusual to use up to DKK 200,000 on securing intellectual property.

Read more about the innovation system in Denmark at www.mva.org/patentguide

Financial support for the protection of inventions can also be found via research funds. It can consequently be a good idea to include a budget for patenting expenses when applying to research funds for financial support.

In Sweden, it is possible to cover patenting expenses by loans. The main source of finance for the first Swedish priority application, as well as Patent Cooperation Treaty (PCT) applications in Sweden, is Stiftelsen Innovations Centrum (SIC). In order to finance the first steps in the patent work, soft loans of SEK 50,000 are available for Swedish priority applications, and the same amount for PCT applications, through SIC funds. Swedish scientists in Medicon Valley can seek funding through Teknopol or Innovation Skåne. This also applies to projects generated by scientists, students and employees at the relevant or related universities and colleges. The loan is normally for SEK 400,000, but can in special cases be increased by 50 percent.

More info at www.innovationscentrum.se. See also the expert profiles later in the guide.

Read more about the innovation system in Sweden at www.hynell.se/frames/frames_finansiering.htm

Medicon Valley Investment Guide. Contact info, profiles and key figures of 41 investors focusing on biotech and medicotech in Medicon Valley (see www.mva.org).

Intellectual property and investment in biotech

BY FLORIAN SCHÖNHARTING & CHRISTIAN HANSEN, PARTNERS AND FOUNDERS OF NORDIC BIOTECH

The present reality in drug development, and for that matter in many other technology-intensive fields, is that almost any technology or compound can rapidly be reverse engineered – i.e. re-created through analysis and copying. This means that significant investment in creating technology and compounds is pointless unless the results are protected. Needless to say, the use of patents, rather than secrecy, is the key instrument for that purpose, and it is essential for biotech companies and their investors.

While the above might seem painfully obvious, it is in our view surprising to note that scientists, entrepreneurs and investors typically devote far less attention to this subject than it merits, particularly during the early stages of company development. This is probably less pronounced now than it used to be, but it is still a subject that occupies the lower end of a priority list.

Great attention is given to the degree of technology validation, the competitiveness of projects vis-à-vis global development pipelines, the quality and experience of management and scientists, the hotness or coldness of a technological fad, etc. It is not that these are unimportant, but the IP position of a company can determine whether it has a great future or no future at all.

Usually, the attention of investors towards an investment opportunity is triggered by the perception that they are able to buy assets for less than the investors think they are worth. Once they are sure of the up-side potential of an investment, investors proceed to due diligence processes in which all underlying assumptions of "the dream" are verified as far as possible. This is when the intellectual property analysis is typically performed – and this is also when the buyer will allege as many points of uncertainty and risk as possible, to argue for a lower price.

Three elements are critical in the assessment and valuation of company intellectual property.

Firstly, a determination of the company's own intellectual property position is performed. Does it really own the intellectual property? At which stage of prosecution is it? When does it expire? How efficiently does it protect the company from competing or similar solutions to the same product opportunities? Are patent applications drafted in a professional manner, focusing on key elements of the

value proposition? This part of the analysis is fairly straightforward, and does not usually cause major concern, since there is a reasonable likelihood that some breadth of protection will be available, although its extent is difficult to predict.

Secondly, a determination of the company's freedom-to-operate (FTO) is performed. Is the end-product covered by the intellectual property of others? Is the envisaged manufacturing method covered? Are all of the steps, reagents, assays, processes, and intermediates necessary for finding and making the product covered? Are the envisaged uses of the product covered? Is the formulation, delivery method or packaging covered? This part of the analysis is typically a very large task if performed to the necessary depth. Not only are individual analyses of all of the mentioned technology elements necessary, but the analyst is unable to see any patent application filed within the preceding 18 months since it is non-public. And given that most ideas arise in minds of similar intelligence, based on similar inputs at similar points in time, the certainty of any conclusion is frustrated. This is one of the major reasons why NPV analysis cannot be used to assess the value of companies in a very early stage of development. It is simply impossible to quantify the likelihood that someone else had the same idea the day before you did.

Thirdly, a determination should be made of the company's ability to conquer further territory through aggressive and intelligent patent filing. Are there large areas which are not covered? Can the learning from one project be used to extrapolate results to parallel fields? Can less creative competitors be boxed in? Again, this is an easy analysis to make, but it can be a strong contributor to the "dream" potential of a company.

At Nordic Biotech, we combine our considerable in-house experience with collaboration with patent attorneys, so as to optimise the intellectual property outcome for the benefit of our company and its investors.

Any company seeking investors which is capable, up-front, of including all three of the above elements in a well-prepared documentation of the up-side "dream" that it presents, instead of part of the valuation-reducing due diligence process, has done itself, and maybe even its potential investors, a great favour in facilitating the funding process.

6. When and how to draft and file a patent application?

The date of filing and the content of a patent application are among the critical factors to be considered when formulating an effective patent strategy. There is often a natural wish to file a patent application as early as possible. Although this is often a sensible thing to do, a number of both formal and substantial requirements for a patent application should be considered carefully prior to filing a patent application.

FIRST-TO-FILE PRINCIPLE

The Paris Convention states that the date of filing of the first patent application for an invention is regarded as the "priority date". The priority date can be used for determining who has been "first-to-file" a patent application.

The principle of being "first-to-file" determines who has the right to a patent in most countries. Accordingly, if two parties claim patent rights to an invention, the rights to the invention will be awarded to the party who has filed the patent application first ("first-to-file" principle). The exception to this principle is the USA, where the "first-to-invent" principle also regulates who is awarded intellectual property rights. Differences between the USA and Europe are discussed in chapter 9.

Read about the Paris Convention at www.mva.org/patentguide

ENABLING DESCRIPTION OF INVENTION

It is a requirement that the patent application discloses the invention in such a way that a skilled person can carry out the invention based on the disclosure thereof in the patent application. It is thus necessary to ensure that the requirement for disclosure of the invention has been fulfilled, instead of filing a patent application which does not enable a skilled person to carry out the invention.

If the requirement of an enabling disclosure is later regarded by the patent authorities as not having been fulfilled, the patent application risks being rejected for lack of an enabling disclosure. As an inventor you must – often in collaboration with a professional patent attorney – ensure that the requirement of an enabling disclosure is fulfilled when filing a patent application.

Read the related sections:

Claims must be clear and concise
Structure of patent claims

at www.mva.org/patentguide

WHEN TO FILE DOCUMENTATION SUPPORTING THE INVENTION

When deciding to file a patent application, additional considerations relate to the fact that a broader protection of an invention can often be afforded when the applicant is more capable of providing a detailed disclosure of the invention. However, this can also be achieved by filing additional information on the invention subsequently. Depending on the time of filing of such information, it can either be included in an updated patent application, or be included in the official file in the possession of the patent authorities.

When filing a patent application directed to a biotech invention – particularly in the field of pharmaceuticals – experimental results are often not available at the time of filing the patent application. Experimental results documenting the effects of, for example, a pharmaceutical composition can be filed during the prosecution of the patent application. Such results can be filed at any time, but they can only be included in an updated patent application when filed before the expiry of the priority year.

NOVELTY SEARCH BEFORE FILING A PATENT APPLICATION

A pre-filing evaluation is an essential requirement when drafting patent claims. The knowledge obtained from such an evaluation can result in a more effective protection of an invention. A pre-filing evaluation can be used:

- as inspiration, before launching new development activities
- as a basis on which to assess the possibilities of new activities in the area
- to assess a new product's commercial viability
- to acquire knowledge of the relevant operators within a given field
- to check whether the rights of others will be infringed
- to check in which countries rights apply

Links to literature about patents may be found at www.mva.org/patentguide.

Essential requirements of a good patent application:

- **Broad patent claims, citing a combination of physical and functional features**
- **Concise claim language that clearly defines the scope of protection**
- **A carefully-drafted claim structure, offering optimal protection**
- **Enabling disclosure of the invention**
- **A good understanding of the novelty situation**

A careful consideration of the above criteria for drafting a strong patent application will give the best chance of effectively protecting an invention.

Once a patent application has been filed, several other considerations and decisions must be made in order to ensure optimal protection of the rights to an invention.

FILING A PATENT APPLICATION AND CREATING A PRIORITY

The effect of having a right to a priority is that the filing date of a first patent application is regarded as the date of filing, rather than the filing date of a later, updated patent application, provided that the same subject matter is disclosed in the two applications.

A claim to priority is based on both the claims and the description of a first patent application. If the combination of features of a particular claim in a later patent application can also be found in a first patent application (priority patent application), then that claim has a valid right to priority. If, for example, a priority patent application claims a combination of elements X, Y, and Z, a claim to priority for a patent claim in an updated patent application citing only features Y and Z will not be valid. Y and Z will be given the date of filing of the updated patent application as the effective filing date.

An updated patent application can claim priority from one or more earlier patent applications, provided that the earliest patent application is filed less than one year prior to the filing of the updated patent application. In such a situation, different claims are likely to have different priority dates.

The countries in which the owner of an invention will apply for patenting must relate to the main markets - including those of licensees. Also, the countries of production, as well as those of the competitors must be closely examined. Europe, USA, Canada, Japan, Australia and China are the countries that most often will be considered for patenting.

IPR management in a booming industry

BY MÅRTEN ÖBRINK, DEPUTY CEO, PRECISE BIOMETRICS

Biometrics, the verification of identity based on physical characteristic such as fingerprints, was hardly heard of five years ago when Precise Biometrics was founded. Fingerprint verification was then the only method used for crime prevention – end of story. Today, using biometrics to ensure network security or control access to buildings is viewed as a-state-of-the-art security solution. The biometrics industry is expected to grow by 50-70% per year during the coming years. In a market such as this, in which intellectual property rights (IPR) and an IPR strategy are crucial, Precise Biometrics has had a focus on patents and trademarks from day one.

THE BALANCING ACT

The balancing act a start-up company needs to perform is to file patents for its core technology and important basic inventions, but not too many – as patents are expensive. Precise Biometrics started out by filing patents for its matching algorithm, this being the core technology. The next step would have been to apply for patents for applications and solutions in which our core technology is used. Knowing this would be very expensive, resulting in tens of applications for a small start-up company, we chose not to do that.

Instead, after closely monitoring the industry and taking Precise Biometrics´ competence into consideration, we chose to focus our business, resources and IPR strategy on biometrics for mobile terminals and smart cards. Precise Biometrics is very aggressive in filing patents in its chosen field, but has chosen not to file patents for generic biometrics inventions – applications and system solutions comprise our core technology.

There is a certain risk attached to this strategy, in that competing companies may file surrounding patents, but since Precise is licensing biometrics technology to other, larger companies, this threat is considered an acceptable one. Solutions can often be tweaked so as not to infringe on a certain patent, but basic patents are often impossible to circumvent.

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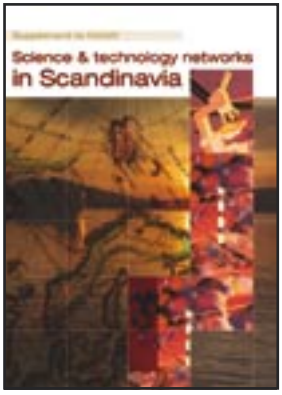
Upcoming Supplement to *Nature*

Science and technology networks in Scandinavia



December 12th 2002 Nature Publishing Group will publish a supplement to *Nature* giving you a totally unique view of Scandinavian science.

Editorial from *Nature* & *Nature Biotechnology* reveals the drivers of success in this burgeoning region. And discovers how collaboration and synergy have resulted in world-class science.

Industry, academic, financial, legal and governmental organisations will present their operations within the suppliment too. Creating a useful guide to partnership and advancement within this region.

For more information and to take advantage of this forthcoming suppliment call our dedicated Scandinavian consultants:

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IPR BUSINESS

When setting the focus for our IPR strategy, we found a patent application filed by a competitor of ours that was uncomfortably close to our chosen path. When the time was right, we acquired this application. This gave a broader protection of our core technology and supported our business strategy accordingly.

Today, Precise Biometrics has five patents granted and applications for 16 inventions filed. We have taken out patent insurance to cover the expenses of defending our rights in court, should that prove necessary

The focus on IPR has remained high within Precise Biometrics. We believe IP is an important tool for achieving success in a booming market.

7. Patent application drafting and prosecution

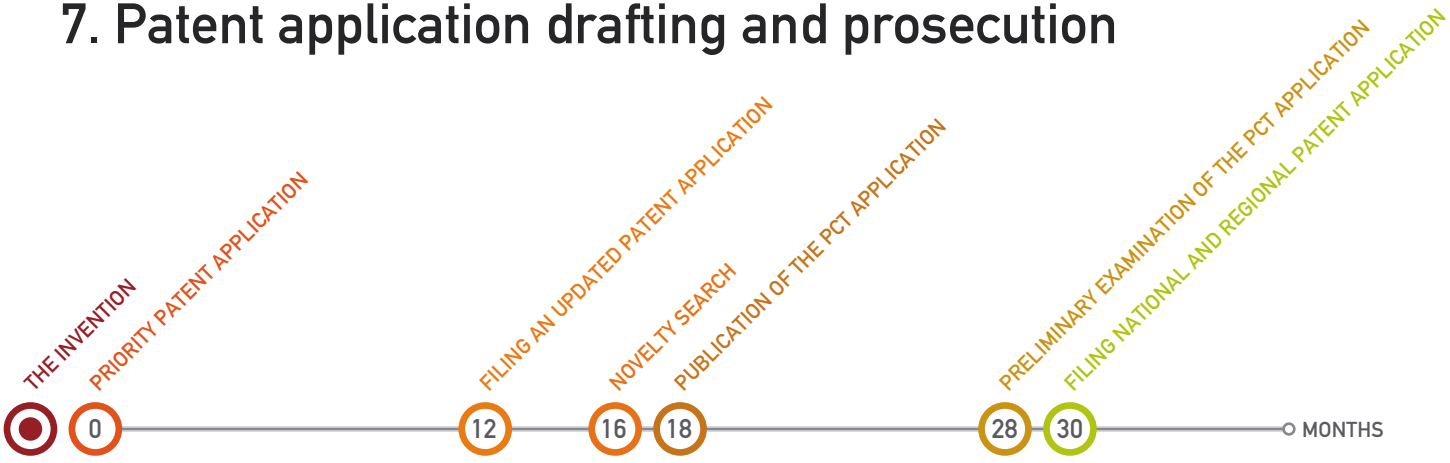
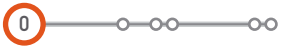


FIGURE Patent application process

This chapter describes many of the activities an inventor must deal with once a priority patent application has been filed. Various stages of the prosecution of a PCT application are described in detail, including budgets normally associated with prosecution of a PCT application relating to a biotech or medicotech invention. The budgets are excluding VAT and including official fees and attorney fees, if any, payable to the patent agency handling the PCT application.



PRIORITY PATENT APPLICATION

Apart from assessing the novelty of the invention, it is often advisable to carry out a pre-filing evaluation of the invention. You can carry out this investigation yourself, or use expert technical advice. See also chapter 6.

The first patent application describing an invention is a priority-founding patent application, establishing the right to claim priority under the Paris Convention (see www.mva.org/patentguide).

In order to establish the best possible priority basis for the filing of an updated patent application, a priority-founding patent application should have a content describing the invention in both general and more detailed terms. In case new, important knowledge concerning the invention is acquired within the priority year, it is recommended that such new aspects be described in a new priority-founding patent application or in an updated patent application to be filed before expiry of the priority year. A priority year is a period of 12 months after the filing of a priority-founding patent application.

The establishment of a priority implies that an applicant may within the priority year file an updated patent application in the states having ratified the Paris Convention. An updated patent application filed under claim of priority from a priority-founding patent application will be regarded as filed on the filing date of the priority pat-

ent application. The priority date of a patent application is of importance in connection with judging the novelty of an invention and the relation of the patent application to younger patent applications, and it can therefore be important to obtain an early filing date.

It is recommended that a priority patent application be subjected to a novelty search carried out well in advance of the expiry of the priority year by, for example, the European Patent Office (EPO). A "Standard Search" performed by the EPO renders it possible – before filing an updated patent application – to judge the novelty of the invention and the inventive step thereof on the basis of the patent claims filed.

It costs around DKK 16,000 to have a "Standard Search" carried out. On top of this comes a possible examination of and commentary on the material resulting from the novelty search. When filing PCT application, the "Standard Search" will entitle the applicant to a reduction in submission fees, as the authorities will allow the result of an earlier "Standard Search" to be incorporated, to a certain extent, into the novelty search carried out for the PCT application.

The Patent Cooperation Treaty (PCT)

When availing of the PCT system, an applicant needs initially only to file a single, updated patent application (PCT application). In the PCT application the applicant can list (designate) all the PCT member states in which patent protection should be secured. More than 115 countries are members of the PCT.

Read more at www.mva.org/patentguide

12

FILING AN UPDATED PATENT APPLICATION

It is possible to update a priority patent application, if this takes place no later than 12 months after the filing of the priority patent application. Updating a priority patent application can be done by filing e.g. an international patent application (PCT application) or a European patent application.

Filing a PCT application secures an applicant, the right to file national or regional patent applications in PCT contracting states at a later stage. One advantage of filing a PCT application is that the application will initially be prosecuted in a centralised, international phase of the procedure, and only later entered into the national or regional phase. The entry into the national or regional phase involves the filing of national or regional patent applications. The cost of filing national or regional patent applications can be postponed by initially filing a PCT application. Prior to filing a PCT application, it should be considered to file national patent applications in states not party to the PCT. For states which are not members of the PCT, but which recognise claiming priority under the Paris Convention, an updated patent application can claim priority from, e.g. a Danish priority patent application. This is not the case with states that do not recognise claiming priority under the Paris Convention.

The cost of filing a PCT application is typically DKK 35,000-55,000.

NOVELTY SEARCH

Having filed an updated patent application as a PCT application, an international search report is issued about 16-18 months after filing the first priority creating patent application. This report identifies relevant prior art references. The cost of having a patent agency to examine prior art references cited in the Novelty Search is typically DKK 5,000-15,000.

PUBLICATION OF THE PCT APPLICATION

The content and filing of a priority patent application is kept secret at the time of filing the priority patent application. The public will not become aware of the filing of a priority patent application until 18 months after the filing, when the PCT application is published.

PRELIMINARY EXAMINATION OF THE PCT APPLICATION

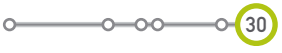
A demand for a preliminary examination of the PCT application must be filed no later than 19 months after the filing of the first priority patent application. The preliminary examination involves issuance by the PCT authorities of a detailed preliminary examination report on the novelty and inventive step of the invention in question.

One reason for requesting a preliminary examination – besides postponing until 30 months the entry into the regional/national phase of the PCT application – can be the wish to obtain a preliminary examination report acknowledging that the invention is novel and associated with an inventive step – essential requirements for later obtaining a patent and also important, when seeking venture capital.

Having prosecuted the PCT application in the centralised PCT phase can benefit the PCT application when it subsequently enters the regional/national phase, as many regional/national patent authorities will be inclined to recognise the conclusion of the preliminary examination report drawn up in the PCT phase.

A request for a preliminary examination of the PCT application at the European Patent Office (EPO) costs around DKK 16,000.

If the preliminary examination is carried out by the Swedish patent authorities, the cost is DKK 8,500. A request for a preliminary examination at the EPO will entitle the applicant to a reduction in fees of about DKK 5,500 if the PCT application is later submitted to the European authorities as a European patent application.



FILING NATIONAL AND REGIONAL PATENT APPLICATIONS

At about 30 months after having filed the first priority patent application, the PCT application must be entered into the individual countries in which it has decided to obtain patent protection. The budget for filing national and regional patent applications depends on the number of applications filed and the number of translations into a national language which are required.

8. Disclosure of an invention

FILE A PATENT APPLICATION BEFORE DISCLOSING THE INVENTION

In the absence of any detailed knowledge about the requirements for patentability, inventors have been known to publicly disclose an invention before the date of filing of a corresponding patent application.

A public disclosure of an invention – made before filing a patent application – will be citable against the later filed patent application in Europe and elsewhere.

A public disclosure of an invention by an inventor does not affect patentability in the USA negatively, provided that a patent application is filed within a grace period of one year after the public disclosure of the invention (see chapter 9). A grace period of six months applies in Japan.

When an unintentional disclosure of an invention has taken place, it is necessary to consider carefully what has been made public, and what the public can actually learn about the invention from the disclosure. What has not been disclosed to the public cannot deprive the novelty of an invention contained in a later filed patent application.

DISCLOSURE OF THE INVENTION DURING THE PRIORITY YEAR

Should the invention or a part thereof be disclosed to the public during the first 12 months (the priority year) after the filing of a first priority patent application, such a disclosure will be citable against an updated patent application claiming priority from the first application.

It is not recommended that an invention be disclosed during the priority year unless there is a strong need for disclosing the invention to the public. Should the invention be further developed during the priority year, it is recommended that a patent application be filed containing such further developments before the developments are made publicly available.

SECRECY AGREEMENT

Discussions with investors, licensees and other partners can take place during the priority year, provided that the parties have signed a secrecy agreement. The secrecy agreement should cover the period up to at least the point when the patent application is made publicly available. Discussions of know-how that is not disclosed in the patent application should be kept secret for a longer period of time.

9. Differences between Europe and USA

There are a number of differences between the patent laws of Europe and USA. One example is the way in which the right to an invention is determined. In contrast to the "first-to-file" principle, which applies in Europe, the "first-to-invent" principle applies in the United States. This means, in principle, that if two or more parties are claiming patent rights to an invention in the USA, the party that can prove itself to have been the first to invent will be awarded the right to the invention. However, in the United States, an early filing of a patent application will normally also be an important consideration when securing the right to an invention.

In relation to the USA, it is important that the documentation of being "first-to-file" can be based on, for example, the records of your work. This may prove essential in legal proceedings if the right to an invention is disputed. However, besides being "first-to-invent", there are other criteria involved in the determination of an early filing date in the USA. The date of "reduction-to-practice" also plays an important role in determining who has the earliest invention date in the USA. "Reduction-to-practice" refers to the date on which the invention is reduced to practice, i.e. developing a prototype, obtaining proof-of-concept of the invention, or filing a patent application. Accordingly, in the USA, the timing of filing a patent should also be carefully considered.

GRACE PERIOD

In Europe, if the invention has become publicly available in any way before a patent application is filed, the application will be rejected for lack novelty. However, as the USA has a one-year grace period, an inventor can decide to patent an invention in the USA even after the invention has been made publicly available without losing patent rights in the USA.

BEST MODE REQUIREMENT

US patent law requires that the best way to practise the invention is included in the patent application. In this way, US patent law ensures that it is impossible to obtain a patent and still keep some essential or advantageous aspect secret.

In contrast, European patent law has no such requirement. At least one way of practising the invention must be included in the application, but it is a possibility to disclose a good way, let alone the best way, to carry out the invention.

PUBLICATION OF A PATENT APPLICATION

Until recently, US patents were only published after they had been granted. This has now been changed; US patent applications are now published 18 months after their filing date (or priority date), unless they have been filed with a non-publication request stating that the application is a

… to be continued

10. Strategic use of a patent

… continued

US patent application only. In Europe and in the rest of the world, all patent applications are published 18 months after their filing date (or priority date).

The publication of a patent application is not an indication of the patentability of the invention disclosed in the published patent application. However, publication can give rise to a "provisional protection", subject to national law. The provisional protection does not necessarily provide the same protection as a granted patent, but it does provide a means to seek damages if there is an infringement of the published patent claims.

PROCEDURE AFTER GRANTING

Within nine months of the granting of a European patent, anyone can file an opposition with the European Patent Organisation (EPO) and provide documentation as to why the European patent should not have been granted. The patent holder and the opponent will enter inter partes proceedings, and the EPO will take a decision based on the facts, evidence and arguments presented by both sides. Both parties can appeal the decision, which once again results in an inter partes proceeding, terminated by a decision reached by the EPO Boards of Appeal.

While the USA has a re-examination procedure, it does not resemble the European opposition procedure. Although anyone can present arguments and evidence to the patent authorities in the USA and thereby challenge the validity of a granted USA patent, it is for the patent holder and the patent office to establish in ex parte proceedings the validity of the arguments and the evidence filed. As such, the challenger is not a part of these proceedings.

In their early stages of development, almost all biotech and medicotech companies depend heavily on their technology for commercial success. It is important to map out future growth areas, as well as prevent competitors from gaining access to an emerging market.

Only a minor part of R&D companies in Denmark and Sweden have a patent strategy. However, formulating and using a patent strategy is essential if a technology-based company is to obtain and sustain a competitive advantage.

A patent strategy can focus on:

- the protection of in-house technology and development
- effectively preventing competitors from obtaining protection of competing technologies

Effective protection of a company's technology is usually sought by way of patents, whereas the goodwill of the company and the branding of innovative products are most commonly protected by means of trademark registration.

As an effective patent strategy is a key factor in commercial success, an ineffective strategy or even neglect of intellectual property assets may very seriously hamper a company's ability to compete in the marketplace.

A company's patent strategy must seek to answer fundamental questions about the competitive market forces in order to ensure coherence with its overall business strategy.

Although many companies succeed on the basis of their ability to maintain a strong presence in the market,

or by offering competitive prices, the competitive edge of a specific product depends almost always on the product technology.

A successful company must seek to answer the following questions:

- what forces are driving the competition in our industry and in the industrial fields we would like to enter?
- how are industries in these fields likely to evolve?
- what actions are our competitors most likely to take?
- how should we respond to such actions?
- how can we improve the competitive advantage of our company in the short term and in the long run?

It can be helpful to use management tools to manage and evaluate patents and trademarks. An example of such a tool is the Ipscore model, which can give a picture of the strategic value for companies of a patent or a trademark. Ipscore forms a basis for evaluating to which extend companies must act in order to increase the value of their rights (see www.ipscore.com).

By claiming the rights to its proprietary technology and branding its products, a company can effectively reduce the threat of competition and lessen the threat of substitute products and services appearing. When properly directed, patents not only play a role in protecting a company's business, but often develop into valuable and tradeable assets in themselves. Therefore, selling and licensing patents are of increasing importance in effective business strategies. Read more about licensing in the next chapter.

As a company matures and becomes better known, its goodwill begins to play a more important role, and the sale of products and the provisions of services becomes heavily dependent on associated brand names and on the technology embodied in them.

It should be noticed that it is not sufficient merely to focus on the protection of the company's own assets; it is also of the utmost importance to continue to survey competitors' intellectual property rights and, if necessary, find ways to avoid infringing these.

Companies may also form alliances or carry out other commercial transactions based on the intellectual property rights afforded by a key patent. In addition, "spin-off" inventions originating from an original project may themselves be viewed as tradeable assets, generating capital from royalties and other payments. It is thus clear that an informed strategy for patenting innovative technologies can produce a variety of commercial benefits.

Speed, aggression, surprise

Capturing maximum value with intellectual property

BY CHRISTIAN HANSEN, PHD, MBA, PARTNER AND CO-FOUNDER OF NORDIC BIOTECH

When founding ProFound Pharma A/S in the beginning of 1999, I was inspired by the motto of the British commando unit, the Special Air Services (SAS): Speed, Aggression, Surprise. It is the recipe for how a small, agile, and highly efficient unit can strike with great impact at the key positions of much larger forces, and beat the likes of Amgen, Biogen, Chiron or Genentech.

ProFound was based on the following observations:

- Protein-based pharmaceuticals constitute 10% of global drug sales
- There are several protein-based drugs on the market and under development
- Most of the important products in the area were developed and patented in the early 1980s and face patent expiry in 2005-2010
- The problems and desired improvements of 1st generation protein drugs were known, as well as technologies addressing these shortcomings
- The owners of several major 1st generation products had not efficiently created and patented 2nd generation versions of their products
- There is (was) an opportunity for creating and patenting these 2nd generation products via a new entity – ProFound.

It goes without saying that the ability to rapidly identify and hire a group of highly talented people in the area was necessary, and fortunately possible.

This reality, and the fact that the opportunity could be pursued by others as soon as it became public knowledge, dictated an SAS-like approach to the situation:

Speed in conceiving the potential for improvement of important proteins, **aggression** by filing a very large number of patent applications for many newly-conceived molecules, and **surprise** by not telling anyone of this strategy until it was too late for them to counter-attack.

This turned out to be a fruitful model for creating and capturing value very rapidly, and reaffirmed my basic philosophy concerning patents (also somewhat inspired by armed conflict): shoot first and ask questions later – file now and reduce to practice later.

So what does "file now and reduce to practice later" mean?

Not being an educated patent attorney allows me to simplify the matter a bit, and real patent attorneys might want to furnish more nuances. Nonetheless, patent law has no requirement for an invention to have been physically reduced to practice, i.e. actually made in the laboratory, but only that the patent application enables "the skilled man" to do so.

Having many creative AND skilled men and women in the organisation, we were able to conceive of thousands of modified proteins with a likely potential of having properties superior to those of 1st generation molecules, and to file, within a year of starting the company, more than 50 patent applications concerning such improvements to most of the important protein-based drugs in the market.

This multi-pronged approach, in turn, reserved a large space for ProFound to operate in while choosing the best few projects to pursue, identifying the best molecules among all of the conceived molecules, and awaiting the publication of competing patent applications for 18 months after our initial filings. It also provided a protective wall around our favourite candidate molecules against other parties´ molecules which offered the same improvements in performance, but which had different structures.

358 days after the foundation, about 9 months after the first experiment had been performed, and before any of our patent applications had been published, the owners of ProFound agreed to sell the company to US-based Maxygen for more than DKK 500 million, demonstrating the forcefulness of a speedy, aggressive and surprising approach to IP in the biotech business.

We question everything that is safe and good!

When the market changes the company must be prepared to change its reality. That is easier said than done - it is much easier to do like you did yesterday.

Now and then you might need somebody to see the necessary changes – and also to help you carry them out.

That is our area of expertise. We change everything that is safe and good today to make it even better tomorrow.

Within the pharma, the medico and the biotech area our focus is to ensure
- strategic focus and efficient management processes
- consolidation and growth in innovative companies
- managing the innovation culture under pressure from milestones.

For further information regarding our experiences within the pharma, the medico and the biotech area please contact Carsten Frølund Jensen, Michael Nielsen, Kirsten Meldgaard or Jakob Grane by phone +45 70 10 50 00.

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11. What is a patent license?

This chapter provides a basic understanding of the nature of patent licenses and some of the terms used in licensing transactions.

WHY A PATENT LICENSE AGREEMENT?

A license agreement is a very important kind of agreement; license agreements contribute substantially to the income of many small, medium-sized and even large enterprises. The 1998 Novo Nordisk accounts provide a good illustration: the annual report reveals that total profits before tax were DKK 3,740 million, of which the net income from licensing alone was DKK 1,469 million.

A patent license agreement may be entered into for various reasons. Some of the main reasons are:

- the licensor lacks adequate production and/or marketing facilities
- the licensor lacks the financial and/or technical resources needed to further develop the invention
- the transportation costs of the invented product from the licensor's production
- facilities to the market in question are prohibitively high
- the exploitation of the invention does not fall within the core business of the licensor
- the licensee has more adequate production and/or marketing facilities, better financial and technical resources, etc.
- the licensee needs the technology in order to run and/or develop his business
- the grant of a license, or of reciprocal licenses, is an important ingredient in the settling of patent infringement disputes

As mentioned, a patent gives you as a patentee the right to prevent others from exploiting the invention covered by the patent. This also enables you to grant others a right to exploit the invention. An agreement in which such a right is granted is called a patent license agreement. The patentee is called the licensor, and the party to whom the license is granted is called the licensee. If the licensee, in accordance with the patent license agreement, is permitted to grant licenses to third parties to exploit the invention, he is said to have sub-licensing rights, the licenses granted by him are called sub-licenses and his licensees are sub-licensees.

DIFFERENT KINDS OF LICENSES

A patent license agreement will often include a provision forbidding a licensor from exploiting the invention himself and/or granting similar licenses to third parties. A license is called a "non-exclusive license", when no such restrictions have been imposed on the licensor. If the licensor may not grant similar licenses to any third parties, but the licensor is not prevented from exploiting the invention himself, the license is called a "sole license". If the licensor must refrain from granting licenses to third parties as well as exploiting the invention himself, the license is called an exclusive license. A license and the exclusivity granted to a licensee may be world-wide or may be limited to certain countries, or even to particular regions within a country.

"Sole license" and "exclusive license" are commonly regarded as being very precise terms with specific meanings. Unfortunately, they are not. If a Danish licensor, for example, has granted an Italian licensee the "exclusive license" to produce and sell a certain product in Italy, it is not necessarily clear whether the licensor may or may not sell the product in Denmark to an Italian company which clearly wishes to take the product to Italy and put it on the market there. When major players in a market are involved

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in patent licensing transactions in the European Union, exclusivity clauses are subject to a quite complicated set of competition law rules. Non-compliance with these rules may be met by rather drastic sanctions. There are thus several reasons for exercising care when drafting exclusivity clauses in a patent license agreement.

THE LICENSEE'S PAYMENT

The licensor's interest in granting a license is normally the prospective income involved. The licensee's payment for the license may take several forms, and the various forms can be combined in different ways. An up-front payment is a payment which is to be made when the license agreement is signed. If no further payments are required, the license becomes a paid-up license. If the licensee is required to pay certain amounts if and when various milestones are met – e.g. after proof of concept, when phase 2 of the clinical trials is initiated etc. – the payments are called milestone payments. When the amount to be paid by the licensee depends on the extent of the licensee's exploitation of the invention – typically a percentage of the relevant part of the licensee's turnover – the payment obligation is termed an obligation to pay a royalty.

The word "license" is quite often – but erroneously – used as the term for a running fee paid by the licensee to exploit the patented invention, if this fee in some way reflects the extent of the exploitation. The correct term for such a running fee for a license is a "royalty".

ROYALTIES

In the royalty provisions of a license agreement it is often agreed that the licensee shall pay a minimum amount every quarter, every year, or the like. This is a minimum royalty obligation. Care must be taken when drafting a minimum royalty provision, as it can have extremely unpleasant taxation consequences if it is not done correctly. All license agreements granting the licensee exclusivity of some sort should have adequate minimum royalty provisions in order to ensure that the licensee is seriously interested in the exploitation of the invention, and will not abuse the exclusivity, with the result that the invention is exploited neither by the licensee, nor by the licensor or any third parties (potential licensees), who, due to the exclusivity agreement, may not exploit it in the licensee's territory.

Commercial exploitation of intellectual property

BY DOMINIC CLARK, GENERICS GROUP

The fundamental role of patents is to provide legal protection that supports the commercialisation of products and processes. In consequence, the management of intellectual property is increasingly assuming a higher profile on the high-tech corporate agenda. It is well accepted that in a small company, the quality of people comes first, followed closely by the quality of the intellectual property portfolio. In a large company, a similar hierarchy applies, except that intellectual property is usually classified under intellectual assets, which includes know-how, human resources, goodwill, etc, as well as intellectual property, representing those assets capable of being protected according to legal statute. Generally, the market value of a corporate asset exceeds its book value, and the difference is generally attributed to the value of the intellectual assets. In short, in most corporate settings, intellectual property value is getting much more attention.

Biotechnological and biopharmaceutical start-ups, and other small companies, are even more dependent upon intellectual property. In the absence of revenue from 'real' products, the company will often be valued in terms of the strength of the intellectual property covering its potential products. In selected cases, this may extend to its ability to dominate, and hence secure revenue from, others.

Consequently, it is important to be vigilant with regard to changes in the global intellectual property landscape. In consequence, we recommend that regular searches be made for all US and EPO-granted patents, as well as for all newly-published PCT and US patent applications. A thorough analysis must be made of any relevant new patents by persons skilled in the relevant technical area and the fundamentals of patent law. In this way, key documents can be flagged early and 'dealt with' to minimise the impact on the company's proprietary position. With currently over 100,000 PCT applications being received by World Intellectual Property Organization, WIPO, per annum, and over 170,000 US granted patents being issued in the year 2001, one can see the importance of keeping abreast of global technical developments is obvious. The stimulus to internal developments from exposure to other innovations is a valuable spin-off from this process.

As a company grows, new challenges and opportunities arise in the commercial exploitation of intellectual property. Virtually any company supporting an R&D group will aim to develop inventions that clearly support the company's product / service portfolio. Mergers, acquisitions, changes in strategic focus, external forces and the passage of time generally lead to the more typical scenario, in which a significant percentage of patents in the portfolio may become 'non-core'. What this means is that they do not directly support actual offerings in the marketplace, or the products or services in development, or the technology platforms that support them. This scenario is often a reality in the small to medium size company that has been in existence for several years, and it leads to the question: how can we optimise the commercial potential of our portfolio while reducing the management costs? The approach we recommend can be termed a commercial intellectual property audit. This has several results. Specifically, it can:

- show that the intellectual property base has a demonstrable value to the business
- identify the intellectual property that is core to the current business
- identify potential opportunities for additional revenue generation and future growth
- identify potential for cost reduction by disposal of (selling or discontinuing support for) redundant intellectual property

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This is a commercial process that must necessarily involve R&D, marketing and commercial managers as well as the intellectual property department. The first step is to cluster patents into families and review the key patent in each family with the relevant R&D manager, in order to ascertain the relationship between patent families and products/technologies. A higher-level commercial analysis can then classify each family as Core, Defensive, Dormant or a Disposal opportunity. Each of these categories will have associated action plans.

If there is a large patent portfolio, high-level visualisation techniques can be used to provide an overview and mapping of the patent portfolio as a patent estate. A number of techniques have been developed to partly automate this process. However, these need to be driven by individuals with commercial and technical knowledge, as the processes of patent clustering and mapping are iterative and dependent upon the effective selection of clustering criteria. Using this technique, it is possible to identify islands of intellectual property and the relationship between these islands.

The next stage can be to broaden the analysis to include actual and potential competitors who are either already known or have been identified as a result of the analysis. A patent landscape map that includes the intellectual property of competitors can be a powerful high-level tool for providing input into business development decisions. These include identifying potential disposal routes for non-core intellectual property, either through exclusive out-licensing, non-exclusive out-licensing, or the establishment of a joint venture. Another route for identifying out-licensing opportunities for non-core intellectual property is through the analysis of patent citations. If a core patent for assignee A cites a non-core patent for assignee B, then assignee A may have an interest in licensing the non-core patent from assignee B, as it strengthens the intellectual property position of A. The analysis can go further, in that intellectual property that is core to a product or technology platform in a certain field of application may have other potential applications in different industry sectors. This presents new out-licensing possibilities and other routes for commercial exploitation, which means that the creation of potential new revenue streams can be based on intellectual property that is already core in one field of application through the identification of potential new fields of application.

12. Litigation Insurance

According to the Danish Patent and Trademark Office, more than 60% of Danish companies have experienced 1-5 infringements of their intellectual property rights within the last 5 years!

One of the most dramatic demonstrations of the importance and strength of patents was exhibited several years back when the Polaroid Corporation sued Eastman Kodak for infringement of some of its patents relating to its instant picture technology. Kodak, after losing this infringement suit, was ordered to pay Polaroid damages in the amount of US$800-900 Millions and was forced to close a plant where it had invested a sum of about US$1-1½ Billion. Thus, in addition to getting a large monetary compensation, the patent gave Polaroid an absolute monopoly.

Source: www.patents.co.il/artsum17.html

In this guide, it is argued that patenting is a necessity when exploiting inventions. However, when patenting, it is recommended to be aware of the consequences if you are confronted with intellectual property litigation. For companies, intellectual property litigation can be disruptive, expensive and, in extreme cases, ruinous.

Intellectual property litigation insurance offers comprehensive protection to businesses against the high legal costs associated with intellectual property litigation and the damages that can be awarded.

The scope of cover available will vary according to differences in national legislation and in the incidence and severity of litigation and liability around the world, but coverage may in general be obtained for the following:

EXPLOITATION AGREEMENTS

These cover the professional fees and expenses incurred in enforcing the contractual terms inherent in an agreement. In many cases, cover can also apply to the defence of an unintended breach. This aspect of cover is important to any company, which is involved in 'licensing-in' or 'licensing-out' intellectual property rights. Confidentiality and non-disclosure agreements can also be covered.

DEFENCE

This covers professional fees and expenses incurred in defending a claim by a third party that the products or methods are used or sold by the assured intellectual property rights. Cover can often include any liability damages that the client may be obliged to pay in the event that the defence is unsuccessful.

INVALIDITY / OWNERSHIP

This covers the professional fees and expenses incurred in defending a challenge to the ownership, validity or title to intellectual property rights. The cover can apply to rights that have been granted.

PURSUIT

This covers the professional fees and expenses incurred in pursuing those who infringe intellectual property rights. Cover can apply to virtually all forms of intellectual property rights, from patents to copyright, trade secrets, domain names or unfair competition.

It is normally possible for cover to apply to an entire portfolio of rights, wherever these exist.

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MEDICON VALLEY
ACADEMY

Medicon Valley Patent Guide is published by Medicon Valley Academy

Medicon Valley Academy's (MVA) objective is to develop Medicon Valley into the most attractive bio-region in Europe. MVA has set out to reach this goal by means of a three-pronged strategy: Create, transfer and exploit knowledge.

To create a scientific environment of global excellence in the region
To transfer knowledge, technology and new ideas from research to industry
To exploit transferred knowledge and technology

Join MVA

MVA is a regional non-profit Danish/Swedish organisation. MVA's members include all the relevant university faculties, health care organisations, the majority of biotech and medico-related companies, and other organisations located in the Øresund region. Organisations and companies located outside the region can join MVA as associated members.

All members share a common interest in the development of the biotech, medico and health sectors in Medicon Valley. MVA membership includes service benefits regarding priority access to a knowledge and network platform and participation in MVA arrangements such as seminars and conferences. In addition, MVA membership includes exclusive company/organisation profile and other services at our website.

www.mva.org

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AFTER THE EVENT

A common dilemma for many businesses and their advisers is that they discover the availability of intellectual property litigation insurance too late.

It is now possible to arrange cover on an 'after the event' basis in many jurisdictions, to enforce intellectual property rights, contractual obligations and even defend third party actions.

After the event policies can protect the insured party from the downside of known litigation by covering legal costs (and certain disbursements) in the event that the action is lost. In certain cases, the potential liability can also be insured. The policies are not activated if the insured party wins the case, or if a settlement is reached which is in favour of the insured party.

This form of policy often requires an assessment of the case by specialist advisers selected by insurers. The cost of the assessment is met by the assured party on the understanding that if insurers decline to offer terms, or the assured party decides not to proceed with cover, the assessment fee is non-refundable. If insurers issue terms which are accepted by the assured party, the fee is discounted from the premium.

ASSET PROTECTION

Intellectual property asset protection insurance complements the cover provided by litigation policies.

The litigation policies mentioned above focus on the costs of litigation and on questions of liability. Asset protection policies, on the other hand, focus on the revenue streams generated by intellectual property rights and their value. The basis of indemnity is tailored to clients' individual circumstances. Just as the prosecution process for registered intellectual property rights has three main phases, the basis of indemnity varies between:

- reimbursement of R&D costs – for intellectual property still under development
- loss of profit calculated on future projected earnings – for businesses whose products are newly launched
- loss of profit calculated on past earnings – for mature products

The policies require the intellectual property to be valued prior to inception, so that all parties are agreed on the value of the rights and are aware of the method of valuation. In addition, a legal audit is undertaken to identify any potential problem areas before cover is effected.

The types of event that can trigger a claim include:

- an unsuccessful defence of an infringement action, resulting in the insured party being prohibited from marketing a product
- the invalidity or revocation of the rights in whole or in part
- governmental action preventing the exploitation of rights
- adverse or misleading reports

In organisations with a complex corporate structure, the level of importance placed on intellectual property and its value can have a significant impact on that organisation's ability to enforce its rights and to achieve compensation in case of infringement. The audit and valuation process is one way of achieving greater efficiency in the management of a company's intellectual property and reducing risk in areas not directly related to the insurance policy.

Patent experts and authorities in Medicon Valley

Patent experts and authorities in Medicon Valley

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The Danish Patent and Trademark Office is a government agency under the Danish Ministry of Economic Affairs and Trade. The Danish Patent and Trademark Office issues patents and registers trademarks, utility models and designs.

As experts in technical research, we are a powerful partner in innovation. We assist companies as well as individuals in the innovation phase, whether these are companies launching a new product, or actors who are just beginning the process and require some assistance in the various phases of innovation.

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Swedish Patent and Registration Office, PRV, is one of the world's twelve international patent offices. The Patent Department processes national and international patent applications, and handles new product searches in behalf of the European Patent Office and our own Commercial Department. We handle applications from all technical fields, such as mechanics, electronics, biotech and chemistry.

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BioVision is a pre-seed financing company specialised in funding commercial research in the area of biomedicine and biotechnology. In addition to providing capital, we can offer active management assistance, based on our knowledge of technology and the market.

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Converting research into business can be complicated. CAT offers competent project managers and venture capital, as well as a physical infrastructure and administrative support.

CAT/DTU is mainly concerned with engineering, science research environments, micro-technology, communications technology and electronics.

CAT/Risø mainly deals with materials, sensors, optics, energy, etc.

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The university and the university hospitals have established a close cooperation on the administration of the new act governing researchers' patents, as many of their research projects are also conducted in collaboration. Each of the three partners, however, has its own set of contact persons.

The University of Copenhagen faculties represented include those of medicine and natural sciences, with basic and strategic research in life sciences, health sciences, molecular biology, chemistry and general biology, as well as geoscience and physics.

The university hospitals are all very active in research within basic and applied "human" biotechnology and medical technology, including the use of information technology in medical care.

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Danish Science Park aims to provide the most attractive and flexible environment in Scandinavia for knowledge-based companies and institutions working in the fields of biotech, medicotech, the environment and IT.

Danish Science Park encompasses 66 companies and institutions, and has more than 3,000 employees.

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In accordance with the Act on Inventions at Public Research Institutions, scientists employed by the University must notify the University concerning any inventions produced by them during their terms of employment. Consequently, the Patent Office deals only with inventions produced by university staff.

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DTU Innovation invests in research-based start-ups in the greater Copenhagen area. We prefer to invest in projects based on IPR with substantial market and growth potential. Seven of the biggest Danish companies and a group of private investors provide us with market knowledge, technical know-how, contacts, and adequate financial resources.

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Forskarpatent i Syd AB was established to increase the commercial value of the results of scientific research performed mainly at universities and institutes in southern Sweden. Forskarpatent i Syd AB invests in scientific inventions and offers professional management of patent and licensing issues, through agreements with individual scientists or groups of scientists.

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The Ideon Science Park lies in the heart of the extensive Øresund region, which encompasses Lund and Malmö in southern Sweden, and Copenhagen in Denmark. Ideon Science Park, with 180 companies and 2,100 employees, of which 30% are from the biotech area, offers the ideal conditions for high-tech and research-based growth companies.

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Innovation Skåne is a professional coach to inventors within Skåne. The mission is to help capitalise and exploit the social and commercial potential of an idea. Innovation Skåne focus energy on helping individuals and companies achieve their potential by offering free consultation and by financial support.

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Medeon offers incubator services for start-up businesses. The target group is composed of researchers within the medical and biochemical field, doctors, nurses and hospital technicians, and spin-offs from the industry.

Medeon, together with the incubator's sponsors, can offer advice on business strategies, patents, finance, accountancy, etc. Medeon also provides access to a wide range of local and international networks, covering companies, organisations and academics. Medeon helps both established and newly-founded companies in the Malmö region to find useful business partners.

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PROFILE

In the event of inventions made at the Royal Danish School of Pharmacy or inventions made within a cooperation agreement with the Royal Danish School of Pharmacy, please give notice of this to the contact person mentioned above.

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Symbion

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ESTABLISHED 1986

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PROFILE

Symbion is a privately-owned incubator, located in the heart of Copenhagen. At our 20,000 square metre premises, projects and ideas are provided with optimal conditions and support as they develop into viable businesses. We have specialised in providing assistance to knowledge-intensive, high-tech and innovation-based start-ups within the areas of biotechnology, pharmaceuticals and IT.

MEMBER OF MEDICON VALLEY ACADEMY

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ESTABLISHED 1994

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PROFILE

Teknopol AB specialises in developing ideas that originate from research and/or high technology. Very often, the first step in our work is help to protect the idea.

The first intellectual property service Teknopol AB provides involves placing the IP in the context of a business idea, market and business model. At this early stage, our work is free of charge for the client. If the invention seems novel and has a defined target market with an obvious customer need, the next step is to identify a source of finance for the patent work. We have good contacts with highly reputable patent agencies.

MEMBER OF MEDICON VALLEY ACADEMY

Symbion Capital

www.symbion.dk

Knowledge for Growth

Symbion Capital is the largest private venture fund in Denmark in the pre-seed and seed segments.

We invest in unique, innovative, high-tech, and research-based ideas with international market potential in the following industries:

- IT and telecommunications
- Biotech, pharmaceuticals and medico

We invest in promising teams and technologies with outstanding market potential.
For **Symbion Capital,** an investment is the beginning of a partnership.
We work with ambitious entrepreneurs towards building successful, internationally oriented companies.
Our goal is to turn knowledge into growth.

Symbion
Knowledge for growth

Albihns

ALBIHNS

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ESTABLISHED 2001

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PROFILE

The Albihns Group is one of Europe's leading intellectual property law firms, with offices in Sweden, Denmark and Germany. Albihns has over 200 employees, including more than 100 IP attorneys, many of whom are authorised European Patent Attorneys and European Trademark Attorneys. They cover all technical, scientific and IP law fields.

MEMBER OF MEDICON VALLEY ACADEMY

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ESTABLISHED 1897

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PROFILE

Awapatent is one of Europe's leading company in patents, trademarks and registered designs. Our team of Attorneys at Law and Patent Attorneys specialized in the protection of innovation in life sciences has the knowledge and experience required to give qualified advice on legal matters and prosecution of patent applications in this complex field of technology.

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ESTABLISHED
Budde, Schou & Co in 1901
Ostenfeld Patentbureau in 1937
Merged in 1999

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PROFILE

Budde, Schou & Ostenfeld A/S is a Danish intellectual property firm numbering more than 75 employees. We possess expert knowledge within all aspects of intellectual property protection. We have a strong biotech team exclusively devoted to protecting biotechnological inventions, and offering the best possible technical advice and assistance.

MEMBER OF MEDICON VALLEY ACADEMY

Let's Protect Your Pearl ...

Let's Protect Your Biotechnological Invention

Biotechnological inventions require effective patent protection in order to secure the future of your company.

BUDDE SCHOU OSTENFELD is one of Denmark's leading firms of patent and trademark attorneys and includes a highly competent biotech team holding extensive expert knowledge within international patent protection of biotechnological inventions.

For further information, please contact our Biotech Team which is headed by Team Manager Steen Wadskov-Hansen, M.Sc. (Biotechnology), Ph.D.

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BUDDE SCHOU OSTENFELD is a well established Danish-owned firm of consultants offering professional technical and legal advice within the field of intellectual property right protection. The company counts more than 75 employees and holds more than 100 years' experience in providing intellectual property services.

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ESTABLISHED 1896

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PROFILE

Chas. Hude provides advisory services within all fields of intellectual property rights.

Our specialists in various technical areas – biotechnology, software, mechanical engineering, etc. – are also highly-experienced European patent attorneys. Chas. Hude has a well-established global network.

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ESTABLISHED 2000

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PROFILE

Comlic A/S specialises in the commercialisation and licensing of intellectual property. Our clients are to be found in industry, state research institutions and universities. Via our international network of contacts, we can turn your patents and technology into revenue-generating assets by placing you in contact with potential technological partners.

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ESTABLISHED 1869

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PROFILE

As the oldest patent and trademark attorney firm in Scandinavia, we are capable of representing the interests of our clients in every technological field with regard to national and international authorities and courts of law. Over the years, we have represented a number of clients from the medical and biotechnological fields and guided them towards commercial success.

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ESTABLISHED 1870

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PROFILE

Hofman-Bang Zacco A/S is part of the Zacco group which is located in Denmark, Norway, and Sweden. With more than 300 employees, Zacco is the leading Nordic IPR consultancy.

Our Danish Life Science Group comprises 14 patent consultants experienced in patent matters on all levels, as well as consultants with a legal background, experienced in contract drafting. We specialise in: genomics, proteomics, bioarrays, bioinformatics, environmental matters, foods, allergies, antibodies, pharmaceuticals, drug delivery, diagnostics, and licensing.

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ESTABLISHED 1994

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PROFILE

Holme Patent A/S is a firm of patent, design and trade mark attorneys founded on the philosophy of providing quality work.

Staff experience ranges from patent law in the chemical, biochemical, and biotechnological engineering disciplines, to trade mark protection, unfair competition, licensing, joint ventures and IP-portfolio management.

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ESTABLISHED 1995

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PROFILE

Høiberg A/S advises on all aspects of IPR associated with innovation and business development, including the drafting and prosecution of patent and trademark applications, technology transfer, license agreements, venture capital acquisitions, joint ventures, strategic alliances and outsourcing.

Høiberg A/S believes in adding value to our clients' business development in all phases – from idea to realisation. We do this according to a proactive IPR strategy by patenting the future areas of technology of interest to our clients. As branding is often very important for our clients' business, we also help to define and promote our clients' business development using trademarks and trade names.

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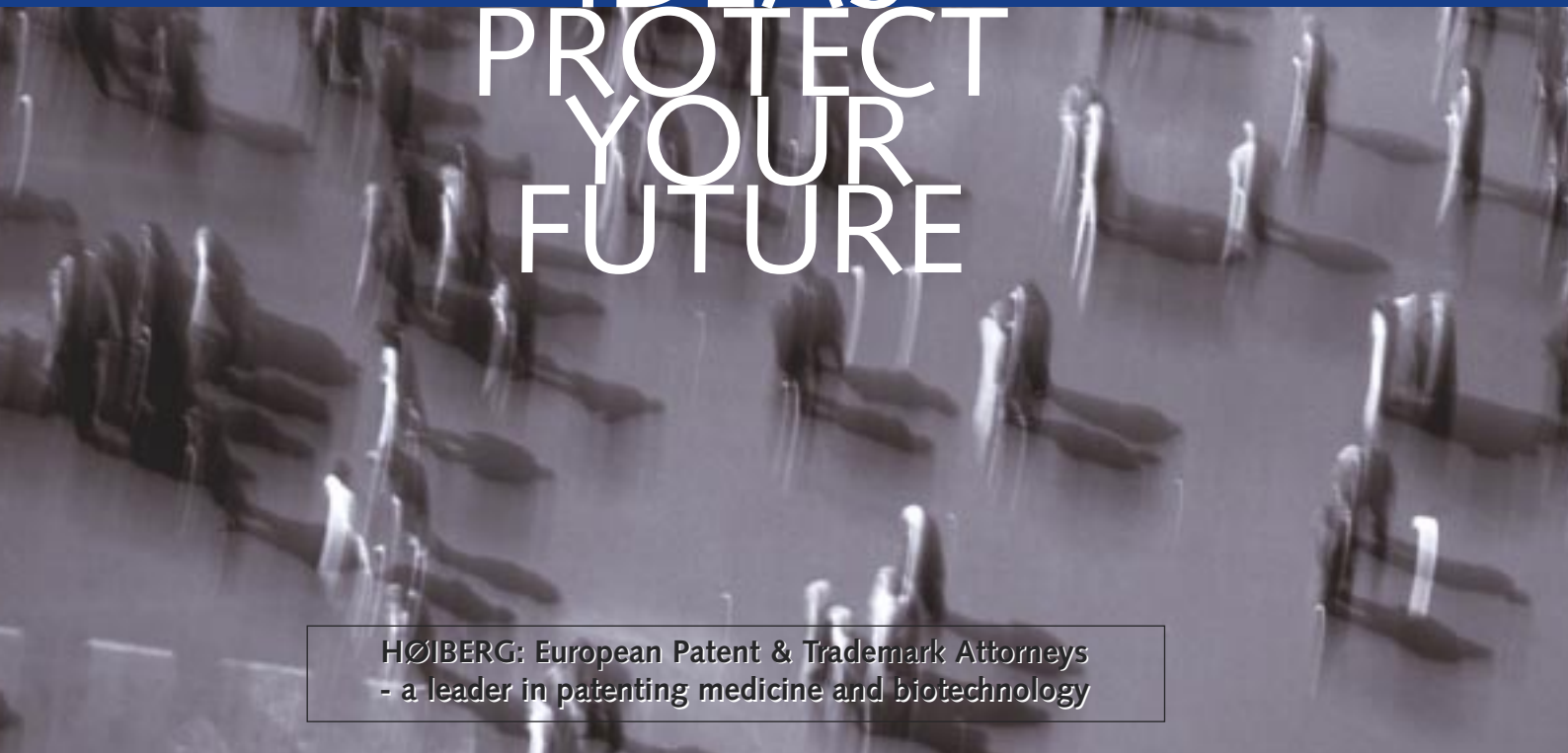
PROTECT YOUR IDEAS PROTECT YOUR FUTURE



HØIBERG: European Patent & Trademark Attorneys
- a leader in patenting medicine and biotechnology

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ESTABLISHED 1860

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PROFILE

World wide consultancy in all aspects of IPR, including the establishment and enforcement of patent rights, legal disputes, analysis of infringement, freedom to operate, etc., within all technical areas, including life sciences, biotechnology, pharmaceuticals, medical technology, food products, agrochemicals and general chemistry.

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ESTABLISHED 1973

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PROFILE

Intellectual property consultancy, covering strategic business development, innovation management, licensing, surveillance of competitors' patent activities, filing and prosecuting oppositions and appeals, drafting and prosecution of patent applications related to i.a. life sciences, chemistry and software. Offices in Copenhagen, Aalborg and Munich.

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ESTABLISHED 1999

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PROFILE

Medical Patent AB performs patent and literature analyses within the medical/pharmaceutical fields by searching commercially available databases. The company has also developed its own software tools, which are now commercially available. Medical Patent AB can also offer your company help in formulating a long-term patent strategy.

Our customers are patent attorneys and pharmaceutical and biotech companies.

MEMBER OF MEDICON VALLEY ACADEMY

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ESTABLISHED 1922

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PROFILE

Plougmann & Vingtoft is a subsidiary of ARATOR, a Nordic intellectual property firm represented in Alicante, Copenhagen, Gothenburg, Helsingborg, Linköping, Lund, Malmö, Munich, Reykjavik, Ronneby, Stockholm, Aalborg and Aarhus, with core competencies in Life Sciences & Chemistry, Technology & Software, Brands & Identity, and Legal Counselling.

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PROFILE

Primary fields of expertise:

- Negotiation and drafting of contracts such as licence agreements, R&D agreements, cooperation agreements and consulting agreements.
- Patent law including patent infringement law.
- Intellectual property law and EU competition law.

Ström & Gulliksson

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PROFILE

Ström & Gulliksson Intellectual Property Consulting co-operates with and is included in the ARATOR international group of companies, together with, amongst others, the Danish patent attorneys Plougmann & Vingtoft.

We offer a complete range of technological and legal services to assist in the creation, development, commercialisation, protection and maintenance of good ideas and business concepts.

Within the field of Life Sciences & Chemistry, we offer specialist knowledge in such areas as biotechnology, biology, microbiology, biochemistry, organic and inorganic chemistry, pharmaceuticals, health care systems, plant science, food science and polymer physics.

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PROFILE

Wiborg ApS is assisting biotech/pharma companies and research institutions with licensing and technology transfer.

The firm assists with the entire licensing process including analyzing the technology and markets, finding the partners, negotiating and making the contracts – and managing the deals. Wiborg ApS also provides business development services to biotech start-up companies making market analyses, business plans, establishing and running companies, etc.

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PROFILE

– see Hofman-Bang Zacco A/S page 67

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PROFILE

AssuransSelector AB is well-established on the Swedish market. Our main business is in the export industry, with companies ranging from small, rapidly-growing biotech, IT and medical equipment companies, to large groups.

AssuransSelector AB is focused on developing new products, and gives this field a high level of service. Our specialities include Products Liability, Directors' & Officers' Liability, and Intellectual Property Litigation Insurance.

MEMBER OF MEDICON VALLEY ACADEMY

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PROFILE

Our clients range from small, fast-growing entrepreneurial companies to large exporters.

We specialise in the following areas: Intellectual Property Litigation Insurance, Global Liability Insurance, Directors and Officers Liability, Professional Liability, Property, Business Interruption and life and pension schemes.

We have established a special team dealing with the protection of intellectual property in the pharmaceutical and biotech industries.

MEMBER OF MEDICON VALLEY ACADEMY

dahlberg assurance brokers

INTERNATIONALE FORSIKRINGSMÆGLERE

Insurance solutions for fast growing entrepreneurial companies

dahlberg assurance brokers is Denmark's leading independant insurance broker, operating internationally and at Lloyd's Of London.

dahlberg assurance brokers is a full service insurance broker, specialising in provision of insurance and pension scheemes for the Danish Business Sector.

dahlberg assurance brokers has a strong focus on healthcare and other growth companies and has built up considerable experience in providing insurance solutions of Intellectual Property rights.

To find out how to protect and enforce your Intellectual Property right and safeguard your company's future please contact our head office in Copenhagen, phone: +45 33 11 48 28

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"Intellectual Property which cannot be defended through the courts is property without value"

Glossary

Best mode ~ page 35
Requirement for patentability in the United States - the inventor must describe the best way to carry out an invention

Claim ~ page 8, 27
The patent claims define the protection conferred by a patent

Enablement ~ page 11, 26
A patent application must enable a skilled person to carry out the invention based on the description thereof in the patent application

"First to file" principle ~ page 26, 35
A patent right is normally granted to the inventor who first filed a patent application for the invention

"First to invent" principle ~ page 26, 35
In the United States, the inventor who first contrived an invention can also be granted a patent right even if the inventor is not the first to file a patent application for the invention

Grace period ~ page 34, 35
Period in which an inventors public disclosure of an invention does not eliminate the novelty of the invention

Industrial applicability ~ page12
Criteria for patentability - most inventions are capable of being exploited in a field of industry

Infringement ~ page 45, 47
Unauthorised exploitation of an invention by carrying out actions which falls within the claims of the patent

Inventive step ~ page 11
Criteria for patentability - an invention is associated with an inventive step if a skilled person would not have had any expectation of success when making the invention. Simple and predictable routine developments are not associated with an inventive step

Novelty ~ page 10, 11, 27, 32, 33
Criteria for patentability - an invention is novel if the combination of technical features defining the invention have not been publicly disclosed before the filing of a patent application for the invention

Patent application ~ page 26-27, 31-33
Request for being granted a patent for an invention - a patent application after its publication can create a provisional protection of the invention

PCT ~ page 32
Patent Cooperation Treaty

PCT application ~ page 31-33
Updated patent application in the form of an international patent application filed under the provisions of the PCT

Publication ~ page 33, 35
An updated patent application is made publicly available 18 months after the filing of the first priority patent application

Preliminary examination ~ page 33
Assessment of the novelty and inventive step of an invention described in a PCT application

Prior art ~ page 8
Anything published or otherwise made available to the public before the date of filing a patent application. To be patentable, an invention must be novel over the prior art cited by the patent authorities against the claimed invention

Prior art citable (material) ~ page 8
Material believed to be of relevance for an evaluation of an invention is identified by the patent authorities and listed e.g. in a novelty search report as references relevant for an evaluation of the novelty or the inventive step associated with the invention

Priority date ~ page 26, 27, 32, 35, 36
The date on which a specific subject matter is first introduced into a priority patent application

Priority patent application ~ page 31-33
Patent application filed during the priority year - makes it possible to obtain an earlier filing date for an updated patent application

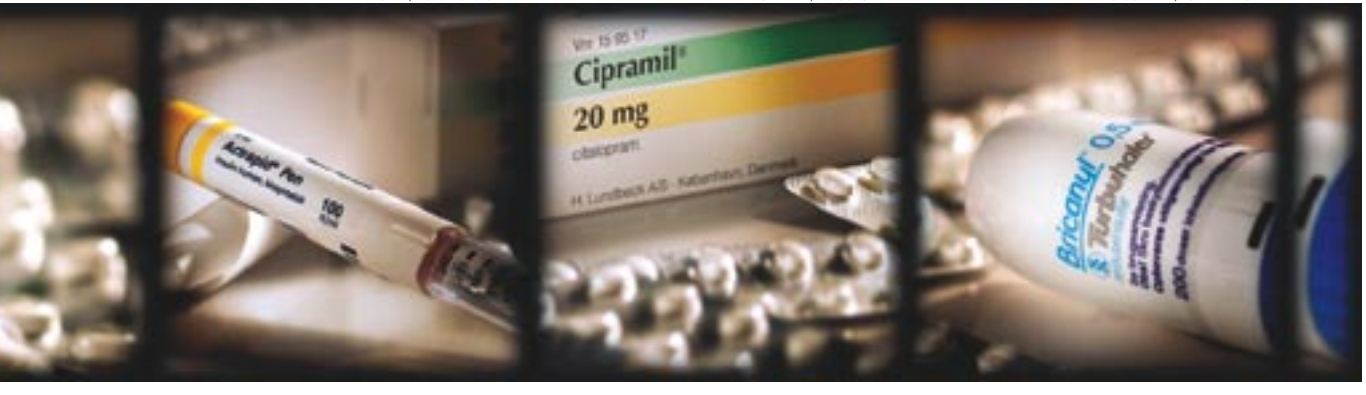
Priority year ~ page 31, 32, 34
The year following the filing of the first priority patent application

Updated patent application ~ page 26-27, 31-36
Patent application filed before the end of the priority year - updates one or more priority patent applications filed during the priority year

NOVOPEN, NOVO NORDISK

CIPRAMIL, LUNDBECK

TURBUHALER, ASTRAZENECA



Excellent research - intelligent use of patents

LARSEN & BIRKEHOLM A/S

SKANDINAVISK PATENTBUREAU

LARSEN & BIRKEHOLM A/S, Skandinavisk Patentbureau, was established in 1973 and now employs a staff of 25 dedicated to processing primarily patent, utility model, design and trade mark matters.

Our field of competence includes all matters relating to intellectual property such as:

Intellectual property consulting, in particular strategic business development and innovation management, licensing, surveillance of patent activities of competitors, filing and prosecuting oppositions and appeals, drafting and prosecution of patent applications related to i.a. life science, chemistry and software, enforcement of patents, trade marks, and copyrights, and defence in IP infringement suits.

For further information, please contact Mogens Hegner.

Our firm is located in the centre of Copenhagen neighbouring the Central Railway Station which has direct connections to Copenhagen Airport less than 30 km away.

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