

**How to patent pharma,
biotech & meditech inventions**

Medicon Valley Patent Guide

medicon valley alliance

Creating Opportunities

HØIBERG

European patent & trademark attorneys

IMPRESSUM

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Patents enable sustainable R&D and commercialization

In Medicon Valley, we have many things to be proud of; both when it comes to individual life science stakeholders and as a life science cluster. This is the result of competence, research and the continuous strive for making people's lives better. It is also a result of our willingness to cooperate, share and think outside the box that leads to steps, and sometimes even leaps, in development and results.

Medicon Valley is one of many clusters aspiring for the attention of investors and life science talents, KOL's and leading experts to become the place to be, the place to make a difference. To become this and be able to harvest the results of this, we need to become even better in spreading the word about our strongholds, our results, our willingness and openness. At the same time, this focus on further value creation must be driven by an understanding that adding further value to Medicon Valley is the key for sustainability and growth. To open up to our treasure chest without having control over ownership and be able to take part of the value that collaboration and investments bring, is detrimental.

Patents are one of many available tools to secure the sustainability and future strength of Medicon Valley. Patents enable a sustainable environment for R&D and commercialization. It also helps to further develop stakeholders' openness and willingness to collaborate. Patents are thus crucial building stones in the successful Medicon Valley that we all want to see now and in the future. That many agree and want to contribute in sharing knowledge about patents and its processes is evident when taking part in this updated Patent Guide. We, as a life science cluster, still have improvements to implement to enable quicker and smoother collaborations and win-win outcomes, however, knowledge, insight and actual usage of patents are necessary steps to make these improvements possible. So use this guide, discuss, raise questions and work towards the next big thing in collaboration with other great minds in and outside Medicon Valley. This while holding your own unique key guarding your treasure chest, that is, your patent.



SØREN BRGENHOLT

*Chairman of the Board, Medicon Valley Alliance
Corporate Vice President, and Head of External Innovation
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We'll make sure that IP is not what keeps you up at night

HØIBERG A/S is proud to present this Patent Guide in collaboration with Medicon Valley Alliance, an organization with which we share many values: the will to cooperate, to share information and particularly, to think outside the box. These are some of the reasons why we are sponsoring this Patent Guide: because it is only by sharing our knowledge with you that you will be able to fully reap the benefits of the dedication, hours and hard work you put into your great ideas, inventions and research.

HØIBERG A/S was founded with the vision of assisting fledgling life science and medtech companies in order for them to improve the lives of us all with their great ideas. We have been doing this for more than 20 years and have become the IPR firm of choice in the field. That's because we know what you are dealing with: tight budgets, the need to secure the next round of investments and particularly the need to share vital information about your core technologies in order to keep developing. We'll make sure that IP is not what keeps you up at night; because sharing is fine – as long as your core technology is protected – in other words: patented.

Great inventions require great protection and no two inventions are the same, therefore there is no such thing as a "one size fits all" IP strategy, each is as unique as the idea itself. Nevertheless, there are several IP basics that you should know about before sharing your great idea – that's why we have made the Patent Guide, to show you what you need to know, not just according to us, but according to all the people you'll be encountering on your journey.

The investors, the companies as well as we, share our thoughts in this guide on why IP and patents in particular are of crucial importance to any firm in the Medicon Valley. So read and enjoy, we are always available if you have questions – and keep collaborating, sharing and thinking outside the box – just remember to patent your great ideas first.



PERNILLE WINDING GOJKOVIC

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Why patent?

A basic principle behind the patent system is that the description of the invention becomes public and thereby contributes to the general knowledge of society. In return, the applicant of a patentable invention obtains the right to prevent others from using the invention for 20 years. Therefore, patents are of great importance to society, since they both facilitate further development and research and ensure that the patented invention can be exploited and used. An alternative to patent protection is maintaining the technology as a trade secret.

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, pharma, and mediatech.

A patent can be used to protect an invention, but it can also be regarded as a strategic asset aimed at improving the competitive advantages and the earning capacity of a company.

For young companies which are in the building phase, patent applications play a large role in substantiating the major commercial assets of the company by transforming inventions into a tangible asset. A granted patent or even a filed patent application can make a large difference in the evaluation of the company and facilitates the attraction of investors.

In seeking to establish contact with key collaborators, it is a major asset that the technology is protected by a patent application. A filed patent application facilitates communication and ensures that the inventions can be shown to other parties, such as investors.

A patent can be used to protect an invention, but it can also be sold or licensed to other parties, or even used as collateral just like any other property, such as for example real estate, equipment, or a car.

How can patents and patent applications be useful?

- In preventing others from copying or using your invention.
- In substantiating a major commercial asset of innovative companies into tangible assets.
- In facilitating the build-up of a new company, for instance by attracting investors.
- In establishing collaborations and facilitating dialogue with future collaborators.
- In increasing return of investment in research and development.
- In selling or licensing your IPR.

If the commercial exploitation of the invention requires resources which the company does not have or cannot attract itself, it is an option to sell or license the invention to other interested parties which have these resources.

As an example, a major part of new innovative companies in the biotech and mediatech fields primarily focus on the pre-clinical phases of research and development and are heavily dependent on collaborators for the clinical testing and development of a future product. For such new companies, the protection of inventions, filing of patent applications and obtaining patents are crucial for establishing collaboration and securing return of investment in research.

There are many reasons for seeking protection of intellectual property rights (IPR) by filing patent applications, and few reasons for not doing so.

In a few cases it may be better to postpone or even avoid the filing of a patent application. In some cases it may be more advisable to avoid the publication of the invention.

One example is when it is difficult to enforce the IP right and prevent others from using the invention once published. This could be the case if the invention is a platform technology such as a screening technique which enables further research that leads to development of products or methods. In some cases, it may be difficult to prove that other parties have used the platform technique in order to develop their own products or methods, since they may be able to arrive at the same result using a different technique.

Pursuing patent protection in the whole world is very expensive and suing potential infringers is even more expensive. In most cases a limited number of countries are selected for patent protection. However, if the platform technology is easily transferred to and

implemented in countries where there are no patent rights, it may be an advantage to avoid publication of the technology and keep it as a trade secret.

Reverse-engineering represents a risk for products which are not protected by patent applications, since the sale of one single product can destroy the patentability of the product. In cases where it is impossible to reveal the composition of a product by reverse-engineering, it may be questioned whether a patent application should be filed.

It is also advisable to reconsider filing a patent application if proof-of-concept cannot be provided within a reasonable time-frame. There is an increasing requirement from the patent authorities that proof-of-concept is presented in order to proceed to granting of a patent. If proof-of-concept cannot be properly established within a reasonable time, the risk is that the patent application only leads to publication of the invention, but does not lead to the grant of a patent and protection of the invention. Once the patent application is published, it is part of the prior art for future developments and can therefore be an obstacle to future patent applications.

If it is decided not to protect an invention by a patent application, it is advisable to take relevant measures to ensure that the invention is kept secret. One reason is that the legal protection of trade secrets is dependent on the efforts made to keep the information a secret.

Measures to be considered when a technology is not protected by patent applications:

- Use non-disclosure agreements (NDA) whenever the technology is disclosed for employees, collaborators, investors and other parties.
- Describe the technology (*i.e.* the secret) in specific terms and formalise who is allowed to know about the technology and who is not.
- Restrict information access for employees.
- An IP strategy includes detailed policies regarding which inventions are to be kept secret and measures to be taken to ensure the maintenance of these secrets.

CASE 1

IPR application as a drive for structure, planning and development

Interview with Olof Jarlman, R&D Manager, Instant Advice AB

Instant Advice AB is an mHealth company which has developed solutions for years without a patent in place. The main idea, that has been the basis for the continuous development, is an application function (software) for mobile phones that enables the consumer and/or patient to initiate a dialogue with the experts/product owners regarding a certain focus area which in turn leads to a personalized response. Olof Jarlman, R&D Manager, says that

"It is a struggle for this kind of company to attract capital because you need a solution that is interesting enough and which, at the same time, is protected from being copied".

Instant Advice is now, in 2015, in the process of getting a patent in place. It has been a long time coming due to the characteristic reality of a small mHealth company; a very fragmented and busy one and no money. Raising money for development of a groundbreaking product is also very much time dependent; if you do not have a solution in place and enough money in your pocket to get your patent in place when investors come knocking, you miss the opportunity. Instant Advice missed out in 2008, when there was a willingness to invest in their specific solution. Unfortunately, the entirety of the company's assets had gone into a database that proved to be useless. A new approach was needed since there was no money available to initiate a patent process. What was frustration in 2008 is today a realization that the delay in the patent application has actually created a bigger gap between Instant Advice and competitors, which can be further improved depending on coming development processes and upcoming patent application processes.

Olof Jarlman states that Instant Advice's application portfolio has grown and is now covering many application areas. The multitude of adaptation possibilities of the original mobile application opens up to a very dynamic and rapid development but also creates challenges. The main challenge to solve is to be able to keep up the speed of innovation, by letting innovation and development flow freely between necessary development partners, for example mobile application specialists and product specialists. This can only



be done by having the rules of ownership in place which creates security and structure. The patents thus drive innovation and do so long term, as having a patent in place means that investors are motivated to invest. The patent itself is thus both a goal and a driver for further development.

mHealth, and other areas of eHealth, opens up to the realm of truly personalized medicine according to Olof Jarlman. These areas are thus on their way to revolutionize the health care system. As the regulatory system has not been able to keep up with the development and the customer demand, Olof Jarlman sees the patent process as a process that can help businesses handle some of the uncertainty and lagging behind of the regulatory systems. Patents, he says, is a way to keep up the pace of innovation. We cannot wait for yesterday to catch up with the future we are already in.

CASE 2

Developing and strengthening patents through partnerships



Interview with Christina Furebring, PhD (Vice President, Research), Alligator Bioscience AB

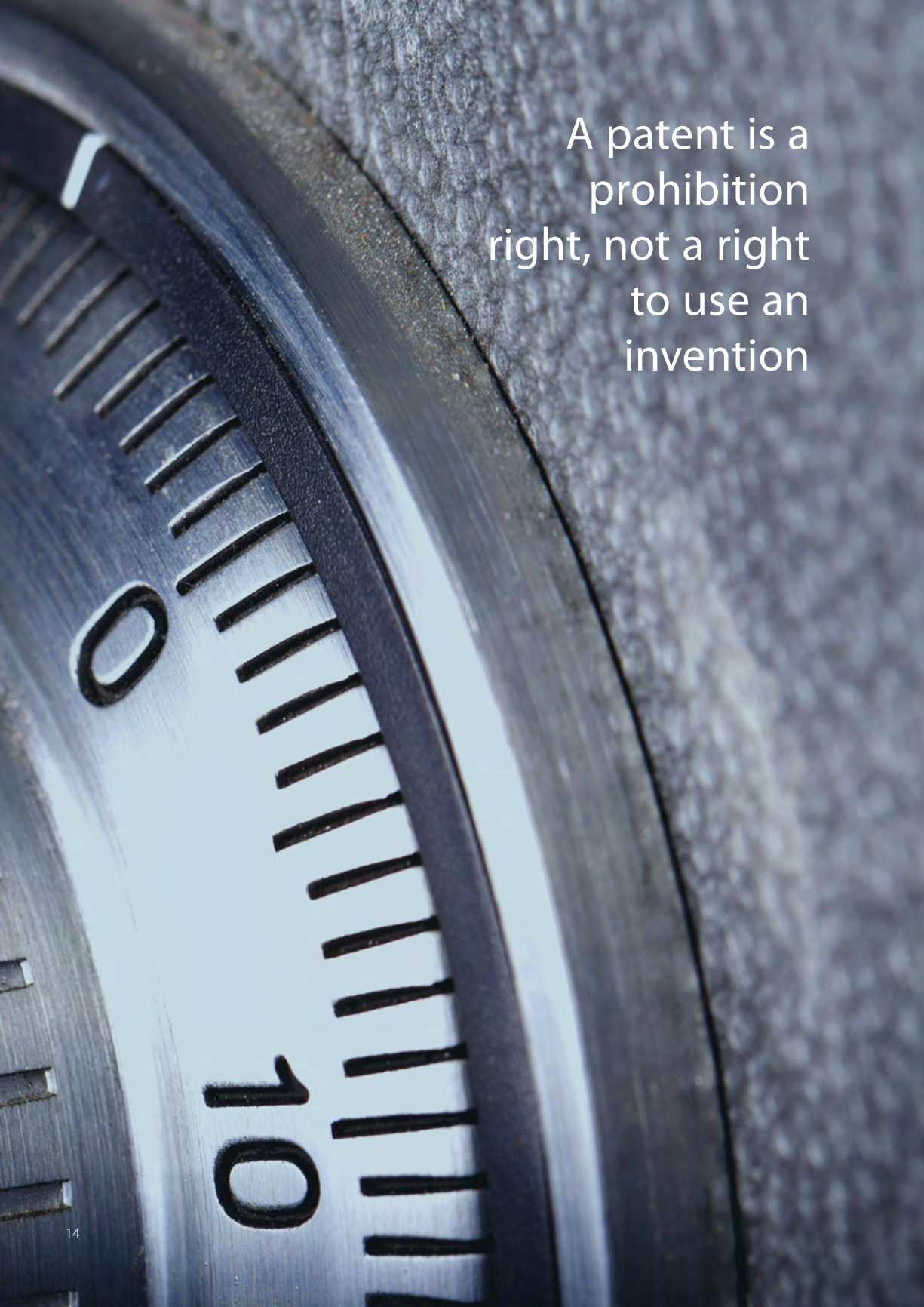
Alligator Bioscience AB (Alligator) develops antibody-based therapies for cancer immunotherapy, enabled by their technology platforms, notably the fully human antibody library (ALLIGATOR GOLD®) and the protein optimization technology (FIND®). Generating strong IPR portfolios for the pipeline compounds is important for future out-licensing to Pharma. The company has an experienced in-house team, but recognizes the value of external collaborations. The company strategy is to establish early partnerships in order to share costs and risks. A prerequisite forming a partnership is the ability to share innovative research data externally, which is facilitated by securing IPR at an early stage.

Alligator sees collaborations with researchers and companies as valuable both from a research perspective and for the patenting of this research. The key factor for selecting partners is their assets in terms of specific know-how and technologies that may act in synergy with Alligator's technology platforms. Alligator has a very clear view of how the collaboration should be managed in order to discover and develop patentable technologies.

It is important to define the IP rights to the research results generated in the collaboration in agreements. When it comes to collaborations with researchers, one of the key points in an agreement is the right of Alligator to reasonably postpone publication of findings to allow the securing of IPR. Academic research partners are compensated in different ways e.g. by supplying additional resources that enable them to develop within their chosen field of expertise. Present research collaborations include Stanford University, Uppsala University, Lund University, Manchester University, Pamplona University and the Korean antibody company AbClon.

The partnerships are managed by a joint steering group where a senior researcher is representing Alligator. The partners share servers and have regular meetings and the detailed project structure depends on the goal of the collaboration. According to Alligator, the success factors, irrespective of the collaborative structure, are common goals and personal chemistry. This, in short, accelerates Alligator's IP strategy and facilitates the company's long term success.



A close-up, high-contrast photograph of a metallic dial or gauge. The dial is curved and features a scale with markings from 0 to 10. The number '0' is prominently displayed on the left, and '10' is visible further along the scale. The dial is set against a dark, textured background, possibly a metal plate or housing. The lighting creates strong highlights and shadows, emphasizing the metallic texture and the precision of the scale.

A patent is a
prohibition
right, not a right
to use an
invention

What protection does a patent provide?

A patent is an exclusive right as well as a prohibition right. Thus, a patentee can prohibit others from working the patented invention. However, a patent is not sufficient clearance for the patentee to work the invention himself. Thus, issuance of a patent does not automatically establish a right to use an invention. Other factors may inhibit the patentee from entering the market with his invention including existence of dominating patent rights.

Therefore, using an invention could for instance be hindered if using the invention involves utilization of a patent-protected product or process technology. In certain instances, it may be necessary to obtain a licence from other patent owners in order to be able to use a patented invention.

In all WTO member states, a patent to a product gives the patent owner the right to prevent others from making, using, selling or importing the product. A patent to a process gives the owner the right to prevent others from using the process, but the patentee can also prevent others from using, selling or importing the product prepared directly by the process. In most countries, there are a few exceptions to the protection conferred by a patent, for example most countries have a research exemption. Also studies for obtaining a marketing authorization for medicine can be freely undertaken without the risk of infringing patents in many countries.

Once a patent owner has brought a patented product to the market, he has exhausted his patent rights, and the buyer can then use the patented product without infringing the patent in the country of purchase. A patent is valid for a minimum of 20 years after the filing date provided that the patent owner has undertaken all required actions and paid all fees.

It is the responsibility of the patent owner to enforce his patents. Thus, in general, official authorities do not aid in enforcement of patent rights on their own volition. To enforce a patent, the patent owner must normally take legal action if no agreement can be reached with an infringer out of court.

Who is the rightful owner of a patent?

Once an invention has been conceived, the rights to a patent on that invention belong to the person who invented it. Thus, as a starting point a patent simply belongs to the inventor.

However, even if the starting point is very simple there are many challenges in assuring correct ownership of a patent. First of all, in order to establish the ownership of a patent it is very important to identify who is(are) the inventor(s).

Many inventors are contractually obliged to assign their rights to any invention they make. For example, in many countries employees at universities are obliged to assign their rights to the university, provided that the university wishes to take on the patent process. Also many private employees are obliged to assign their patent rights to their employer. This is usually regulated through their employment contract or in some countries by law.

Thus, even though the inventor in principle should be the owner of the patent, the employer of the inventor may in fact frequently be the actual owner of the patent.

Nowadays most inventions are conceived by a team, and thus as a starting point the invention belongs jointly to the people on that team. If all inventors are employed by the same company, and they are obliged to assign the rights to their inventions to their employer, then the patent simply belongs to that company. If the inventors however are employed by different companies, the patent will be co-owned by several entities. Also in the case that the inventors are not obliged to assign their rights to the patent, the patent will be jointly owned.

The joint ownership creates challenges that are preferably addressed up front. In Denmark and most other European countries co-owners must act jointly, which effectively gives each co-owner a veto right with regard to licensing or selling a patent. In contrast in the

United States each co-owner can act independently. Thus, it is recommendable to ensure clear agreements regulating the rights of each co-owner.

If no contracts regulate the joint ownership, then in the United States one owner can license out the patent, without the consent of the other owners. This may result in reduced license fees, since there will be an internal competition between co-owners. Also it will not be possible for any of the co-owners to grant an exclusive license without an agreement. In Europe one owner can block a license, which another owner may wish to grant. Therefore a good contract is essential.

Accordingly, prior to embarking on a joint development program, it is highly advisable that the firms involved regulate the rights to any ensuing patents contractually. This is also true for collaborations with sub-contractors. Even if the research leading to an invention is paid for by an ordering firm, then the rights to a patent do not automatically belong to that firm. The rights to a patent belong to the inventor or possibly the inventor's employer. Thus, for the ordering firm it is crucial to ensure that a sub-contractor's employees are obliged to assign patents to the sub-contractor and that the sub-contractor is contractually bound to assign the patent rights.

In conclusion, in order for a company to control ownership of future patents, it is important to understand who may be the inventor in the future, and to have all the right contracts in place that will allow the company to take over the ownership from the inventors or their employers.

The rights to a patent belong to the inventors

- Important to identify who are inventors
- Many inventors are obliged to assign their rights to their employer



Criteria for patentability

In principle any invention fulfilling the following three basic criteria is patentable. Thus the invention must be

- novel
- associated with an inventive step
- industrially applicable

However, there are several exceptions. Some inventions are not patentable for moral reasons, such as methods for cloning human beings. Other inventions are specifically exempt from patentability in one or more jurisdictions, for example plant varieties cannot be patented in many countries.

Novelty

A product is novel if an identical product has not previously been disclosed. Thus, a product is not novel if another product characterized by the same specific combination of physical and functional features has previously been made publicly available.

A product can be protected by a patent by claiming its physical features, or its functional features, or a combination of both. Frequently, at least some physical features need to be defined, and thus it is often desirable to claim a product by a combination of physical and functional features. Functional features frequently 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 in general 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 in general 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 in general always results in a novel method for producing the product.

A method for using a product for a particular purpose can disclose:

- use of the product for carrying out the method
- the method steps carried out when performing the method
- the technical results obtained from carrying out the method

Frequently, it may be preferable to claim such methods by defining the steps carried out when performing the method. A method for using a product is novel when either the product is novel, or when the method steps are novel. A method for using a product can in some instances also be novel when the technical result is novel.

An evaluation of patentability must clarify what has been made available to the public, and whether the invention is non-obvious in view thereof.

Inventive step

An invention complies with the requirement for inventive step if the invention was not obvious to a skilled person based on what was known in the art. Inventive step is evaluated based on what was known at the time of filing the patent application from the viewpoint of a person skilled in the art. Inventive step can for example be based on a superior effect, an advantageous method, a surprising solution or a result which could not reasonably be expected.

When evaluating 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.

It is important not to use hindsight when evaluating inventive step. When using hindsight many inventions could appear obvious, but inventive step should be evaluated without using the actual knowledge of the invention.

In Europe a very strict approach is used for evaluation of inventive step, namely the “problem/solution approach”. According to that approach, the piece of prior art most closely resembling the invention is identified. It is then evaluated whether the difference between that prior art and the invention was obvious to a skilled person.

In other countries less formalized approaches are employed to evaluate whether an invention is obvious or not.

Industrial applicability

In Europe an invention must also be industrially applicable in order to be patentable. Industrial applicability should be understood in the broad sense, as including any activity that can achieve a technical result in any industrial field. As such, most inventions will be regarded as industrially applicable. In the United States the standard is slightly different. Instead the requirement is that the invention must have utility. The outcome is however similar, and most inventions fulfill the requirement.

What can be patented?

Many countries have chosen to exclude specific subject matter from patentability for a variety of reasons.

There are many exceptions to patentability in the fields of pharma, medictotech and biotech, however most inventions in these fields can in fact be patented. Below, we introduce some examples.

Medictotech

In the field of medictotech most inventions are patentable. Many inventions in this field 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 medictotech. Examples of medictotech 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.

However, in many countries including Europe, methods of treatment are not patentable. Thus, it may be difficult to patent methods of treatment using a particular device in these countries.

Biotech

Within the field of biotech the exceptions from patentability vary from country to country. In Europe a wide variety of biotechnological inventions can be patented including 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 – cells, proteins (including antibodies), genes, partial gene sequences, cDNAs and SNPs. In the United States the aforementioned subject matter can also be patented provided that it does not exist in nature. Thus, naturally occurring genes or proteins are not patentable in the United States.

Biotechnological methods are widely patentable even though there are a few exceptions. In Europe biological methods for producing plants or animals cannot be patented. In the United States many diagnostic methods cannot be patented.

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

- a nucleic acid, *e.g.* a gene of a particular sequence – in the United States only if it is not a naturally occurring sequence
- a vector comprising a gene
- a polypeptide – in the United States only if it is not a naturally occurring polypeptide
- an isolated biological cell – in Europe not an embryonic stem cell – in the United States not if naturally occurring
- transgenic plants – only in some countries
- an antibody
- a method for identifying binding partners for a polypeptide
- a method for identifying agonists or antagonists for a polypeptide
- a compound *e.g.* polypeptide or nucleic acid for use in a method for therapy
- a diagnostic method using a nucleic acid or polypeptide – in the United States with some restrictions

Pharma

Medicaments are generally patentable with the exceptions outlined above. However, many countries impose restrictions on patents to methods of treatment. The restrictions vary from country to country, but in most countries patents can be obtained for specific uses of known medicaments. For example if it is found that a known medicament can be used in the treatment of a new disease, this would be patentable in most countries. New dosage regimens or methods of administration are only patentable in selected countries including Europe and United States.

CASE 3

IP as Value Driver for Investments

By Kim L. Dueholm, Novo A/S

As one of the most prolific life science investors in the world Novo A/S invests in companies in which intellectual property (IP) plays no role at all. But it is rare. Extremely rare. Novo A/S also invests in companies in which IP plays a crucial role. Like 98% of the time.

When we look at an early stage company and value it at 5, 10 or 50 million euro it is not because of its assets such as buildings, manufacturing equipment etc. It is because of the IP and the unique knowledge it protects. In fact the vast majority of our investments go into companies which follow one particular business model – the commercialization of intellectual property.

Occasionally, we make the difficult decision to decline an investment in a company after weeks or maybe even months of due diligence because of IP or freedom to operate (FTO) issues. The decision is difficult because we are well aware that for that particular company finding other investors after such a process can be very difficult indeed – maybe even impossible.

Therefore it cannot be emphasized enough that for a young biotech or medtech company taking IP and FTO very seriously is crucial. Having experienced people involved is key. Using a competent external IP firm is most often required. It can be expensive but it is a necessary investment in building a biotech or medtech company. But outsourcing this work should not be an excuse for management to “forget” about IP and FTO. When speaking with investors not knowing your own IP or third party IP space can be detrimental.

By its very nature IP can never be a value driver in itself. Nobody invests in a company just because of the IP. Or because it has freedom to develop and market its products. Just like nobody invests in a company because of how well it is insured. Just like insurance IP does not have a lot of “sex appeal” and as a consequence IP can sometimes be ignored. Many entrepreneurs dream of building a company based on great science – few dream of building a company with an extensive IP portfolio. But if you want the great science, do not ignore the IP. If you do, the great science will most likely never be commercialized. At least not if external investors are required.





Filing – when and where?

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. In some circumstances this may be the sensible thing to do, but several factors should be considered before deciding when to file.

Priority date

After filing a first patent application, applicant can within one year – the priority year – file additional patent applications claiming priority from the first application (the priority application). The date of filing of the first patent application is known as the priority date, and the priority date is decisive for determining the state of the prior art. Thus, anything published before the priority date may be taken into account when determining novelty and inventive step. Furthermore, the priority date can be used for determining who has first filed a patent application. If two parties claim patent rights to the same invention, the rights to the invention will be awarded to the party who has filed the patent application first (“first-to-file” principle).

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. If the updated application introduces completely new aspects of an invention, the new aspects will not have the right of priority. However, the updated application can contain new data supporting the invention and still retain the priority date.

Early filing of a patent application gives rise to an early priority date and the benefits associated therewith. However, at least two factors may favor a late filing date, namely the requirement for an enabling description and the wish for a longer patent term.

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. In many countries it is not sufficient to describe how an invention can be carried out, it is also a requirement to demonstrate that the invention has in fact been carried out.

If the patent authorities consider that the requirement of an enabling disclosure is not fulfilled, the patent application risks being rejected for this reason. Such an objection can be difficult to remedy after filing.

Accordingly it is generally recommended not to file a patent application before sufficient experimental data is available to support the invention. If the invention is a well-defined specific invention then a single example demonstrating the invention may be sufficient to support the invention. However, if broader claims are desired, then it is preferable that the patent application provides several different examples demonstrating different ways of carrying out the invention.

It is not a requirement that a patent application provides actual proof that the invention works. However the application should at least render it credible. Thus, for example in the field of pharmaceuticals data from clinical trials are not required. It is sufficient to provide data from an established *in vitro* model or from animal studies.

When to file documentation supporting the invention

The need for an early priority date may thus have to be weighed against the fact that a broader and/or stronger patent protection can be obtained, when the applicant is more capable of providing a detailed disclosure of the invention.

During the priority year it is possible to file an updated application, which may comprise additional data supporting the invention. Thus, up to one year from the priority date it is possible to supplement a patent application with additional data supporting the invention while maintaining the priority date.

After the priority year has passed it is no longer possible to add additional data to a patent application. However, in some instances it is possible to file additional information on the invention directly to the patent authorities. It varies greatly between different countries to what extent additional data can be supplied after filing of the patent application.

In general data can only be supplied after filing if they support the assertions already made in the patent application. In many East Asian countries, post filing of data is very limited, whereas the practice in Europe and United States is much more liberal.

Patent term

With a few exceptions a patent expires at the latest 20 years after filing provided that all fees have been paid. In relatively slow progressing fields, such as in the fields of biotech or pharma it is frequently the last years of the patent term, which are the most valuable. Accordingly, it may be advantageous that the patent expires as late as possible.

For that reason it may be desirable to delay patent expiry by filing the patent application as late as possible. The term of 20 years is calculated from the actual filing date of the patent application, and not from the priority date. Thus, for the longest possible patent term it is desirable to exploit the full priority year.

Where to file

The priority application can be filed in any country, which is a member of the Paris Convention. Currently, 176 countries are parties to the Paris Convention and thus a priority application can in principle be filed almost anywhere.

Some countries have legal restrictions regarding where to file priority applications, but for Scandinavian inventions the applicant generally has freedom to choose where to file. For practical reasons priority applications originating in Scandinavia are frequently filed with the Danish, the Swedish or the European Patent Offices.

During the priority year a decision must be made about where to file patent applications. In relatively slow progressing fields like biotech and pharma the international (PCT) route is often chosen, which delays the need for deciding where to file (see more details in chapter 7).

Eventually, the applicant must however decide in which countries to seek patent protection. Several factors are important for this decision. First of all it is important to cover the main markets, which may depend on the particular invention. It is important to remember that patents may be valid for up to 20 years, and thus it is possible that emerging markets can be main markets before expiry of the patent. Furthermore, it may be desirable to have patent protection in the home countries of the most relevant competitors. Another factor to consider is potential production countries. For almost all inventions in the fields of biotech and pharma patent protection is sought at least in Europe and the United States. The countries then most often considered for patenting are India, China and Japan closely followed by South Korea, South Africa, Canada and Australia. Brazil and Russia are also common countries in which to seek patent protection.



Patent application drafting and prosecution

This chapter describes many of the activities an applicant must deal with, from drafting a patent application and until a patent is finally granted.

Before filing a patent application

It is recommendable to obtain a pre-filing evaluation of an invention, which for example can be prepared by a patent attorney. This evaluation is essential for determining whether to apply for patent protection, and is also very helpful for drafting the patent application. The knowledge obtained from such an evaluation can result in a more effective protection of an invention. A pre-filing evaluation can for example be used:

- to determine whether an invention is patentable
- to determine the probable scope of a patent
- as inspiration, before launching new development activities
- as a basis on which to assess the possibilities of new activities in the area
- to assess the commercial viability of a new product
- to acquire knowledge of the relevant operators within a given field
- to obtain information on whether the rights of others will be infringed

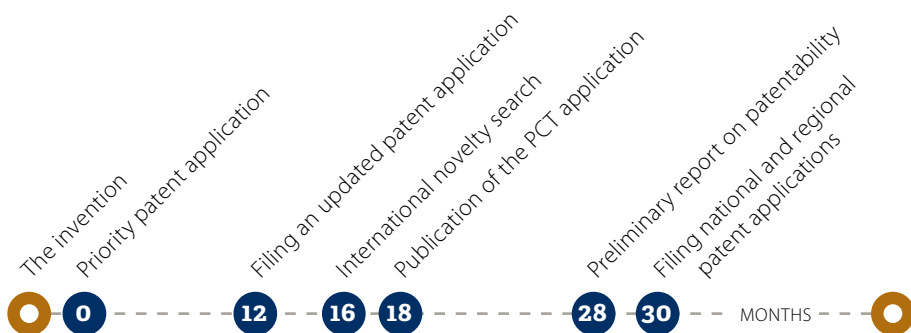
The patent application

The single most important document in the patent process is the patent application. Accordingly it is of paramount importance that the patent application is of good quality. A good quality patent application is characterized by the following features:

- Broad patent claims
- Narrow claims specifically defining the preferred aspects of the invention
- Intermediate claims
- Alternative claim language
- Concise claim language that clearly defines the scope of protection
- Carefully-drafted claim structure providing basis for multiple combinations
- Enabling disclosure of the invention
- Examples to support the claims
- Prioritized fall-back positions
- Description of technical effect of alternatives

In addition it is preferable that the patent application is setting the scene for the invention and tells the story about the invention, preferably based on sound scientific reasoning. This will facilitate other people's understanding of the invention, including the examiner's. It is also important to draft the application in an understandable language using common terms within the given field. The terminology should be consistent and any unclear terms should be defined. The most relevant prior art may also be briefly discussed.

As described in chapter 6 (Filing – when and where) it is generally advantageous first to file a priority patent application and then follow up with an updated application during the priority year. Preferably both the priority application and the updated application should contain the features listed above. Thus, even if an update can be made, the priority application should also be of good quality.





0

0 months Priority patent application

The first patent application describing an invention is a priority-founding patent application, establishing the priority date. In order to establish the best possible priority basis for the filing of an updated patent application, a priority patent application should be an application of good quality and contain the features described above.

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 patent application or in an updated patent application to be filed before expiry of the priority year.

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 a patent authority, for example by the European Patent Office (EPO). This can be achieved by filing the priority application as a European patent application or by filing the priority application with either the Danish or the Swedish Patent Office and requesting that the application is subjected to an international type search by EPO. A novelty 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.

The Patent Cooperation Treaty (PCT)

When taking advantage of the PCT system, an applicant initially only needs to file a single, updated patent application (PCT application). The PCT application can later be converted into national patent applications in the more than 140 countries presently members of the PCT.

12

12 months Filing an updated patent application

It is possible to update a priority application, if this takes place no later than 12 months after the filing of the priority application. The updated application can be filed nationally in the countries of interest and/or as an international application (PCT application) depending on the strategy chosen.

Filing a PCT application secures an applicant the right to file national or regional patent applications in the 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, which is one of the most expensive single steps of the patent prosecution. 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 the few states not party to the PCT.

In the following the procedure for prosecution of a PCT application is outlined in more detail.

16

16 months International novelty search

After having filed an updated patent application as a PCT application, an international search report is issued about 16-18 months after the priority date. This report identifies relevant prior art references, and also provides a first written opinion regarding patentability.

18

18 months Publication of the PCT application

The content and filing of a priority application is kept secret at the time of filing. Also the updated PCT application is not made publicly available right away. The public will not become aware of the filing of a patent application until 18 months after the priority date, when the PCT application is published. At the same time the priority application will also become available.

28

28 months Preliminary report on patentability

Depending on the strategy chosen and the contents of the first written opinion, applicant may choose to file a demand for a preliminary examination of the PCT application. In general it may be advantageous to demand preliminary examination if it is foreseen that the application will enter national phase in many countries, and the first written opinion raises objections which can be overcome by arguments and/or amendments. It is also recommendable to demand preliminary examination if a positive opinion is important for future investors.

A demand for preliminary examination must be filed no later than 22 months after the priority date and gives applicant the opportunity to discuss patentability with the patent authorities in writing and sometimes also by telephone. The preliminary examination is concluded with issuance by the PCT authorities of an international preliminary report on patentability, which is typically issued about 27 to 28 months after the priority date.

Having prosecuted the PCT application in the centralised PCT phase can benefit the PCT application when it subsequently enters the national phase, as many national patent authorities will be inclined to recognise the conclusion of the preliminary report on patentability drawn up in the PCT phase even if they are not obliged to do so.

30

30 months Filing national and regional patent applications

At about 30 months after the first priority date, the PCT application must enter national phase in the individual countries or regions in which it has been decided to obtain patent protection. The cost 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.

Extension of patent term

In many countries an extended patent term is available for pharmaceutical patents. For example in Europe a supplementary protection certificate (SPC) is available. An SPC is a patent term extension of up to 5 years, which can be assigned to a drug on the market to compensate for the often lengthy approval procedure of the drug. This patent term extension may even be extended by an additional six months if the marketed drug has completed an approved pediatric investigation plan. An SPC application must be submitted within 6 months from issue of the corresponding patent or 6 months from the granting of a marketing authorization for the drug, whichever expires later.

The SPC was introduced in 1992 for products having a valid marketing authorization. An SPC is issued to the owner of a national or European patent under the same conditions in all European member states. It is irrelevant that the marketing authorization may have been issued to a company which is not identical to the patent owner.

The patent term extension is only valid for the product contained in the approved drug, *i.e.*, the active ingredient or combination of active ingredients. If the product contains a combination of several active ingredients, the patent term extension covers the same combination of active ingredients.

In order to obtain the five years of patent term extension conferred by an SPC, four conditions must be met:

1. Patent protection

The product must be protected by an issued patent which is in force at the time of application. Thus, if a patent owner wishes to apply for an SPC in Denmark based on a European patent, the patent must be validated in Denmark and the patent shall be in force. The product must be described in the European patent and must be defined by the wording of the patent claims. Generally, the product must be described by a chemical name or a structural formula, either a specific structural formula or a Markush grouping. If the product is a combination product (A + B), the specific combination A and B must be included in the wording of the claims.

2. Marketing authorization

There must be a valid authorization to market the product as a medicinal product. The SPC application can only be filed by the owner of the patent, this also applies in cases where the marketing authorization has been issued to another company.

3. First marketing authorization

The marketing authorization must be the first marketing authorization for the product as a drug. In Denmark, the first marketing authorization for the product is considered to be the first marketing authorization for a drug, which comprises the product as an active ingredient. Thus, if the SPC application concerns a product containing only one active ingredient (A), then the marketing authorization could relate to a drug containing only A or a drug that contains one or more active ingredients in addition to A. For combination products (A + B), the first marketing authorization is the one which covers a product containing both A and B as active ingredients.

4. No previous SPC for the same product

At the time of filing an application for an SPC, no previous SPC must have been issued for the same product. However, the patent owner may submit several SPC applications, and previously filed SPC applications, which have not yet issued, do not prevent the subsequent filings of new SPC applications. In this case, however, the applicant must choose which application should lead to the issuance of an SPC. Also, an owner of several patents covering the same product cannot obtain more than one SPC for that particular product. In cases where different applicants have applied for SPCs for the same product, each applicant may obtain an SPC as long as their application was filed before the issuance of the first SPC.

An SPC starts already at the drafting of the patent application

In order to meet the four criteria above, it is extremely important to consider which active substances may be included in a future medicinal product. These considerations should be implemented already in the preparation of the patent application, and if it is possible that the future product will contain a combination of two or more active substances, then this specific combination should be mentioned already in the patent application in order to obtain a possible patent term extension on the product.



International patenting

The world of patents is an international world. Few applicants file their applications in only one country. That applies especially for applicants from the Medicon Valley Region because our home markets, Sweden and Denmark, are relatively small.

Because of the international aspect, the patent world is home to some of the oldest international conventions that still exist. The first Paris Convention was signed in 1883! The Paris Convention defines very basic concepts of patenting, for example the priority year and the equal right of nationals from all the contracting states.

Most applicants from Medicon Valley get in contact with the Patent Cooperation Treaty, in short the PCT, which today includes 148 countries and sets forth a uniform standard for the format of applications and how they are filed, searched and examined during the first 2½ years of a patent's lifetime. (See details in chapter 8)

Finally there are a number of regional patent treaties that regulate the filing and grant of patents by regional patent offices in Europe (EPO, the European Patent Office), in the former SNG republics (EAPO, The Eurasian Patent Office), and in Africa (ARIPO and OAPI).

Another important international treaty is the 1994 TRIPS treaty (Agreement on Trade Related Aspects of Intellectual Property Rights), which was prepared under the auspices of the World Trade Organisation and requires the signatory states to provide patent protection in all fields of technology (with a few exceptions).

Because of all the international efforts a lot of harmonization has taken place. Patent applications across the world face practically the same prior art, they are all published 1½ years after filing, they have a basic patent term of 20 years and all need to fulfill the same basic patentability requirements: novelty, inventive step/non-obviousness, enablement, and clarity.

Despite these efforts there are still a number of differences in the practice of the various patent offices around the world. In the following we will focus on the most important local specialties. One important aspect to keep in mind is that a patent application must from the very beginning be drafted so that it fulfills the patentability requirements in all the relevant countries in which it is to be filed. Drafting a patent application for the home market is not enough.

Europe

The European Patent Office, the EPO has a centralized procedure for filing patent applications that can subsequently be registered (validated) in the national European countries. The office covers 38 European countries from east to west and north to south. The EPO is independent of the European Union and includes non-EU member states such as Switzerland and Norway. In the future, the EPO will also be tasked with registering the so-called Unitary Patents (aka the EU patent).

Since its start in 1978, the EPO has been a huge success.

The EPO is known for being the most expensive patent office in the world with fees at least twice that of any other patent office. However, the EPO is also known for its very high and consistent quality of examination of patent applications.

One thing to keep in mind when filing EP applications is that the EPO has a very strict amendment practice. In particular the EPO has a very strict approach to making combinations of different elements from different parts of the patent application. In order to make sure that a patent application is prepared for this strict practice it is necessary that the application contains sufficient description of relevant fall back positions and combinations of different features from the application.

The EPO also has a similar strict approach to priority. This means that a patent claim in an application must find almost verbatim basis in the priority application in order to maintain the right to priority. Consequently, if a priority application was filed with very few details and the invention was published during the priority year, it may prove challenging to draft claims that are entitled to priority and thus avoid the publication as prior art. Therefore it is advisable to start with a complete patent application that has all the fall back positions needed.

The EPO does not allow for patenting of method of treatment claims because medical doctors should not be prevented in their practice by patents. Instead claims can be granted for use of compounds or drugs for treatment of disorders. These claims are normally only infringed by the pharmaceutical company marketing the drug for the claimed indication. There is no requirement of actual clinical data. A patent application can be granted based on *in vitro* data or by reference to literature demonstrating that drugs of the claimed type can treat the claimed indication or that the drug target is involved in the indication.

The United States

The United States is the biggest pharmaceutical market in the world. It can be covered by one single patent application, so for most biotech and pharma companies as well as for universities and hospitals, the United States is the most important country to get a patent in.

The US patent law has evolved independently and separately from the rest of the world. Realising the need for harmonization, the US Congress has passed several bills over the past 20-25 years to harmonise the US patent law with the rest of the world. Today, US patent applications are published after 1½ years, US patents (normally) have a patent term of 20 years, and the prior art basis is almost the same.

Unfortunately, the patent practice has not been harmonized with the rest of the world. A series of decisions from the Supreme Court of the United States over the past 10 years has made life for applicants hard in the United States.

The non-obviousness/inventive step bar has been raised from a relatively low level to one of the highest in the world. In addition, the Supreme Court has decided that products isolated from nature, *e.g.* isolated DNA, isolated proteins and isolated small molecules are not inventions because they are not created by the inventors. Finally, laws of nature are not considered inventions. This may appear uncontroversial, but the Supreme Court has decided that the correlation between a biological marker and a particular disease is also a law of nature. This means that a lot of diagnostic tests are no longer patentable.

The pendulum has taken a huge swing but it is bound to swing back and find a new position balancing society's different interests and requirements. Meanwhile, getting patents granted in the United States is challenging but not impossible. Patents are getting granted, often more narrow than in Europe. More effort is needed often in the form of interviews with examiners to understand their concerns. It is possible that the challenges will be solved by new decisions from the Supreme Court or by another change to the US patent law.

Far East Asia

One notable difference between patenting in Europe and in Far East Asia is the requirement for support of the invention. Whereas in Europe it is sufficient for a patent application to describe the invention in such a manner that the skilled person can perform the invention, it is a requirement in most countries in Far East Asia that the patent application contains several working examples including data. If only one working example is provided, then in the field of life science it is frequently required that the claims are limited to the specific subject matter shown by the example and very similar alternatives. Typically, functional homologues of nucleic acids or proteins cannot be claimed unless working examples are provided in the application. If no working example with data is provided it is generally very difficult to obtain patent protection in Far East Asia. It is important that the working examples are contained in the application as filed. Thus, there are only very limited possibilities for supplying additional data after filing of the patent application.

It is also worth noting that Taiwan is not party to the PCT and thus to obtain patent protection in Taiwan, a national application must be filed within the priority year.

Latin America

An international patent application covers 148 countries with more joining continuously. However, several Latin American countries are not party to the PCT, most notably Argentina. Thus, for patent protection in *e.g.* Argentina a national application must be filed within the priority year.

In many Latin American countries, most notably in Brazil, the patent authorities have chosen a very strict approach in relation to patents in the pharmaceutical field. Thus, typically more is required to have inventive step acknowledged and it may also be challenging to obtain claims much broader than what is actually demonstrated by the working examples. Furthermore, prosecution times are very long and the grant of pharmaceutical patents takes an average of 3 to 4 years more than patents from other technological areas.

How and when to publish

One very common prejudice against the patent system is that it prevents free sharing of information by preventing scientists from publishing their science. The fact is that the patent system forces inventors to publish their findings, because patent rights are only granted in exchange of a written description of the technology behind the invention. The word “patent” comes from the Latin word “patere” which means “to lay open” – in other words to make what is disclosed in the patent available to the public. In the absence of patents, many private corporations would never publish their research.

There is nothing that prevents a scientist from filing a patent application and publishing their research in peer-reviewed scientific journals so that they can reach their publication goals and be judged by their scientific contributions.

Corporations that are not dependent on making scientific publications also need to take some precautions before they publish their inventions. Corporations may need to publish the content of patent applications as part of their marketing efforts. Putting a product of a patent application on the market also constitutes a publication as the word is understood by the patent law.

Publishing before filing

Publishing before filing is detrimental to patentability. This cannot be emphasized enough. And this applies to all kinds of publications, whether an article, an abstract, a lecture, a brochure, a pamphlet, sales materials or offering a product for sale. All of these types of acts are considered publications as they all serve to convey the information about the product to the public.

If a publication has been made less than one year prior to filing a patent application, it is still possible to file a patent application in the USA if the authors of the article and the inventors on the patent application are the same. Many American academic institutions

still use this strategy. There is nothing wrong with doing it as long as it is clear that patent protection outside the USA is in effect prevented. As always there are a few exceptions. A few countries also have a so-called grace period allowing for publications from the inventors to be disregarded as prior art.

Publishing during the priority year

Once the priority patent application has been filed it is normally safe to publish the invention. The priority patent application provides protection against publications made during the priority year but only to the extent that the later pursued patent claims are supported by the filed priority application. If the priority patent application is a high quality patent application with the necessary level of details, definitions, support and fall back positions, then a publication during the priority year should do no harm. But if the priority application was a "quick and dirty" patent application then there is limited protection against a publication during the priority year.

Some applicants would like to save as much money as possible initially and want to file a patent application with a manuscript and a cover sheet. This type of patent application is known in the USA as a "cover-sheet provisional". Even if that application is updated to become a prime quality patent application by the end of the priority year, it will not provide protection against a publication during the priority year. This is because it is unlikely that the first filed manuscript describes the invention in such detail as is needed to support the patent claims. In that case the prior art date will be the filing date of the PCT application filed at the end of the priority year and the manuscript published during the priority year will constitute full prior art.

Whenever the need for publication arises during the priority year, it should always be checked that the patent application contains support for whatever is in the intended publication. If something is missing, the patent application can be updated and re-filed. Often the amount of updating is limited and can be done very quickly so the publication need not be postponed.

A meeting with potential investors and partners should also be regarded as a potential publication unless the investor or partner has signed a confidentiality agreement. If any confidential information is provided to the investor/partner it is also a good idea to update the patent application just before the meeting.

Publishing after the PCT application has been filed

Normally, at the end of the priority year, a PCT application or one or more national applications are filed. Once this application has been filed the text can no longer be changed. At this stage a publication cannot count as prior art against the patent application. Still one needs to be cautious before publishing. One reason for this is that during the period

between filing and publishing the PCT application a new patent application can be filed claiming a trivial variant of the invention in the priority patent application. Until its publication, the PCT application does not count as full prior art and a new patent application filed at this stage need only be novel – not inventive – over the PCT application.

If new discoveries are made during this period, one should consider whether a so-called second generation patent application should be filed before publication of the patent application and before publication of the new findings. In fact, corporations often file this type of patent application just before the priority patent application is published in order to protect commercially important variants and potentially also to extend the lifetime of the patent protection as the second generation patent application will expire between 12 and 18 months later than the priority patent application.

Publishing after publication of the patent application

At this stage the priority patent application can no longer be updated and any new findings will need to be patentable in view of that publication.

At this stage, one only needs to make certain that a publication does not question the findings in the earlier patent application or casts doubts on the data presented there. It does not happen often that a scientific publication at this stage harms the published patent application but it does happen.

- Never publish before you file the patent application
- Posters, abstracts, and presentations are also publications
- Talk to your patent attorney before you publish after filing
- Be careful not to discredit the invention in publications



Freedom to operate

The concept of “Freedom to operate”, often abbreviated “FTO”, is used worldwide to describe the situation that a product may be marketed without infringing third party IP rights. An FTO analysis is the tool used to evaluate whether patents belonging to a third party may block access to the market in one or more countries, so-called dominating patents.

Unfortunately, considerations about FTO often disappear among all the other tasks to be carried out when developing and marketing a new product even if the entire investment may be lost if the product cannot legally be brought onto the most interesting markets because of the patent rights of others. Or the FTO analysis is postponed until the product is fully developed, maybe in order to be entirely sure that the costs of the FTO analysis are not wasted if the development comes to a halt.

This is, however, really a shame because an FTO analysis at an early stage of the development provides more possibilities of navigating safely, relative to others’ patents, either because there is a possibility of negotiating access to the dominating patents through licenses or acquisitions without having the back against the wall, or simply because the development may work around and thereby avoid the dominating patents.

Psychology of the FTO analysis

Perhaps very understandable human factors come into play when companies postpone an FTO analysis.

The optimism involved in the development of a new product and drafting of broad patents may vanish in a second, if the FTO analysis ends with a pessimistic message about problems in bringing the product onto market before the competitor’s patents have expired. The consequence may be that it is easier to postpone the FTO analysis until later rather than facing any negative information at an early stage.

To this should be added that the FTO analysis may also disclose that the competitors are at the same phase of their development – or worse, that their development has reached higher levels than your own, which could completely remove all faith in the future.

Economy of the FTO analysis

Similar considerations come into play when an FTO analysis is considered in a financial setting. All costs relating to product development and patenting may be viewed as investments in the future whereas the costs of an FTO analysis could rather be regarded as a tax on the development as the outcome may be negative.

However, it ought to be the other way around because an early FTO analysis provides a much better starting point to avoid trouble with third party patents. In an ideal world, the FTO analysis is among the first investments when development of the new product has been decided, because the company's future market position will thus be strengthened.

To this should be added that a focused FTO analysis drafted in close cooperation with the company's developers who know the product well is usually no more expensive than the drafting of a first patent application for the product.

Results of the FTO analysis

It is obvious that the result of an FTO analysis will provide knowledge about any dominating patents, however, it is an often overlooked fact that at the same time you get knowledge about the competitors' stage of development as well as behaviour in the patent field, and last but not least are provided with a number of details from the patent literature that may be used as inspiration in your own development. There is no reason for reinventing a variant of the wheel if it has already been described in the patent literature.

Dominating patents are not necessarily restricted to similar products, but may also be patents which – although they are focused on other products – have nevertheless been issued with a scope of protection that is so broad that it also covers the very product under development.

Experience shows that every FTO analysis usually identifies at least 1-2 patents having a scope of protection directly covering the company's product and therefore requiring some kind of action. No matter whether the action is an attempt to gain access to the patent right, rethinking the product, or an attack on the patent, there are far more options if these patents are identified early in the process.

Focused FTO analysis

A focused FTO analysis consists of 3 phases:

1. The search phase – identification of potentially dominating rights
2. The analysis phase – analysis of any dominating rights
3. The assessment phase – are the dominating patents valid?

Before initiating the search phase, it is natural to analyse the product, the competitors and competing products in detail in cooperation with developers and marketing at the company. Thereby it will be possible to tailor a search strategy for potentially dominating rights which on the one hand is so “broad” that it may be expected that all potentially dominating patents are identified and on the other hand is so focused that noise from completely irrelevant patents is minimized. However, contrary to a novelty search in which only novelty-destroying documents are searched for, an FTO search cannot be allowed to stop until ideally all potentially dominating patents have been identified. Therefore it cannot be avoided that the search result will subsequently have to be sorted manually.

Analysis phase

In this phase, a close cooperation between patent experts and developers and marketing is necessary in order to separate irrelevant patents from dominating patents in the best possible way. Often the difference between the scope of protection of the identified patent rights and the company's product resides in the details, and here the developers are the experts.

At the end of the analysis phase, the field of dominating patents has been narrowed down to the following:

- Granted patents whose scope of protection covers the product
- Pending patent applications whose broadest claim covers the product

In principle, an FTO analysis could stop here, but it is often very relevant to consider whether the scope of protection that the dominating patents contain, is actually a valid scope of protection. Alternatively, you could be forced to avoid patents which subsequently turned out to be invalid.

Assessment phase and FTO strategy

Therefore the patentability of every dominating patent and patent application should be assessed starting from known references and novelty searches in order to give a final overview of the probable valid scope of protection. Then the FTO strategy may be determined.

An FTO strategy should contain a strategy describing how the company should relate to the patent rights with a dominating scope of protection. Typically the dominating patents are divided into two categories – those whose valid scope of protection will certainly dominate, and those whose present scope of protection is deemed to be invalid and where it is unlikely that they will dominate if they were attacked in an invalidity case.

With respect to the first group, the strategy is directed either to obtain access to the patents via licenses or acquisitions, or alternatively to try to work around the scope of protection.

With respect to the second group, the goal is to avoid long and costly litigation. In this connection, the FTO strategy will contain considerations for an early attack on the patent in order to limit the scope of protection so that it is not dominating. Alternatively, the strategy may merely involve preparations of documenting the invalidity of the patent right in order to be prepared for a later dialogue with the patentee. The final strategy depends on the importance of the case, knowledge about the patentee and other factors such as the needs of business partners and investors for feeling assured that the patent rights do not expose a problem.

Repeat the FTO analysis at regular intervals

After finalising the FTO analysis, when everybody breathes a sigh of relief, the time has come for deciding when to repeat it.

And it must almost always be repeated

- because the competitors do not stop filing patent applications,
- because the development of the product may change direction, and
- because patent applications are secret for 18 months after filing.

The most simple way to stay updated is to monitor the field regularly, for example every quarter or every six months in order to discover any potentially dominating patents as early as possible.





IP strategy and business plan

On war, von Clausewitz defines “strategy” as the overall plan for the entire war whereas “tactics” are rather the plans for the individual battles. These concepts may easily be applied to a company structure. An IP strategy must follow and support the business plan of the company, ensure the earnings by a targeted protection of commercially relevant markets, and at the same time prevent the closure of an interesting market because of other parties’ patents. In the IP strategy, various phases are determined whereas the more detailed tactics may be determined at the entry of the individual phases.

What IP strategy does the company have?

All companies with IP rights, be it patents, trademarks, designs or business secrets, have an IP strategy – it may, however, be between the two extremes: the *ad hoc* “strategy” which is close to pure tactics, and the all-encompassing IP vision. The “*ad hoc* method” entails that decisions on the protection of inventions and trademarks are not made until the invention has been conceived, or the product is on the market, or that the blocking effect of others’ patent is not considered until a lawsuit is threatening. Although this may work in the short term, experience shows that this often leads to a portfolio of rights growing wild and a lack of overview leading to an inefficient use of resources and first and foremost to uncertainty.

A good IP strategy requires knowledge of the various possibilities of protecting the company’s IP and addresses all the company’s IP requirements, both now and in the long term. Moreover, the IP strategy includes the time aspects of every element of the strategy so that they meet the needs of the business plan.

As a minimum, the IP strategy should address the following elements:

Protection of own inventions and products

In development companies, many innovations and improvements emerge, and far from all inventions should be protected by a patent. The IP strategy should address where protection is “nice-to-have” and where it is “need-to-have” and should preferably specify the areas having so great importance to the company that several layers of protection for a product are desirable.

In a small company, the distance from an invention to a decision-maker is small, but in large companies a procedure should be set up in order to make sure that inventions made by various people in the company are actually identified by those who are to decide on the type of protection.

At the same time, the IP strategy should include a strategy for the publication of inventions, be it for example scientific articles or presentations at trade fairs, to avoid spoiling the possibility of patenting by publishing the invention before patent protection has been sought.

Secrecy

Some of the innovations and improvements may advantageously remain the secret of the company, and secrecy should therefore be an element of the IP strategy which should also include a plan so that the secrets remain secret.

Geography

As there are about 200 countries in the world where it is possible to obtain patent rights, a company may quickly get ruined buying patent protection unless the most relevant markets have been defined in the IP strategy, and a plan has been drawn up with respect to the choice of countries, preferably in the form of prioritized lists of countries in which protection is desired for essential inventions and for less essential inventions, respectively.

Portfolio management – patent term extension

An IP strategy should be reconsidered at an interval of a few years and should in particular be brought up to date by changing the business plan. Existing rights which had great importance at the establishment may have lost their importance because of lack of market or lack of development success and should be abandoned or minimized geographically so that the budget is used for the rights that are most relevant commercially.

Furthermore, the IP strategy should include considerations as to the timing of the filing of for example patent applications so that the patent term of 20 years matches the timing of the products on the market in the best possible way. In this connection, it is also relevant to consider the existing possibilities of patent term extension for drugs and plant protection agents, the so-called supplementary protection certificates (SPC).

Freedom to Operate

The classical conflict within IP is an infringement case: The product is on its way to the market, but has it been ensured that there is a direct market access (freedom-to-operate or FTO)? In other words, have other companies blocked the way to the market with their dominant rights which – with a temporary injunction the day after the introduction of the

product – may give rise to serious, expensive and protracted legal problems to be dealt with?

External parties and contracts

Inventors as employees are normally by law or contract obliged to assign their inventions to the company, but this is not necessarily true for consultants and PhD students although they are paid by the company. The IP strategy must define the agreements with external parties already at the start of the cooperation, so that it is avoided that relevant inventions are owned by others than the company itself.

Licensing

It is not always that the company uses its own patents to the full extent, and possibilities of additional earnings by offering licenses for own rights to other companies may advantageously be considered in an IP strategy.

Marking

Patent rights must be used actively, for example in a marketing context, and all relevant people in the company should be aware of the various rights. In this connection, it is also essential to mark products so that buyers are aware that the products are protected by patent or trademark, and the IP strategy should specify routines of marking so that they comply with the legislation in relevant markets.

Align the IP strategy with the business plan

- Evaluate the portfolio regularly
- Adapt your strategy to changes
- Design policies for inventions and inventors
- Address FTO

CASE 4

Cantargia and the importance of a solid IP portfolio during IPO



Göran Forsberg, Ph.D. Assoc Prof, CEO – Cantargia

The early days as a private spin out from Lund University

Cantargia is a small Swedish company with its original roots in Lund University. It was formed 2009/2010 after an original finding around a new strategy to treat cancer. The founders, Thoas Fioretos and Marcus Järås, had discovered that a subunit of the interleukin 1 receptor, IL1RAP, was overexpressed on leukemia stem cells and that antibodies against IL1RAP could eradicate such tumor stem cells.

Cantargia was established by the founders and a local investor group, Lund University Bioscience, LU BIO, providing the necessary capital injection to further explore the initial findings. A critical aspect during this process was the valuation of the company. Cantargia had two assets at this point in time, the knowhow from the founders and the recently filed patent application. Cantargia did not have a product candidate at this time. The patent application had claims towards the use of IL1RAP as a target for therapy of hematological forms of cancers, such as various forms of leukemia. Therefore, if granted, the claims would limit the possibilities for others to develop products in this market segment and would also give some protection from generic competition. As is very often the case in these early stages of development, the patent application was a critical component for the investors to enter the scene and make the initial investment.

The initial investment was used to generate additional data around IL1RAP as a target for eradication of cancer stem cells. Hereby, critical data was generated that could be used e.g. to update the initial priority application around the treatment of hematological forms of cancer, but broader studies also showed that IL1RAP was overexpressed on cells from solid tumors. As a next step, data around the treatment of solid tumors was obtained. Subsequently, Cantargia filed a second priority application in 2011 covering IL1RAP as a molecular target for the treatment of solid tumors, such as melanoma, lung cancer and colon cancer.

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Development of lead candidates

Cantargia made a decision at a very early stage to focus its drug discovery towards the generation of antibodies against IL1RAP. In addition, the primary goal was to use the antibodies as full-length monoclonals, without coupling them to other effector functions or cytotoxics. A screening program was initiated to generate antibodies binding to IL1RAP and test these for the ability to kill tumor cells expressing IL1RAP. Several interesting monoclonal antibodies were obtained using mouse hybridoma technology. Critical parameters included the ability to stimulate immune cells to kill the tumor cells, inhibition of cytokine induced signaling in the tumor cells and binding affinities to IL1RAP. In 2013 Cantargia had reached a stage where a handful of antibodies had been selected after extensive evaluation and characterization. The antibodies were tested for potency in animal models of leukemia and showed promising effects. From this data a clinical candidate was selected and patent applications on the leads and backup compounds were filed. In parallel, the lead candidates were humanized. To advance the project, the work was either performed at the labs of the founders or outsourced to research or manufacturing entities. Financing was limited and primarily carried out by LU BIO and in 2013 a portion was injected by the Danish Venture Capital fund Sunstone Capital. However, it was also time to let more investors come on board as Cantargia had become a development company with a significantly higher need for capital than previously.

Nasdaq First North listing

On the back of the data generated on the promising compounds, Cantargia realized that the current company structure was too limited to take the next steps in the development chain. In 2014, the search for a full time CEO and new funding alternatives started. Göran Forsberg was employed as CEO mid 2014 and at a similar time, local investors provided additional funding to be used for the short term investment needs as well as to provide funding for the initial public offering, IPO, of Cantargia. The optimal time point for an IPO can always be discussed, but as Cantargia's estimated capital need for the next 3-4 years exceeded SEK 100 million, going public was deemed to be the most effective way.

A number of investor meetings were held prior to the announcement to get a second opinion on Cantargia as an investment case and to see if the current data set was enough to trigger interest for Cantargia. Issues that were discussed were for instance milestones and timelines, investments needed to reach these milestones, commercial opportunity and management experience. Of relevance is the short term timelines. Cantargia is planning to start a phase I /II clinical trial late 2016 and with results expected in late 2017, the next step in the development may start 2019 and could be a pivotal trial or a phase IIb trial. Depending on indication and strategy, the first product could be approved a few years later. As this article concerns intellectual property, I will focus on the take home messages obtained.

With patent applications recently filed around composition of matters for the lead compounds, the earlier patent applications around IL1RAP as a target for therapy can be regarded as defensive applications. Clearly the investors were very pleased with the portfolio, the defensive protection would last until 2029-2031 depending on indication while the product would be protected until 2034 excluding the possibilities for additional market exclusivity. It should be pointed out that the Cantargia portfolio is still young enough for the applications to be in the phase of early review by authorities. Therefore, even though most investors would like to see granted patents, the potentially very long patent life and mix of patents were attractive features. Next step is competing patents. Such an analysis is always ongoing and difficult to respond to, but clearly Cantargia's goal is to make sure that the compounds being developed have an appropriate protection and do not infringe other patents. Thus, the key elements are solid protection of your compounds for a period well beyond anticipated launch and no third party issues. Several investors did their own personal due diligence from public sources and there were quite a lot of questions on this subject. The investors did not ask for details about the patent attorneys, but Cantargia has a very serious view of IPR and has made sure that we liaise with experienced attorneys and advisors.

I should not comment on what the investors finally thought of the IPR situation of Cantargia, but the IPO was oversubscribed and the company market cap has increased a lot since then. In the IPO, SEK 44 million was raised which is one of the biggest IPO's in Scandinavian life science.

CASE 5

A Venture Capital Perspective on IPR and IP strategy

Stephan Christgau, Investment Director, Novo Seeds

Researchers and entrepreneurs in life science know that protection of their intellectual property rights is essential if discoveries are to be commercialized. Development of new drugs or other medical products represent investments of many million euros, and thus nobody is likely to commit the required financing unless the ideas and concepts underlying the discoveries are well protected, and can be developed without infringing other patent rights.

However, protection of IPR can be done in many ways and faces different challenges depending on the nature of the project, development stage and competitive situation. It is very difficult, if not outright impossible, to utilize a “one size fits all” strategy when dealing with IPR. Regardless of the stage and nature of a project, it is always a good idea to conduct a comprehensive review of IP possibilities and prepare a strategy for how to proactively secure proprietary rights as the project develops. Especially for early stage projects, it can be a very useful exercise to draft an IP strategy where anticipated developments and planned experiments can be assessed and considered from an IP perspective. A strategic plan may also enable additional development activity to be performed, or experiments modified to increase the strength of existing and future patents. Of course it is rarely a good idea to perform studies solely to file patents. But just as preparation of a target product profile and competitive profiling for a potential new drug may highlight some key data of special importance, making studies for a patent application may reveal some data or results that could be of particular value for securing and expanding IP for the project.

A strategy is more than just a list of individual patents. It should be an overview of intended and planned patent filings, where anticipated future development and possibilities are



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thought into a comprehensive plan. By definition such a strategy will have to be dynamic and opportunistic, changing with the project as new experiments, competitor activities or other data may affect IP. However, it enables a careful planning of individual patents, and hopefully prevents early patent applications from becoming "prior art" for later patent filings, and it may affect all aspects of a biotech project such as development plans, communication strategy, engagement with external advisors and experts, etc.

As a venture investor, receiving hundreds of projects for review and assessment every year, IP is of course a key area of our evaluation. Having an IP strategy in place, even in a preliminary overview form, will facilitate the dialogue on this issue, and help us in the dialogue with new companies or life science entrepreneurs.

Licensing patents

Collaboration

Collaboration between companies and with consultants or universities is beneficial to development. Through collaboration, a company can draw on highly specialized skills that are not available in-house. It can lead to new discoveries and new inventions of great value. For many companies, it is strategically and economically advantageous to buy specialized knowledge externally rather than hiring staff with specialized skills.

There are many strategic reasons for collaboration between companies and between companies and universities. First of all, there can be a need to temporarily access the special skills of the partner. But there can also be collaborations where both parties can get a strategic advantage of cooperation, for example, by combining the two sets of special skills and developing new technology that can be used by both partners for different purposes or in different markets.

Where the business strategy determines the extent to which the company collaborates with external parties, it is part of the IP strategy how collaboration agreements are drafted with regard to ownership of inventions, responsibility for patent prosecution, ownership of data, publications, etc.

A collaboration agreement typically includes provisions on ownership of inventions and further developments of inventions, as well as the party responsible for possible patenting the rights of the two parties for development results, and of course, who the parties are.

Licensing

Companies and applicants may enter into licensing agreements of two types – licensing of rights from another company or institution – and out-licensing, where its rights are licensed to another company.

The extent to which a company in- and out-licenses, is defined by the overall IP strategy. What is the strategy for that part of the IP that the company does not need itself? What does the company do when others own the IP which is necessary for a product or project, or intellectual property, or the IP which can make a product more valuable?

Licensing agreements are typically concluded in the context of collaboration agreements, which also set the terms for licensing the parties' patent rights.

A license agreement creates freedom to operate in exchange for pre-agreed economic conditions. A license may be exclusive or non-exclusive. If a company in-licenses a tool or piece of technology to develop a product, there is no need for exclusivity. Typically the company will be able to have its own patents on the final product. Then there is only need for a non-exclusive license to ensure freedom to operate.

In other cases, an entire project is in-licensed, for example, from a university or a small business, where the larger company is to invest in further development of the technology and bring the product to the market. In this case, the license agreement is typically exclusive and the licensee typically has the right to enforce the patent against infringers.

In addition to regulating the financial terms of the agreement (down payments, milestone payments, royalty rates, minimum royalties, etc), the agreement regulates for how long royalties are to be paid and for which countries. It is always a good idea to make some test calculations to check that royalties can actually be calculated in one and only one way. The mathematics can be very complicated, assuming a royalty rate for countries with patent coverage and a different royalty rate in countries without patent coverage (often called know-how royalties). This can be combined with a time limit on the know-how royalties and perhaps a stepwise increase in royalties with increasing sales. It will in many cases be worthwhile to agree on a very simple royalty structure.

A license agreement also contains provisions on which party is responsible for the patent process, and the extent to which the other party must be heard. What will happen if the claims must be restricted significantly? What will happen if the parties do not agree on patent strategy, or if they do not agree on the patent attorneys to use?

Due diligence

It may be nerve-racking when you are placed under scrutiny by a possible investor or business partner or when the company is up for sale. Due Diligence or just abbreviated to DD has become a commonly used term for the investigations made in order to assess risks and values in a business transaction. Due diligence may be carried out within any relevant field, such as finance, IT, staff, production and not least Intellectual Property Rights (IPR), such as patents and trademarks, in order to have a safe basis before a business transaction.

The stress factors in a due diligence may be considerably reduced if the process is thoroughly prepared including submitting the IP portfolio to a pressure test in the same way that we expect others to do.

An IP portfolio is always created prospectively given certain circumstances and conditions, but it is analyzed retrospectively. Therefore, an IP strategy and the associated rights which initially were the best possible, may be under fire when assessed retrospectively in relation to another commercial landscape than the original one.

As a rule, the due diligence analysis should assess the actual IP portfolio and the possibilities it may give to a future commercial strategy, and it should not focus on the strategy which was originally chosen. Nevertheless it is essential to realize that an investor or a buyer will often arrange the due diligence analysis to specifically look for factors which may help talk the price down, and even when the IP portfolio is of high quality, there may still be problems to be discussed.

A constructive due diligence requires dialogue

The best way forward for both parties to a due diligence is to enter into a constructive dialogue from the beginning and all the way through the analysis. This ensures that misunderstandings do not overshadow the facts as the portfolio holder may explain his strategy and present the portfolio, and the analysts may ask questions about unclear areas or more importantly: ask for details that they know may be essential for their client.

Due diligence in practice

Irrespective of the purpose of the due diligence analysis, it should always provide an answer to one or more of the following essential questions:

- Who are the rightful owners of the patent rights?
- Where are the patent rights in force and for how long?
- What do the patent rights cover?

As a starting point, the due diligence analysis uses the material provided by the patent owner, as well as all other information about the patent family which may be obtained from publicly available sources.

Data room

If there is a substantial amount of material, or if it is desired to gain extended control of the access to the material, it may be advantageous to create a data room. The data room may either be a physical room or a virtual data room created with commercially available software.

Ownership

The name of the owner is shown on the front page of every single patent or patent application, and moreover the names of the inventors are indicated. However, an important initial prerequisite for a due diligence is that no patent authorities check whether the correct inventors are indicated, and not all patent authorities check that the inventors have actually assigned their rights to the owner shown or – which is just as important – whether the inventors have the right to assign to the owner shown.

The due diligence analysis should therefore contain a review of the ownership and among other things investigate whether the correct inventors are mentioned.

Where are the rights in force and for how long?

Another element of the due diligence analysis may be to find out in which countries the various rights are in force and for how long they will be in force.

Generally, patents have a duration of 20 years from the filing date; however, patent rights from the USA filed before 8 June 1995 may have a duration of 17 years from the date of grant. Nevertheless the effective duration may be extended for the entire patent or parts thereof if it covers products requiring a marketing authorization in order to enter into the market such as the case is with medicaments. The extension of the duration is governed by national law, and at the time of writing there is no international harmonization except for common rules for EU and EEA.

Furthermore, patents in the USA and Korea may be extended by the time the examination of the application has been delayed because of official delays, which is normally called patent term adjustment, and may be from a few days up to several years of extension beyond the 20 years.

What do the patents cover?

Ultimately the value of a patent family is a combination of the geographical protection as defined by the number and the relevance of the countries in which the patent protection is in force, and the remaining duration of the patent family, and not least the scope of protection as defined in the patent claims.

Determination of expected valid scope of protection

Many patent applications are granted with a more limited scope of protection than at their filing. The patent claims may have been drafted a bit too optimistically at the outset, or formalistic requirements may be the reason for amending the patent claims before grant.

In connection with a due diligence analysis of pending patent applications, it is essential to include an analysis of the expected scope of protection of an issued patent. As regards granted patents, the same analysis is carried out with the purpose of determining whether the granted scope of protection can be maintained if the patent is challenged in an invalidity case.

When the expected scope of protection has been established, the next step during this phase is to assess whether this scope of protection covers relevant commercial activities for the buyer, and whether the scope of protection can also be maintained when interpreting the patent claims in a possible later infringement case.

Trade secrets and knowhow

In connection with a due diligence, it should be considered whether knowledge relating to trade secrets and other knowhow should be transferred. If this is the case, the analysis should include an assessment of the ownership of the knowledge in question, and an assessment as to whether the relevant steps have been taken in order to secure the secrecy of the trade secrets, *e.g.* password protection, locked rooms and other measures relating to visitors and copying, or whether they have been published or in other ways dispersed to a larger group.

Checklist

Every due diligence process should be carried out as systematically as possible, and this is encouraged by using checklists during the various phases, such as *e.g.* the below checklist covering documents which must be ready for investigation:

- ✓ Portfolio list, divided into families of both owned and licensed rights
- ✓ Applications and granted rights
- ✓ Priority documents
- ✓ File history, including responses and amended patent claims
- ✓ License agreements covering both licensing in and licensing out
- ✓ Relevant publications
- ✓ Non-disclosure agreements and agreements relating to transfer of material
- ✓ Relevant invention disclosure documents
- ✓ Relevant laboratory books
- ✓ Relevant employment agreements and consultancy agreements
- ✓ Assignment deeds and security agreements
- ✓ Correspondence relating to enforcement of rights



Enforcement

Patents provide their owner with the right to stop a third party from carrying out the invention, *i.e.* infringe the patent. If a third party infringes the patent, legal action can be brought before a court of law to stop the infringement and seek damages. While patent applications are examined and granted or refused by patent offices, any action to stop infringement is brought before a court of law.

Legal actions at court require the involvement of a lawyer. Often in patent cases, the lawyer collaborates with a patent attorney as the lawyers are not necessarily technically savvy.

When a patent proprietor starts legal action against an alleged infringer, the alleged infringer normally countersues for invalidity. Therefore, enforcing a patent almost always puts the patent's life at risk.

In many countries it is possible to get an injunction. This means that the court issues an order to a third party to stop the infringing actions or the infringing products immediately. An injunction is a very powerful tool for patent proprietors. Often it can be granted very quickly, in some countries even without the participation of the alleged infringer. In such cases the injunction is preliminary and must be confirmed during trial. The patent proprietor must then place a bond in case the court decides that the injunction was wrongfully granted, for example if the patent was not valid.

In many countries, patent litigation takes place before specialized courts that have some sort of technical expertise and are experienced in handling patent matters. Patent cases can take several years to conclude although some countries can expedite the cases and decide them within about one year. In all cases it is possible to appeal an adverse decision to an appellate court, which will add even more time.

Despite the existence of a European patent system for many years, enforcement of patents is still a national exercise, as patents are national rights. This also means that a decision from one court, in *e.g.* Germany has no direct effect on the situation in other countries, even if the patents, the parties, and the accused product are the same. Thus, in order to stop an infringer in Europe, in principle a case needs to be brought in each and every European country where infringement takes place. As each court is independent and has its own way of reasoning, it happens that the same case has a different outcome in different European countries. Compare this to the USA, where an infringer can be stopped in all 50 states by filing one action at one court.

The European situation is going to change within the next couple of years with the Unified Patent Court. 24 of the 28 EU countries have established a supernational court that will hear patent cases with effect for all the 24 countries. In this way, European patent litigation will be streamlined and harmonised.

Glossary

Claim

The patent claims define the protection conferred by a patent.

Due diligence

Investigations made in order to assess risks and values in a business transaction. A due diligence on patents assesses the ownership, the coverage, weaknesses and strengths of a patent portfolio and the possibilities it may give to a future commercial strategy.

Enablement

A patent application must enable a skilled person to carry out the invention based on the description thereof in the patent application.

Enforcement

Prohibiting others from unauthorised exploitation of one's patented invention. Enforcement is accomplished through legal action.

Filing date

Date of filing the patent application. The patent term of 20 years is calculated from this date.

"First to file" principle

A patent right is normally granted to the inventor who first filed a patent application for the invention.

Freedom to operate (FTO)

An entity has freedom to operate (FTO) a given method or product if no third party has IP rights covering the method or the product or parts thereof.

Grace period

Period in which an inventor's public disclosure of an invention does not destroy the novelty of the invention – only available in selected countries, *e.g.* United States, Canada, and Japan.

IP/IPR

Abbreviation of intellectual property/intellectual property rights. Intellectual property includes patents, designs, utility models, trademarks, brands, copyrights and trade secrets.

Industrial applicability

Criterion for patentability - most inventions are capable of being exploited in a field of industry.

Infringement

Unauthorised exploitation of an invention by carrying out actions which fall within the claims of a patent.

International preliminary report on patentability (IPRP)

Report on patentability of a PCT application prepared by the international patent authorities as conclusion of the international phase.

International Search Report

Report on the result of the novelty search prepared by the international patent authorities. The international search report is accompanied by a written opinion on the patentability of the PCT application.

Inventive step

Criterion for patentability - an invention is associated with an inventive step if it is not obvious to a skilled person based on the prior art. Simple and predictable routine developments are not associated with an inventive step.

License

A patent proprietor may grant a third party a license to use a patented invention. The license may be exclusive (*i.e.* the only license) or non-exclusive. The license may grant the third party rights to use the entire invention, or it may be restricted to some fields only. The license may also be subject to geographical restriction.

National patent application

Application for a patent in a single country. A PCT application must enter national/regional phase as *e.g.* a national patent application after completion of the international phase.

Novelty

Criterion for patentability - an invention is novel if the combination of technical features defining the invention has not been publicly disclosed before the filing of a patent application for the invention.

Novelty search

Search aimed to identify relevant prior art. A PCT application is subjected to a nov-

elty search published as the International Search Report.

Paris convention

An international convention from 1883 defining the basic principles of patents and equal treatment of applicants of different nationality.

Patent application

Request for being granted a patent for an invention - a patent application after its publication can create a provisional protection of the invention.

Patent term

The duration of a patent – the patent term – is with a few exceptions 20 years from the filing date provided all required actions are taken and all required fees are paid.

PCT

Patent Cooperation Treaty – international treaty governing a unified system for filing and preliminary examination of patent applications.

PCT application

International patent application filed under the provisions of the PCT. Typically, the PCT application is an updated patent application claiming priority of a priority application.

Prior art

Anything published or otherwise made available to the public before the priority date. To be patentable, an invention must be novel over the prior art cited by the patent authorities against the claimed invention.

Priority application

First patent application describing the invention – an updated patent application can be filed within one year of filing the priority application.

Priority date

Date of filing the priority application.

Priority year

The year following the filing of the first priority application.

Preliminary examination

Assessment of the novelty, inventive step and industrial applicability of an invention described in a PCT application.

Publication

A patent application is made publicly available 18 months after the priority date.

Regional patent application

Application for a patent in a group of countries having a common patent granting process. Examples of regional patent applications include European patent applications, Eurasian patent applications (EAPO), and African patent applications (ARIPO, OAPI have overlapping countries). A PCT application must enter national/regional phase as *e.g.* a regional patent application after completion of the international phase.

Scope of protection

The subject matter covered by a patent. The scope of protection is defined by the claims.

Second generation patent

A patent application directed to an improvement of an invention described in an earlier patent application from the same

applicant. Often it is filed before the earlier patent application is published.

SPC

Supplementary protection certificate. Extends the term of patents covering medicinal products subject to a marketing authorization in an EU country. The extended protection is restricted to the active compound covered by the marketing authorization.

TRIPS

Agreement on Trade-Related Aspects of Intellectual Property Rights. The TRIPS agreement requires WTO members to provide protection of copyright rights, geographical indications, industrial designs, integrated circuit layout-designs, patents, new plant varieties, trademarks, and confidential information (know-how).

Unified Patent Court, Unitary Patent

An international unitary patent system including the majority of EU member states allowing for enforcement of a patent in the whole territory of these member states. Unitary Patents will be granted by the EPO. The system is an alternative to national registration (validation) of European patents.

Updated patent application

Patent application filed before the end of the priority year - updates one or more priority patent applications filed during the priority year. Frequently the updated patent application is a PCT application.

Validation

The process of registering a European patent before the national patent offices after the patent has been granted.

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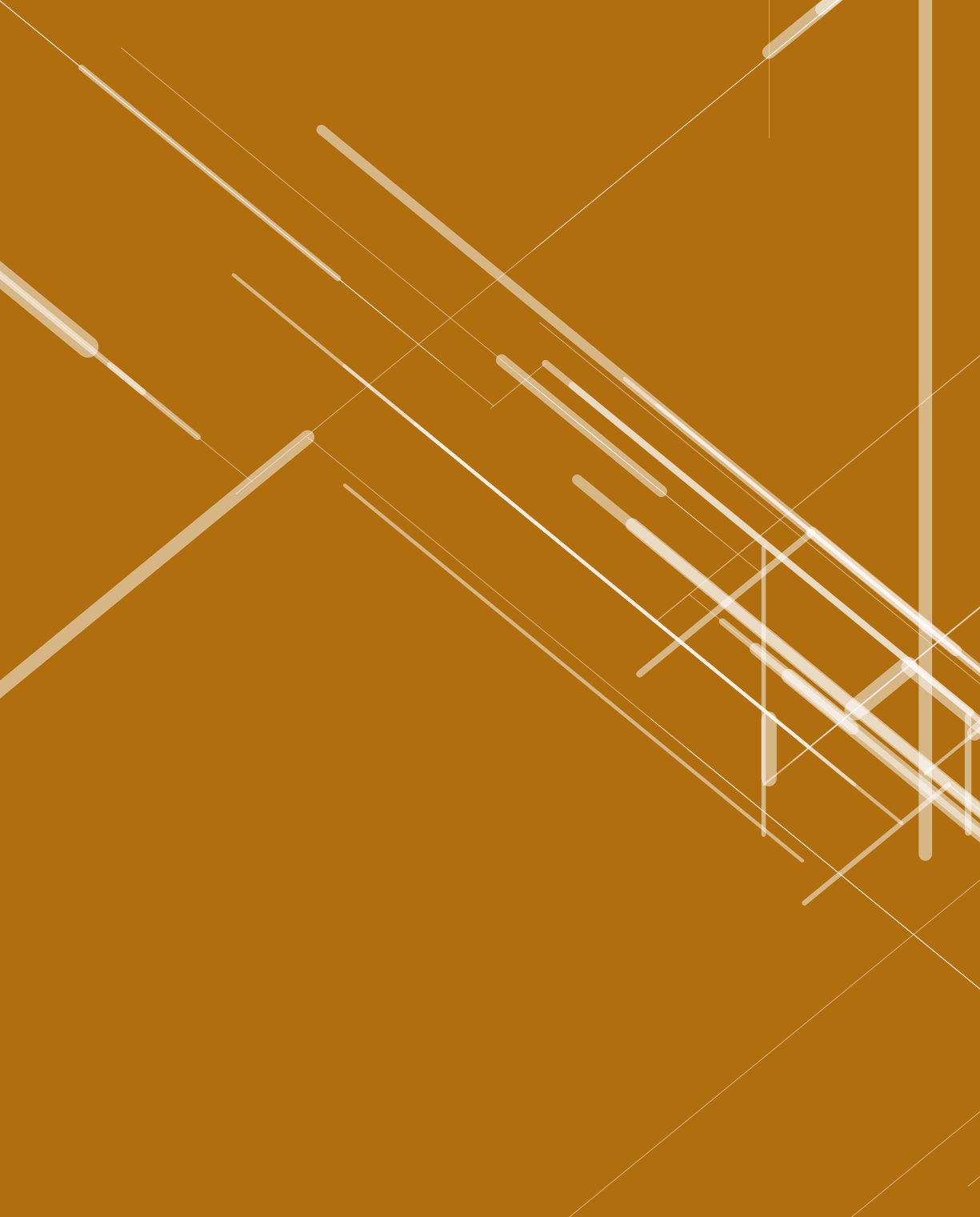
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