Patents and other Intellectual Property Rights

by

Palle Høy Jakobsen
March 2022

ISBN 978-87-94331-29-6

A much more detailed description of patents is provided in the book, *Jakobsen PH. Commercialization of Biotechnology Research. Akademisk forlag 2019, ISBN: 9788750055198*.

Introduction

In order to exploit new innovation commercially, innovators will try to get exclusivity for the exploitation of their innovation by securing intellectual property rights covering the innovation.

There are several types of intellectual property rights: patents, industrial design rights, utility models, trademarks, copyrights and trade secrets.

The mechanisms for obtaining intellectual property are very different as outlined in the table below.

Legal right	Protection of:	Generated by:
Patents	New inventions	Application and examination
Trade secrets	Confidential valuable information	Reasonable efforts to keep secret
Trade marks	Distinctive identification of products or services	Use and/or registration
Registered designs	External appearance	Registration
Copyright	Original creative or artistic forms	Exist automatically

Table. Intellectual property rights.

The preferred way of seeking protection of innovative biopharmaceutical research is to file a patent application. New research discoveries are often called inventions (a conception of an idea plus reduction to practice) in patent documents. An invention can generally be described as a *new, man-made creation*.

A patent right is a national right to stop others from making, offering, putting the product or process on the market, using the product or process or, using/importing a product obtained by a process which is patented. This means that others are prohibited from using the invention for commercial uses or manufacturing the invention for sale. The protection has a duration of 20 years from filing of the patent application. The applicant thus has the right to stop others from exploiting the

patented invention while the patent is active and valid within countries in which the patent has been granted.

In practice, a granted patent is often a prerequisite for commercialisation of an invention, but the grant of a patent does not provide the patent holder(s) with an automatic right to exploit their invention themselves. There may be legislation or other patent rights that prohibit the patent owner from commercialising the invention.

From the patent-holder perspective, the purpose of patenting is to protect his or her own invention from unpermitted commercial use by other parties. From a social perspective, the purpose of granting patent rights is to reward the inventor and to motivate technological progress and knowledge within society.

The main criteria for patentability are:

Novelty: the invention (as defined by the Claims) must be new and unknown compared to everything that has been made available to the public before the priority date of the patent application (that is, the *prior art*).

Inventive step: the invention (as defined by the Claims) must not be obvious to a person skilled in the relevant area of technology as of the priority date of the patent application.

Industrial applicability: the invention must have a commercial use. It is not sufficient to claim recognition of a mechanism of action without stating any indications of use.

There are additional criteria for patentability:

Enablement: the patent application must clearly describe how the invention can be put into practice by a person skilled in the relevant area of technology.

Support: the breadth of the Claims must be justified by the description of the invention given in the patent application.

Patents are very important for maintaining and enforcing exclusivity of marketed pharmaceutical products. The expiry of patents often has a substantial impact on the sales of small molecule pharmaceutical products, which may see sales decrease more than 90%. New cheaper copy products (generic products) are offered for sales immediately upon expiry of patent protection for tablet pharmaceutical products (small molecules). The generic products erode the sales of the original product, because they are offered at a lower price than the original product.

Patent inventorship

An invention will often be defined as a conception plus reduction to practice, and the inventor must make contributions to the conception and the reduction to practice.

In order to be an inventor, a person has to contribute to the specific subject matter that is being claimed as a new invention. It is not sufficient only to have provided general expertise or advice in a particular field, and it is not sufficient to conduct reduction to practice alone (even if a lot of work is required).

Structure of a patent application document

The main components of a patent application document are:

- **The claims**, which defines the scope of protection.
- **The description**, which is often divided into a general part and a detailed part (often including figures and examples) and is used to interpret the claims.
- **An abstract**, which is a summary.

In addition, there are formal requirements for a *title, applicant, inventors* and a summary.

A patent claim is a specification of the technical area from which the applicant or owner may prohibit others from exploiting commercially. It is the patent claims upon which courts build their assessment of infringement or non-infringement.

Filing of patent applications

How to obtain a patent?

- Applications can be filed as:
    - national patent application
    - international patent application
        - PCT, EPO

The process for filing a patent application typically includes the following activities:

- Broad assessment of the economic significance of the invention. This should answer the question: Is protection of industrial property rights necessary and financially realistic seen in the light of the total business and competition situation?
- The economic value of the protection is compared to the expected costs of establishing the protection.
- Clearing up the ownership situation of the patent rights and the list of inventors.
- Novelty search.
- Patentability and freedom to use analysis on the basis of the novelty search.
- Drafting of an English-language priority application and filing of this application, e.g. at the national patent office or at the European Patent Office. The application needs to meet certain requirements:
    - formal (timelines, form and content)
    - scientific

- Official novelty search, e.g. a “standard search” by the European Patent Office.
- Towards the end of the priority year, the initial novelty search should be updated in order to obtain the latest references, and the final, updated version of the application should be drafted.
- Filing of an international patent application (PCT application). This can designate almost all of the economically important countries of the world. A few potentially important countries have not ratified the Paris Convention (which allows priority to be claimed) or the PCT treaty. These countries, which require direct filing of an application before any publication of the invention.
- The patent application is normally published 18 months after submission.
- The PCT application is subjected to an “international preliminary examination”: this preliminary examination must be requested no later than 19 months from the priority date. One of the major benefits of this preliminary examination is that national/regional applications do not have to be filed in the designated countries until 30 months from the priority date.
- The international preliminary examination is carried out by an agency such as the European Patent Office and corresponds to the examination that a “real” European patent application is subjected to, namely: examination as to whether the application fulfils all of the patentability requirements and generally also formal requirements. In most cases the preliminary examination authority (e.g. the European Patent Office) issues one or two “written opinions” containing the patent authority’s assessment of the patentability of the claims. The result of the international preliminary examination is not binding on the various patent authorities, but when a positive preliminary examination report is obtained from the European Patent Office it is normally possible to obtain a European patent very quickly after entering the regional phase.
- The PCT application is filed nationally/regionally at the designated patent offices where this is desired. Note that the applicant is not bound by the original designation of countries in the PCT application.
- The examination phase starts in the individual patent offices. The patent authority’s examination of the case should follow the internationally recognised principles: in order for a reference to derive an application of novelty, this reference alone must completely anticipate the subject matter of a claim. If such a reference is found, the patent claims must be limited.
- The applications will normally be approved by the various patent authorities after an examination process of varying length.
- In many countries, when the patent application has been allowed or when the patent has been granted, third parties have the possibility to file opposition claims. The opposition procedure often takes several years and can involve both examination by a first instance (opposition board) and then by an appeal board.
- The patent right is only finally established when the patent has been granted. It is normally not before this point in time that courts of law will consider stopping any infringing activity. However, for most countries damages can be obtained, in the event of a successful patent infringement suit, back to the time at which the patent application became publicly available in the country in question.

The patent application is submitted to a country’s patent authority (for example, *the Danish Patent and Trademark office*), who examines and decides whether to grant a patent or refuse the application.

The patent system is governed by the priority principle, by which filing of a patent application provides the applicant with a 12-month priority within most countries to the described invention. Within this time period, the applicant can file a final patent application nationally or internationally and claim priority from the first filing. This priority principle is governed by the Convention for the International Protection of Industrial Property (Paris Convention) signed by most countries.

Applicants often file a priority application in the United States at the same time as a national such as Danish priority filing, or just after it, to ensure that the resulting U.S. patent will be cited as a prior art reference from as early a date as possible in the U.S. system.

There are a number of patent formalities to be fulfilled when filing the patent application:

- payment of a fee
- specification of applicant
- specification of inventor(s)
- draft title, description, claims and a summary
- possibly including assignment documents, sequence list, deposition etc.
- paying attention to payment of annual fees etc.

Normally, a patent is issued at a national level 2-5 years after filing of the application (the patent is only issued if it is requested by the applicant and the required fees are paid), and patent protection ceases because of patent expiry (20 years from filing) or if the owner does not pay the annual maintenance fees or because of active abandonment of the patent.

Laws relating to ownership of new discoveries

Ownership, which gives the right to exploit new discoveries, is regulated by law. In general, ownership belongs to the originator of an invention but he or she may have to assign the ownership, by law or by rules specified in an employee contract, in return for some type of compensation.

In Denmark *Lov om Arbejdstageres Opfindelser* regulates ownership rules in private companies. The law specifies that a new invention within the business area of the employer or within a specific work task for the employee belongs to the employer. Inventions outside employer business areas and specified work tasks would generally belong to the employee. New inventions made up to six months after the expiry of an employer contract would also belong to the employer. The previous employee has an obligation to inform the previous employer about the invention and the previous employer has then four months to claim the invention assigned to the employer.

In Denmark *Lov om Opfindelser ved offentlige Forskningsinstitutioner* regulates ownership rules in public research institutions. The law specifies that a new invention within the responsibility area of the institution belongs to the institution if the institution requests ownership. Inventions outside responsibility areas would generally belong to the employee. The employee has an obligation to inform the institution about a new invention and the institutions then have two months to decide and inform the employee if the institution wants a new invention assigned. If the invention is assigned to the institution, the employee will be entitled to a reasonable payment from the institution. The law does not apply for students.

Ownership of Intellectual Property Rights in research collaborations

Discoveries may be made as a part of research collaboration between two or more research institutions and may lead to inventions that are owned jointly by the parties.

Joint ownership may give rise to more complex situations, as the rules will vary from country to country in relation to:

- what rights the joint owners have to work under the jointly owned inventions;
- whether individual patent owners may be granting other parties rights to such inventions.

It is often advisable that the parties agree in advance how ownership of inventions arising out of a joint research project will be divided. It should be considered whether ownership should be divided in other ways than simply according to inventorship.

There are four ways to divide patent ownership in such collaborations:
- *jointly owned patents*
- *ownership depending on claim-type (field of interest)*
- *ownership depending on inventors*
- *one party owns all patents*

Each of these ownership models represents a set of concerns and of potential advantages and they need to be considered carefully, on a case-by-case basis. Thus, if you do not have insight in this area you should always contact a specialist (a patent attorney for example) to get advice in relation to the specific research project and collaboration before you decide which type of ownership you will be able to accept.

Publications

Parties in research collaborations normally have an interest in publishing the results of the research, in order to obtain recognition within the scientific community and to advance the state of scientific knowledge.

Each party normally also recognizes the mutual interest in obtaining valid patent protection and in protecting proprietary business interests.

Research parties to a project should therefore draft a patent and publication policy, which may contain the following elements.

If the proposed publication contains:	**Then this action might be requested:**
Patentable information	Delay for 90 days or another number of specified days to allow time for drafting a patent application.
Trade secret and other confidential information	Remove from publication.

References

Literature:

Prabakaran S. The quest for a magic bullet. Science 349, 389, 2015.

Webber PM. Protecting your inventions: the patent system. Nature Reviews of Drug Discovery. vol 2, page 823-830, 2003.

Free patent databases & sources of patent documents

www.dkpto.dk (link to Danish *Patent og Varemærkestyrelsen*)

http://dk.espacenet.com/search97cgi/s97_cgi.exe?Action=FormGen&Template=dk/DK/home.hts (link to patent searches under Danish Patent og varemærkestyrelsen)

www.epo.org (link to *European Patent Office*)

www.uspto.gov (link to US Patent & Trademark Office)

Commercial patent databases
www.prv.se

http://info.thomsoninnovation.com

Derwent Innovation Index (ThomsonScientific)

www.isiknowledge.com

Other web-based patent & law sources

http://www.wipo.int/portal/index.html.en (link to World Intellectual Property Organization)
http://www.wipo.int/ipcpub/#refresh=page&notion=sch eme&version=20120101, WIPO (IPC classifications)

www.ipo.org (link to Intellectual property owners organization)

Danish law
https://www.retsinformation.dk/