

Patents – the exploitations of inventions in the life sciences

According to statistics from the European Patent Office, a total of 1065 biotechnological patents were filed in 2007 by inventors based in Germany. This puts Germany second behind the USA. In the coming years, experts expect that a much larger number of biotech patents will be filed. For life sciences inventors, the registration of patents quite often represents a real challenge. People entering the world of patents and licences, are faced with a veritable jungle of clauses.



In the coming years, the number of biotechnological patent registrations will further increase in Germany
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A patent is a set of exclusive rights granted by a state to an inventor for an invention; it is the legal basis for the economic utilisation of an invention. In the same way as all other inventions, biotechnological inventions need to fulfil three special claims that define whether a new invention is patentable: they must be new (i.e. must not be state-of-the-art), involve an inventive step (i.e. must be the result of an inventive activity and not natural phenomena), be susceptible to industrial application, and be repeatable and comprehensible.

The same procedure applies to so-called "biological material" containing genetic information that is reproducible in a biological system. This has not always been the case. For a long time, biological methods and products were not included in the field of technology due to the fact that they were not sufficiently repeatable, which meant that they were not eligible to be given patents. Biotechnology finally heralded a new era - nowadays, biotechnological methods and their technical results can be reproduced. Today it is possible to patent not only new products, but also new processes that are used to produce already known products.

From ideas to patents – no simple process

Inventors, whether they are scientists at universities, research institutions or business people, not only rely on creativity and a promising idea. They also have to check the patent situation of their invention and overcome many obstacles. This process starts with a thorough patent search which guarantees that the invention is a novelty, so that, once it is on the market, it does not infringe the

rights of others. Basically, the search for potential property rights is the same as the assessment of a person's own invention and hence the ability to practice or use the invention. This phase also includes a thorough investigation of the market potential and the development and investment expenditures of an invention. Inventors can make use of professional sources of information and support by commissioning patent investigations, e.g., with a patent research institute or to a patent attorney. In addition, Germany has more than 20 patent information centres that provide comprehensive information on all issues relating to intellectual property rights. These centres are often run by universities or chambers of commerce and industry.

Inventors who want to do their own research have at their disposal a broad range of electronic databases, including the "DEPATISnet" database run by the German Patent and Trademark Office (DPMA), which currently offers patent searches of around 30 million patent documents from all over the world. Another important information service offered by the DPMA is the DPMA-Online-Patent Gazette that provides information on the public registers for the individual types of intellectual property rights, detailing current laws and procedures. On the European level, the "Espacenet" database is available free of charge through the European Patent Office. The European Online Patent Register provides information on European patents.

Biopatents: EU directive controls protection

Patents for biotechnological inventions is a subject of intense and heated debate, more so than any other topic that is located at the borders of science, ethics and law. An EU directive of 1998 (directive 98/44 EC for the legal protection of biotechnological inventions) clearly defined what could be patented in the fields of biotechnology and medicine and what could not. Amongst other things, the directive made it clear that human gene sequences can only constitute patentable inventions under certain circumstances. Under the directive, human gene sequences can only be patented for an application specifically described in the patent. According to this regulation, processes for modifying the germ line genetic identity of human beings are not patentable, nor is the use of human embryos for industrial or commercial purposes, and gene sequences with no known function. In general these are inventions whose commercial exploitation would be contrary to public order or morality.

What is allowed? What is not allowed?

In general, naturally occurring biological material that is produced by means of a technical process or which is isolated from its natural environment by means of a technical process may be the subject of an invention even if it previously existed in nature, e.g., DNA, RNA, vectors, proteins and antibodies. It is also possible to patent plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety, e.g., viruses, microorganisms, transgenic plants and animals, or an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

However, the human body in all phases of its development, plant varieties and animal breeds, or in general biological processes for the production of plants and animals, i.e. methods that consist entirely of natural phenomena such as crossing or selection, are considered unpatentable. In addition, the EU prohibits the patenting of processes for the cloning of human beings, processes for modifying the germ line genetic identity of human beings, or processes for modifying the genetic identity or the use of human embryos for industrial and commercial purposes.

However, the European directive that came into effect in 1998 also specifies the regulations that have to be taken into account when applying for a patent involving biological material: for example, in order to assure reworkability of an invention involving biological material, a sample of the biological material to be patented needs to be deposited in a recognised patent depository (IDA) such as the German Collection of Microorganisms and Cell Cultures (DSMZ) no later than one day after the filing of a patent. The directive also outlines how scientists must render the biological material available to third parties. The large number of laws and directives makes the support of patent attorneys indispensable.

The patent attorney's office Reitstötter, Kinzebach & Partner (GbR) based in Munich, Germany, is a leading patent attorney's office in the field of life sciences. The attorneys look after several hundreds of mandates of patent-protected nature every year, said patent attorney Dr. Thomas Wolter. Wolter, who studied chemistry and biology, explains that he and his colleagues "need to always be up to date on state-of-the-art research and jurisdiction". This means that the attorneys have to constantly exchange information and ideas with the scientists who work for their clients, they have to participate in conferences and meetings and to study expert literature. Like many of his colleagues who have worked in the chemical industry, Dr. Thomas Wolter has also worked in research himself.

Patentanmeldungen zu Arzneimitteln mit biotechnologischem Bezug	
1995	2007
USA 352 (54,6 %)	468 (42,1 %)
Deutschland 65 (10,1 %)	102 (9,2 %)
Japan 28 (4,3 %)	173 (15,5 %)
Großbritannien 41 (6,4 %)	42 (3,8 %)
Frankreich 41 (6,4 %)	52 (4,7 %)
Sonstige 118 (18,3 %)	276 (24,8 %)
Insgesamt 645 (100 %)	1,113 (100 %)

The number of patent applications for drugs with biotechnological reference has been increasing worldwide since 1995
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Different objectives

Patents have a different relevance and function depending on their origin, i.e. whether they are filed by companies or by scientific institutions. For big life science companies, patents mainly represent an essential protection against imitation. In addition, they also guarantee that the often very high expenditures for research and development can be covered by the generation of profits. Due to the lengthy patent application process, there are usually only a few years from the time a certain product is marketed to the expiry date of the patent. "Big companies have in-house research and patent departments and usually have clear ideas on how to deal with the inventions

of their researchers,” said Dr. Thomas Wolter who is very familiar with patent applications in the field of therapeutics, diagnostics and biotechnology.

For scientific institutes as well as small- and medium-sized biotechnology companies who have a far smaller budget, patents and licences are often taken as a reflection of their research quality and performance. Patents help such institutions increase their attractiveness to licensees, cooperation partners and investors, as well as strengthening and promoting the scientific and commercial cooperation and the market-oriented implementation of technical innovations.

According to Dr. Wolter, another important difference is that small life science companies have usually been established by one to three pure scientists on the basis of a specific research result that appeared to be very interesting. Such small groups of scientists working together often underestimate the capital requirements and the length of time needed for a marketable product to be produced or a patent to be obtained and the dangers of development being restricted or completely halted because the rights are held by third parties.

Patent applications: white biotechnology as the leading force

In general, patent applications are a barometer of public opinion and a basis for the assessment of a country's innovative power. According to a recent patent analysis carried out by the Boston Consulting Group (BCG), Germany comes out top in the field of white biotechnology on the global level, in particular in the industrial application of white biotechnology. Germany is third behind the USA and Japan in terms of patent applications. In the field of ingredients used by the skin care and food industries Germany has a top ranking. According to BCG this is mainly due to the traditional strengths of the Germans in methods and fermentation as well as due to the existence of a number of big companies with more than 1000 employees that are specifically focused on this particular sector of research. According to another statistical evaluation of the German agrobiotechnology sector carried out by BCG, Germany holds a relatively good position in basic research and methods in this sector (e.g., DNA sequences).

However, Germany has a lower profile in application-oriented topics such as gene expression or herbicide resistance. The USA has a strong start in green biotechnology. While Germany only owns around eight percent of the worldwide patents in this area, the USA accounts for around 45 per cent of all patents issued in this field. The BCG study has a less positive outlook for medical biotechnology: Although Germany can look back on a long tradition in drug research, over the last 20 years it has had a great number of drawbacks with regard to competition from the USA. Amongst other things, this is due to the fact that many German pharmaceutical companies have relocated abroad or have moved part of their research to the USA. BCG finds that the German biotech companies lack a sufficiently large number of projects that are close to market introduction, something that is also reflected by the small number of patent applications.

Literature:

1. European Patent Office: https://www.biooekonomie-bw.de/www.epo.org/about-us/office/statistics_de.html
2. Boston Consulting Group, „Innovationsstandort Deutschland - quo vadis“, 2007

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