

# Patents Bring Protection to Biotechnology Inventions

■ **Many inventions or at least parts of inventions in the fields of biochemistry, biotechnology and medicine can be patented. The patenting criteria are becoming clearer and more logical each year and case.**

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The patent system originally protected machines, equipment, and industrial processes, and later on chemical inventions. Inventions in the field of biotechnology differ from other technology areas since they use biological material, which contains genetic information and is capable of reproducing itself or being reproduced in a biological system.

During the last 30 years, however, the patent system has slowly been adapted to also include biotechnology inventions. Special laws and regulations have been drafted, a lot of case law has emerged and there is background in biotechnology for patent examiners and attorneys handling these inventions.

A patentable invention is novel, non-obvious for a skilled person, and industrially applicable. In the field of biotechnology, however, more restrictions in patentability exist than in other technology areas. Some scientists may, due to this, harbour the prejudice that their biotechnology invention cannot be patented and, therefore, publish it. And only later learn that their most commercially valuable invention could have been protected by a patent.

## **Living matter can be patentable**

Biological material, such as enzymes, microorganisms and genes, may be patentable despite occurring in nature, if it is isolated from its natural environment

or produced by technical means. In that case, the material is considered new, since it was not previously technically available to the public and in that sense could earlier not be used by the public.

Products made or modified by microorganisms as well as microbiological processes in which microorganisms are used to make or modify products or in which new microorganisms are developed for specific uses, are also patentable. Biological material should likewise fulfil the other patentability criteria, it must be non-obvious and industrially useful.

In patent practice, the term microorganism is broader and generally includes unicellular organisms with dimensions beneath the limits of vision, which can be propagated and manipulated in a laboratory. These include bacteria, plasmids, viruses and unicellular fungi, yeasts, algae, protozoa as well as human, animal and plant cells.

Genetically modified plants and plant cells as well as processes changing the genome of a plant by technical means are also patentable. In Europe, the law excludes plant and animal varieties and essentially biological processes, such as traditional cross-breeding methods for the production of plants or animals, from patentability.

This is partially due to historical reasons, since plant varieties can be protected under a special legal protection (the UPOV protection). A number of applications also concern plants obtained by new breeding techniques, however, and the patentability of this subject matter may still cause discussion.

## **Restrictions in the medical area**

Although certain restrictions exist in the medical area, new molecules or useful substances, the use of a known or new substance for treatment of a disease, the use of a known substance for treatment of a new target disease, a method for isolation or production of a substance, a method for synthesis of a molecule, a drug

comprising a new substance and a new drug comprising a known substance or substances, for example, are patentable.

Surgical or therapeutic treatment and diagnostic methods practiced on humans or animals are not patentable in Europe. The reasoning is that medical doctors should have sufficient freedom to treat humans or animals needing the treatment in question.

A problem arises when the same method is useful as both a curative and non-curative, *e.g.* cosmetic, treatment.

A decision by the European Patent Office's (EPO) Enlarged Board of Appeal held that any physical intervention on the human or animal body is a method for surgery and therefore excluded from patentability.

A later Enlarged Board of Appeal decision, however, took a milder stand, defining that the term treatment by surgery must cover interventions requiring professional medical skills to be carried out and involving health risks. Techniques, such as hair removal by optical radiation or micro abrasion of the skin, although invasive, should thus be patentable.

## **Differing views in USA and Europe**

Less special legislation exists in the U.S.A. for biotechnology and medicine than in Europe. For example, methods for disease treatment are patentable. On the other hand, in the U.S.A., patent practice is formed by case law.

Sometimes grounds different from European arise in court cases as hindrance for patentability. The U.S. Supreme Court recently regarded an invention concerning a correlation between blood test and patient health as not patentable, since patent protection was directed to a natural phenomenon. The Court held that new patents involving correlations between natural phenomena must do more than simply recite the natural correlation and tell the user to apply it.





## Develop a patent strategy

Having decided to protect one's invention the scientist should think about the future patent strategy. He or she should ask the following questions: Am I able to demonstrate that my invention can be put into practice? Do I urgently need patent protection? How am I going to use the patent? How broad a protection is needed?

With a patent one can deny one's competitor use of the invention and thereby gain a better market. One can also sell one's invention, patent or patented invention to someone who then denies his competitor use of the invention. Moreover, one can grant a license, exclusive or non-exclusive, to one's patent to one or more parties to use the invention.

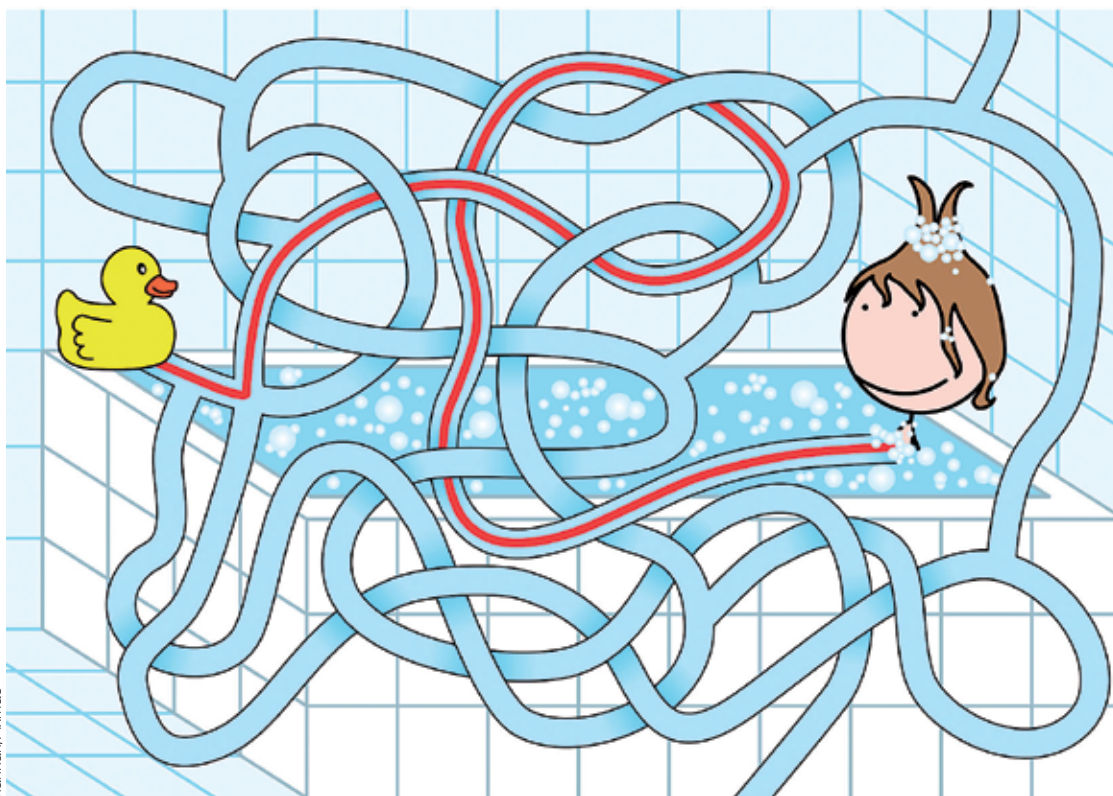
The invention is definitely more interesting to investors if a patent application is at least pending compared to the invention merely been published.

It is worthwhile to thoroughly consider the use of the potential patent, because it effects the drafting of the patent. In some cases a very broad scope may be important to one's business. In that case the disclosure and experimental part given in the application should disclose the invention so that it supports all aspects of the invention.

Typically, one may save money and time by applying a patent directed to applications, which can be demonstrated in the experimental part of the patent application.

### Example of a patent application process

- file the first patent application in Finland or at the European Patent Office
- file a PCT application within one year, which is an international patent application based on the first (priority) application
- file national patent applications based on the PCT application within 30 months from filing of the first application
- patents are granted within about 2 to 8 years from filing of the first application



A new invention—**heureka!** Luckily, many biotechnology inventions or at least parts of them can be patented just like any other invention.

►►► The European Patent Office, on the other hand, did grant the corresponding patents, though with slightly different claims. The patent was not, however, tested in opposition or appeal procedures.

In Europe, processes for cloning human beings, modifying the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes and human at the various stages of its formation and development or the simple discovery of one of its elements are excluded from patent protection.

The patenting of inventions using human embryonic stem cells has caused and still causes much discussion. The EPO's Enlarged Board of Appeal view is that human embryonic stem cells, which cannot be obtained without destroying human embryos, are not patentable. The issuance of a recent judgment by the Court of Justice of the European Union also affects the current EPO practice.

Stem cell related inventions using animal stem cells and inventions using stem cells originating from somatic cells are, however, patentable.

The patent law, all the restrictions and court decisions may seem to be an infinite jungle. Nevertheless, if an invention seems to be valuable for one's business, it is worth consulting a patent attorney specialised in biotechnology, who will know the latest news and cases in the field and usually provide assistance for finding the best possible way of protecting the invention. □

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