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Patents on life?

European law and practice for patenting
biotechnological inventions



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Biotechnology patents: a threat or a promise?

Advances in the life sciences, whether in health, agriculture or the environment, have had an extraordinary impact on life expectancy and the quality of life. Biotechnology has already provided life-saving medicines such as human insulin to treat diabetes, erythropoietin to treat anaemia and monoclonal antibodies to treat cancer, and holds promise for cures for conditions currently regarded as untreatable. In agriculture, biotechnology is used to modify plants to improve their resistance to disease, herbicides or difficult environmental conditions, or to achieve higher yields. And biotechnology has been at the heart of many advances in environmental protection.

In the past decades biotechnology has been one of the fastest-growing fields of technology, and this is reflected in the number of patent applications filed in this area with the European Patent Office (EPO). As the field covers a wide range of areas from micro-organisms to agriculture and medical applications, and involves publicly disputed techniques and products such as genetically modified plants, animal cloning or human embryonic stem cells, the debate about patents is more heated than in other technological areas.

In some cases, there is concern about the potential risks and ethical implications of the technology behind an invention, for example in the debate about human embryonic stem cells. In other cases, the social and economic effects of patents are called into question. Critics claim that since patents confer an exclusive right on the patentee, they can limit public access to goods, such as medicines or food crops, or hinder research by restricting access to essential research tools. However, as economic studies have repeatedly shown, many of these important innovations would probably not have reached the market without patents.

A definition

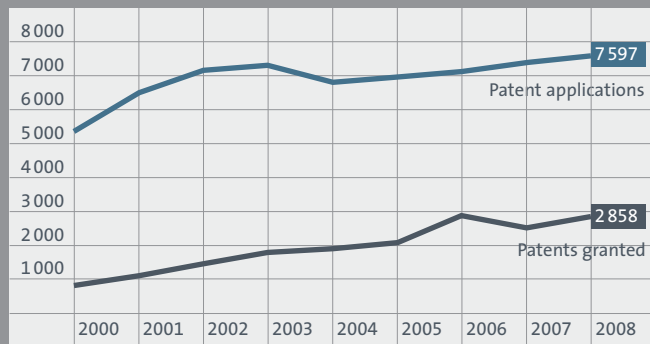
According to the European Patent Convention (EPC), "biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Rule 26(2) EPC).

"Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Rule 26(3) EPC). This covers living organisms and DNA.

A growing field

Over the past few years, biotechnological inventions have consistently ranked among the 10 largest technical fields in terms of the number of patent applications filed with the EPO. Roughly half of these filings come from scientific institutes and universities.

Patent applications filed with the EPO and patents granted by the EPO in the field of biotechnology



What patents do

A patent is a legal title granting its holder the right to prevent others from making, using, selling, offering for sale, or importing an invention without his consent. It only confers these exclusive rights for a limited period (in Europe, 20 years from filing) and for a limited geographic territory, in principle the territory of the state in or for which it is granted. European patents can be granted for up to 38 countries (the contracting states to the EPC) but then have to be validated in each country where the patentee seeks protection.

Patents promote innovation in two ways. Firstly, they provide a strong **incentive to innovate** and, maybe more importantly, **to invest with a view to bringing a product to market**. For example, drug companies would hardly be prepared to fund costly clinical trials without being able to claim exclusive rights. Secondly, the applicant has to fully disclose his invention in the patent application, which is published 18 months after filing. Patents thus provide **access to information** about the latest innovations, which adds enormously to society's knowledge base and advances science and technology by allowing others to "stand on the shoulders of giants". The EPO's patent databases, available to everyone at no charge via the internet, are the largest in the world and contain over 60 million documents. This is an important source of technical information on which new inventions can build.

What patents do not do

The grant of a patent **does not authorise its holder to use or implement an invention**, but merely entitles him to exclude others from using it. Permission to use and, in particular, to commercialise a patented invention may still have to be obtained. The inventor of a new medical compound, for example, cannot simply rely on his patent to market the drug without approval from the European Medicines Agency or the corresponding national authorities. Equally, a patented genetically modified plant has to be approved by the competent authorities before it can undergo field trials. Therefore patents are not a suitable tool for preventing abuse or risks associated with a given technology. Patent law does not replace national, European or international law which may impose restrictions or prohibitions on a certain use of technology.



When is biotechnology patentable?

As the executive organ of the European Patent Organisation, the EPO examines patent applications and either grants or refuses them on the basis of European patent law, as laid down in the European Patent Convention and interpreted in the case law developed by the Boards of Appeal, the EPO's second-instance judiciary.

In principle, to be patentable, biotechnological inventions have to meet the same criteria as those in any other field of technology. Patents can only be granted for inventions that are **new**, **involve an inventive step** and are **susceptible of industrial application**. A specific legal definition of novelty has developed over the years, with "new" meaning "made available to the public". This means, for example, that a gene, which existed in an organism before but was "hidden" from the public in the sense of having no recognised existence, can be patented when it is isolated from this organism or when it is produced by means of a technical process and all other requirements of patentability are fulfilled.

Given the nature of biotechnology and its ethical implications, there are specific rules which apply when considering the patentability of an invention in this field.

What the law says

European Patent Convention

Articles 52 and 53 of the European Patent Convention say what can and cannot be patented.

Biotechnological inventions are basically patentable.

However, no European patent can be granted for the following:

- any invention whose commercial exploitation would be **contrary to *ordre public*** or morality (Art. 53(a) EPC)
- **plant and animal varieties** (Art. 53(b) EPC)
- **essentially biological** processes for the production of plants and animals (Art. 53(b) EPC), e.g. classical breeding, crossing and selection
- **methods for treatment** of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body (Art. 53(c) EPC)

Discoveries (e.g. the discovery of natural substances, such as the sequence or partial sequence of a gene) are not patentable because, without a description of the technical problem they are intended to solve and a technical teaching, they are not regarded as inventions (Art. 52(2)(a) EPC).

EU legislation

In Europe, a debate on biotechnology patents started in the late 1980s with the aim of clarifying the distinction between what is patentable and what is not, and harmonising EU member states' laws in this area. This led to the adoption on 6 July 1998 of EU Directive 98/44/EC on the legal protection of biotechnological inventions. The directive has now been implemented by all EU member states. In 1999, the contracting states to the EPC decided to incorporate the directive as secondary legislation into the Implementing Regulations to the EPC. Together with the EPC articles on substantive patent law, these rules now provide the basis for deciding on the patentability of biotechnology applications at the EPO.

The incorporation of the EU directive into the EPC confirmed the practice of the EPO in biotechnology, whilst putting greater focus on ethical considerations.

For example, the directive affirmed that isolated biological material is patentable even if it has occurred previously in nature (Rule 27(a) EPC). It also confirmed that plants or animals are patentable if the technical feasibility of the invention (e.g. a genetic modification) is not confined to a particular plant or animal variety (Rule 27(b) EPC).

Furthermore, an invention relating to **gene sequences** can be patented as long as the industrial application of the sequence is disclosed in the application and all other patentability criteria are fulfilled (Rule 29(3) EPC).

However, the directive rules out the **patenting of the entire human body** in all its developmental phases (Rule 29(1) EPC). The same applies to processes for **cloning human beings, processes for modifying the germ-line genetic identity of**

human beings and the use of human embryos for industrial or commercial purposes. Also excluded from patentability are **processes for modifying the genetic identity of animals which are likely to cause them suffering** without any substantial medical benefit to man or animal, and animals resulting from such processes. This catalogue of exceptions to patentability is not exhaustive (Rule 28 EPC).

Case law of the EPO Boards of Appeal

In addition to the provisions of the EPC and the EU directive, the case law of the EPO's Technical Boards of Appeal and the decisions of its Enlarged Board of Appeal (EBoA) form a further source of guidance when considering the patentability of biotechnological inventions under the EPC.

A landmark ruling on **stem cell cultures** was issued in November 2008: in the WARF/Thomson case, the EBoA decided that under the EPC it is not possible to grant a patent for an invention which necessarily involves the use and destruction of human embryos. The EBoA stressed, however, that its decision did not concern the general question of human stem cell patentability.

In line with the EU directive, the EBoA ruled in G1/98 that plants are in principle patentable if no specific plant variety is identified in a product claim. In another, still pending case relating to plants, the EBoA was asked to address the precise meaning of "**essentially biological processes** for the production of animals and plants". In particular, the question was raised where the line should be drawn between classical breeding, crossing and selection, and modern breeding methods which make use of advanced technical means such as genetic markers.



Some examples from the field of biotechnology

What is patentable

- genes and nucleic acid molecules (e.g. disease-related genes for diagnosis or antisense, siRNA molecules for therapy)
- proteins (e.g. insulin, erythropoietin for therapy, cellular receptors for drug screening)
- enzymes (e.g. proteases for washing powder, cellulose-degrading enzymes for the production of bio-fuels)
- antibodies (e.g. for cancer treatment, pregnancy tests, or diagnostics)
- viruses and virus sequences (e.g. hepatitis C virus and HIV for blood testing and the development of vaccines and therapies)
- cells (e.g. haematopoietic stem cells for the treatment of leukaemia)
- micro-organisms (e.g. bacteria for bioremediation, yeast for food production)
- plants (e.g. herbicide resistant soybean, 'golden rice' which accumulates pro-vitamin A, drought-resistant plants, algae and genetically modified yeast for capturing CO₂ from the atmosphere)
- animals (e.g. disease models for research such as the genetically modified 'oncomouse', donor animals for xenotransplantation, dairy animals which produce medicaments in milk)

What is not patentable

- sequences without a known function (e.g. expressed sequence tags (ESTs) resulting from automated sequencing)
- genetically modified animals which suffer but are not associated with a substantial medical benefit. An example would be a genetically modified animal which is solely used to test cosmetics.
- plant varieties (already protected under the Convention of the International Union for the Protection of New Varieties of Plants, UPOV) (e.g. Golden Delicious apples)
- animal varieties (e.g. Holstein cattle)
- human embryos
- processes which necessarily involve the use and destruction of human embryos
- human germ cells (sperm, oocytes)
- human-animal chimera

Public access to information on European patents

All European patent applications and patents can be searched on the Internet at www.espacenet.com, the EPO's free patent information service containing more than 60 million patents and published patent applications worldwide representing technical developments from 1836 to today.



European patents: achieving legal certainty through quality

The EPO examines European patent applications originating from countries all over the world in all fields of technology. The EPO employs more than 3 800 examiners in total, some 260 of whom examine applications in the field of biotechnology.

Before a European patent can be granted, each application is subject to a thorough search and rigorous examination by an examining division consisting of three patent examiners specialised in the technology in question. This ensures that the application fulfils all the strict requirements of the EPC and that only true inventions that merit protection are patented.

Moreover, the EPC provides several legal mechanisms to enable the public to monitor the procedure and to allow decisions taken by the EPO to be challenged.

Once a European patent application has been published (18 months after the first filing), the file relating to it is **open to inspection**. This means that any member of the public can view the communications between the EPO and the parties involved in the procedure. Such file inspections can be made online and are free of charge at:

www.epoline.org/portal/public/registerplus

In proceedings before the EPO, following the publication of the patent application, third parties may submit, free of charge, **observations** concerning the patentability of the invention to which the patent application or patent relates. These observations must be taken into account by the examiner and transmitted to the applicant or patentee for comment.

The EPC also provides a means of centrally **opposing** European patents within nine months of grant. This legal procedure enables anyone to contest European patents. Oppositions are filed against about 5 % of the European patents granted each year. About a third of those lead to the patent being maintained as granted, another third being maintained in an amended form, and the remaining third being revoked.

Any party to proceedings adversely affected by an EPO decision in grant and opposition proceedings can challenge this decision by an **appeal** to the EPO's judiciary, the Boards of Appeal.

After a patent is granted by the EPO, any disputes concerning the **validity** and **infringement** of the patent are subject to national law, and are dealt with by national courts.

The EPO grant procedure and the various possibilities for third parties to intervene ensure that European patents are of high quality and provide legal certainty.

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