

The legal protection of biotechnological inventions Directive 98/44/EC

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Objectives of the Directive 98/44/EC

- **Harmonised legal framework for the EC in order to reduce significant differences and uncertainties which had already been detected in Member States' national patent laws and practices regarding the patenting of biotechnological inventions.**
- **Such a framework should encourage innovation, investments and willingness to take risks in the field of biotechnology, whilst respecting ethical principles recognised in the Community.**

History of the Directive 98/44/EC

- **Adopted on 6 July 1998 after almost ten years of discussions, the final version has taken into account the controversial discussions and various opinions of the European Group on Ethics in Science and New Technologies. The EGE gave positive opinions [\[1\]](#) [\[2\]](#) on the Directive and the patentability of such biotechnological inventions.**
 - **On 9 October 2001 in the case C-377/98, the European Court of Justice confirmed the validity of the Directive and its compliance with certain ethical rules.**
- [\[1\]](#) Opinion n° 8 of 25.09.1996 on the “ethical aspects of patenting inventions involving elements of human origin”**
- [\[2\]](#) Opinion n° 16 of 7.05.2002 on the “ethical aspects of patenting inventions involving human stem cells”**

Key provisions of the Directive 98/44/EC

- **Directive requires EU Member States to protect certain biotechnological inventions under national patent law.**
- **Biotechnological inventions concern a product consisting of, or containing, biological material, or a process by means of which biological material is produced, processed or used.**
- **Determines which inventions relating to plants, animals or the human body are patentable and which are not.**
- **Defines the scope of protection conferred by patents, provisions for compulsory cross-licensing and deposit of and access to a biological material.**
- **Does not contain any provisions as to whether certain research activities are permitted or whether certain research results may be implemented or exploited.**

Provisions of the Directive 98/44/EC

General principle (Art 3):

- Inventions which are new, involve an inventive step and are susceptible of industrial application shall be patentable even if they are related to biological material.
- Inventions which concern plants, animals or micro-organisms shall be patentable.

But, are not patentable (Art 4):

- Plant and animal varieties,
- Essentially biological processes for the production of plants and animals
- Inventions which technical feasibility is confined to a particular plant or animal variety.

Provisions of the Directive 98/44/EC

Human body:

- **Art 5(1):** the human body, in its natural environment, is not patentable. The simple discovery of one of its elements cannot constitute a patentable invention.
- **Art 5(2):** an element isolated from the human body, including the sequence or partial sequence of a gene, may constitute a patentable invention. It does not matter much whether the isolated element is identical to that of a natural element.

Exclusions from protection (Art 6):

- **General principle:** inventions whose commercial exploitation would be contrary to *ordre public* or morality
- **Specific exclusions:** processes for cloning human beings, for modifying the germ line identity of human beings...

Provisions of the Directive 98/44/EC

- **Scope of protection (Art 8 to 11)**
Protection conferred by a patent on a biological material, on a process that enables a biological material to be produced, on a product containing or consisting of genetic information. Farmer's privilege is also provided as an exception to the scope of protection.
- **Compulsory cross-licensing (Art 12)**
between plant variety rights and patents on biotechnological inventions.
- **Deposit and access to a biological material (Art 13 and 14)**
Conditions in which the biological material should be available to the public in accordance with the Budapest Treaty of 28 April 1977.

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For further information:

http://europa.eu.int/comm/internal_market/indprop/invent/index_en.htm