

THE PATENTABILITY OF LIVING HUMAN BEINGS

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I. THE PATENTABILITY OF LIVING HUMAN BEINGS IN COMMUNITY LAW

A/ Adaptation of the 6 July 1998 Directive

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**DIRECTIVE 98/44/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL of 6 July 1998
on the legal protection of biotechnological inventions**

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented.

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

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Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. 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, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

9 October 2001

Judgement rendered by the Court of Justice of the European Communities (CJEC) in the application for annulment of Directive 98/44 led by the Netherlands (case C-377/98).

The Commission of the European Communities holds that the Directive conforms to the fundamental right to human dignity and integrity, in that it does not allow elements taken from the human body to be patented « only where necessary for the achievement and exploitation of a particular industrial application ».

Condamnation of France, Belgium and Luxemburg for failure to transpose Directive 98/44

CJEC, 1 July 2004, case C-448/03, Commission of the European Communities versus France

CJEC, 9 September 2004, case C-450/03, Commission of the European Communities versus Luxemburg

CJEC, 1 July 2004, case C-454/03, Commission of the European Communities versus Belgium

Declaration of the Rights of Man and of the Citizen Approved by the National Assembly of France, 26 August 1789

Article XI

The free communication of ideas and opinions is one of the most precious of the rights of man. Every citizen may, accordingly, speak, write, and print with freedom, but shall be responsible for such abuses of this freedom as shall be defined by law.

Intellectual Property Code (1)

Article L611-18 (*inserted by Act No. 2004-800 of 6 August 2004, Article 17a II, Official Journal of 7 August 2004*)

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner.

Intellectual Property Code (2)

The following, in particular, shall be considered unpatentable:

- a) processes for cloning of human beings;
- b) processes for modifying the germ line genetic identity of human beings;
- c) uses of human embryos for industrial or commercial purposes;
- d) total or partial sequences of a gene as such.

Intellectual Property Code (3)

Article L613-2-1*(inserted by Act No. 2004-800 of 6 August 2004, Article 17 a III, Official Journal of 7 August 2004)*

The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description.

The rights created by the delivery of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L. 611-18 and if it discloses any other particular application of this sequence.

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Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.