LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS


Protection of biotechnological inventions has been the subject of some discussion and controversy over the last ten years.

It will be recalled that the first Directive proposal from the European Commission dated 21 October 1988 was rejected on 1 March 1995 by the European Parliament.

As a result of this rejection, the European Commission submitted a new proposal in February 1996, which was adopted by the Economic and Social Committee in July 1996, and was subject to 66 amendments by the Parliament in July 1997 before being finally adopted on 6 July 1998.

The aim of this Directive is to eliminate any differences, in the protection of biotechnological inventions, between laws and practices of the different Member States and thus to harmonise protection of these inventions, in particular to maintain and encourage investment in this field within the Community.

The European Parliament and the Council of the European Union considered that legal protection of biotechnological inventions did not necessitate the creation of a specific law substituting national patent laws within the Member States.

However, they considered that it was necessary to remove any uncertainties, to take position regarding patentability of the human body, to define the scope of protection in certain specific cases, to establish a system of compulsory cross-licencing between breeders’ rights and patents and to introduce specific rules concerning sufficiency of disclosure for biological material.

The national patent laws in each Member State therefore remain the essential basis for legal protection of biotechnological inventions, but should be adapted, if necessary, in order to take into account the rules of the present Directive which concern:

- patentability of the inventions;
- the scope of protection conferred by a patent in respect of biological material;
- compulsory cross-licencing;
- filing of biological material.
I- PATENTABILITY OF INVENTIONS

Chapter I of this Directive, relating to patentability, first of all gives several definitions, as mentioned here below.

A/ DEFINITIONS

**Biological material**: any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

**Microbiological process**: any process involving, performed upon, or resulting in microbiological material.

**Essentially biological processes for the production of plants or animals**: Processes consisting entirely of natural phenomena, such as crossing or selection.

**Plant variety**: varieties as defined in Article 5 of EC Regulation No. 2100/94 concerning Community Plant Variety Rights.

B/ PATENTABLE INVENTIONS

New inventions involving an inventive step and susceptible of industrial application are 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.*

After citing the above patentability requirements and stating that an invention involving biological material is also patentable, *the Directive then stipulates that biological material which is isolated from its natural environment or produced by means of a technical process may be the object of an invention, even if it existed previously in its natural state.*

In Articles 4 to 6 which relate to exceptions from patentability, it is stated that the following inventions are also patentable:

- *Inventions concerning plants or animals if the technical feasibility of the invention is not limited to a particular plant or animal variety.*

- *The microbiological processes or other technical processes for producing plants or animals as well as the products obtained by these processes.*

- *Elements isolated from the human body or otherwise produced by means of a technical process, including entire or partial gene sequences, even if the structure of these elements is identical to those of natural elements; the industrial application of an entire or partial gene sequence should be outlined clearly in the application.*
C/ EXCEPTIONS TO PATENTABILITY

a) Unpatentable inventions

- plant and animal varieties;
- essentially biological processes for the production of plants or animals.

b) Objects which may not constitute patentable inventions

The human body, at various stages of its formation and development, as well as the simple discovery of one of its elements, including partial or entire gene sequences.

c) Inventions whose use is contrary to "ordre public" or morality

Inventions whose commercial use would be contrary to "ordre public" or morality are excluded from patentability, such use not being considered as contrary merely because it is prohibited by a law or regulation.

The following will be excluded from patentability for the above reasons:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;
- 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 also animals resulting from such processes.

Thus, the Directive brings an end to numerous debates on patentability of the human body and entire or partial human gene sequences.

It also states that inventions involving plant or animal varieties may be patentable where their technical feasibility is not limited to a specific plant or animal variety.

It is expected that the EPO Enlarged Board of Appeal will now take a stand in this respect.

Finally, the Directive provides a non-exhaustive list of processes which would be contrary to "ordre public" or morality, which correspond in particular to ethical grounds and morality upheld in the Member States. It may be noted that in the recital (38), it is stated that those processes whose application would threaten human dignity, as for example processes for the production of hybrid beings, from human or animal germ cells or totipotent cells, are obviously also excluded from patentability.
II- SCOPE OF PROTECTION

Articles 8 and 9 of the Directive define the scope of protection conferred by a patent relating to biological material, to a process for producing biological material or a product containing or consisting of genetic information.

Protection conferred by a patent relating to biological material having specific properties extends to any biological material derived from this biological material by reproduction or multiplication in an identical or variant form and possessing these same properties.

Protection conferred by a patent relating to a process for the production of biological material having specific properties extends to biological material directly obtained by this process and to any other biological material obtained from the directly obtained biological material, by reproduction or multiplication in an identical or variant form and possessing these same properties.

Protection conferred by a patent to a product containing genetic information or consisting in genetic information extends to any material in which the product is incorporated and in which the genetic information is contained and fulfils its function, with the exception of plant and animal varieties.

Benefits to the Farmer

By way of derogation from Articles 8 and 9, the sale or any other form of trading of plant propagating material, of breeding stock or other animal reproductive material, by the holder or with his consent, to a farmer, implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, or authorisation to use protected livestock for agricultural purposes.

This disposition in respect of the farmer is the same as that foreseen by EC Regulation No. 2100/94 concerning plant varieties.

III- COMPULSORY CROSS-LICENCING

Where a breeder cannot acquire or exploit plant rights without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent.

In the same way, the owner of a patent concerning a biotechnological invention who cannot exploit this without infringing prior plant variety rights may apply for a compulsory licence for non-exclusive use of the protected variety.

In both cases, the applicant for such a licence must prove:
- that he has attempted un成功fully to acquire a contractual licence;

- that the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

IV- FILING OF BIOLOGICAL MATERIAL

In Chapter IV, the Directive defines:

1) the conditions under which a description concerning biological material which is not available to the public will be considered as sufficient;

2) availability of this biological material.

The dispositions of this Chapter are substantially the same as those of Rules 28 and 28a of the implementing regulations to the Convention on the granting of European patents as amended in June 1996.

V- APPLICATION OF THE DIRECTIVE

This Directive entered into force on 30 July 1998. The Member States have a delay of two years to amend their laws, if necessary, in order to conform with the present Directive.

Marie-Louise GILLARD © CABINET BEAU DE LOMENIE - 1998