

Opinion no. 5 of 9 February 1998 on the legal protection of biotechnological inventions

Request for an opinion from 22 February 1996

from Mr. Elio Di Rupo, deputy prime minister and Minister of the Economy and Telecommunication,

regarding the “Proposal for a Directive from the European Parliament and Council on the legal protection of biotechnological inventions (version from 19 November 1997, cf. Document 95/0350 COD).”

The most important considerations underpinning this opinion:

1. The awarding of a patent is subject to strict criteria (the novelty of the invention, its effectiveness, the industrial applicability). The patent is awarded for a period of 20 years, starting from the date of application.
2. The awarding of a patent is one moment in a complete process which originates in scientific, technological research and results in industrial and commercial exploitation. The research and the exploitation (marketing, sales) are subject to their own conditions and criteria (e.g. ethical rules on experiments involving human persons during the research phase, and rules on safety and health when authorising the marketing of medications).
3. It is widely recognised that the clear and consistent legal protection ensured by a patent is very important for both scientific and technological research, and economical development in Europe in the field of biological and medical sciences and technologies.
4. Since the 19th century, there is a tradition and patent law which apply to biological material, including that of human origin.
5. However, there are various moral concerns regarding the current increase and relative novelty of the procedures (e.g. genetic technologies) and the objects (e.g. human gene sequences) subject to legal protection.
6. The patent law applicable in Europe already makes reference to ethics, given that an invention is not allowed to fundamentally conflict with “the public order and morality.”
7. The Committee has interpreted its task as being limited to the ethical issues directly related to the human person and the human body, in particular respect for human dignity, issues which undeniably fall within the Committee's mandate. This restriction does not mean that other questions may not be posed during the Proposal for a Directive, such as issues involving the environment, biodiversity and animal welfare, nor that it would not have been interesting to have analysed the full text or the text in relation to socio-economic issues, particularly with respect to developing countries.
8. The part of the Proposal for a Directive which we demarcated on the above grounds and subjected to research, is equal to articles 5 and 6 (paragraphs 1, 2a, 2b, 2c and 2d), which reads as follows (version from 19 November 1997):

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.*

Article 6

1. *Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public [the public order] or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*
2. *On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:*
 - (a) *processes for cloning human beings;*
 - (b) *processes for modifying the germ line genetic identity of human beings;*

(c) use of human embryos for industrial or commercial purposes;
(d) 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.

These considerations led to the following opinion.

OPINION

1. The reference, present in European patent law, to “the public order and morality”, offers a means of guiding the ethical evaluation of a patent application for an invention involving elements of human origin.

2. This moral concern can and should be further elaborated and clarified by the formulation of a number of clearly stated principles.

3. A first principle is that it is not *a priori* unethical to grant a patent to inventions which make use of biological material, including elements of human origin.

4. Other, more specific principles can clarify the conditions under which the patentability of inventions which, in some way, make use of elements of human origin, is permissible.

5. In this context, two principles regarding the concept of respect for the human person are essential:

- the non-commercial character of the human body;
- informed and free consent.

6. The non-commercial character of the human body means that the human body (understood as the body of a single distinct person), as a whole or in part, cannot be considered as property. It can neither be bought nor sold. It is neither a commodity nor an inheritance. This principle has consequences for the person from whom biological material is taken as part of a process which leads to a patentable invention. According to this principle, this person can make no claim to any possible benefits resulting from the exploitation of the patent. Furthermore, this person can in no way be considered as the inventor of the patented technology. It is worth emphasising in this regard that research and development are independent of the good will and solidarity of those prepared to participate in the research process. The principle that the body is not a commodity, does not exclude the possibility of compensation for those who contribute biological material, for inconveniences suffered. Some members of the Committee fear that if the logic of patentability and commercialisation is followed, individuals with exceptional DNA sequences (e.g. offering resistance to AIDS) may try to obtain payment for the reproduction of the use of their sequences. Other members are of the opinion that patents, an expression of intellectual ownership, are in any case in contradiction with the principle of the non-commercialisation of the human body.

7. The principle of informed and free consent means that information which is as comprehensive as possible must be given to the person who, freely and without coercion, is invited to participate in a research process involving the taking of biological material. It is appropriate to emphasise that this information should mention the possibility of an industrial and commercial application of the results of the experiment.

8. Article 5 (“*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*”) should be supplemented with an explicit reference to the principle of non-commercialisation, in the sense indicated above. Similarly, the right of an individual to be fully informed, if involved in research which can lead to a patent application, should be explicitly mentioned. In particular, following on from point 3 of article 5 (“*The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application*”), it should be emphasised that intellectual property must be clearly established and subject to an appropriate and not extensive legal protection. As long as the status of genetic information remains problematic, it would be wise, in any case, not to extend the protection of the patent to the mere knowledge of such information, nor, consequently, to all applications not yet precisely defined but which could in the future be based upon this knowledge.

9. Article 6 contains an explicit reference to moral concerns (reference to public order and morality), and illustrates this for four domains (a, b, c and d; see above article 6, second point). This manner of clarifying the concept 'morality' by means of examples of domains in which it could be applied, is in itself not very convincing. This approach is incomplete, and unable to be used as a guide for subsequent evaluations. The explanation of the ethical concern should only consist of a clear statement of general ethical principles as indicated above. Moreover, in the event that point (b) is interpreted as also referring to germline gene therapy (treatment of a genetic condition by intervening in the germline or sex cells, thus impacting the offspring), this illustration is questionable. It is after all not clear to what extent germline therapy is immoral in itself if it is confined to therapeutic purposes, and not confused with genetic interventions aiming at a superior sort of human. This notwithstanding, the opinion was also expressed that granting patents for methods involving human germline gene therapy is unethical. This issue thus remains controversial.

The opinion was prepared by Select Committee 96/4, consisting of:

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The working documents of the Select Committee 96/1 (reports, opinions of the experts, bibliography, texts of discussions, etc.) are kept under Annex no. 96/1 at the Committee's documentation centre, where they are available to be consulted and copied.

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