BELGIAN ADVISORY COMMITTEE ON Bioethics

Opinion no. 12 of 10 January 2000 on the legal protection of biotechnological inventions

Request for an opinion from 22 June 1999
from Mr. Elio Di Rupo, deputy prime minister
and Minister of the Economy and Telecommunications,
regarding the draft law transposing Directive 98/44 of 6 July 1998 of the European Parliament and of the council Council on the legal protection of biotechnological inventions.

The most important considerations underpinning this opinion :

The considerations set out in Opinion 5 of 9 February 1998 on the legal protection of biotechnological inventions apply. Opinion 5 is attached as Annex 1.

Opinion

1. With respect to the conditions necessary for the granting of a patent for elements of human origin, the Advisory Committee for Bioethics remains in full support of the recommendations of Opinion 5. Sections 7 and 8 deserve special attention:

   "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."

2. In so far as it is meaningful to elaborate legal arrangements, the Advisory Committee is of the opinion that elements such as those mentioned in the earlier amendment 76 of the European Parliament (see Annex 2) and the considerations 26, 27 and 56 of the Directive (see Annex 3), would be better incorporated in general legislation arranging the protection of patients and test subjects.

3. The Advisory Committee finds that the subject of the law in its current form requires serious adjustments.
   The text of article 4 § 3, amending the law of 28 March 1984 on patents for inventions, is attached as Annex 4.
   Regarding article 4 § 3 first paragraph, the Advisory Committee is of the opinion that the text should be interrupted after "without the consent for such use by the donor." The complete text beginning with "the validity of the patent" must be deleted, as this passage declares that the validity of a patent under certain circumstances cannot be challenged, even if the donor did not give consent. Since the conditions stated for ignoring the lack of consent are vague and open to interpretation, this will mean in practice that there will always be arguments available to get around the necessity of consent. If these provisions are left in the law, there is no point first stating that the consent of the donor is in general necessary.
   Regarding article 4 § 3 second paragraph, the Advisory Committee is of the opinion that, regardless of the restriction mentioned in point 7 of the most important considerations of Opinion number 5, the text should be interrupted after "the law of the land of origin of the materials." The complete text beginning with "the validity of the patent" should be deleted, as it encourages breaking the law.

4. Regarding the sanctions concerning breaching the ethical rules in this context, the Advisory Committee first suggests that it is better to situate these sanctions in the broader context of the legislation for the particular behaviour condemned. The withdrawal of the possibility for protection through a patent can, in this context, be used as an additional sanction.

This opinion was prepared by members of the Select Committee 96/1, who prepared Opinion number 5 of 9 February 1998 on the legal protection of biotechnological inventions.

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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.

This opinion is available on the website www.health.belgium.be/bioeth under the "List of Opinions" section.

Annex 1 of Opinion no. 12 : Opinion no. 5 of the Advisory Committee for Bioethics

Annex 2 of Opinion no. 12 :

From Amendment no. 76 of the European Parliament:

> [French]
> « 1. Si l'objet d'une invention consiste en une matière biologique d'origine végétale ou animale ou utilise une telle matière, l'invention ne peut être brevetée que si la spécification du brevet précise l'origine géographique de la matière et que si le requérant fournit aux autorités la preuve que la matière a été utilisée conformément aux dispositions régissant l'accès juridique et l'exportation sur le lieu d'origine.
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> 2. Si l'objet d'une invention consiste en une matière biologique d'origine humaine ou utilise une telle matière, l'invention ne peut être brevetée que si la demande de brevet porte le nom et la signature de la personne sur laquelle cette matière a été prélevée ou bien de son représentant légal ou de ses proches et que si le requérant fournit aux autorités la preuve que cette matière a été utilisée avec le libre consentement donné en pleine connaissance de cause de la personne sur laquelle elle a été prélevée ou bien de son représentant légal ou de ses proches. Les autorités s'abstiennent de publier le nom et la signature de la personne concernée, de son représentant légal ou de ses proches. »

Annex 3 of Opinion no. 12 :

Considerations 26, 27 and 56 of Directive 98/4/EC of the European Parliament and of the Council:

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

Annex 4 of Opinion no. 12 :

Draft law amending the Law of 28 March 1984 on invention patents, in particular the insertion of § 3 in artikel 4, which reads as follows:

"§3. The use of an invention is in particular in conflict with the public order and morality if it is shown that the invention was developed in circumstances which go against the public order and morality, for example in the following cases:

- if the invention was developed on the basis of human samples without consent for such use by the donor; however, the validity of the patent cannot be challenged if the person who had to give consent, his lawful beneficiary, his successor or any other person acting in his name or on his behalf made the consent dependent on the payment of a substantial sum of money or some other substantial cash benefit, or if consent were refused without giving a valid reason;

- if the invention was developed on the basis of plant or animal material exported in violation of the law of the country of origin of the materials; however, the validity of the patent cannot be challenged if the holder of the patent has reached an agreement with the state whose law is violated by the export of the plant or animal material."

Original text (Dutch/French):

Wetsontwerp tot wijziging van de wet van 28 maart 1984 op de uitvindingsoctrooien, waarbij meer bepaald een § 3 in artikel 4 wordt ingevoegd, luidend als volgt :	**Projet de loi modifiant la loi du 28 mars 1984 sur les brevets d'invention visant notamment à insérer dans l'article 4 un § 3, rédigé comme suit :**
"§3. De toepassing van een uitvinding is in strijd met de openbare orde en met de goede zeden, inzonderheid als wordt aangetoond dat de	« § 3. L'exploitation d'une invention est contraire à l'ordre public et aux bonnes mœurs notamment lorsqu'il est établi que

uitvinding werd ontwikkeld in omstandigheden die indruisen tegen de openbare orde en goede zeden, dat is bijvoorbeeld het geval :	l'invention a été développée dans des conditions contraires à l'ordre public et aux bonnes mœurs, tel est le cas par exemple :
- als een uitvinding wordt ontwikkeld op basis van menselijke afnamen zonder de toestemming voor een dergelijk gebruik van de donor ; de geldigheid van het octrooi kan echter niet meer in het gedrang gebracht worden als de persoon die zijn toestemming moet geven, zijn rechthebbende, zijn rechtverkrijgende of elke andere persoon die in zijn naam handelt of voor zijn rekening handelt de toestemming afhankelijk gemaakt heeft van de betaling van een betekenisvolle som geld of van elke betekenisvolle aanzienlijke prestatie in geld of indien de toestemming geweigerd werd zonder inroeping van een geldige reden ;	- lorsqu'une invention est développée à partir de prélèvements humains sans le consentement du donneur pour une telle utilisation ; la validité du brevet ne pourra cependant plus être mise en cause lorsque la personne devant donner son consentement, son ayant droit, son ayant cause ou toute personne agissant en son nom ou pour son compte a conditionné le consentement au paiement d'une somme significative d'argent ou à toute prestation significative appréciable en argent ou lorsque le consentement a été refusé sans qu'un motif valable ait été invoqué ;
- als een uitvinding wordt ontwikkeld op basis van plantaardig of dierlijk materiaal dat uitgevoerd werd in overtreding van de wet van het land van herkomst van die materies ; de geldigheid van het octrooi kan echter niet meer in het gedrang gebracht worden als de titularis van het octrooi tot een akkoord gekomen is met de staat wiens wetgeving overtreden werd door de uitvoer van plantaardig of dierlijk materiaal."	- lorsqu'une invention est développée à partir de matière végétale ou animale exportée en violation de la loi du pays d'origine de ces matières, la validité du brevet ne pourra cependant plus être mise en cause lorsque le titulaire du brevet a trouvé un accord avec l'Etat en violation de la législation duquel la matière végétale ou animale a été exportée. »