



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

OPINION
18/CNECV/97

on

**The European Parliament's
and Council of the European Union's Bill**

Proposing a Directive for

THE JURIDICAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

(COM (95) 661; Dec.13, 1995)

1. General Considerations

The Bill we are asked to analyse was submitted following a rejection by the European Parliament, on the 1st of March, 1995, of a previous Bill with the same title, on which the National Council of Ethics for the Life Sciences (CNECV) had already emitted an Opinion on the 6th of April, 1994 (7/CNE/94).

Thus, this ethical reflection by the CNECV on the subject of the juridical protection of biotechnological inventions is not original.

For that reason, and also due to imperative reasons of time relating to the recent start of a new mandate, the CNECV shall address to that earlier Opinion the ethical reflection on the principles involved, where it was more deeply elaborated – for that reflection still stands as regards its considerations and conclusions.

Nevertheless, because we have to do with a new Bill, and because it contains perspectives and enunciates now formulated for the first time, we shall outline a comparative analysis of the main ethical aspects found in the new Bill and reflect upon them.

2. The ethical aspects of the new Bill and its present necessity

An Opinion requested of the European Union's Economic and Social Committee states that "*biotechnology, naturally, presents a challenge to*



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industry and the economy, generating employment and commercial opportunities”¹.

In effect, registration of a patent guarantees the monopoly on the commercialisation of an invention for a period of 20 years, so as to compensate the inventor for the intellectual and economic investment made.

As referred in the previous reflection by the CNECV, the necessity to adopt a common juridical framework in the countries of the European Union as regards the application of the patent rights of biotechnological inventions arises, in the first place, from the absence of such a framework in the various countries of the Union.

In fact, not only national but also supra-national legislations in the Union² failed to foresee that, with the evolution of science and technology, the right of exclusive use of biological material would become possible, as it is today; just as they did not equip themselves with a common and uniform instrument of application that might impede the possible divergence of criteria from country to country in the evaluation of biotechnological inventions filed for patenting. And although, undoubtedly, the jurisprudence of the European Agency of Patents might be invested with harmonising such criteria, the truth is that, pursuant to the Munich Convention, that same jurisprudence may be over-ruled by a national judge. Accruing to this is the non-existence of a common interpretation relative to patent pre-requisites such as the “*non-contrariety to public order*” or the “*respect for moral decency*”.

As a direct consequence of this absence of a common orientation, European scientific research and investments to finance it are discouraged, which fragilises its competitiveness in the face of research done outside the European Union.

On the other hand – and most significantly from an ethical perspective – without joint dispositions to safeguard ethical aspects concerning the human body, there can be no guarantees of its protection.

Culminating with this presupposition, the ethical aspects of the previous Bill became perhaps the principal theme of debate, and sufficient cause to reject that Bill. Thus, the main reason for the failure of the first Bill submitted is said to be its essentially technical and juridical character and its deficient approach of some problems, especially those of an ethical nature.

¹ Cf. the Opinion of the Economic and Social Committee with the same title as the present one -i.e. *Proposta de directiva (CE) do Parlamento Europeu e do Conselho relativa à protecção jurídica das invenções biotecnológicas* (96/C 295/03).

² Cf. the Code of Industrial Property and the European Convention on Patents, and other relevant Conventions.



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In truth, the absence of clarification of what was meant by “*the human body or elements of the human body as such*” – one of the conditions considered to exclude patent rights – and particularly of the expression “*as such*”, raised much doubt over the admissibility of the right of exclusivity in the use of the human body or of its natural constituent elements. In fact, the differentiation between *invention* (patentable) and *discovery* (non patentable) was not defined in that enunciate in unequivocal manner.

3. Amendments in the new Bill conducive to an ethical approach.

The text of the new Bill aims at making more precise the frontiers between invention and discovery, when it states that “*the object of an invention involving biological matter cannot be considered a discovery or as devoid of novelty simply because such matter already existed in Nature*” (Art.8). It must be recalled that discovery is considered to be non patentable, insofar as Man does not intervene in the modification and utilisation of a phenomenon that already exists in Nature.

Nevertheless, and as regards inventions (it must be borne in mind that one of the conditions of eligibility for patent rights is that they apply to inventions), resulting from a technical process – which result Nature is unable to obtain through the simple application of its laws – patent rights may be applied for when these aspects accrue to the other pre-requisites for the granting of patents.

In fact, this new Bill evidences a strong concern with the clarification of definitions, since it not only introduces a differentiation between invention and discovery but also it defines what is meant in this Directive by *biological matter* (it must be noted that not all biological matter is living matter), by *microbiological process*, and by *an essentially biological process of obtaining plants or animals* (Art. 2).

The fundamental alteration, from an ethical point of view, is the clarification of the conditions of exclusion from patentability of the human body and its elements, achieved by replacing the expression “*as such*” with “*the human body and its elements in their natural state*” (Art. 3, #1).

Because of its helpfulness in the interpretation of this principle, we must not fail to refer consideration no.16 of the Bill, which clarifies some fuzzy situations when it says that “*(...) an isolated element of the human body, or one produced differently, cannot be considered as non patentable in the same way as an element of the human body in its natural state, that is to say, it cannot be put on a par with a discovery, for the isolated element results from technical processes which identified it, purified it, characterised it and multiplied it outside of the human body, and these processes can only be carried out by the human being, Nature being incapable of carrying them out alone.*”



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As mentioned above, one of the pre-requisites underlying the patentability of an invention is that its exploitation must not run counter to public order and moral decency.

These pre-requisites are also provided for in the new Bill (Art. 9, #1), which specifies two cases of non patentability: methods of germinal genic therapy of the human being and such “*processes of modification of the genetic identity of animals as may cause them suffering or diminishment of physical capacities without substantial utility for either humankind or the animal (...)*”.

In a previous Opinion, the CNECV has already stated its position on the admissibility, from an ethical perspective, of granting patents to alterations of the human genome, that is in the genic therapy of cells of the germinal line. Human genic therapy is defined as “*the deliberate transfer of genetic material to a patient’s cell with the aim of curing or preventing a disease*”³, saving the fact that it is not yet possible today to remove genes from cells but only to add them on. Genic therapy on cells of the germinal line is defined as that which is performed on “*spermatozoa or ovules and their precursory cells as well as those cells of the first stages of the human embryo*”⁴.

Even though such germinal therapy is expressly forbidden by the legislation of some countries⁵, and the Council of Europe itself supports that position⁶, this does not mean, contrary to the conclusions of some authors⁷, that the present interdiction entails ruling out any future form of utilisation.

As the matter stands, despite the possible future benefits for Humankind, namely the eradication of genetic diseases, there seems to be a consensus in the scientific community that the present state of scientific knowledge does not yet allow conditions of safety nor probabilities of success. On the other hand, and from an ethical perspective, we are confronted with the question of knowing whether the principle of human dignity might not collide with the right of future generations to inherit a genetic patrimony that has not been manipulated.

A last word about patenting animals and plants, and about the introduction of the disposition contained in Article 4 of the new Bill. Item 2 of

³ Definitions extracted from the *Opinion on Genic Therapy* by the Group of Advisors on the Ethical Implications of Biotechnology (European Commission), 1994.

⁴ Cf. the same Opinion mentioned in 3 above.

⁵ Such as Sweden.

⁶ Recommendations 934 and 1100.

⁷ MM. Harold Edgar e Thomas Tursz, *Opinion on Human Genic Therapy*, UNESCO, *op. cit.*, and Luís Archer, “Genic Therapy 92”, in *Brotéria Genética XIV CLXXXIX*, Lisbon 1993, p. 79.



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that Article, especially, by allowing the patentability of plants, animals or parts thereof obtained through a process that is not essentially biological, seems to confirm that the exclusion of patents on plant and animal varieties must be interpreted restrictively. This position seems to confirm, therefore, the juridical orientation of the European Patent Office, particularly as regards the patenting of transgenic animals such as the Harvard rat and others.



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CONCLUSIONS:

The considerations above lead us to the following conclusions:

- a) Bearing in mind that certain biotechnological inventions imply the utilisation of elements of human origin – and that the juridical protection of such inventions should become effective once they have been patented – an imperative must be placed on respect for human dignity and abeyance to the principles that proceed therefrom, to wit, the non-commercialisation of the human body and the right to free and informed consent.
- b) In spite of evident benefits to Humankind, powerful economic motivations also move the biotechnological industry. In this context, it is urgent to emphasise that the interests and well-being of the human being must always prevail over the interests of society and Science, as expressly laid down in the Convention on Human Rights and Biomedicine of the Council of Europe.
- c) The definition of concepts and the clarification of the cases where patenting is ruled out are evidence, in the newly submitted Bill, of commendable progress
- d) On the other hand, there is no sense in the elimination from the text of the new Bill of the expression “*not contrary to the dignity of the human person*”. The expression should be re-introduced in the new text.
- e) The text of the new Bill is too restrictive when it excludes from patentability all methods of germinal genic treatment of the human being. And it is ambiguous in not extending such a restriction to cases of genetic engineering for genetic improvement, or in eugenic practises. The CNECV would prefer a text that would not contain a categorical rejection of genic interventions on cells of the germinal line, recommending however an interdiction on genic interventions done merely for the purpose of improvement.

Lisbon, January 8th, 1997

The Reporter,
Dr. Paula Martinho da Silva

The President of the CNECV,
Prof. Dr. Luís Archer