

NATIONAL BIOETHICS COMMISSION

RECOMMENDATION ON THE PATENTABILITY OF BIOTECHNOLOGY APPLICATIONS

The National Bioethics Commission was convened by the President thereof on 15.11.2002, 20.12.2002, 17.01.2003, 18.04.2003, 16.05.2003, 20.06.2003 and 19.09.2003 in order to consider the ethical and social issues within its jurisdiction with regard to the patentability of biotechnology applications and draft a related proposal pursuant to article 10, Act 2667/1998.

The Commission recognizes that patents on biotechnology applications currently constitute a powerful motive for raising funds in a field of costly research with a high failure rate, which nevertheless promises significant improvements in the quality of modern life.

Biotechnology applications are essentially different from other technical applications in that they involve biological systems or elements thereof, on the one hand, and they use biological processes – such as reproduction – for their purposes, on the other hand. In this respect, they are not innovations due exclusively to human creativity but depend to a large extent on the application of biological phenomena.

The question of patents is primarily a matter of law. In view of the peculiarity of biotechnology applications, however, it raises fundamental questions of ethical-social evaluation in order to harmonize patents with freedom of research in particular. It is worth noting that European Union law already includes Directive 98/44/EU on the subject which has been transposed in Greek law (by p.d. 321/2001).

The present recommendation aims, first, at facilitating the interpretation of this Directive by the relevant authorities. At any rate, the recommendation is not bound by this legislation. By adopting a different view to certain aspects it urges our country to take initiatives to modify this legislation in the future.

A. General comments

1. Biotechnology and human inventiveness

The term biotechnology refers to a combination of science and technology with a view to exploiting applications arising from the study of biological systems or elements thereof. However, the vast majority of structural elements that make up any organism or the biological processes that keep it alive cannot be artificially reproduced without using natural biological processes such as reproduction or growth. Therefore, human inventiveness in biotechnology is actually limited to skillful manipulation and modification of organisms or elements thereof.

2. Inventiveness and patents

Human inventiveness is a fundamental expression of personality and as such it is protected in all free societies. Contemporary law actually takes a step further: it grants patents to reward and encourage inventiveness recognizing it as a motor of freedom of research and economic freedom as well. In a nutshell, patents consist in granting a right of exclusive exploitation to the author of a product of invention for a certain period of time. However, legal systems vary as to what they consider as product of invention and, consequently, object of patents. With regard to contemporary biotechnology applications in particular, these variations have become critical.

3. General principle: invention, object of patent

As a general principle, the Commission shares the prevailing view that only “inventions” can become object of patents and not things occurring in the external world, excluding thus “discoveries”.

This admission is in tune with the general direction of legal tradition, especially the European one. In ethical terms, the interest is focused on rewarding those inventions that lead to designing and realizing innovations. In this sense, a discovery cannot be considered as invention though the process or method that led to discovery can be innovative and, therefore, liable to patentability. The Commission does not feel that this position underestimates the particular inventiveness associated with discovery. The latter

is rewarded by the possibility to claim patents for innovative ways or methods leading to discovery, as already pointed out. In addition, the Commission thinks that granting exclusive exploitation rights on discoveries even for a limited period of time would isolate entire areas of knowledge in favour of certain research bodies and, thus, substantially restrict freedom of research and science in a law-ruled society.

The Commission does not think biotechnology applications should be exempted from this general principle allowing the patentability of discoveries based on biotechnology merely because they promise significant benefits by improving the quality of life. This view is based on two grounds: on the one hand, inventiveness is rewarded through the possibility to claim patents on methods; on the other hand, especially in a rule of law society, any general purpose (such as the prospect of improving quality of life by biotechnology) should be pursued within the given framework of protection of fundamental rights. This would be frustrated if, in view of this general purpose, freedom of research and science were to be restricted by granting patents on discoveries, as mentioned earlier. This line of argument determines the Commission's positions on the patentability of biotechnology applications.

B. Specific positions

1. Unpatentable biotechnology products

The Commission takes the view that simple description or isolation of biological systems or elements thereof involving morphological, structural or functional characteristics cannot be patented.

As a result the Commission considers that the genome of organisms or isolated sequences thereof, the functions performed by the genome or by parts thereof, as well as cells, tissues or organs and organisms as such cannot be patented to the extent that they constitute discoveries.

The Commission points out that this principle emanates directly from the distinction between invention and discovery adopted by the system of patents and recognizes that this position is counter to Directive 98/44/EC, particularly articles 3 (2) and 4 (2) of p.d. 321/2001 transposing the directive into national law.

2. Patentable biotechnology products

The Commission feels that from the ethical/social viewpoint, awarding patents – and consequently, exclusive exploitation rights – on forms of living can be justified only to the extent that it does not concern human beings. As it is, human beings as “persons” cannot be subjected to any form of “exploitation” whatsoever since the principle of human value lies at the heart of the modern moral and legal civilization. At any rate, other organisms, animals or plants, are liable to exploitation in principle and therefore may be patented subject to the above-mentioned terms and conditions (see A3). Yet, the recognition of such patents does not mean that animals, in particular, may be ill-treated by the rightholder. The minimum moral status of animals as embedded in international legal instruments lays down certain limits. The Commission believes that biological systems or elements thereof may be patented if not occurring in nature. In the Commission’s view, modified biological systems like transgenic organisms or parts thereof such as modified cell lines, including human ones, may in principle be patented. Besides, the Commission believes that modified biological systems must be submitted to authorized biological banks in the spirit of Directive 98/44/ EC (article 11 (1) p.d. 321/2001).

3. Patentable biotechnology methods

In the Commission’s opinion, a novel method is by definition an “invention” regardless of whether its product or object is life. Therefore, biotechnology methods in themselves are patentable though the patent may not extend to their products. In this context, methods of description or isolation of biological systems or parts thereof may be patented independently of the origin of the system (human, animal or plant).

4. Scope of protection

a) *Claims*: claims for patents on biotechnology products or methods must specify accurately the product or method they refer to. Claims to extend a patent “*mutatis mutandis*” to other products or methods are to be rejected both for reasons related to safety of transactions (avoiding overlapping rights of more than one rightholders) as well

as to avoid undue restriction of freedom of research by “isolating” and granting exclusive exploitation rights on wider areas of knowledge.

b) Mandatory licenses: the Commission is in favour of adopting a system of mandatory licenses granted to third parties by the responsible public authorities for patented biotechnology applications in order to avoid restrictions to scientific research, and alleviate the developing countries from excessive economic burdens.

c) Duration of protection: due to the rapid rate of developments in biotechnology, the Commission does not exclude the adoption of a different duration of protection for biotechnology inventions other than the established 20 years and invites the responsible authorities to consider that matter.