PRESIDENTIAL DECREE No. 321/24.09.2001

"Adaptation to Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions"

THE PRESIDENT
OF THE HELLENIC REPUBLIC

Having regard to the following:

1. article 4 of L. 1338/1983 Application of community law" (GG 34, A), as replaced with Article 6, par. 4 of L. 1440/1984 "Participation of Greece in equity, reserves and provisions of the European Coal and Steel Community and of the EURATOM Supply Agency (GG 70, A') and Article 22 of L. 2789/2000 (GG 21, A);

2. provisions of Article 2 in L. 2077/1992 "Ratification of the Treaty on European Union and related protocols and declarations incorporated in the final act" (GG 136, A);

3. provisions of Article 29A in L. 1558/85 (GG 137, A), as supplemented by Article 27 in L. 2081/92 (GG 154, A) and replaced with Article 1, par. 2a in L. 2469/97 (GG 38, A) and to the fact that provisions in this presidential decree entail no expenditure under the national budget;

4. provisions of PD 27/1.2.96 (GG 19, A) on “Merging of the ministry for tourism, the ministry for industry, energy and technology, and the ministry for commerce into the ministry for development”;

5. opinion No. 402/2001 by the Council of State, following a proposal submitted by the minister for national economy, the minister for justice and the minister for development, the following is hereby decided:

CHAPTER ONE

GENERAL PROVISIONS

Article 1
Scope

This presidential decree aims to adapt the Greek law to Directive 98/44/EC of the European Parliament and of the EU Council dated July 6 1998 on the “Legal protection of biotechnological inventions", published in the Greek language in the Official Journal of the European Union on July 30 1998 (EEL 213).

CHAPTER TWO

PATENTABILITY

Article 2

1. For the purpose of implementing this presidential decree the following interpretations shall apply:

a) "biological material": any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
b) "microbiological process": any process involving or performed upon or resulting in microbiological material;

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of ‘plant variety’ is defined by Article 5 of Regulation (EC) No. 2100/94 (OJ L 227/9LI).

Article 3

1. For the purpose of implementing this presidential decree inventions specified in provision of Article 5 par. 1 of L. 1733/1987, whose object is a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used shall be patentable.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

3. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Article 4

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 of 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 5

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to the public order or morality; however, exploitation shall not be deemed to be contrary to the public order or morality merely because it is prohibited by the applicable law.

2. Pursuant to paragraph 1 the following, in particular, shall be unpatentable:

a) processes for cloning human beings;

b) processes for modifying the germ line genetic identity of human beings;

c) uses 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 animals resulting from such processes.

CHAPTER THREE

EXTENT OF PROTECTION

Article 6

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material in an identical or divergent form and possessing the same characteristics.

Article 7

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 4, par. 1, in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 8

The protection referred to in Articles 6 and 7 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the propagation or multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication

Article 9

1. By way of derogation from Articles 6 and 7, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No. 2100/94.

2. By way of derogation from Articles 6 and 7, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

CHAPTER FOUR

COMPULSORY LICENSES DUE TO INTERDEPENDENCE

Article 10

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.

Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

b) 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.

4. The authority responsible for granting the licence referred to in paragraphs 1 and 2 is the Court specified in Article 13, par. 10 of L. 1733/1987. Provisions in Article 13 of L. 1733/1987, shall apply correspondingly. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No. 2100/94.

CHAPTER FIVE

DEPOSIT, ACCESS AND NEW DEPOSIT OF BIOLOGICAL MATERIAL

Article 11

1. Where an invention concerns biological material which is not available to the public and which cannot be described in a patent application filed with the Industrial Property Organisation (OBI) in such a manner as to enable the invention to be reproduced by a person skilled in the art or entail the use of such material, the description shall be considered inadequate for the purposes of patent law unless:

a) the biological material has been deposited no later than the date on which the patent application was filed with a recognised depository institution. At least the international depository authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty`, as ratified by Law 2128/1993 (GG 56, A') shall be recognised;

b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

c) the patent application states the name of the depository institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

a) up to the first publication of the patent application, only to those persons who are so authorised under international treaties or under national patent law;

b) between the first publication of the patent application by OBI and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

a) not to make it or any material derived from it available to third parties; and

b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn under Article 8, par. 1 and 2 of L. 1733/1987, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

Article 12

1. If the biological material deposited in accordance with Article 11 ceases to be available from the recognised depository institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit filed with the Industrial Property Organisation shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

Article 13

The Industrial Property Organisation (OBI), having its seat at Athens, shall be responsible for the implementation of this presidential decree (Article 1 of L. 1722/1987).

Article 14

Entry into force

This presidential decree shall enter into force upon its publication in the Government Gazette.

The minister for development shall be responsible for the publication and implementation of this decree.