

On the basis of the second paragraph of Article 10 of the Industrial Property Act (Official Gazette of the Republic of Slovenia, No. 7/03), the Government of the Republic of Slovenia hereby issues the following

DECREE¹
ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Article 1

This Decree defines detailed conditions for the grant of patents for biotechnological inventions, which have to be fulfilled beside those prescribed by the Industrial Property Act.

Article 2

(1) For the purposes of this Decree,

(a) “biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) “microbiological process” means 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) “Variety” shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

Article 3

(1) For the purposes of this Decree, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

¹ Published in the Official Gazette RS, No. 81/03. Entry into force: 2 September 2003.

(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.

Article 4

(1) The following shall not be patentable:

(a) plant and animal varieties; and

(b) essentially biological processes for the production of plants or animals.

(2) 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.

(3) Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

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 ordre public 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) 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 also animals resulting from such processes.

Article 7

(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 through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 8

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 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 9

The protection referred to in Articles 7 and 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of the Republic of Slovenia by the holder of the patent or with his consent, where the multiplication or propagation 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 10

(1) By way of derogation from Articles 7 and 8, 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, according to Article 16 of the Protection of New Plant Varieties Act, for propagation or multiplication by him on his own farm.

(2) By way of derogation from Articles 7 and 8, 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.

Article 11

(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.

(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.

(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.

Article 12

Applications for patents for biotechnological inventions which were filed before the date of entry into force of this Decree shall be treated in accordance with the provisions of this Decree.

Article 13

This Decree shall enter into force on the fifteenth day following its publication in the Official Gazette of the Republic of Slovenia.