

ACT No. 206/2000 Coll.

of 21 June 2000

**on the Protection of Biotechnological Inventions
and on the Amendment to Act No. 132/1989 Coll., on the Protection of Rights to New
Plant and Animal Varieties, as amended by Act No. 93/1996 Coll.**

PART ONE

PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Section 1

Definitions

For the purpose of this Act,

- 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,
- c) essentially biological process for the production of plants or animals means such a process, which consists entirely of natural phenomena such as crossing or selection.

Section 2

Patentable biotechnological inventions

Biotechnological inventions are patentable, if they concern

- a) biological material, which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,
- b) plants or animals, if the technical feasibility of the invention is not confined to a particular plant¹⁾ or animal²⁾ variety, or
- c) microbiological or other technical process and a product, other than a plant or animal variety, obtained by this way.

Section 3

Exclusions of patentability

Patents shall be not granted to

- a) inventions, whose commercial exploitation would be contrary to public policy or to principles of morality, namely to processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, processes of using human

¹⁾ Section 2 letter a) of the Act No. 132/1989 Coll., on the Protection of Rights to New Plant and Animal Varieties, as amended by Act No. 93/1996 Coll.

²⁾ Section 2 letter c) of the Act No.132/1989 Coll.

embryos for industrial or commercial purposes or 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 to animals resulting from such processes; however, the contradiction to public policy or to principles of morality shall not be deduced merely from the fact that the exploitation of the invention is prohibited by legal regulation,

- b) human body at 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; it does not apply to 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, even if the structure of that element is identical to that of a natural element, and
- c) plant and animal varieties or essential biological processes for the production of plants or animals.

Section 4

Provisions of the special legal regulation³⁾ will be applied to the procedure of the invention application and its requisites and to the patent of invention, consisting of biological material or containing biological material or concerning the process applied to production, treatment or exploitation of biological material (hereinafter referred to as “biotechnological inventions”).

Section 5

Special provisions on the application of biotechnological invention

(1) Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate unless:

- a) the biological material has been deposited no later than the date, from which the right of priority belongs to the applicant, with the recognised depository institution, which has acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, (hereinafter referred to as the “Budapest Treaty”),⁴⁾
- b) the application of invention as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited, and
- c) the patent application states the name of the depository institution and the accession number of the sample.

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

- a) between the first publication of the application and the granting of the patent, to anyone requesting it (hereinafter referred to as the “petitioner”) or, if the applicant so request, only to an independent expert, or

³⁾ Act No. 527/1990 Coll., Act on Inventions, Industrial Designs and Rationalisation Proposals as amended.

⁴⁾ Decree No. 212/1989 Coll., on Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and Implementing Regulations to it.

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

(3) The sample shall be supplied only if the petitioner or an independent expert in terms of paragraph 2 undertakes, for the term during which the patent is in force:

- a) not to make the sample or any material derived from it available to third parties, and
- b) not to use the sample 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) The applicant is entitled to limit access to the deposit material for 20 years from the date on which the patent application was filed to anybody, except an independent expert, even in case, where the application is refused or withdrawn; in that case, paragraph 3 shall apply.

(5) The applicant shall notify the limitation of access to the deposit biological material, mentioned in paragraph 2 letter a) and in paragraph 4, to the Industrial Property Office (hereinafter referred to as the "Office") at the latest on the date, on which the preparations for publishing the patent application have been completed. The Office will publish such a limitation of access to the deposit biological material together with the invention application in the Bulletin of the Industrial Property Office.

(6) If the biological material deposited in accordance with paragraph 1 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.

(7) Any new deposit shall be accompanied by a statement signed by the depositor and certifying that the newly deposit biological material is the same as that originally deposited.

(8) If the application concerns an invention of the sequence or partial sequence of a gene, their industrial applicability must be made obvious in the patent application.

Section 6

Scope of protection

(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 this 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.

(3) The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, in which the product is incorporated or in which the genetic information is contained and performs its function, except the human body at the various stages of its formation or development.

Section 7

Exhaustion of rights

The patent holder is not entitled to prohibit the propagation or multiplication of biological material being subject of the patent, if it has been placed on the market by himself or with his consent, and if the propagation or multiplication necessarily results from the application for which the biological material has been marketed, provided that the obtained material is not subsequently used for other propagation or multiplication.

Section 8

Limitation of rights of patent holder

(1) The person, who has obtained the plant propagating material being subject of the patent from its holder or with his consent, is authorised to use for reproduction during his agricultural activity except commercial exploitation, also the product of his harvest.

(2) The person, who has obtained the animal reproductive material being subject of the patent from its holder or with his consent, is authorised to use this material during his agricultural activity except commercial exploitation; this includes making the animal or other animal reproductive material available.

Section 9

Compulsory licence and compulsory cross-licence

(1) If a breeder⁵⁾ cannot obtain or exploit a plant or animal 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. The Office will grant the compulsory licence, if the breeding certificate holder applied unsuccessfully to the holder of the patent to obtain a contractual licence and if the plant or animal variety constitutes significant technical progress of considerable economic interest compared with the invention, protected by the patent. In this case, the holder of the patent will be entitled to a cross-licence to commercial use of protected variety on the same conditions, as applied for a compulsory licence according to a special legal regulation.⁶⁾

(2) If a compulsory licence to commercial use of protected plant or animal variety has been granted to the holder of the patent according to a special legal regulation⁶⁾, the breeding certificate holder will be entitled to a cross-licence to use the patent of invention.

PART TWO

Amendment to the Act No. 132/1989 Coll., on the protection of rights to new plant and animal varieties as amended by Act No. 93/1996 Coll.

Section 10

⁵⁾ Section 2 (g) of the Act No.132/1989 Coll.

⁶⁾ Section 10 of the Act No. 132/1989 Coll.

In Section 10 of the Act No.132/1989 Coll., on the Protection of Rights to New Plant and Animal Varieties, as amended by Act No. 93/1996 Coll., the paragraphs 3 and 4 are added, having the following wording:

“(3) If a holder of a patent of a biotechnological invention cannot exploit this patent without infringing a prior right to plant or animal variety, he may apply for a compulsory licence for non-exclusive use of the plant or animal variety. The Ministry will grant the compulsory licence, if the holder of a patent applied unsuccessfully to the breeding certificate holder to obtain a contractual licence and if the invention protected by the patent constitutes significant technical progress of considerable economic interest compared with the plant or animal variety. The paragraph 2 applies for stipulation of amount of licence fees in case of granting the compulsory licence. In this case, the breeding certificate holder will be entitled to a cross-licence to use of the biotechnological invention.

(4) If a compulsory licence to use of the biotechnological invention has been granted to the breeding certificate holder, the holder of a patent will be entitled to a cross-licence to commercial use of the plant or animal variety.”.

PART THREE

ENTRY INTO FORCE

Section 11

This Act shall enter into force on 1st October 2000.