

“Special Provisions Governing Biotechnological Inventions in Poland”

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In Europe, more than five years ago an important piece of legislation was passed which specifically addresses many of the relevant issues in coherent and comprehensive manner: in 1998 the EU Directive 98/44/EC on legal protection of biotechnological inventions was enacted. Also the new Polish Patent Law includes modified regulations concerning the patentability of the biotechnological inventions, and last spring amendment harmonises the Polish Patent Law with the EU Directive. Please find below the appropriate chapter of the Polish Industrial Property Law* (The Consolidated Text Of The Act)

Chapter 9

Special Provisions Governing Biotechnological Inventions

Article 93¹

Any reference in this Chapter:

(i) to “biotechnological invention” means the invention, within the meaning of Article 24, concerning a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used,

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

(iii) to “microbiological process” means any process involving or performed upon or resulting in microbiological material.

Article 93²

1. The following, in particular, shall be considered as biological inventions eligible for patent protection:

(i) inventions, the subject of which is biological material which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,

(ii) elements 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,

(iii) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety.

2. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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Article 93³

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. The following, in particular, shall be considered as biotechnological inventions, whose exploitation would be contrary to Public order or morality within the meaning of Article 29(1)(i), or with public morality:

- (i) processes for cloning human beings,
- (ii) processes for modifying the germ line genetic identity of human beings,
- (iii) uses of human embryos for industrial or commercial purposes,
- (iv) 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 93⁴

1. The protection conferred by a patent on a biological material possessing specific characteristics indicated in a patent claim or claims 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 indicated in a patent claim or claims 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.

3. 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 93³(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

Article 93⁵

1. The protection conferred by a patent shall not extend to biological material obtained by means of a single act of propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent, where the propagation or multiplication necessarily results from the application of the biological material.

2. Any party who has acquired or otherwise obtained the patented biological material from the holder of a patent or with his consent for agricultural use, shall be authorised to use it for propagation or multiplication on his own farm, the extent and conditions of this derogation being the same as provided for the use, without the plant breeder's consent, of plant propagating material of the plant variety protected under the regulations on seed production.

3. The provision of paragraph (2) shall apply accordingly to breeding stock or other animal reproductive material.

Article 93⁶

1. Where an invention involves the use of biological material which is not available to the public and which cannot be described in the description in such a manner as to enable the invention to be reproduced by a person skilled in the art, the disclosure thereof may be made by reference to the material deposited, at the latest at the filing date, in a depositary institution

recognised under an international agreement or in a national depositary institution, which is mentioned by the President of the Patent Office in an announcement published in the Official Gazette of the Republic of Poland "Monitor Polski".

2. The President of the Patent Office shall announce the acquisition of the status of the national depositary institution, referred to in paragraph (1), after having received, at the request of the institution concerned, acceptance from the minister competent in respect of the subject of deposited biological materials.

3. Where the deposit referred to in paragraph (1) has been made, the application must be accompanied by an attestation issued by the depositary institution, furnished by the applicant. The attestation should include at least the name of the institution, the date of the deposit and the accession number given to the biological material.

4. The attestation issued by a depositary institution may be furnished within six months from the filing date. In case of late furnishing of the said attestation the deposit of the biological material shall not be considered equivalent to its disclosure in the application.

5. Access to the deposit referred to in paragraph (1) before the publication of the particulars of the patent application shall be limited to the parties mentioned in Article 251(1). At the applicant's request submitted to the Patent Office before the publication of the particulars of the patent application, the above limitation shall extend for the entire term during which the application is processed.

6. After the particulars of the application have been published, unless the request referred to in paragraph (5) has been submitted, and after the patent has been granted, access to the deposit may not, subject to the condition referred to in paragraph (7), be denied to third parties. This provision shall apply accordingly notwithstanding invalidation or lapse of the patent.

7. The sample of the biological material shall be supplied only if the person requesting it undertakes in writing, vis-à-vis the applicant or the holder of the patent, for the term during which the patent remains in force:

- (i) not to make it or any material derived from it available to third parties,
 - (ii) not to use it or any material derived from it except for experimental purposes
- unless the applicant or the holder of the patent expressly waives such an undertaking.

8. Where the Patent Office makes a decision to refuse the grant of a patent or to discontinue the patent granting proceeding, access to the deposited biological material, at the applicant's request submitted within the term provided for in paragraph (5), shall be limited to the parties, mentioned in paragraph (5), for 20 years from the date on which the patent application was filed. The provision of paragraph (7) shall apply accordingly.

Article 93⁷

If the biological material deposited in accordance with Article 93⁶ ceases to be available from the depositary institution, a new deposit shall be permitted on the terms as laid down in an international agreement.