



Industrial Property Office of the Slovak Republic

Protection of Biotechnology Inventions in Slovakia within the European Context

WIPO International Seminar

Current Challenges in Intellectual Property Rights and
Biotechnology

Banská Bystrica, 2. - 3. May, 2007

History



- **1973-1990:** Act No. 84/1972 Coll. - author's certificate for microorganisms producing industrial goods
- **1989:** access to the Budapest Agreement on International Recognition of Microorganism Deposit for Purposes of Patent Proceeding and Its Implementing Regulation
- **1991-2001:** Act No. 527/1990 Coll. - patent protection of microorganism producing industrial goods, biotechnological processes and its products
- **1998:** Directive 98/44/EC on the legal protection of biotechnological inventions

The legal basis for granting biotechnological patents in Slovakia



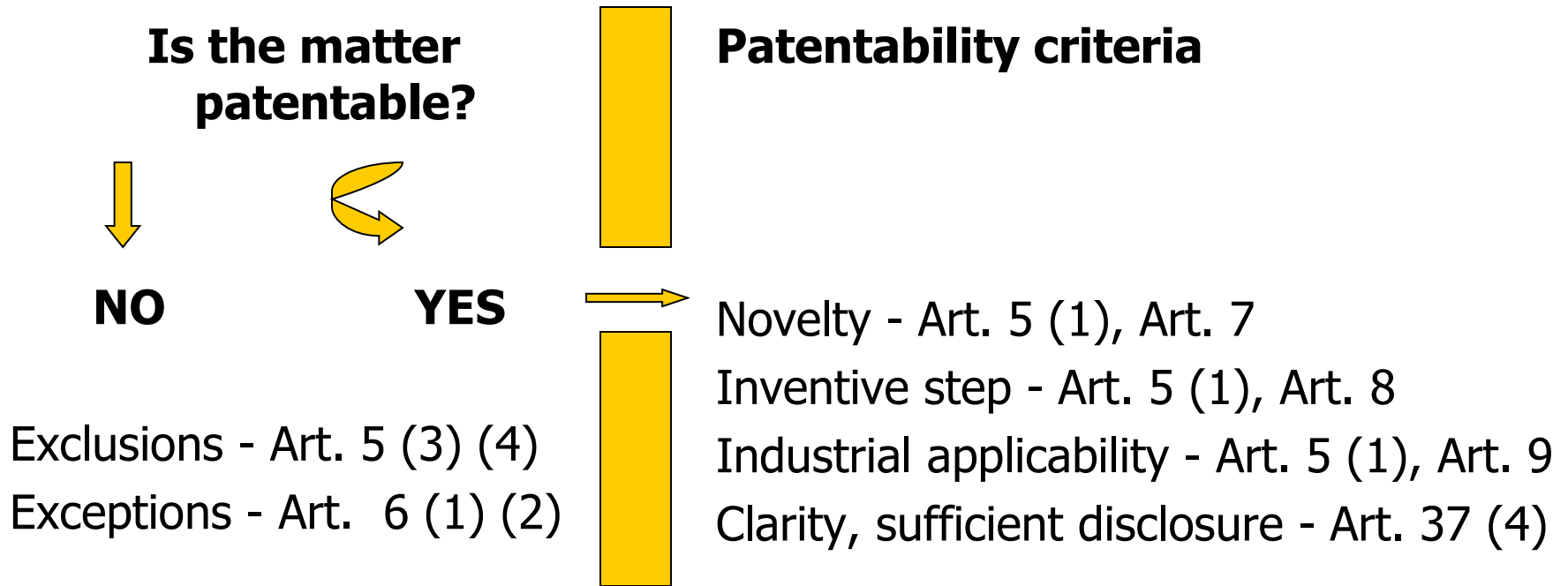
- **Act No. 435/2001 Coll.** on Patents, Supplementary Protection Certificates and on Amendments of Some acts as Amended (The Patent Act), which is in accordance with the EU Directive 98/44/EC on the legal protection of biotechnological inventions
 - ➔ Amended by the Act No. 402/2002 Coll. and Act No. 84/2007 Coll.
- **Decree No. 223/2002 Coll.** implementing the Act No. 435/2001 Coll. The Patent Act

Biotechnological inventions



- “inanimate material” such as structural proteins, antigens and enzymes (traditional biotech-products)
- “inanimate material” such as DNA, RNA, gene portions (modern biotech-products)
- “animate” matter such as microorganisms and cell lines (traditional biotech-products)
- “animate” matter such as plants and animals (modern biotech-products)

Borderline between patentable and non-patentable inventions



Basic patentability criteria

Art. 5 (1)



Patents shall be granted for inventions in

- ➔ **all fields of technology**
- ➔ which are **new**
- ➔ involve **inventive activity** and are
- ➔ susceptible of **industrial application**

Patentability of biotechnological inventions

Art. 5 (2)



Patents shall be granted for biotechnological inventions which concern

- **a product** consisting of or containing biological material
- **a process** by means of which the biological material is produced, processed or used

➔ Art. 3 (a)

biological material shall mean any material containing genetic information capable of reproducing itself or being reproduced in a biological system

Patentable subject-matter

Art. 5 (2)



- **biological material** which is isolated from its natural environment or is produced by means of a technical process, already occurred in nature
- gene, protein, cell, microorganism (bacteria, viruses and phages), tissue
- invention concerns a **plant** or an **animal**, if the technical feasibility of the invention is not confined to a particular plant or animal variety
- invention concerns a **microbiological** or other **technical process** or a **product** obtained by means of such process

Patentable subject-matter

Art. 5 (2)



- invention concerns 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, including the case when the structure of such an element is identical to the structure of a naturally existing element
- ➔ Art. 38 (8)
if the subject-matter of the application is a sequence or partial sequence of a gene, the **industrial application** of the invention has to be explained in the application

Non-patentable subject-matter

Art. 5 (3)



Exclusions

- discoveries, scientific theories and mathematical methods
e. g. DNA without function - industrial application
- presentation of information
e. g. database, 3D protein structure, crystal models

➔ Art 5 (4)

Subject-matters or activities stated in paragraph 3 shall be excluded from the patentability only to the extent to which a patent application relates to these subject-matters or activities as such

Non-patentable subject-matter

Art. 6



Exceptions to patentability

- plant and animal varieties - Act No. 132/1989 Coll. of the Legal Code about protection of the rights to the new plant varieties and animal breed in the sense of Act No. 22/1996 Coll., Act No. 435/2001 Coll. and Act No. 84/2007 Coll.
 - essentially biological processes for the production plants or animals
- ➔ Art. 3(c)
essentially biological process for the production of plants and animals shall be a process consisting exclusively of natural phenomena, such as breeding or selection

Non-patentable subject-matter

Art. 6



Exceptions to patentability

- methods of surgical or therapeutic treatment of the human or animal body and diagnostic methods and methods of illness prevention practised on the human or animal body
- inventions which concern the human body in various stages of its formation or development or concern the simple discovery of some elements of the human body, including the sequence or partial sequence of a gene
- inventions whose commercial exploitation would be in contradiction with public order or morality

Non-patentable subject-matter

Art. 6 (2)

Exceptions to patentability - not ethical

Inventions whose commercial exploitation would be in contradiction with **public order or morality**, in particular, shall not be considered patentable

- processes for cloning human beings - Convention on Human Rights and Biomedicine and its Additional Protocol on Prohibition of Cloning Human Beings
- processes for modifying the germ line genetic identity of human beings
- the use of human embryos for industrial or commercial purposes - Act No. 576/2004 Coll. on Health Care

Non-patentable subject-matter

Art. 6 (2)



Exceptions to patentability - not ethical

- processes for modifying the genetic identity of animals which are likely to cause suffering to the animals while not having substantial medical benefit for people or animals, or for animals which result from such processes
 - e.g. the naked mouse - transgenic mouse used to test hair cosmetic products

Special provision on the application of biotechnological invention

Art. 38 (1)

- If the subject-matter of an invention is biological material or the use of biological material, which is not publicly available and which cannot be described in the application in such a manner so as to be carried out by a person skilled in the art, the description shall be considered adequate only on condition that
 - ➔ **the biological material has been deposited** in a recognised depository institution no later than by the filing date of the application
 - ➔ the application as filed contains **information on the characteristics of the deposited biological material**, which was available to the applicant
 - ➔ the application states the **name and seat of the recognised depository institution**, as well as the **deposit number** of the deposited sample



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Thank you for your attention.

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