

Subregional Seminar on the Legal Protection of Biotechnology and Genetic Resources

Banska Bystrica, May 2 and 3, 2007

Biotechnology and Intellectual Property: Overview

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WORLD
INTELLECTUAL
PROPERTY
ORGANIZATION

Overview

- Some Distinctions
- Two Definitions
- The Intellectual Property Dimension
- The Policy Dimension



Some Distinctions

- **Broader: Technology based on biology**
traditional biotechnology used in agriculture, food science, medicine
examples: beer, bread, cheese, fermentation, plant and animal breeding
- **Narrower:**
modern biotechnology involving genetic engineering, biochemistry, bioinformatics, cell biology etc.
- **Red, green, grey, blue biotechnology**



Two Definitions

- Convention on Biological Diversity
- Cartagena Protocol on Biosafety



The Convention on Biological Diversity

Article 2. Use of Terms

"Biotechnology" means **any technological application that uses biological** systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.



Cartagena Protocol on Biosafety

Article 3 Use of Terms

- (i) "Modern biotechnology" means the application of:
- a. **In vitro nucleic acid techniques**, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - b. **Fusion of cells** beyond the taxonomic family, that **overcome natural** physiological reproductive or recombination **barriers** and that are not techniques used in traditional breeding and selection;



The Intellectual Property Dimension

- Paris Convention
- Budapest Treaty
- International Patent Classification
- WTO TRIPS Agreement
- Directive EC 98/44/EC on the Legal Protection of Biotechnological Inventions
- European Patent Convention
- National Patent Laws



Paris Convention for the Protection of Industrial Property (1883)

Article 1 Establishment of the Union; Scope of Industrial Property

(3) Industrial property shall be understood in the **broadest sense** and shall apply not only to industry and commerce proper, but likewise to **agricultural** and extractive industries and to all manufactured or **natural products**, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.



Budapest Treaty / IPC

- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)
 - Disclosure of an invention by the deposit of a sample of the microorganism, with a specialized institution
 - international recognition of the deposit with any “international depository authority”
- Strasbourg Agreement Concerning the International Patent Classification (1971)
 - classification of technology to find documents in a specific technology area
 - eighth edition: January 1, 2006



WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1995)

Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, **patents** shall be available for **any inventions**, whether products or processes, **in all fields of technology**, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable **without discrimination** as to the place of invention, the **field of technology** and whether products are imported or locally produced.



WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

Article 27 Patentable Subject Matter

2. Members may **exclude** from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect **human**, **animal** or **plant life** or **health** or to avoid serious prejudice to the **environment**, provided that such exclusion is not made merely because the exploitation is prohibited by their law.



WTO Agreement on Trade-Related

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Paris Convention

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Article

Article 4^{quater}

Patents: *Patentability in Case of Restrictions of Sale by Law*

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The **grant** of a patent shall **not be refused** and a patent shall not be **invalidated** on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to **restrictions or limitations** resulting from the **domestic law**.

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WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

Article 27 Patentable Subject Matter

3. Members may also **exclude** from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the **treatment** of **humans** or **animals**;
 - (b) **plants** and **animals** other than micro-organisms, and essentially **biological processes** for the **production of plants** or **animals** other than non-biological and microbiological processes. However, Members shall provide for the protection of **plant varieties** either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.



Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (1998)

Article 3

1. For the purposes of this Directive, **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.
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.



Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

- **Article 4**
(not patentable)
- **Article 5**
(the human body)
- **Article 6**
(*ordre public* or morality)



European Patent Convention

- **Article 52 Patentable inventions (EPC 2000)**

(1) European patents shall be granted for any inventions, in **all fields of technology**, provided that they are new, involve an inventive step and are susceptible of industrial application.

- **Article 53 Exceptions to patentability (EPC 2000)**

European patents shall not be granted in respect of:

- a) inventions the commercial exploitation of which would be contrary to "**ordre public**" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- b) **plant or animal varieties** or **essentially biological processes** for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- c) methods for **treatment** of the **human or animal** body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.



European Patent Convention

Biotechnological inventions

Rule 26 General and definitions (EPC 2000)

(2) "Biotechnological inventions" are **inventions** which **concern** a **product** consisting of or containing biological material or a **process** by means of which **biological material** is produced, processed or used.



National Law

(http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf)

- **Czech Republic:** Act No. 206/2000 Coll. L of 21-06-2000
- **Bulgaria:** Law on patents and utility model registration
(*Title amended, State Gazette No. 64/2006; in force as from 09.11.2006*)
- **Croatia:** Patent Act of 8-11-2003
- **Hungary:** Act. XXXIX of 2002
- **Poland:** Ustawa z dnia 30 czerwca 2000 r.
- Prawo własności przemysłowej adopted 30-06-2000
- **Romania:** Patent Law No. 64/1991,
as amended and completed by Law No. 203/2002 of 19 April 2002 (OJ Nr. 212/1991, Nr. 340/2002) approved by Government Decision No.499/2003 of 18 April 2003 (OJ Nr. 348 of 22 May 2003)
- **Slovenia:** Decree n° 3873 published on 18-08-2003
- **Slovak Republic:** Act. No. 435/2001 Coll. Patent Act



The Policy Dimension

Blood is a juice
of very special kind.

Johann Wolfgang Goethe, Faust



Biotechnology

- **Fundamental human needs and hope for new solutions**
 - food
 - health
 - environment
- **Questions with ethical implications**
 - technology and living beings
 - *ordre public* and morality
- **Questions with technical implications**
 - biodiversity and access and benefit issues
 - genetic transformation overlaps ‘classical’ plant breeding



Intellectual Property

- **Public policy role of intellectual property**
 - promotion of innovation
 - dissemination of technology
- **Private rights**
 - contract between private and public
 - rights, obligations and restrictions
- **Specific legal provisions, e.g.:**
 - TRIPS
 - Biotechnology directive
- **Specific questions, e.g.**
 - invention or discovery
 - privatization of nature
 - biotechnology inventions can be self-replicating
 - private rights and public funds



Approaches

- **Special legal provisions**
 - Art. 27 TRIPS, Directive EC 98/44/EC, plant variety protection
 - exceptions: *ordre public*, research, public interest use
- **Quality of patents**
 - patentable subject matter and patentability criteria
 - examination guidelines
- **Use of Patent information**
- **Review of practice**

