

# Subregional Seminar on the Legal Protection of Biotechnology and Genetic Resources

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## 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<sup>quater</sup>

#### 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](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**

