DEPARTMENT OF INTELLECTUAL PROPERTY
MINISTRY OF COMMERCE

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities

Topic 6: Flexibilities Related to the Definition of Patentable Subject Matter

Bangkok, Thailand
March 29 to 31, 2011

Patentable subject mater - TRIPs Agreement Art. 27

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, involved an inventive step and are capable of industrial application…

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**…

3. Members may also exclude from patentability:

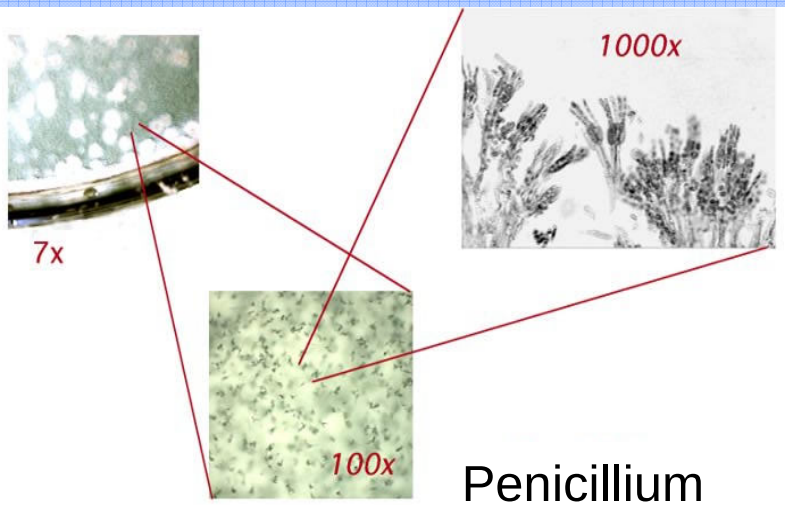
   (a) **diagnostic, therapeutic and surgical methods** (human or animals)

   (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.

Patentability of living material

Discovery

= Description of something that already exist

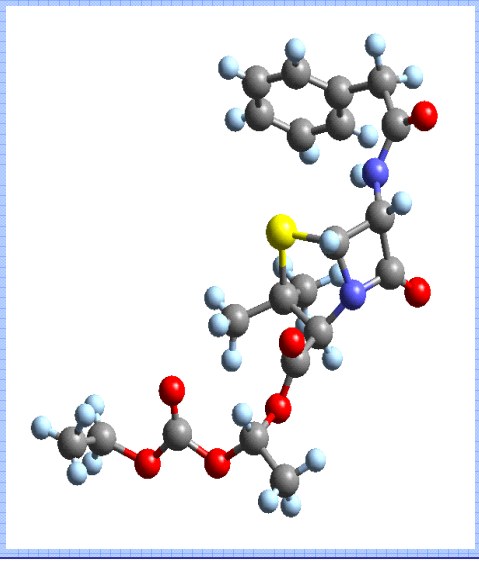


Penicillium notatum

Invention

= Instruction about solving a problem with technical tools

Penicillin



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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**…
3. Members may also exclude from patentability:

   (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

Article 4

1. The following shall not be patentable:

(a) **plant** and animal **varieties**;

(b) **essentially biological** processes for the production of plants or animals.

European Patent Convention

The Enlarged board* took the view that Art. 53(b) EPC defined the borderline between patent protection and plant variety protection. **The extent of the exclusion for patents was the obverse of the availability of plant variety rights.**

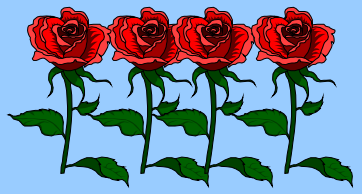
*of the EPO

European Patent Convention

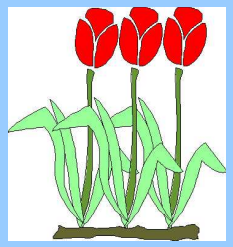
Thus, a **patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of the claims**. If plant varieties are individually claimed, they are not patentable, irrespective of how they were made
(**G 1/98** (OJ 2000, 111).

(**The term 'plant variety' is now defined** in the new R. 23b (4) EPC **in accordance with the UPOV Convention**)

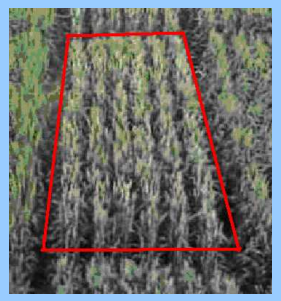
Invention X (e.g. herbicide tolerance HTX)



Variety A



Variety B

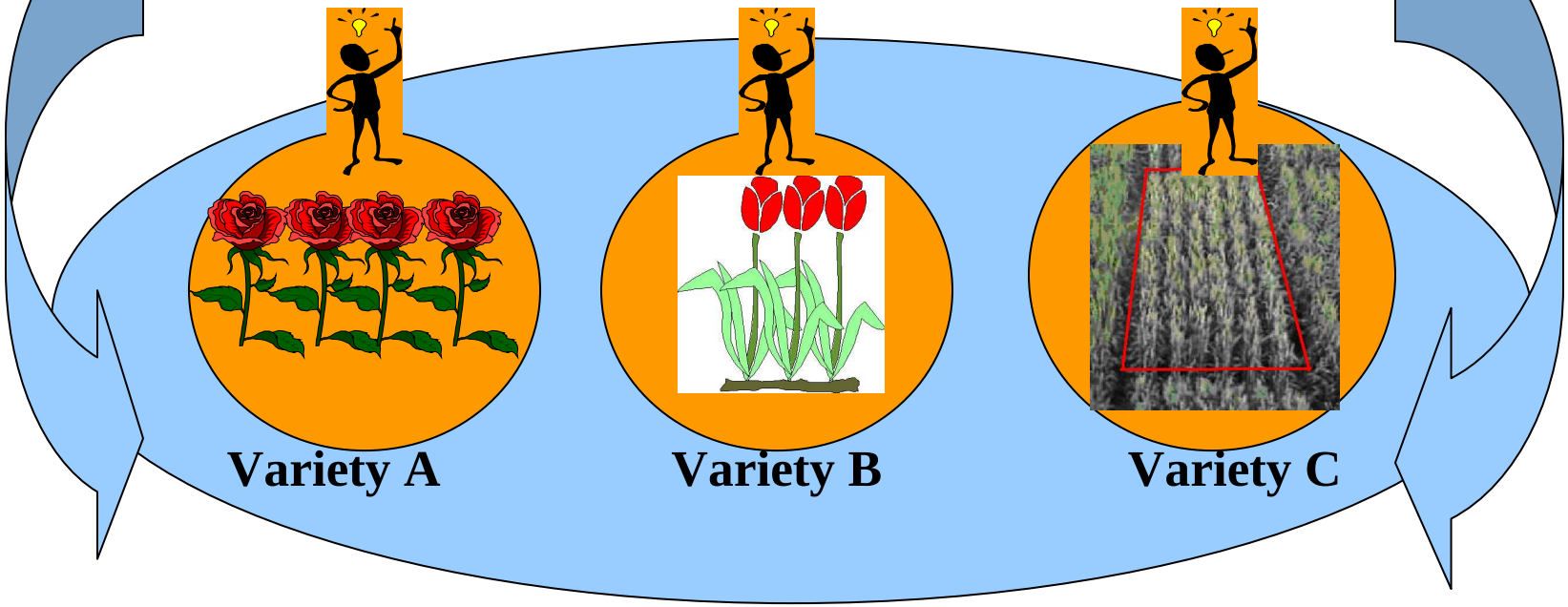


Variety C

Patent claim covering all HTX plants (therefore, varieties):
ACCEPTABLE

"DUAL PROTECTION"

Invention X



Patent protection	Invention X	Invention X	Invention X
Variety protection	Variety A	Variety B	Variety C

Micro-organisms

- the defining property is its microscopic size: it is something not visible to the naked eye. Decision of the Elarged Board of Appeals of the European Patent Office EPO in T 356/93 (OJ 1995, 545)

- Important differences exist in relation to what shall be comprised within that term.

  From the scientific point of view it is clear that a wide range of differences exist: i.e., while the Institute of Science UK states that " Multicellular organisms are normally not included, nor fungi, apart from yeast", another definition provided by Brock, Biology of Microorganisms includes "cells and cell clusters" and another definition, by Evans and Killington, includes "fungi".

  EPO case law (T 356/93) has established that micro-organisms comprise "bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plants cells…including plasmids and viruses".

Micro-organisms

- “The Absence of a definition of the term “microorganism” in TRIPS means that it is legitimate for WTO Member to make a reasonable definition themselves” (CIPR Report)
- except when the definition adopted by a given country has the effect of denying the protection provided for in TRIPS Agreement
- genetically modified microorganisms v. naturally occurring ones

Ethical limits to patentability

Some subject matter is excluded from patentability even if it constitutes an invention:

Inventions shall be considered unpatentable where their **commercial exploitation would be contrary to *ordre public* or morality;** however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

(Article 6(1) EU-Directive / Article 2(1) new Swiss Patent Law)

The human body

"The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, […], cannot constitute patentable inventions." **(Article 5(1) EU-Directive)**	**"The human body as such, at all phases of his formation and development, including the embryo, is not patentable."** **(Article 1*a*(1) new Swiss Patent Law)**

Gene sequences

"… a mere DNA sequence without indication of function does not contain any technical information [teaching] and is therefore not a patentable invention."

(Recital 23 EU-Directive)

"A naturally occurring sequence or partial sequence of a gene as such is not patentable."

(Article 1*b*(1) new Swiss Patent Law)

Gene sequences = patentable subject matter?

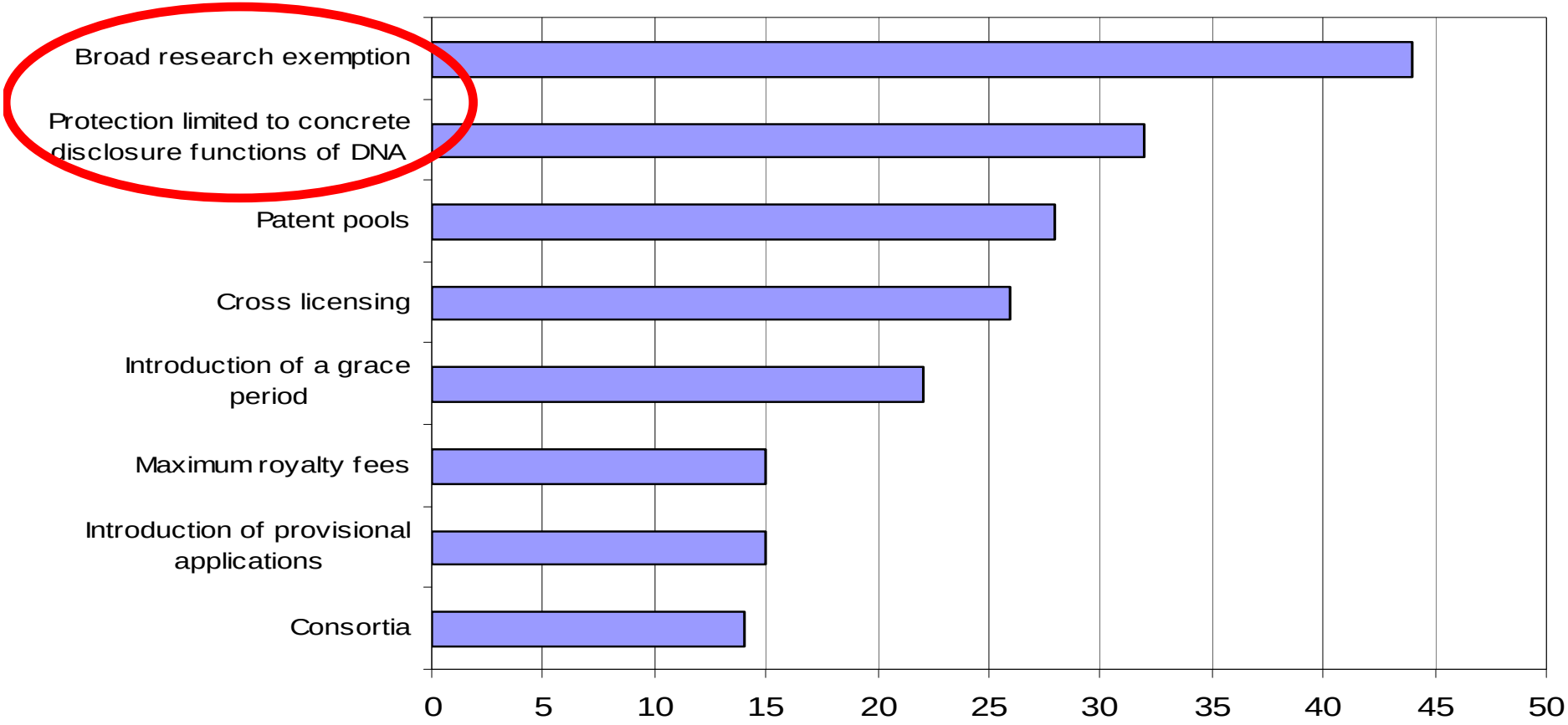
"An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

(Article 5(2) EU-Directive)

"Sequences deriving from a naturally occurring sequence or partial sequence of a gene are patentable as inventions, if they are produced by means of a technical process, if their function is concretely disclosed and if the other criteria of article 1 (novelty, inventive step, industrial applicability) are fulfilled."

(Article 1*b*(2) new Swiss Patent Law)

Possible remedies withim the IP system to solve the tension caused by the protection



CH Survey: 8.2 Remedies, Fig. 35 (named as many times as effectively to ...)
(http://www.ige.ch/E/jurinfo/documents/j10005e.pdf)

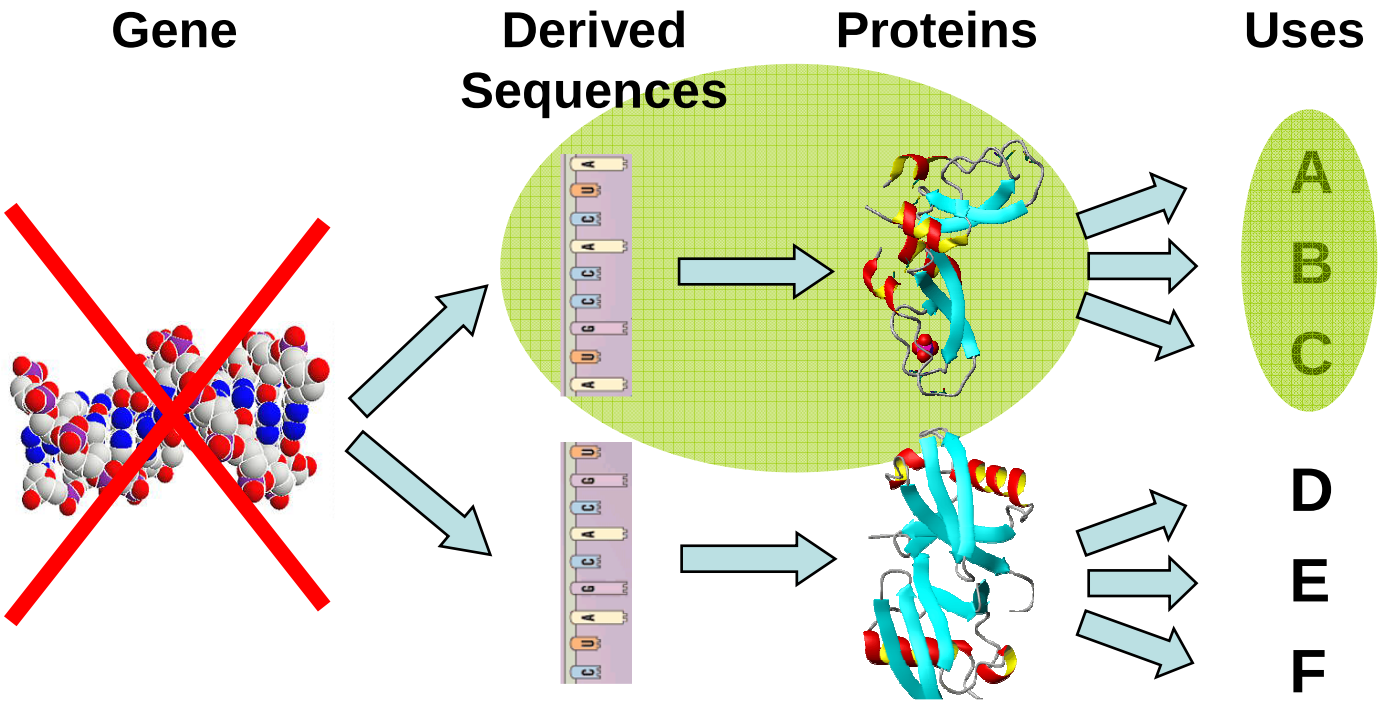
The approach of the new Swiss Patent Law: Absolute product claims on restricted sequences

Article 8*c* new Swiss Patent Law :

(DNA sequences: Scope of protection)

The protection of a claim, containing a nucleotide sequence, which is derived from a naturally occurring sequence or partial sequence of a gene, is restricted to those parts of the sequence, which is performing the concretely described function.

The approach of the new Swiss Patent Law



Patent laws that exclude from patentability subject matter that coincide with naturally occurring products

- Some LA Countries (such as Brazil, the Andean Countries, Argentina, Chile, the Dominican Republic, Nicaragua and Uruguay)

- There are important differences between these legislative provisions, but they share the idea that when a product already exists in nature, human intervention aimed to isolate, purify or produce synthetically the product does not suffice to make the outcome of the human development patentable.

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Thank you!

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