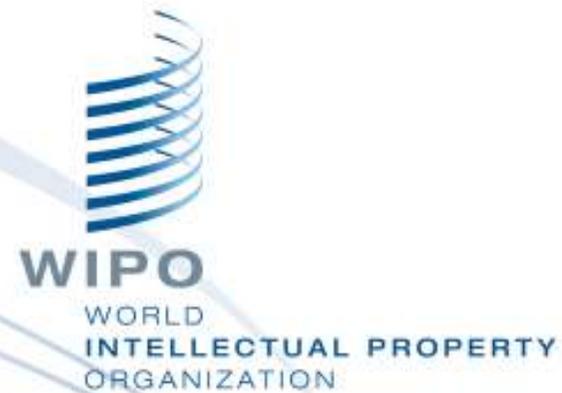




REPUBLIC OF SOUTH AFRICA



Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

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

**Durban, South Africa
January 29 to 31, 2013**



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Flexibilities Related to the Definition of Patentable Subject Matter



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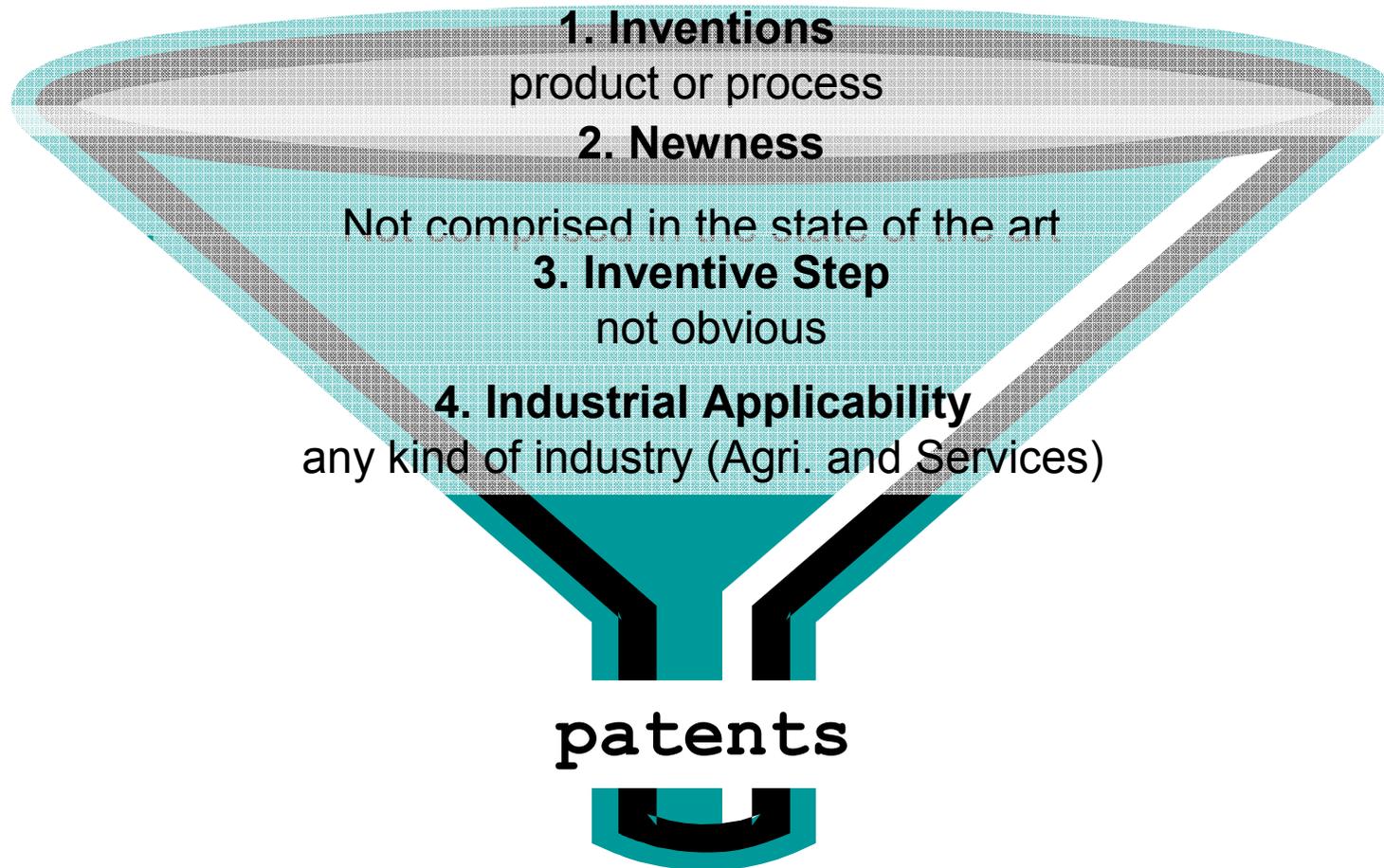
Marco M. ALEMAN

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Advice Section, WIPO

(Outline)

- **WIPO administered treaties do not deal with patentability subject matter**
- **The TRIPS Agreement (Art. 27) Deals with: criteria and **subject matter****
 - a. Expressly allows Members to excluded from patent protection
 - 1. Plant and animals, and essentially biological processes
 - 2. *Ordre public* or morality (prevention of com expl.)
 - 3. Diagnostic, therapeutic and surgical methods
 - b. Implicitly allow Members to exclude
 - 1. Discoveries
 - 2. Substances existing in nature
 - 3. Second medical use
 - c. Expressly oblige Members to protect
 - 1. inventions, whether products (including pharmaceutical, Art. 65.4) or processes, in all fields of technology (including pharmaceuticals and agricultural chemical products)
 - 2. micro-organisms

Patentability criteria



Patentable subject matter - 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.

Plants and animals

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.

Bangui Agreement, 1999, (Annex I) Article 6 (c).
“inventions having as their subject matter plant varieties, animal species and essentially biological process...”

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

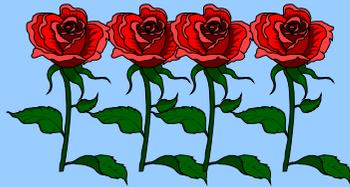
European Patent Convention

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

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Ethical limits to patentability

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

Bangui Agreement, 1999, (Annex I) Article 6 (a).

“inventions the exploitations of which is contrary to order public or morality, provided that the exploitation of the invention shall not be considered contrary...merely because it is prohibited by law or regulations”

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 1a(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?

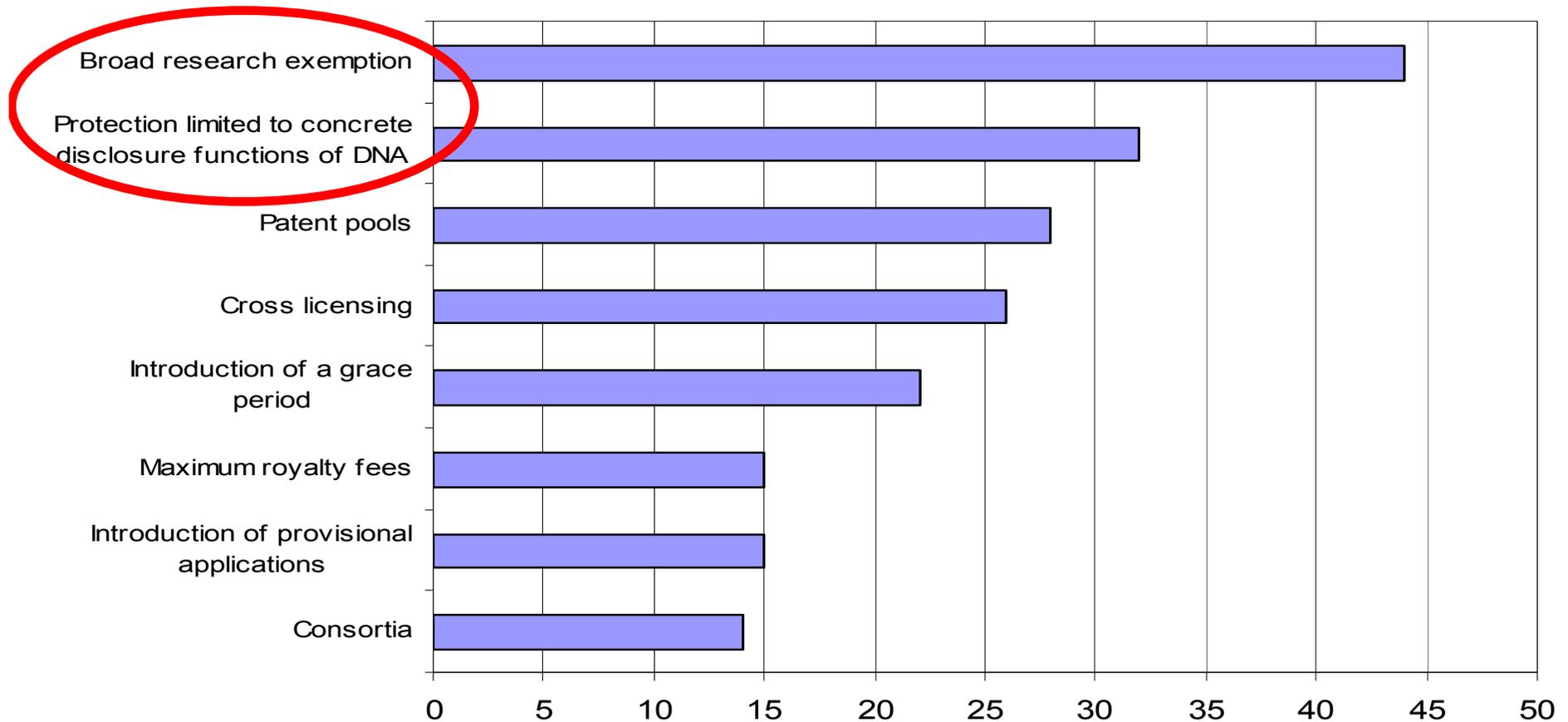
“An element **isolated** from the human body **or otherwise produced by means of a technical process**, including the sequence or partial sequence of a gene, may constitute a **patentable** invention, even if the structure of that element is identical to that of a natural element.”

(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 1b(2) new Swiss Patent Law)

Possible remedies within 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>)

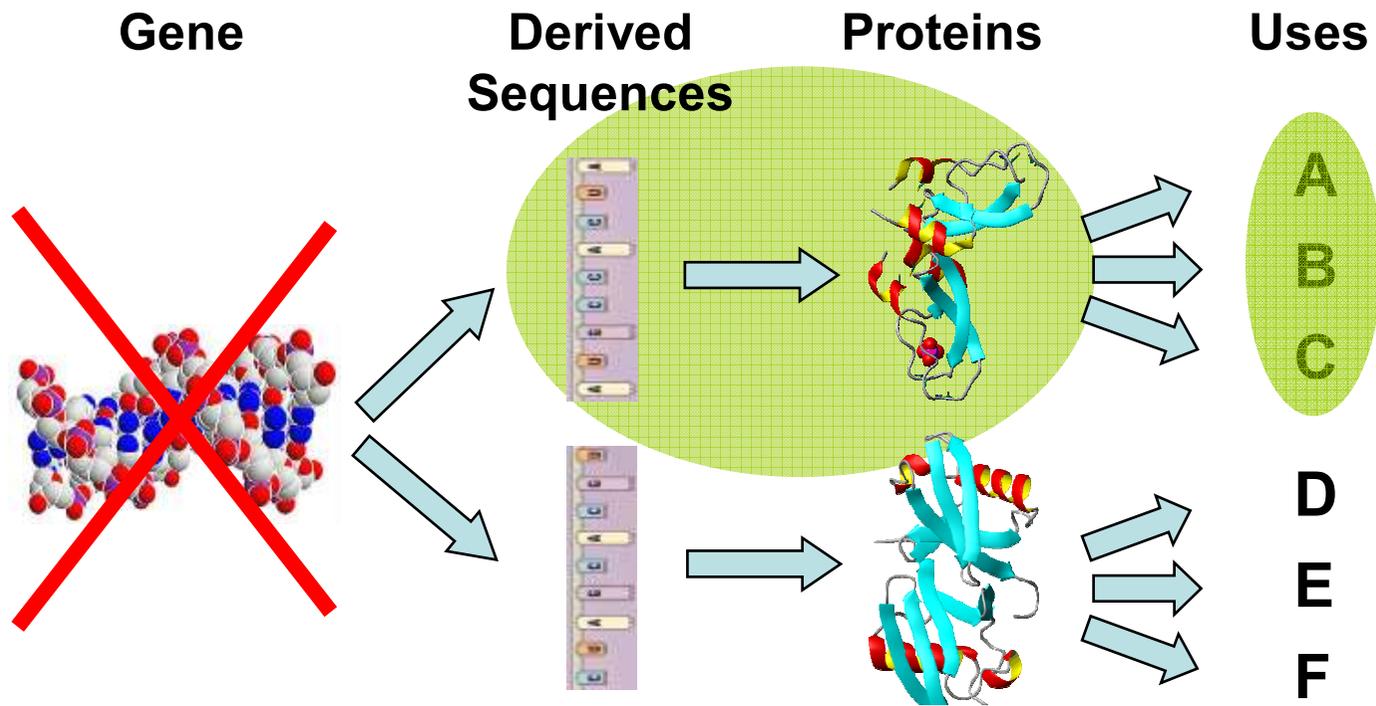
The approach of the new Swiss Patent Law: Absolute product claims on restricted sequences

Article 8c 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



Patentable subject matter - TRIPs Agreement Art. 27

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3. Members may also exclude from patentability:
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 - (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.

Diagnostic, therapeutic and surgical methods

Bangui Agreement, 1999, (Annex I) Article 6 (e). “methods for the treatment of the human or animal body by surgery or therapy, including diagnostic methods”

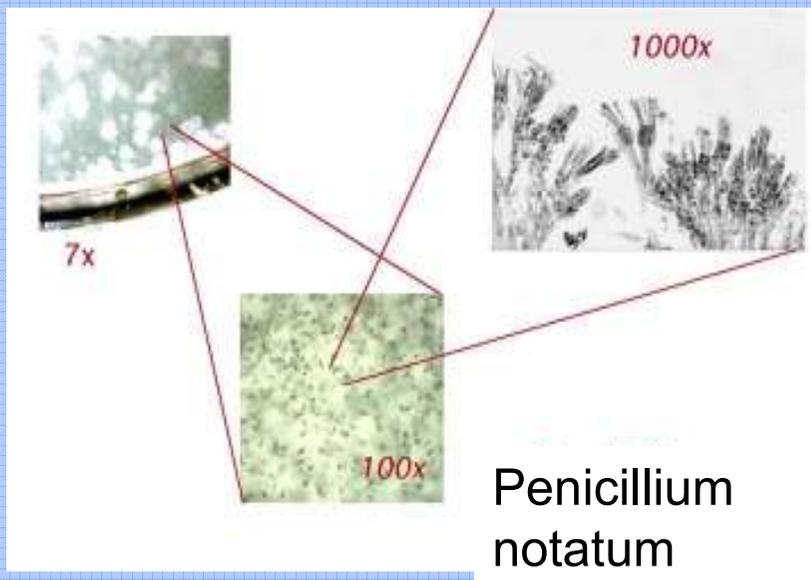
SA Patents Act No. 57 of 1978, Section 25 (11). “ An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnostic practiced on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture”

■ Discoveries

Patentability of living material

Discovery

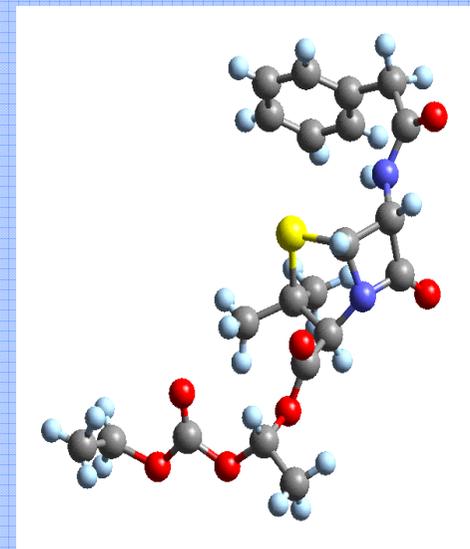
= Description of something that already exist



Invention

= Instruction about solving a problem with technical tools

Penicillin



■ Patentability of Substances existing in nature

International Legal framework



- Art. 27.3 TRIPs
 - No definition of products of nature or discoveries
 - No specific notion of invention
 - No explicit obligation to protect or exclude from protection products of nature
 - Mandatory protection for microorganisms (but no definition)

- Budapest Treaty on the International Recognition of the Deposit of Microorganisms → deposit of a microorganism worth as a description of the invention

Patentability of substances existing in nature

- Products of nature doctrine: not patentable given they constitute a mere work of nature without any human contribution
- Attention: patent protection for processes using living organisms is widely accepted
- Biotechnology



Love-in-a-Puff (*Cardiospermum*)

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)
- Some legislation contain an express general exclusion from patentability of substances existing in nature (Djibouti, Zambia and Zimbabwe) and/or discovery (Botswana, Ethiopia, Ghana, Kenya, Liberia, Rwanda, Uganda and SA)

discovery

- **BOTSWANA:** *Section 9 (1) (a) of the Industrial Property Act No. 14 of 21/08/1996.* For the purposes of this Act, the following shall, even if they are inventions, not be protected as patents: “a discovery”
- **GHANA:** *Section 1(3) (a) and (b) of the Patent Law No. 305A of 30/12/1992.* The following shall not be regarded as inventions within the meaning of subsection (1) of this section: “discoveries”

substances existing in nature

- DJIBOUTI: *Articles 26 (a) and (c) and 27(a) of the Protection of Industrial Property Law No.50/AN/09/6th L of 21/06/2009* Ne sont pas considérées comme des inventions : « les découvertes, les substances, matières et organismes tels qu'ils existent dans la nature, ainsi que leurs parties ou éléments »; « le corps humain et les matières qui composent le corps humain aux différents stades de sa constitution et de son développement ainsi que ses éléments y compris la séquence ou la séquence partielle d'un gène »
- ZAMBIA: *Section 14 (7) of the Patent Act of 1958 (Chapter 400) as last amended by Act No. 26 of 28/12/1987* “Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature”.
- ZIMBABWE: *Section 9 (7) of the Patents Act (Chapter 26:03) no. 26 of 1971 as last amended by Act 20/1994 (S.7)* “Where a complete specification claims a new substance, the claims shall be construed as not extending to that substance when found in nature”.

Legislative implementation. Specific provisions allowing or excluding

- Specific provisions allowing (e.g., [EU](#)) or
- excluding the patentability of subject matter that consists of, or which is derived from, naturally occurring products (in others regions [Brazil and Andean Community](#) are examples; in Africa [Rwanda](#))

Specific provisions allowing

- EUROPEAN UNION: *Articles 3 (2) of the Directive 98/44/EC of 06/07/1998 on the legal protection of biotechnological inventions.*

“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”

Specific provisions excluding

- Law No. 9,279 de 1996 of Brasil.

Article 10. The following are not considered to be inventions or utility models:

“IX. all or part of natural living beings and biological materials found in nature, **even if isolated therefrom**, including the genome or germoplasm of any natural living being, and the natural biological processes”

Article 18. The following are not patentable:

“II. all or part of living beings, except **transgenic microorganisms** that satisfy the three requirements of patentability—novelty, inventive step and industrial application—provided for in Article 8 and which are not mere discoveries.

Sole Paragraph. For the purposes of this Law, **transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions.**”

Specific provisions excluding

- RWANDA: *Article 18 (1) 1), 4) and 6) of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property.* The following shall be excluded from patent protection even if they constitute inventions under article 5 (7): of this Law;

4) substances, even if purified, synthesized or otherwise isolated from nature; nevertheless, this provision shall not apply to the processes of isolating those substances from their original environment;

6) plants and animals, including their parts, other than micro-organisms, and essentially biological processes for the production of plants or animals and their parts, other than non-biological and microbiological processes and products obtained from those processes;

■ Second Medical Use

Second Medical Use

The practice of the EPO Art. 54 (5)

The first medical use.

Special concept of Novelty (T 128/82)

Purposed related product claim (G 5/83)

Second or further Medical use.

Claims drafting (use or method: T 893/90)

The exclusion from patentability (therapeutic methods)

Second or further second (non medical) use (T 231/85)

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

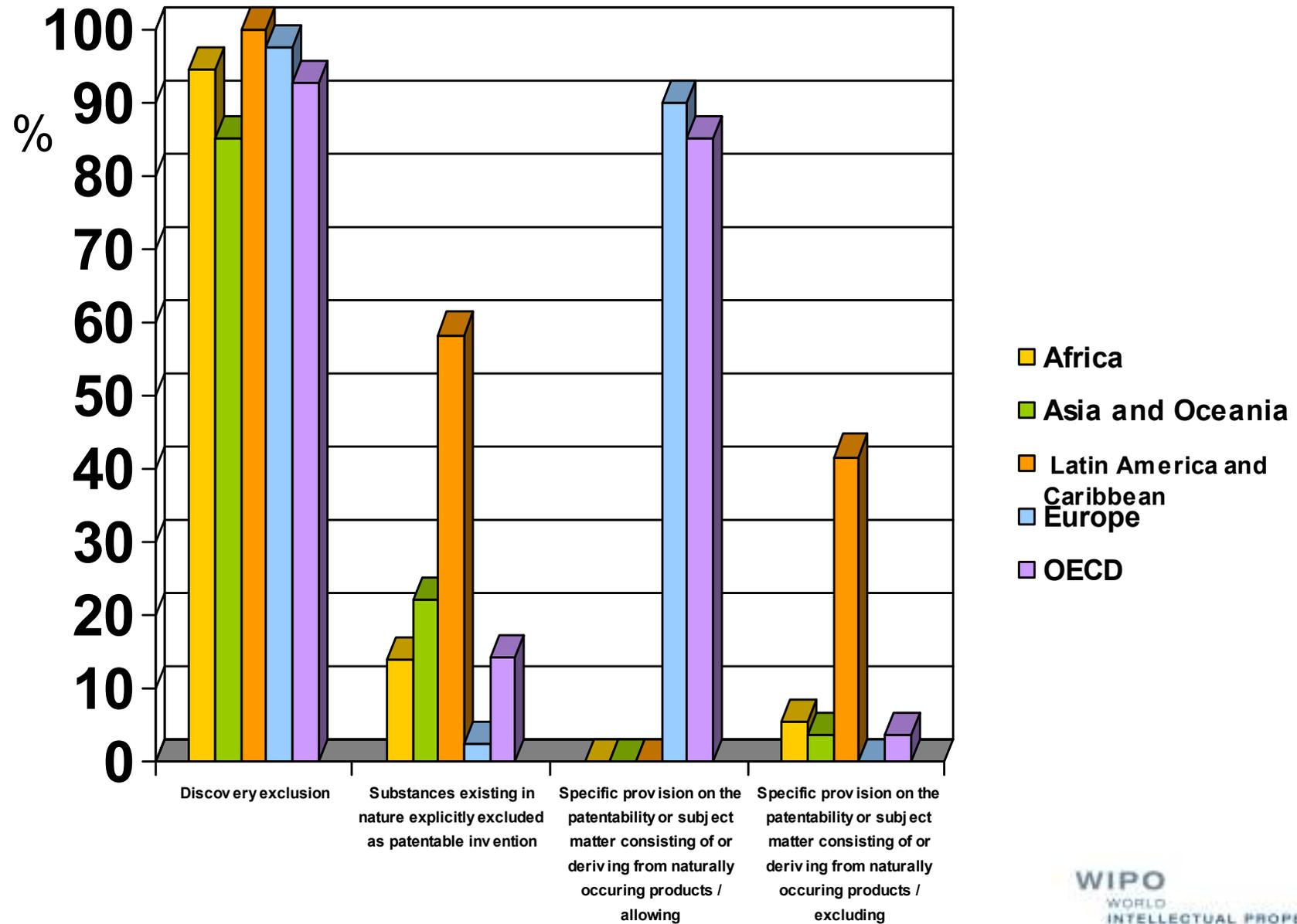
Micro-organisms

- the defining property is its microscopic size: it is something not visible to the naked eye. Decision of the Enlarged 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”.

Patentability of substances existing in nature



Many thanks
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