WIPO Sub-Regional Workshop on Patent Policy and its Legislative Implementation

Topic 9: The implementation of multilateral patent-related flexibilities on the national patent law of Caribbean countries

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PATENT RELATED FLEXIBILITIES. LEGISLATIVE IMPLEMENTATION

- I. The Multilateral legal framework of patents
- II. The implementation of Multilateral Treaties
- III. The implementation of Multilateral flexibilities in certain Caribbean countries
- IV. WIPO Surveys and Discussions

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I. The Multilateral Legal Framework

- Total freedom of countries
- 1883: Paris Convention (asymmetries)
- 1994: TRIPS Agreement. The period of minimum standards

II. Implementation of Multilateral Treaties on Patents

- Direct Implementation vs. Adoption of national laws
- Self executing vs. Non-self executing international law
- Room to manœuvre left to the national legislator

Tentative working definition

Idea of « alternative ways » for:

- Legislative implementation

- To accommodate national interests

It goes without saying that all this ways must be compatible with the provisions and principles of the Treaty

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III. Some examples of flexibilities

- Exhaustion of rights
- Utility Models
- Patentability of Substances existing in nature
- Disclosure related Flexibilities
- Substantive examination
- Compulsory licenses and Government Use
- Research exemption
- Regulatory review (*Bolar*) exception

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Exhaustion of rights

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Territoriality

- Patent rights, like other intellectual property rights, are territorial in nature, which means that each patent provides its owner the exclusive right of exploiting the invention within the limits of the country or countries where the patent was granted.
- One invention could be the object of patent protection in several countries, creating rights that are independent from each other (Article 4*bis* Paris Convention)

TRIPS Provisions

- Article 28 of the TRIPS Agreement (Rights Conferred) enumerates the exclusive rights. It includes among them the “right of importation” because the exclusive right derived from a patent could be affected by the importation of the patented product from another country.
- Article 28 contains a footnote regarding the right to prevent importation, stating that this right, “like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.
- Article 6 of the TRIPS Agreement does not establish which level of exhaustion (i.e., national, regional or international) members shall adopt.

National Exhaustion

- National level of exhaustion, the rights of the owner of the patent are exhausted only in respect to goods that have been put on the market in the country with his consent.
- It seems that this level of exhaustion has been adopted by several Caribbean countries: Barbados, Belize, Dominica, Grenada and Trinidad & Tobago.

Exhaustion (national)

BARBADOS : *Article 6 b) of the Patent Act No. 18 of 26/07/2001*

[Limitations of rights.]

6.-(1) The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to

(b) acts in relation to products that have been put on the market in Barbados by the owner of the product or with his consent;

Regional exhaustion

- Regional exhaustion takes place when goods are released with the consent of the owner of the patent in any country member of a regional market or union.

- An example of regional exhaustion is that of the European Union, based on Articles 28 and 30 of the Treaty of Rome dealing with the free movement of goods.

EU Exhaustion regime

- The elaboration of the regional exhaustion doctrine in the European Union goes back to a groundbreaking decision of the European Court of Justice (ECJ) in the early 1970s. *Deutsche Grammophon, GmbH v Metro-SB-Grossmarket, GmbH & Co,* Case 78/70, [1971].

- "the guarantee that the patentee, to reward the creation effort of the inventor, has the exclusive right to use the invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grand of licenses to third parties, as well the right to oppose infringements" ECJ, Case 15-74 [1974], *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc*.

International exhaustion

- Under a system of international exhaustion, goods put on the market by or with the consent of the patent owner anywhere in the world would result in the patent owner's rights being exhausted in the country concerned.
- Some examples of countries applying international exhaustion are: In Africa, Egypt (Section 10(1) of the Law on the Protection of Intellectual Property Rights no. 82/2002) and South Africa (Section 15c of the Medicines Act). Also several Latin-American countries have adopted international exhaustion, such as Argentina (Article 36c) of the Patent Law), the Member countries of the Cartagena Agreement (Art. Decision 486), and Costa Rica (Section16 of its Patent Law of 25/04/1983, No. 6867). In Asia, some examples are: India, Malaysia and China (it seems that Article 63 of the Patent Law, modified in 2009, provides an international exhaustion system).
- In the Caribbean region Antigua and Barbuda has adopted this type of exhaustion regime.

Exhaustion (international)

ANTIGUA AND BARBUDA : *Section 11 (4) a) of the Patent Act No. 23 of 2003*

Rights conferred 11.

(4) (1) The rights under the patent shall not extend:

(a) to acts in respect of articles which have been put on the market in any country by the owner of the patent or with his consent; or

No legislative provisions, so case law…

- Certain countries, such as Japan[1] or the United States of America,[2] have not adopted express legislative provisions on exhaustion, leaving it to jurisprudence to determine the evolution of this matter;

  [1] In Japan, a recent decision of the Supreme Court seems to point to an international level of exhaustion (*Recycle Assist, Co. Ltd. v Canon, Inc*., Japan Supreme Court, Heisei 18 (jyu) 826).

  [2] In the U.S.A. the exhaustion doctrine has been developed since the 1873 case *Adam v Burke* in which the Supreme Court enunciated the principle according to which a patent's monopoly ends with the first sale or disposition of an article embodying the claimed invention by the patentee, or by a licensee of the patentee acting within the scope of the license. Historically this doctrine seems more oriented towards national exhaustion, but openings to international exhaustion are found in a recent decision of a U.S. federal court of first instance, *LG Electronics Inc. v Hitachi, Ltd*. (No. 07-6511 CW, ND Cal, 13th March 2009).

Utility Models

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Different system of Utility Model protection

- Three Dimensional Regime → the protectable invention must be embodied in a three dimensional form
- Patent type regime → same requirements to obtain a patent. Differences at level of examination (only formal for UM) and sometimes at the level of a “less stringent” inventive step required.
- In certain Caribbean countries there is no definition of UM, namely, Antigua and Barbuda, Belize, Dominica and Trinidad & Tobago; so it would be difficult to categorize them among the two systems

Example of three dimensional type regime

- JAPAN : *Articles 3 of the Utility Model Act No. 123 of 1959 as last amended by Act No. 55 of 2006*

- *Article 3 (Conditions for Utility Model Registration)*

(1) A creator of a device that relates to the shape or structure of an article or combination of articles and is industrially applicable may be entitled to obtain a utility model registration for the said device (…)

Example of patent type regime

- MALAYSIA : *Sections 17 of the Patent Act of 1983 as last amended in 2006*

- *Section 17*. Definition. For the purposes of this Part and any regulations made under this Act in relation to this Part, “utility innovation” means any innovation which creates a new product or process, or any new improvement of a known product or process, which is capable of industrial application, and includes an invention.

Main features of Utility Models (1)

Substantive criteria

- The conditions for granting UM are less stringent than those of patents:

  Novelty may be “universal”, “relative” or “local”.

  Certain Caribbean Countries do not require Inventive Step, namely, Antigua and Barbuda, Belize, Dominica and Trinidad & Tobago, but request novelty and industrial applicability
- UM may, in some countries, be limited to certain fields of technology and available only for products (not for processes. Above all in three-dimensional regime type)

  Certain Caribbean Countries excludes from UM protection the same of what is exclude from patents, namely, Antigua and Barbuda, Belize, Dominica and Trinidad & Tobago

Article 22 of the China Patent Law

Article 22. Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and usefulness.

- "Novelty" means that the invention or utility model shall neither belong to the prior art, nor has any entity or individual previously filed before the date of filing with the patent administrative department under the State Council an application on an identical invention or utility model which was recorded in patent application documents or other gazette patent documents published after the said date of filing.
- "Inventiveness" means that, compared with the prior art the invention has prominent and substantive distinguishing features and represents a marked improvement, or the utility model possesses substantive distinguishing features and represents an improvement.
- "Usefulness" means that the invention or utility model can be made or used and can create positive results.

The "prior art" referred to in this Law refers to any technology known to the public before the filing date of the patent application in China or abroad.

Example of different items excluded from UM protection

DOMINICAN REPUBLIC: Article 51 of the Industrial Property Law No. 20-00 of 08/05/2000

Article 51.- Items Excluded from Protection as Utility Models

The following cannot be the object of a patent for utility model:

a) procedures.

b) chemical, metallurgical or any other kind of substances or compounds.

c) items excluded from protection by invention patent invention pursuant to this law.

Main features of Utility Models (2)

Granting procedure

- Procedures for granting UM are generally faster and simpler than for patents:
  - only formal examination
  - voluntary substantive examination

- Acquisition and maintenance fees generally lower than those applicable to patents

Main features of Utility Models (3)

Duration of protection

- Shorter that that given to patents

  Between 6 and 15 years (Malaysia: 20 years).

  Most commonly 10 years (China, Costa Rica, Indonesia)

- Kazakhstan, Kyrgyzstan and Belarus: 5 years, renewable for other 3 years

- Thailand, Portugal and Romania: 6 years, renewable for two periods of 2 years each

- Japan: 3 years, renewable for 3 years

- Patentability of Substances existing in nature

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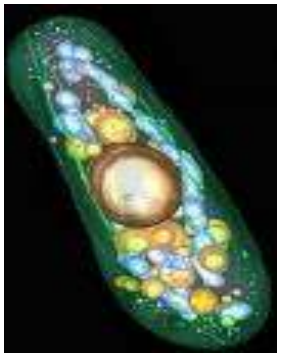
Patentability of substances existing in nature

- 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



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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

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?

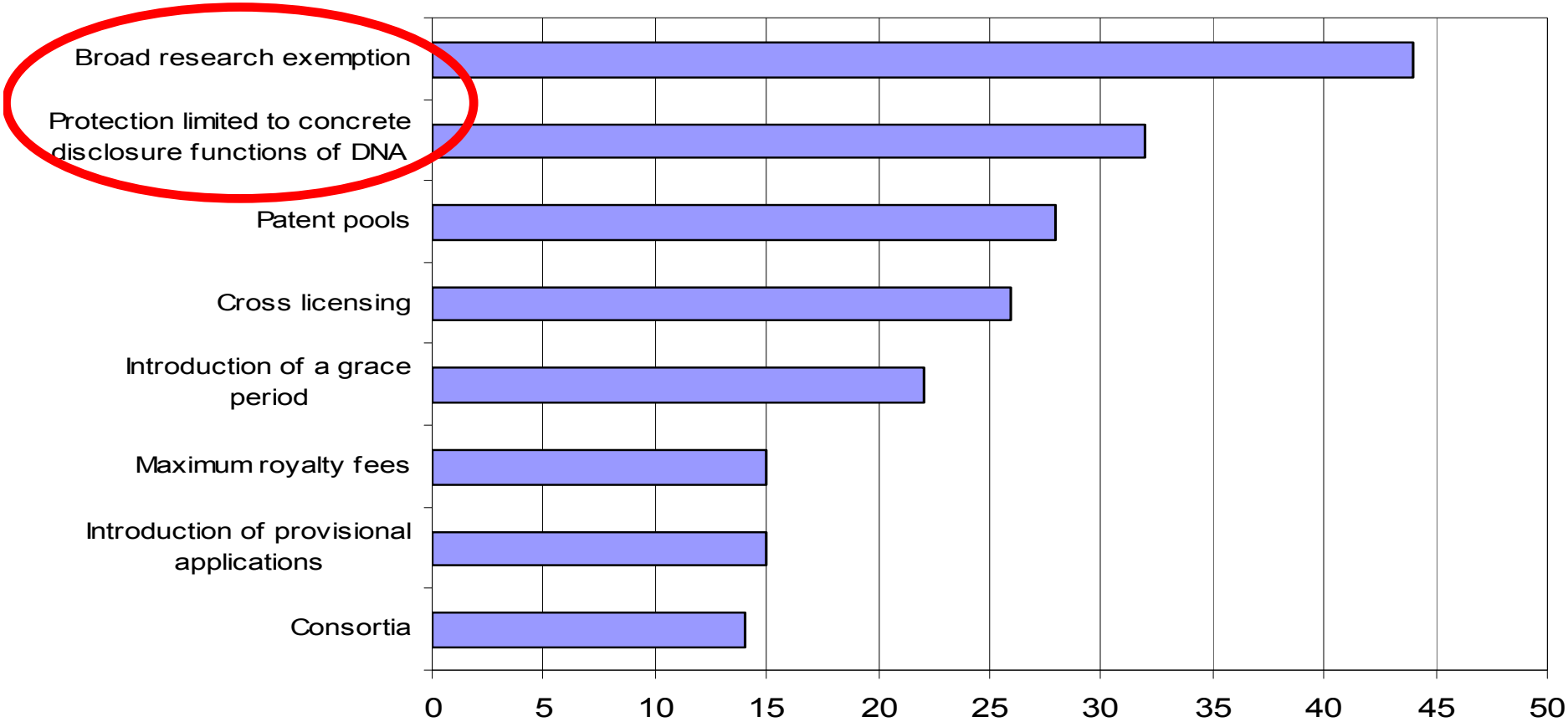
"An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

(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)

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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.

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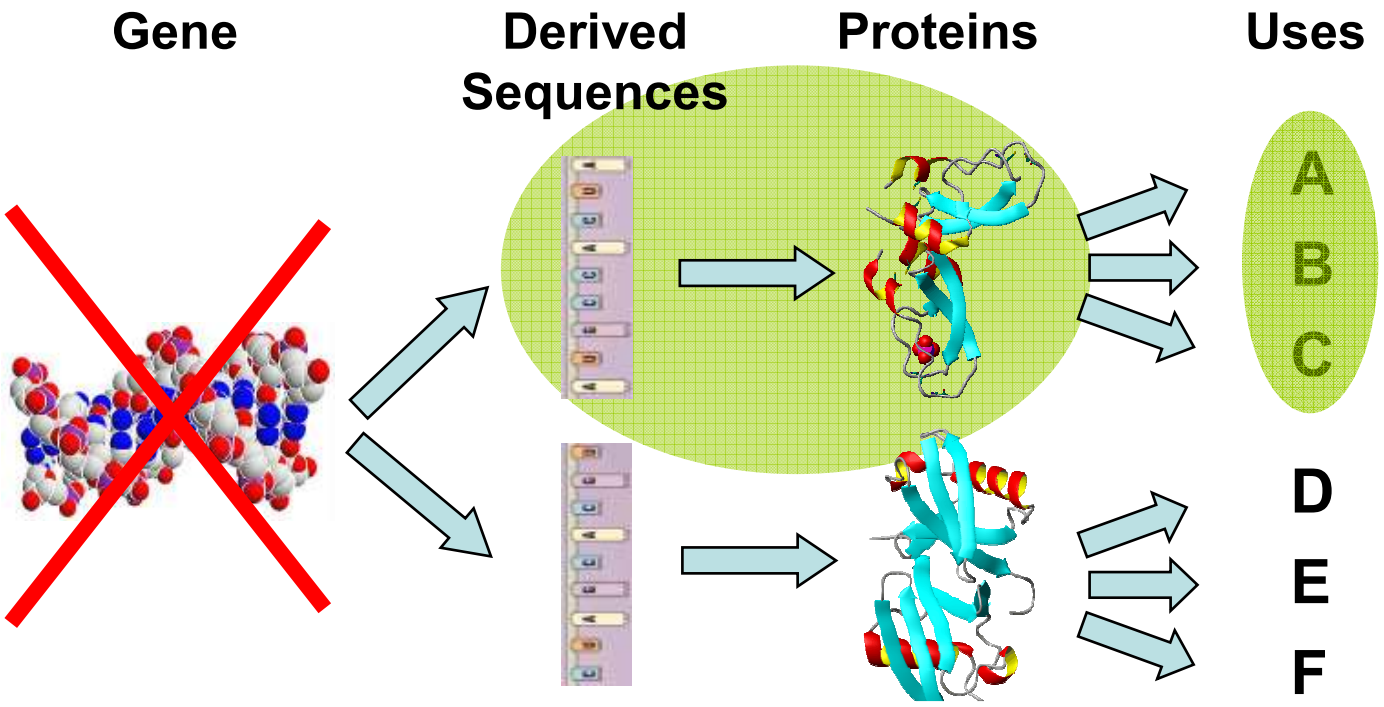
The approach of the new Swiss Patent Law



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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.

Legislative implementation

- Express general exclusion from patentability of substances existing in nature (no in the Caribbean region) and/or discovery (Antigua and Barbuda, Barbados, Belize, Dominica, Grenada, Saint Lucia and Trinidad & Tobago)

- Specific provisions allowing (no in the Caribbean region) or excluding the patentability of subject matter that consists of, or which is derived from, naturally occurring products (no in the Caribbean region)

discovery

- ANTIGUA AND BARBUDA: *Section 2 (2) (i), (iv) and (v) of the Patents Act No. 23 of 29/12/2003*

  (2) The following, even if they are inventions within the meaning of subsection (I), shall be excluded from patent protection:

  (i) discoveries, scientific theories and mathematical methods;

substances existing in nature

- INDIA: *Section 3 (c) and (j) of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005*

  3. What are not inventions

  The following are not inventions within the meaning of this Act;

  c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

Specific provisions allowing

- SLOVAKIA: *Articles 5 (2) and (3) (a) and 6 (1) (b) and (d) of the Patent Act No. 435/2001 as last amended by Act No. 202/ 2009 Coll.*

  Article 5 Patentable subjects

  (2) Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilized, including cases when invention relates to

  a) biological material which is isolated from its natural environment or is produced by means of a technical process, already occurred in a nature,

  d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element.

Specific provisions excluding

- BRAZIL: *Sections 10 (I) and (IX) and 18 II of the Industrial Property Law No. 9.279 of 14/05/1996 (as last amended by Law No.10.196, of 14/02/2001) and Article 31 of the Provisional measure No. 2.186-16*

  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.

Disclosure related Flexibilities

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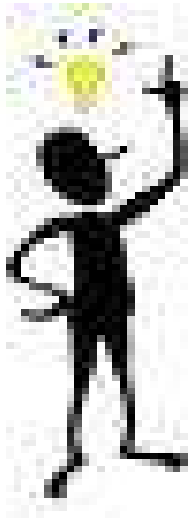
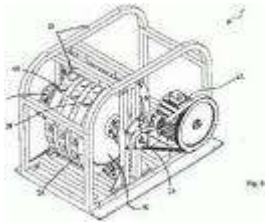
Disclosure related flexibilities

- Notion: description of the invention by the inventor/applicant, who shares with society the content of his/her invention making the knowledge contained in the patent application available to everybody in order to stimulate future innovation.





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Disclosure: main elements

The inventor shall:

- Describe his/her invention clearly enough to allow an expert in the field/skilled in the art, to understand it and make and use it without undue experimentation
- Set the boundaries of what he/she is claiming to be protected by the description→ claims shall be supported by the description

Elements of the disclosure

- Enablement
- Written description
- Best mode

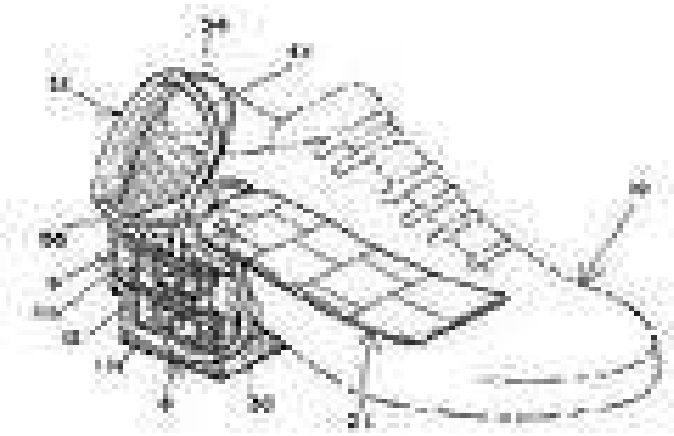

FIG.2

International legal framework

- Art. 29.1 TRIPS

- Invention disclosed in a clear and complete manner
- Allowing a person skilled in the art to carry out the invention

- Art. 29.2 TRIPS: information concerning the applicant's corresponding foreign applications and grant

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Substantive examination

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Substantive examination

- Control concerning the compliance with conditions of patentability of the invention
- Pros: legal certainty of the patent and confidence in the patent system by society at large
- Cons: complex tasks and cost associated with it

Different options of examination

- Mere formal examination
- Formal examination + prior art search (But: no substantive examination!)
- Substantive examination

International legal framework

- Art. 12 of the Paris Convention
- Special Industrial Property Service
- Publish an Official Periodical Journal (proprietors of the patents granted and a brief designation of the invention)
- Art. 62 of the TRIPS
- Subsection 1: principle of reasonableness of procedure
- Subsection 2: taking place of the procedure within a reasonable period of time

Compulsory licenses

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Compulsory licenses

Country	Provisions of Law
Antigua and Barbuda	Sections 13-14 of the Patent Act No. 23 of 2003
Barbados	Articles 49 and 50 of the Patents Act no. 18 of 26/07/2001
Belize	Articles 38 and 39 of the Patents Act, Chapter 253, of 21/06/2000
Dominica	Sections 35, 38 and 39 of the Patent Act No. 8 of 7/10/1999
Grenada	Sections 14 and 14 A of the Industrial Property Bill of 2002
Saint Lucia	Sections 51-61 of the Patents Act No. 16 of 27/08/2001
Trinidad and Tobago	Sections 46-48 of the Patents Act No. 21 of 1996

Research Exemption

- *Canada-Patent Protection of Pharmaceutical Product* case (DS114) the WTO Dispute Settlement Panel has referred to the research exemption as “one of the most widely adopted Article 30-type exceptions in national patent laws”.
- The panel defines the research exemption as follows:

  “the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement”.
- Certain Caribbean Countries includes this exception expressly in their laws, namely, Antigua and Barbuda, Barbados, Belize, Dominica, Grenada, Saint Lucia and Trinidad & Tobago

Research Exemption

- ANTIGUA AND BARBUDA : *Section 11 (4) c) of the Patent Bill No. 23 of 2003*

(4) (1) The rights under the patent shall not extend:

(c) to acts done only for experimental purposes relating to a patented invention;

- BARBADOS : *Article 6 (1) of the Patents Act, 2001-18*

Article 6(1): The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to:

(a) the use of the invention for scientific research only;

Regulatory review exception

- Various entities are vested with the power to authorize the commercialization of certain regulated products (pharmaceutical products, herbicides and pesticides, animal feeding stuffs, flavoring substances and medical equipment).
- The process of marketing authorization takes place in parallel with and independently of the process of protection for the invention of the product for which authorization is sought (certain tensions as a consequence of the delay in granting the authorization, i.e., from the right holder's perspective, it may suffer a net loss of the effective time of patent protection, since the 20 year period protection starts from the patent application; from the competitors and consumers perspective, they may be deprived of the possibility of an early entry into the market of non-patented products as soon as the patent expires)

Regulatory review exception

- The regulatory review exception is also known as the “Bolar exception”, after a well known 1984 U.S. case, *Roche Products v Bolar Pharmaceuticals* (733 F.2d. 858 Fed. Cir. 1984).

- In the law of the Caribbean Countries which legislation was analyzed, no example of the RRE was found

Regulatory review exception

- INDIA : Section 107A of the Patent Act of 1970 as last amended in 2005

  107A. For the purposes of this Act,-

  (c) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product.

IV. WIPO Surveys and Discussions

- Patent Related Flexibilities Document's in the framework of the CDIP

  1) CDIP/5/4Rev

  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-main1.pdf
  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex1.pdf
  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex2.pdf

  2) CDIP/7/3 and Add

  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-main1.pdf
  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-annex1.pdf
  http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-annex2.pdf

- Regional meeting

  WIPO Seminar for certain Asian countries on the effective implementation and use of several patent related flexibilities, Bangkok, Thailand, February 15 to 17, 2011

  http://www.wipo.int/meetings/en/details.jsp?meeting_id=22602

  WIPO Regional Seminar on the Implementation and Use of Several Patent-Related Flexibilities, February 6 to 8, 2012, Bogota, Colombia

  http://www.wipo.int/meetings/en/details.jsp?meeting_id=24982

  Seminar for Certain African Countries on the Implementation and Use of Several Patent-related Flexibilities, January 29 to January 31, 2013, Durban, South Africa

  http://www.wipo.int/meetings/en/details.jsp?meeting_id=27882

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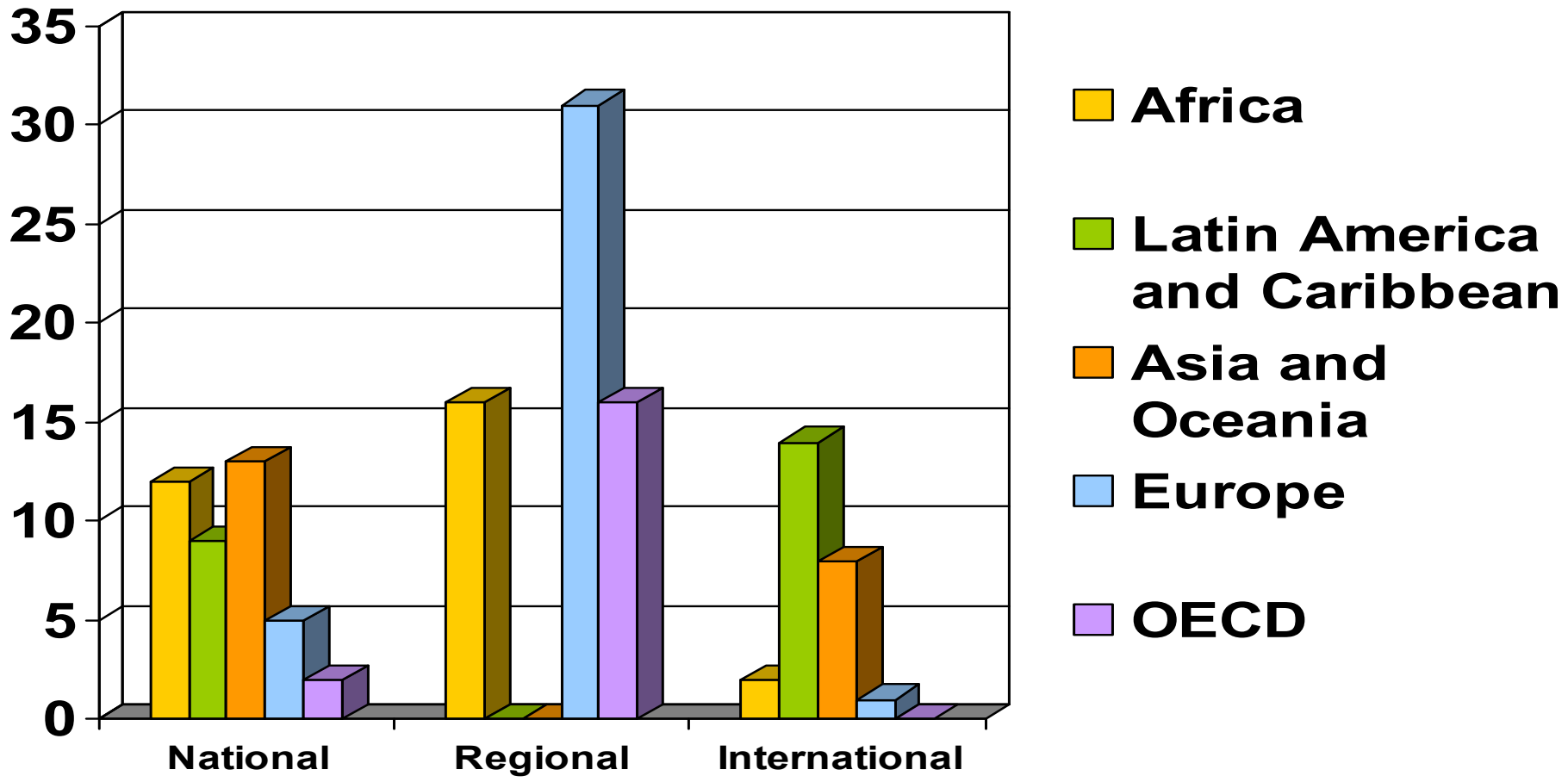
Countries analyzed: Exhaustion



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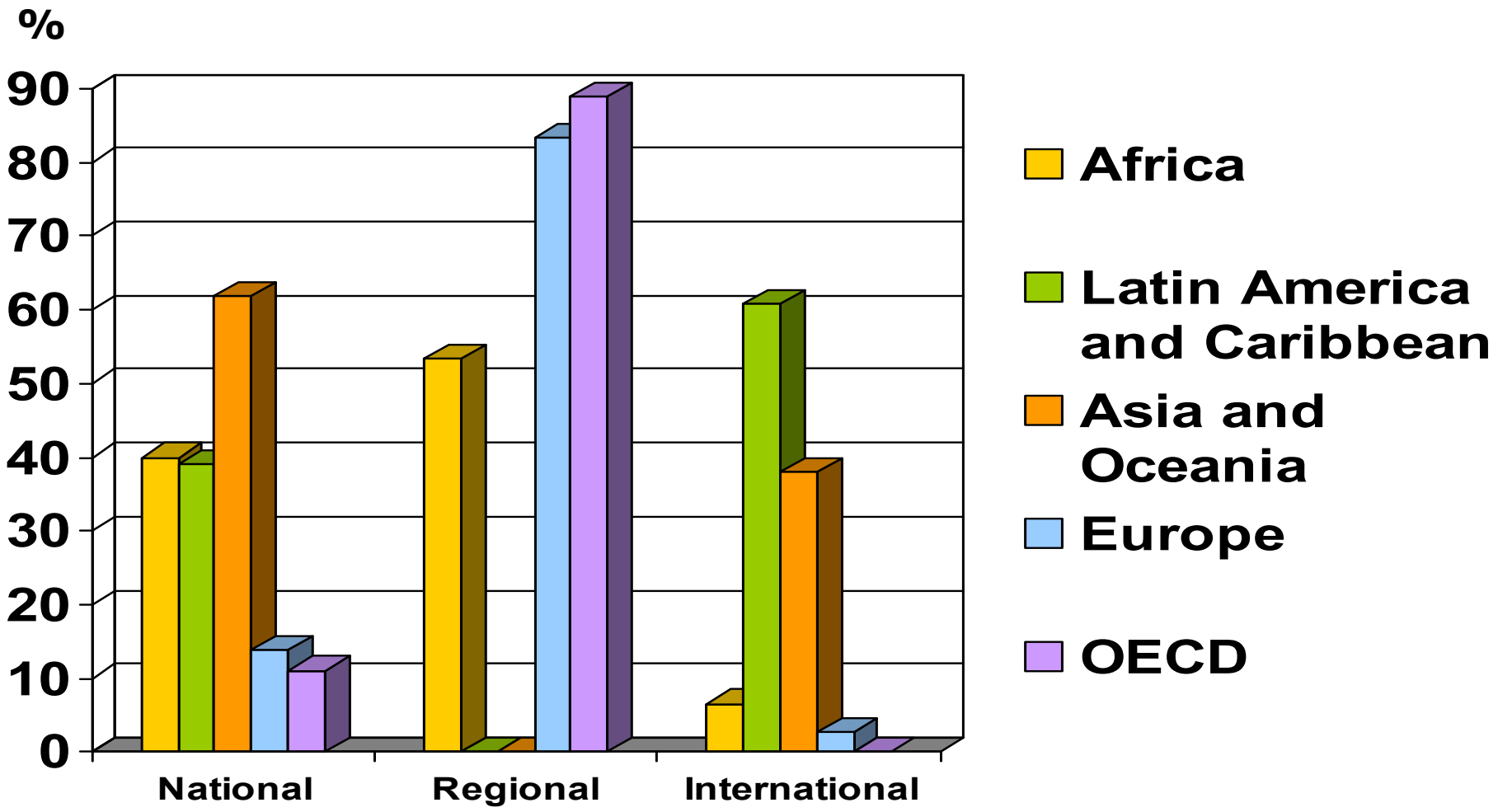
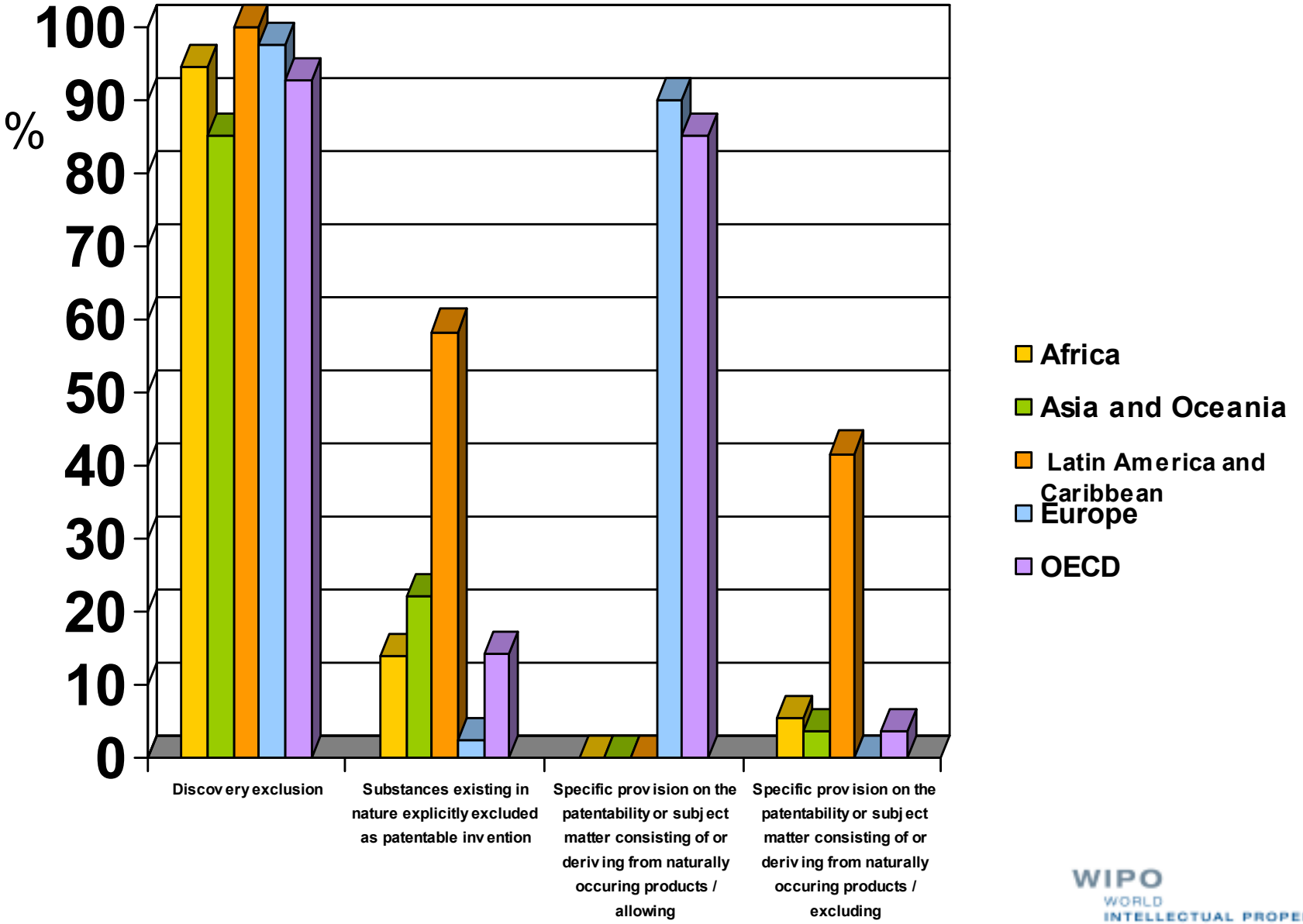
Statistics: Exhaustion



Patentability of substances existing in nature



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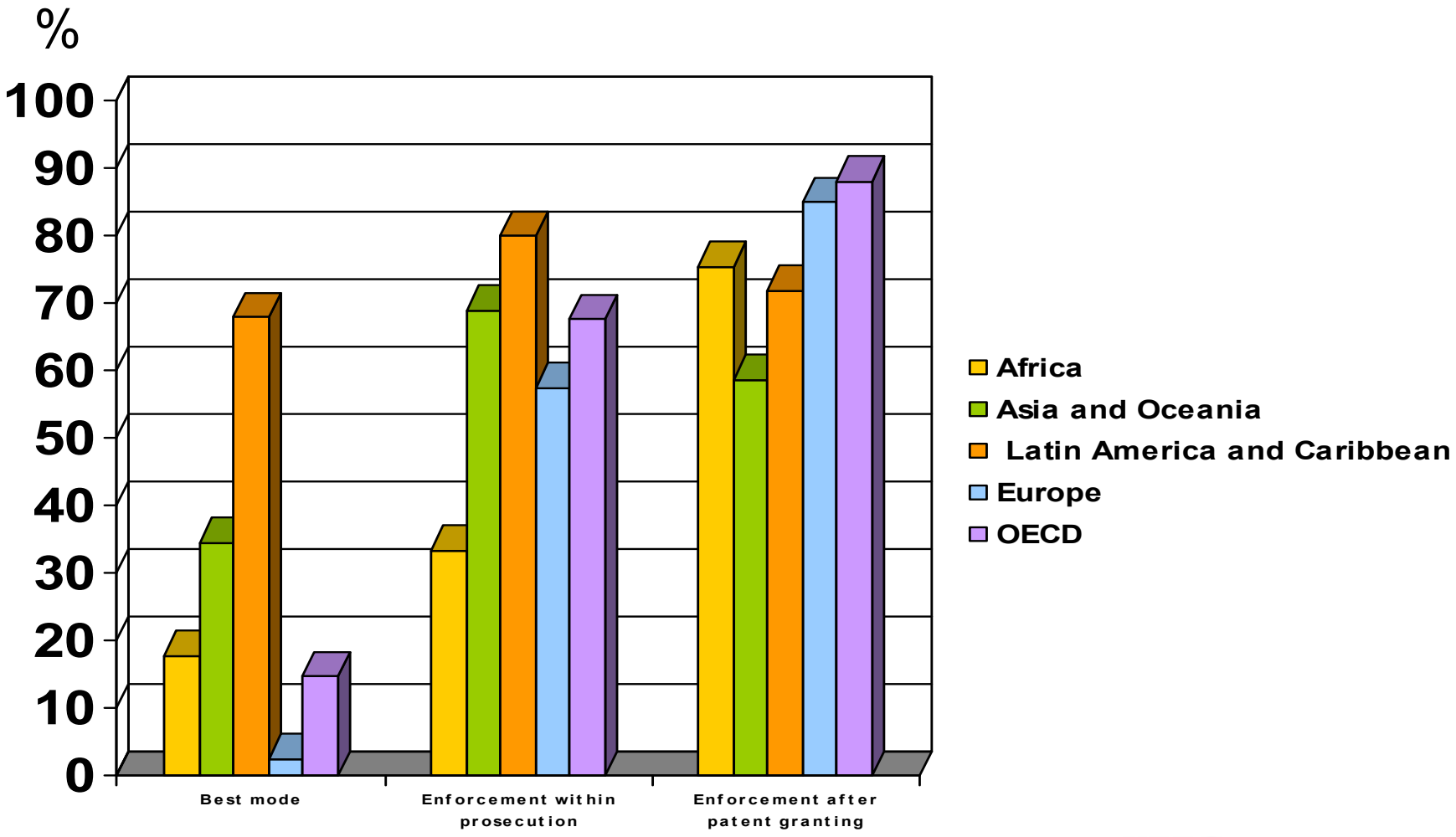
Disclosure related flexibilities (1)



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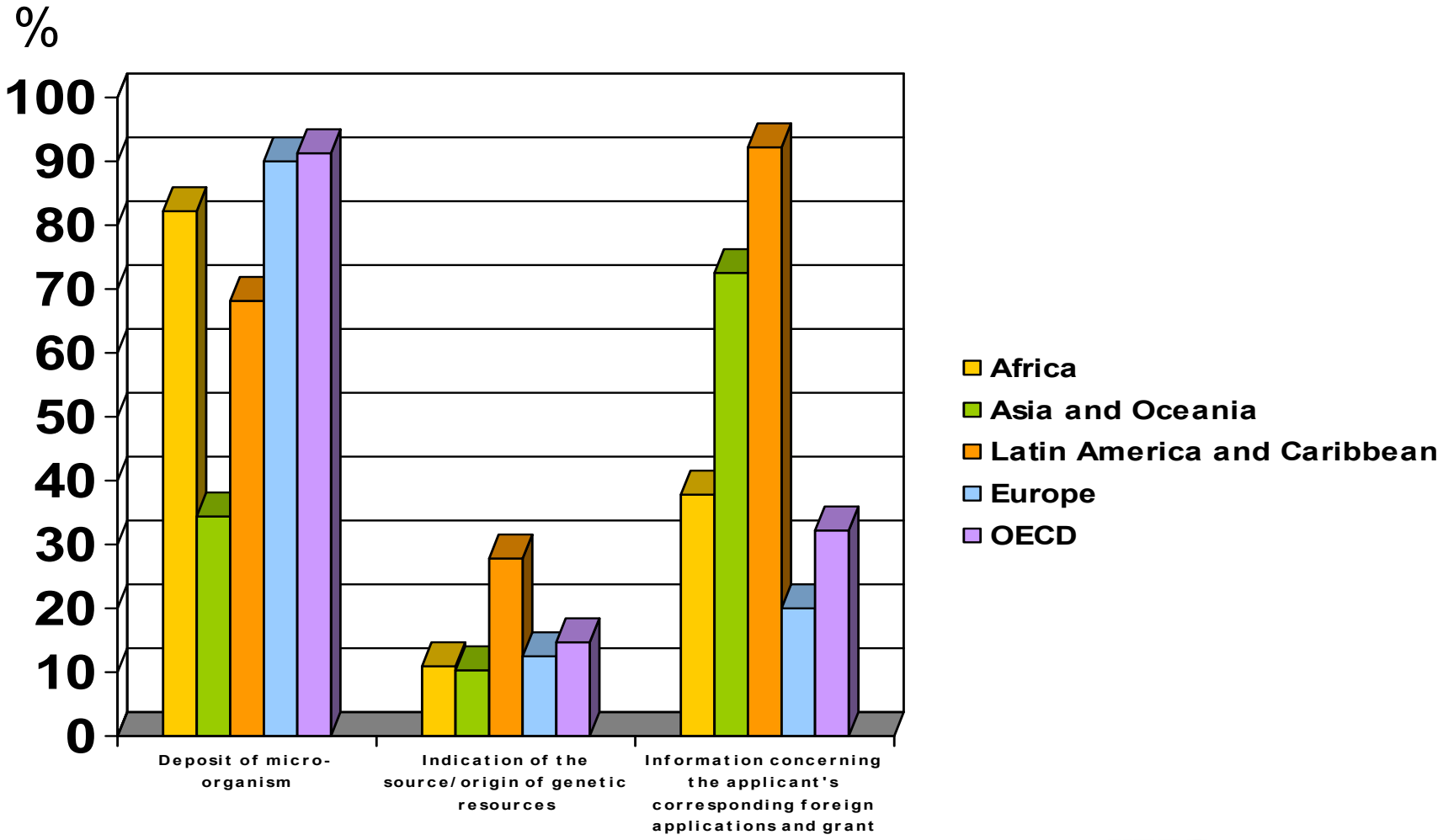
Disclosure related flexibilities (2)



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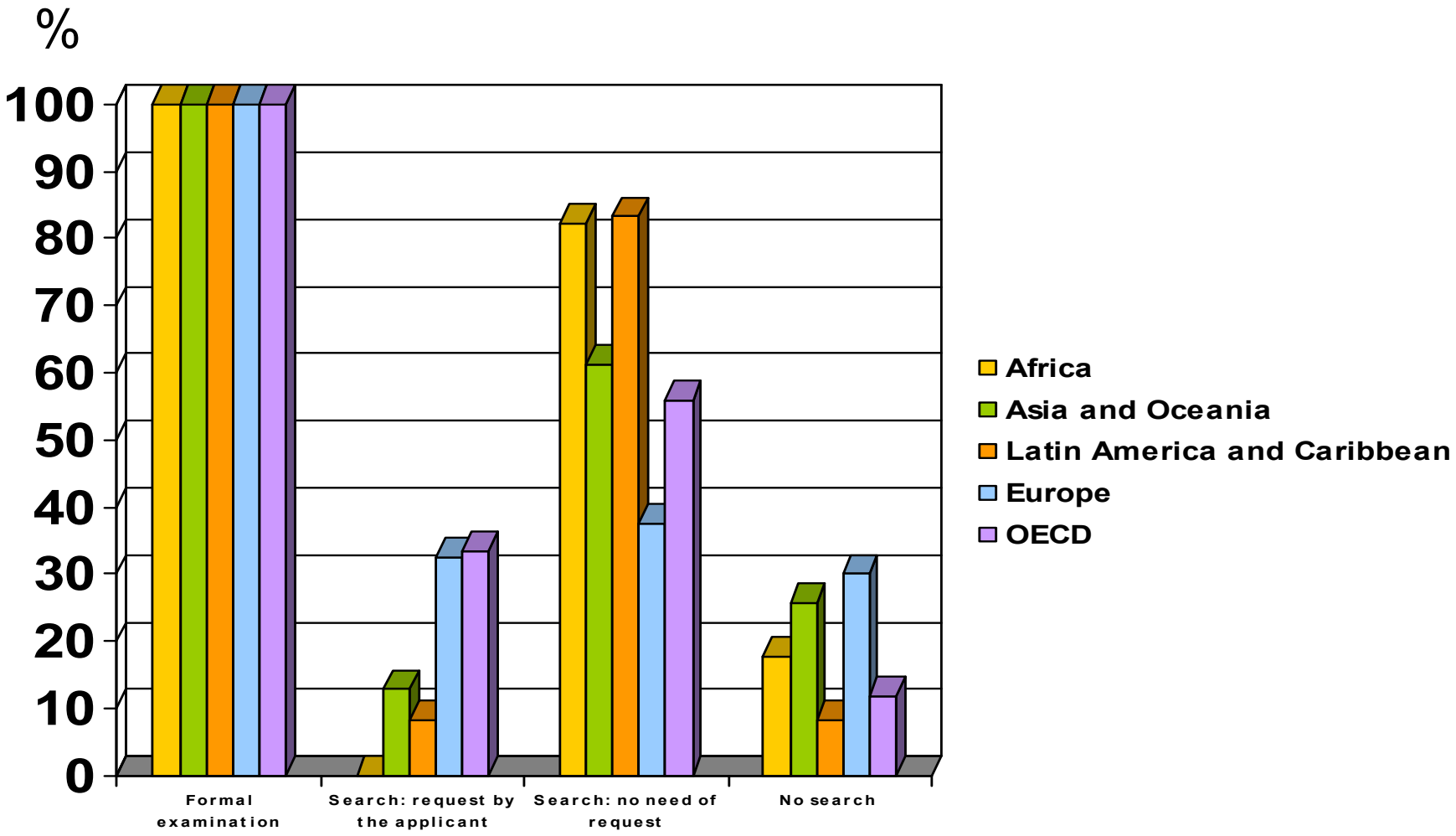
Substantive examination (1)



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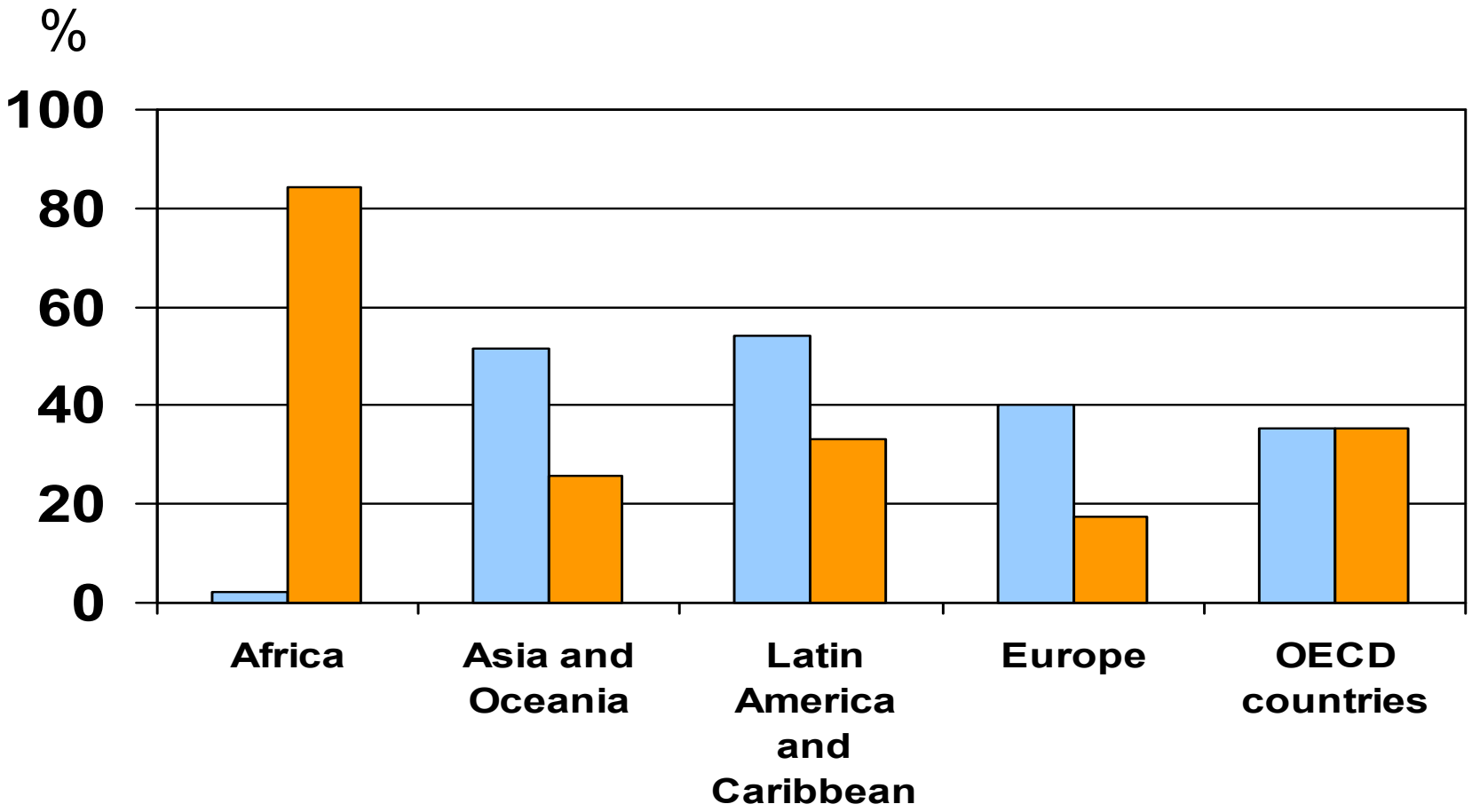
Substantive examination (2)



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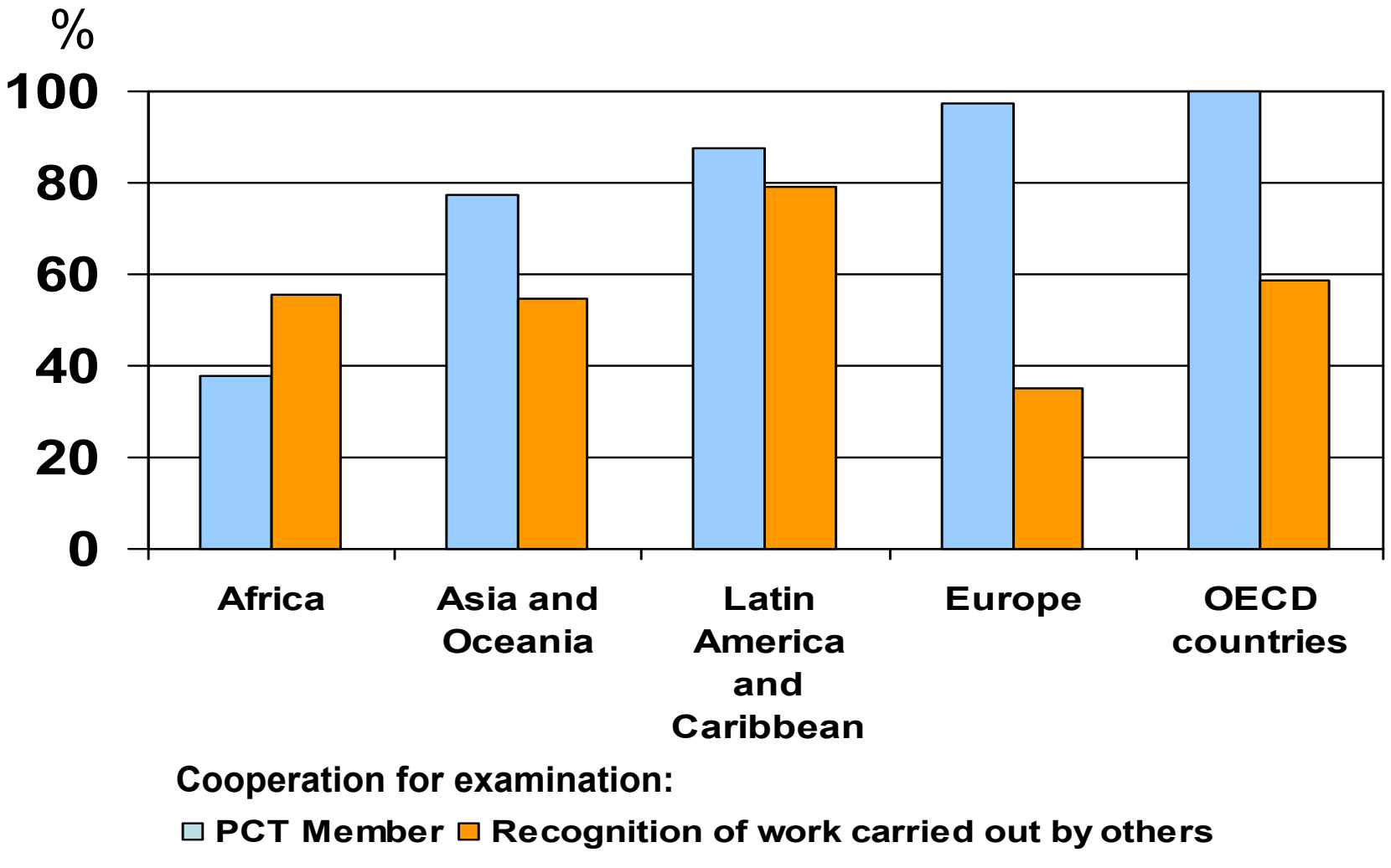
Substantive examination (3)



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Many thanks

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