



Intellectual Property and Public Health - International Framework and Recent Developments in WIPO: SCP and CDIP

WTO-ESCAP-IIUM REGIONAL WORKSHOP ON IP AND PUBLIC HEALTH AND ENVIRONMENT POLICY FOR THE ASIAN AND PACIFIC REGION

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Kuala Lumpur

July 10 to 12, 2012

Medical innovation and patents

- Some issues around patents and medical innovation
 - Scope of protection and scope of exceptions
 - Morality and ordre public issues
 - Interaction with other forms of IP and non-IP law (including the regulation of pharmaceuticals)
 - Breadth of claims (research tools)
 - IP management in the public interest
 - Compulsory licensing and government use provisions

Areas of flexibility

Pre-grant:

- choice of what is patentable, and what is not
(e.g. higher life forms, morality exceptions, medical treatments)
- decision whether or not to seek a patent, and who applies
(e.g. role of public sector institutions – Bayh-Dole)

Post-grant:

- choice of how to exercise the patent
(working the patent, what obligation to license?)
- choice of scope or reach of patent rights
(what kind of research exception, what reach of claims?)
- choice of how to regulate the patent, once granted
(compulsory licensing, government use)

Some specific legal issues

- Additional protection
 - Some legal systems offer protection to types of inventions that lose part of effective patent term due to marketing approval procedures. Examples:
 - Europe:
 - Special title of protection called Supplementary Protection Certificates (SPC). Conditions: medicinal product covered by a patent in force; valid marketing authorization which is the first one, and not already obtained an SPC. Maximum of 5 years
 - Other administrative protection (US)
 - US grant an extension to any patented product (and process) which has been subject to a regulatory review period before its commercial marketing or use
- Linkage with other forms of regulation: regulatory approval of pharmaceuticals

Standing Committee on the Law of Patents (SCP)

WIPO work before 1995

- Paris Convention (1883)
- PCT (1970)
- Negotiations 1985 to 1991 for a Treaty Supplementing the Paris Convention as far as Patents are Concerned; Diplomatic Conference resulted in no treaty, mainly due to differences concerning first-to-file and the grace period
- Patent Law Treaty (PLT, 2000): Harmonizes and simplifies formal requirements for national and regional patent applications and patents. Excludes expressly substantive requirements of patentability

Draft Substantive Patent Law Treaty (SPLT)

- Draft SPLT discussed since 2001 in WIPO/SCP
- Objective: bringing closer together some operational concepts relevant for examination of patent applications. Quality; avoid duplication of work.
- Covers main substantive requirements relevant for the grant of patents, i.e. prior art, novelty, inventive step, industrial applicability, sufficiency of disclosure and drafting/interpretation of claims
- Does not cover after-grant (exploitation) phase; left to national laws
- Certain issues not yet addressed (first-to-file; grace period)

SPLT: challenges

- Differences among industrialized countries
 - patentable subject matter/technical character
 - First-to-file; grace period
 - Prior art effect of earlier applications
- Concerns of developing countries
 - one size does not fit all; fear of “TRIPS-plus”
 - exceptions and grounds for refusal/invalidation of an application (e.g. public health, protection of genetic resources, environment)
 - link with certain policy issues (origin of genetic resources)

SCP: history

No agreement on SPLT nor on SCP work program; deadlock from 2006 - 2008

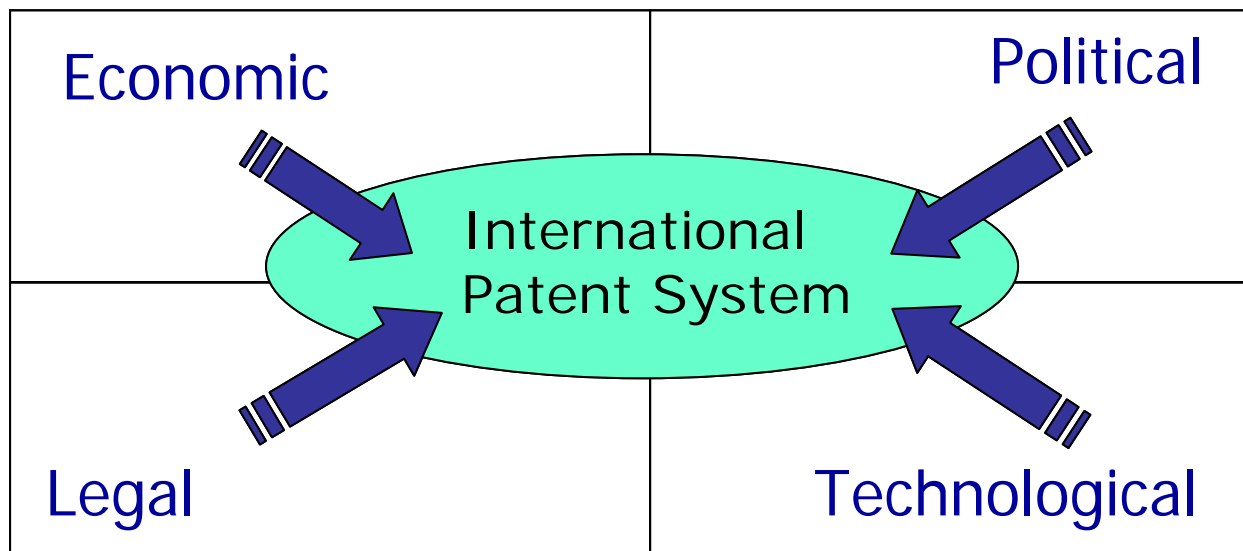
Proposal I (Developed countries)

- definition of prior art
- grace period
- novelty
- inventive step

Proposal II (Group of Friends of Development)

- patentable subject matter
- exclusions from patentable subject matter
- exceptions to patent rights
- anti-competitive practices
- disclosure of origin, prior informed consent and benefit sharing
- effective mechanisms to challenge validity of patents
- sufficiency of disclosure of the invention
- transfer of technology
- safeguarding of public interest flexibility
- alternative models to promote innovation

Global environment and factors influencing the patent system



The international patent system is influenced by various internal and external aspects

Working towards the establishment of a work program: the five issues agreed in 2010

- Exceptions and limitations to patent rights
- Quality of patents (including opposition systems)
- Confidentiality of communications between patent advisors and their clients
- Transfer of technology
- PATENTS AND HEALTH

Exceptions and limitations to patent rights

- Study by external experts on exclusions, exceptions and limitations: coordinated by Professor Linal Bently, Cambridge. Several authors from various parts of the world
- Proposal by Brazil, supported by a number of developing countries. 3 step approach:
 - Exchange of information
 - Relevance of exceptions and limitations
 - Manual of best practices
- Request from member States to prepare a questionnaire

The questionnaire on exceptions and limitations

The draft questionnaire contains the following 11 Sections:

- Section I General;
 - Section II Private and/or non-commercial use;
 - Section III Experimental use and/or scientific research;
 - Section IV Preparation of prescribed medicines;
 - Section V Prior use;
 - Section VI Use of articles on foreign vessels, aircrafts and land vehicles;
 - Section VII Acts for obtaining regulatory approval from authorities;
 - Section VIII Exhaustion of patent rights;
 - Section IX Compulsory licensing and/or government use;
 - Section X Farmer's privilege and/or breeder's exception;
 - Section XI Other exceptions and limitations.
-
- Questionnaire submitted to member States and results available in raw and in summarized form on WIPO's website
 - How to continue with this work?

Proposal by South Africa on health

- Proposal submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group (document SCP/16/7)
 - Studies
 - Compulsory and government use licenses
 - Exhaustion of rights
 - Mandatory disclosure of International Non-Proprietary Names (INNs)
 - Cost-benefit analysis of Markush claims
 - Information exchange
 - Sharing of experience and information on various issues
 - Develop a database on the patent status of diagnostic tools and medicines in Member States
 - Technical assistance

Proposal by USA on health

- Proposal submitted by the Delegation of the United States of America (document SCP/17/11)
- Basic assumption: patents can also have a positive impact on the production of medicines. Weakening patent protection is not necessarily the most productive approach to improving availability of medicines, as many other factors are playing a role as well; alternative approaches should be examined vol. licenses, pools, partnerships etc.).
- Proposal:
 - Study on the positive impact of patent systems in providing lifesaving medicines to developing countries
 - Study to examine the availability of lifesaving medicines that are not protected by patents, and the reasons for their lack of availability
- Common work of WIPO, WHO and WTO

Other documents submitted to the SCP on health

- WIPO Activities on Patents and Health (document SCP/18/5)
- Projects and Activities on Patents and Health in WIPO, WHO and the WTO (document SCP/17/4)
 - SCP
 - CDIP
 - Symposia, trainings, workshops
 - Technology platforms Re:Search; WIPO Essential
- 2 additional documents with comments received from members of the SCP

Future work

- No agreement on specific future work, but agreement to continue work on the basis of agenda of SCP/18 in November 2012
- All 5 topics linked; no one could move forward alone
- WIPO member States now need to reflect upon what they want in the SCP. Long-term benefits of multilateral discussions, even if divergent views, or just a waste of time? Either a balanced work package is agreed, respecting the interests of the various groups, or it will become very difficult to make progress in the SCP in the future

Committee on Development and Intellectual Property (CDIP)

WIPO Development Agenda

- All WIPO activities are now linked to the Development Agenda
- Process started in 2004 (proposal from Brazil and Argentina, supported by some other developing countries).
- Finally, 45 recommendations discussed (19 ready for implementation, 26 to specify implementation)
- Project approach for the 26, partly individual, partly thematic approach
- CDIP adopted several projects, namely, the Project on Intellectual Property and Competition Policy, the Project on Intellectual Property, Information and Communication Technologies (ICTs) and the Digital Divide and Access to Knowledge, parts of the Project on Intellectual Property and the Public Domain and the Project on Developing Tools for Access to Patent Information
- Coordination Mechanisms

Summary of work under the CDIP

- DA Recommendation 14 (on flexibilities)
 - Documents
 - Legislative assistance
 - Regional seminars
 - Examples
- CDIP Project DA_19_30_31_01“Developing tools for Access to Patent Information”
 - Various landscapes
- Projects on technology transfer

I. Scope. Definition of flexibilities

- « A range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPs Agreement »
- Vague international rules, that need to be circumscribed in their content by the national legislation
- Offer alternative ways for:
 - Legislative implementation
 - To accommodate national interests. Need to be compatible with the provisions and principles of the international framework

II. Categories

- Flexibilities based on the point in time at which Members may resort to them: i) acquisition of the right; ii) scope of the right and iii) enforcement
- Flexibilities related to transition period and substantive flexibilities
- More detailed classification:
 - subject- matter which qualifies for protection
 - scope of the protection
 - modes of IP enforcement
 - matters of administration

III. Use of some flexibilities

- Transitional periods
- Disclosure related flexibilities
- Patentability of substances existing in nature
- Compulsory licenses and Government Use
- Exhaustion of rights
- Research exemption
- Regulatory review exception



WIPO's work on flexibilities (1): assistance

WIPO provide assistance to member States on the implementation of the national legal frameworks on Patents, Utility Models, Trade Secrets and Integrated Circuits

- A country that does not have legislation in a particular IP field may request from the WIPO Secretariat a draft law or may prepare a draft law/act which is submitted to WIPO Secretariat for comments
- A country that already has legislation in a particular IP field may consider appropriate to revise it, either because changes in national policies advise to do that or due new multilateral or bilateral commitments
- The WIPO Secretariat also undertakes advisory missions to Member States upon request for bilateral discussions on legislative matters; or receives national officials and policy-makers for discussions at WIPO headquarters.
- Discussions on legislative matters are also addressed in the course of numerous workshops, roundtables, seminars and meetings.

WIPO's work on flexibilities (2): documents

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

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

CDIP/7/3 Rev

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

Future work (document CDIP/9/11) The Secretariat had been requested to:

- Prepare a document that would form the basis for discussions at the tenth session of the Committee on four patent-related flexibilities: i) the scope of the exclusion from patentability of plants; ii) regarding the patentability, or exclusion from patentability, of software-related inventions; iii) the flexibility to apply or not criminal sanctions in patent enforcement; and iv) measures related to security which might result in a limitation of patent rights.
- Another document which compile written comments by MS on other patent-related flexibilities, including those in Article 27. This document will be presented at the tenth session, and Members may submit comments thereon intersessionally between the tenth and eleventh sessions of the Committee, for discussion and decision at the eleventh session of the Committee

WIPO's work on flexibilities (3): regional seminars

- SEMINAR FOR CERTAIN ASIAN COUNTRIES ON THE EFFECTIVE IMPLEMENTATION AND USE OF SEVERAL PATENT RELATED FLEXIBILITIES, BANGKOK, THAILAND, FEBRUARY 15 TO 17, 2011

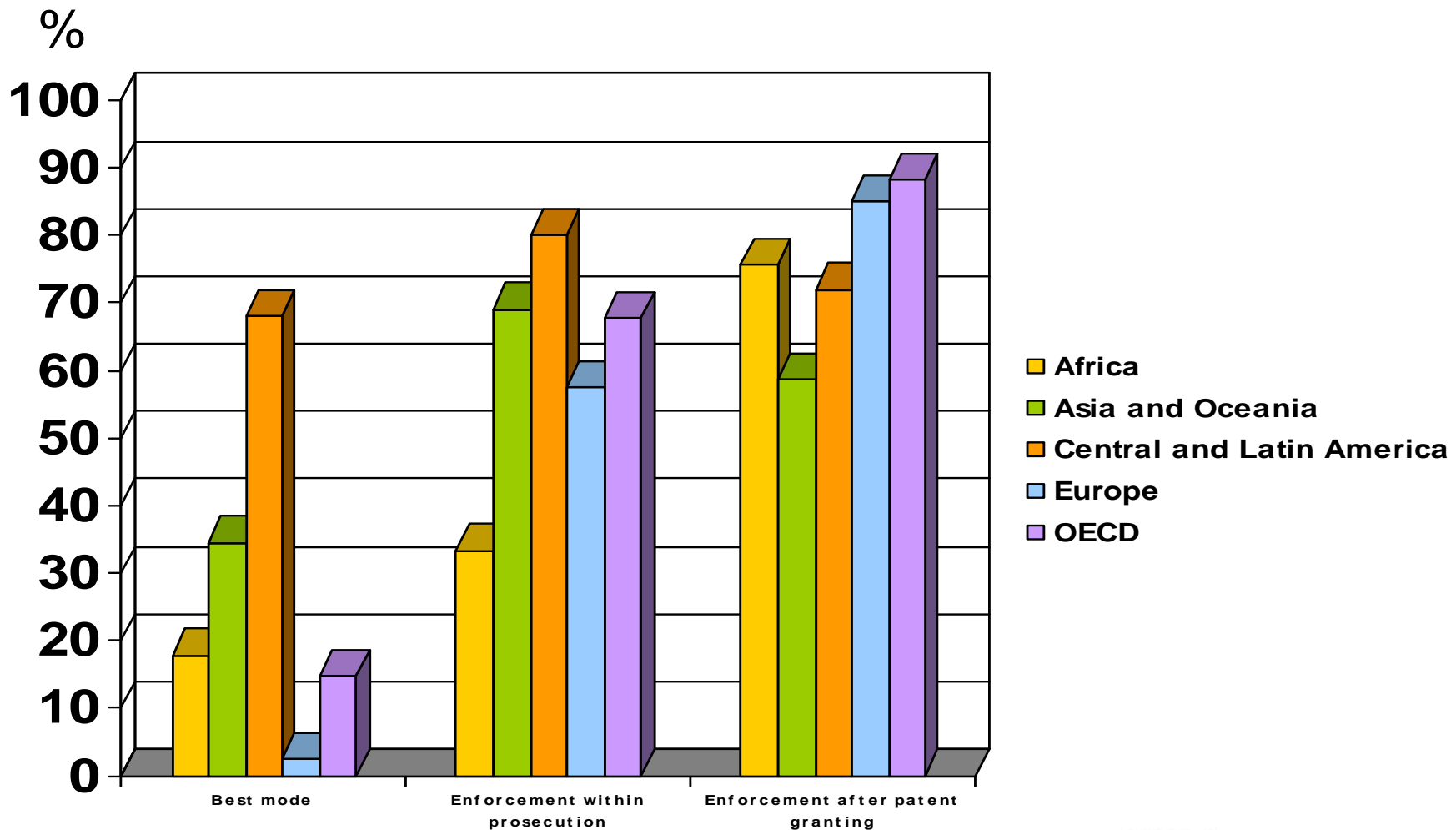
http://www.wipo.int/meetings/en/details.jsp?meeting_id=22602

- WIPO REGIONAL SEMINAR ON IMPLEMENTATION AND USE OF SEVERAL PATENT-RELATED FLEXIBILITIES, FEBRUARY 6 TO 8, 2012, BOGOTA

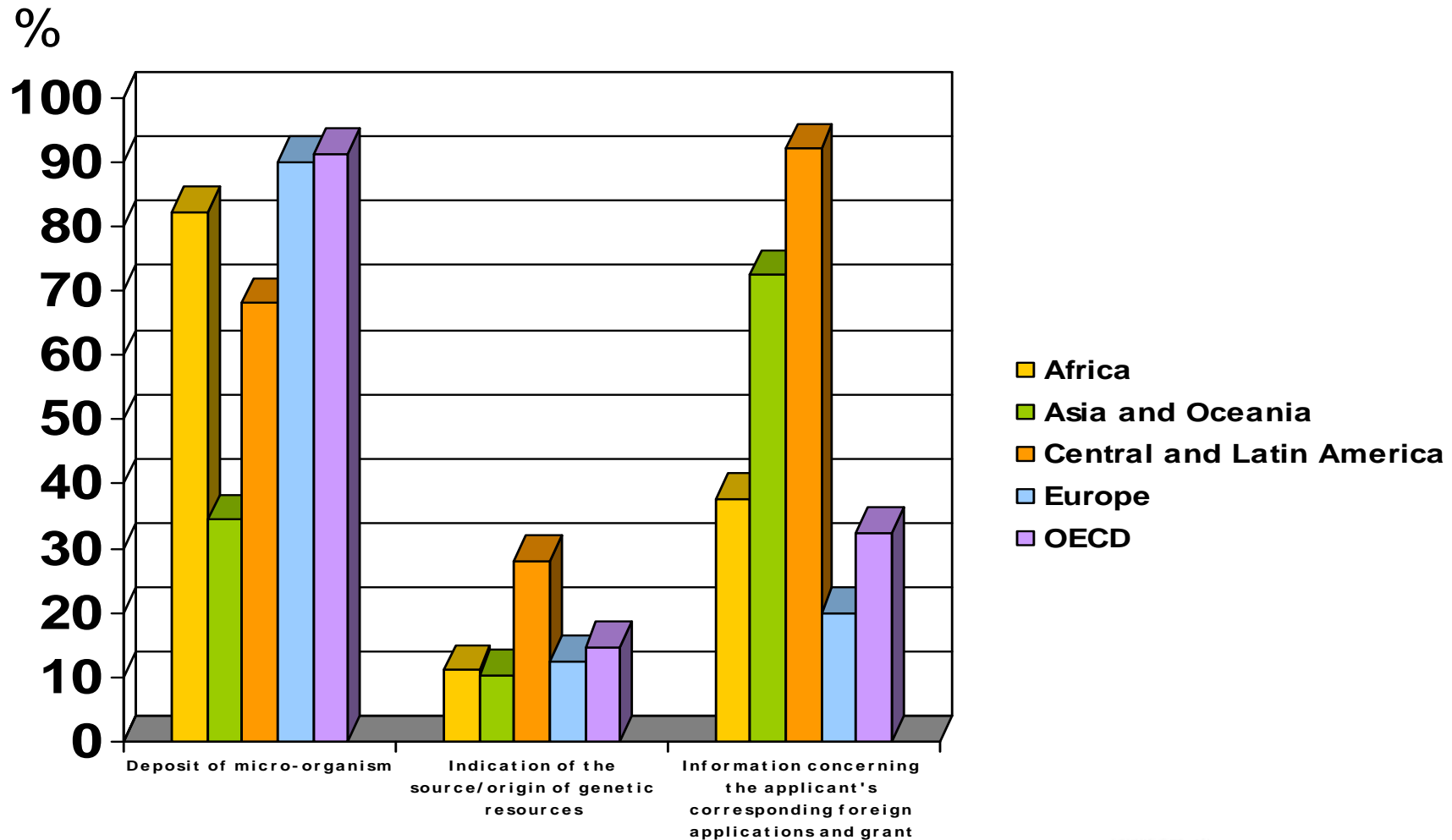
http://www.wipo.int/meetings/en/details.jsp?meeting_id=24982

- Third Regional Meeting. Africa (venue to be define).

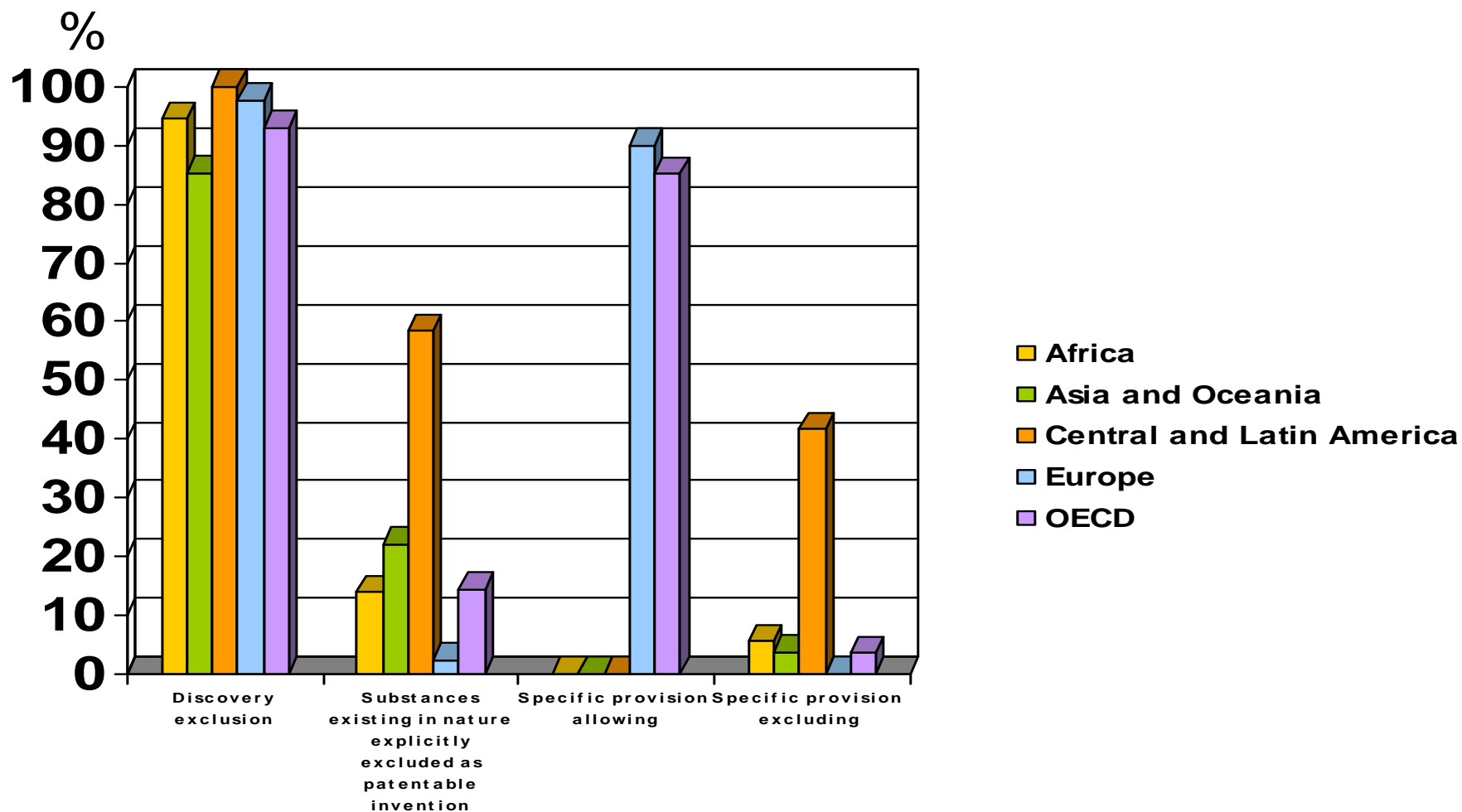
Disclosure related flexibilities (1)



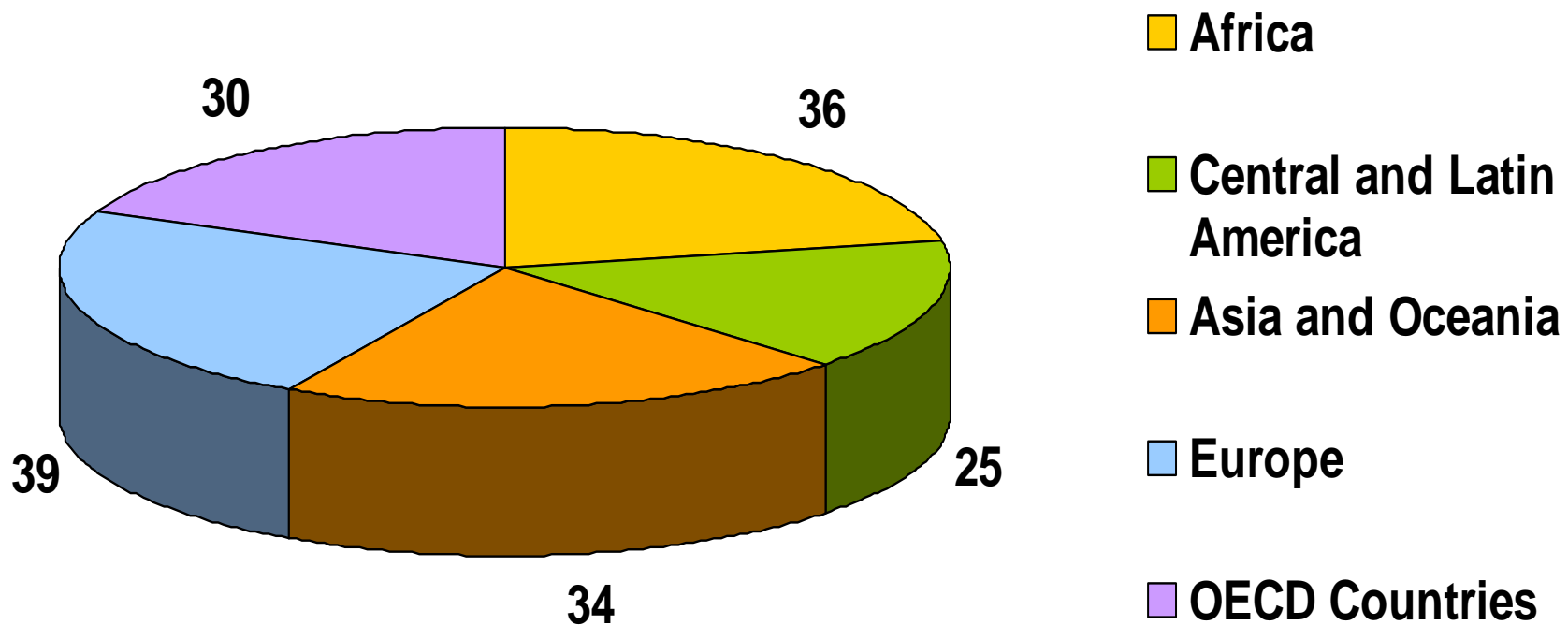
Disclosure related flexibilities (2)



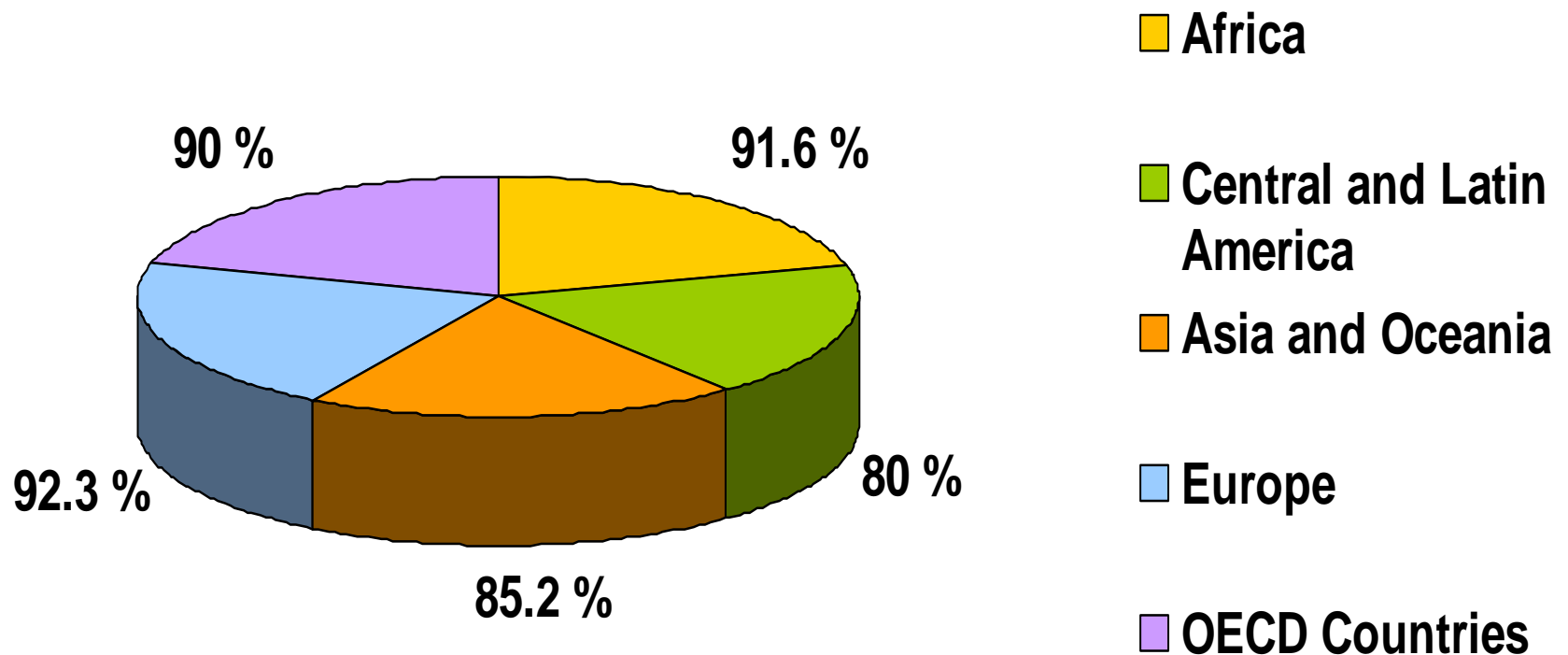
Patentability of substances existing in nature



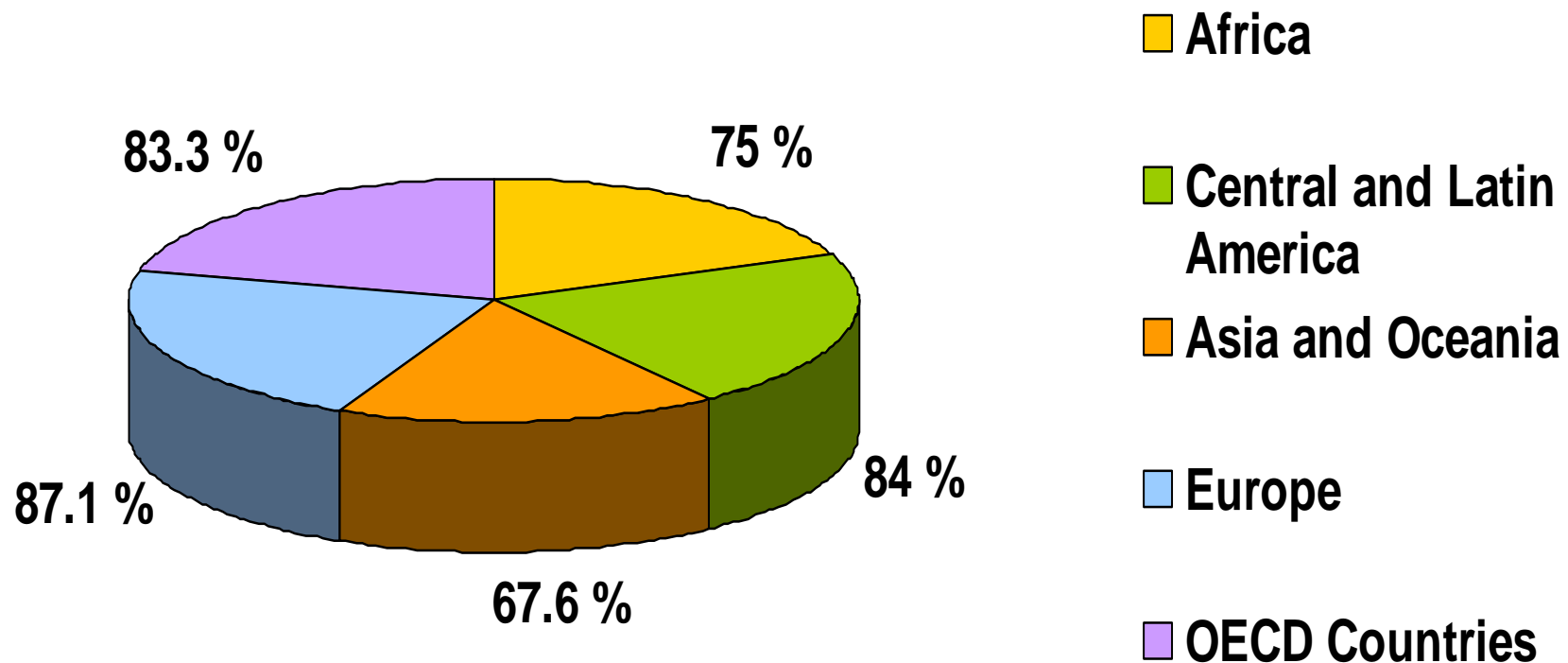
Countries analyzed: Compulsory Licenses



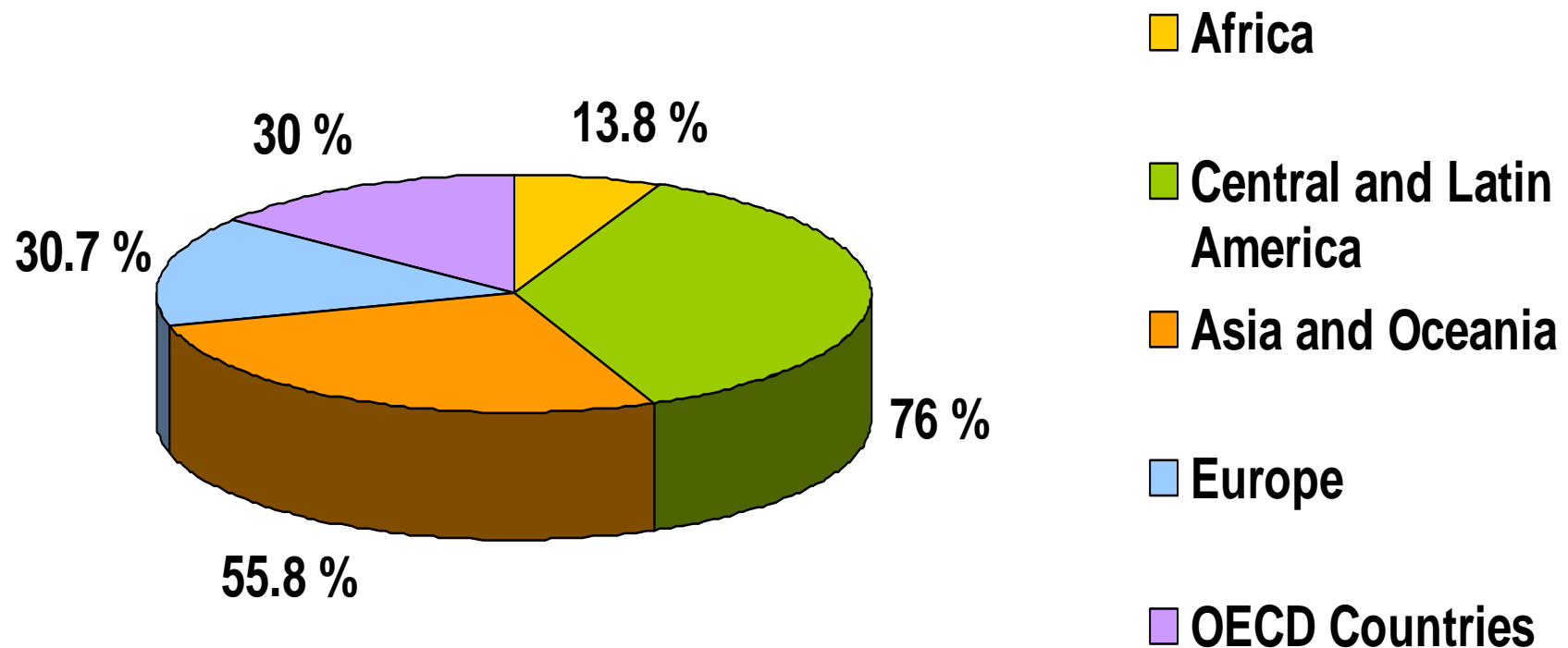
Compulsory Licenses (non-working)



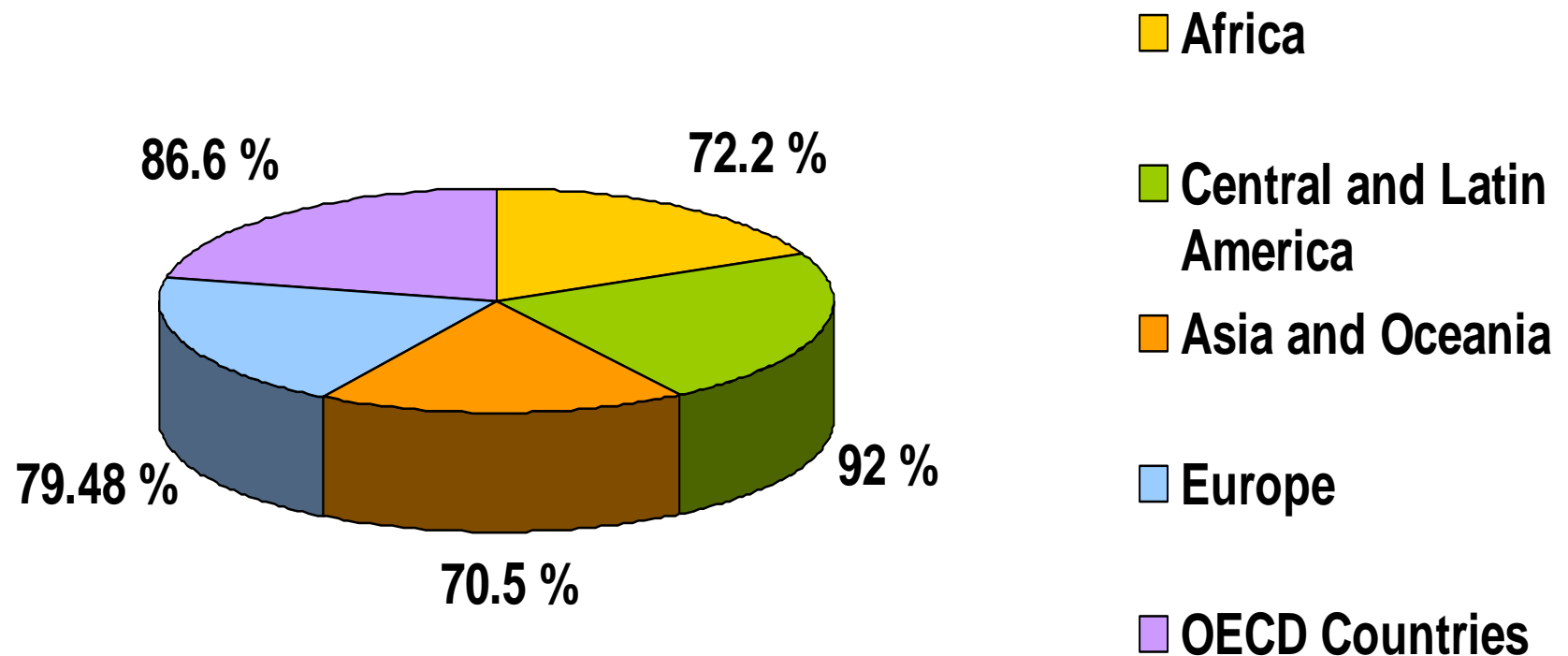
Compulsory Licenses (dependent patent)



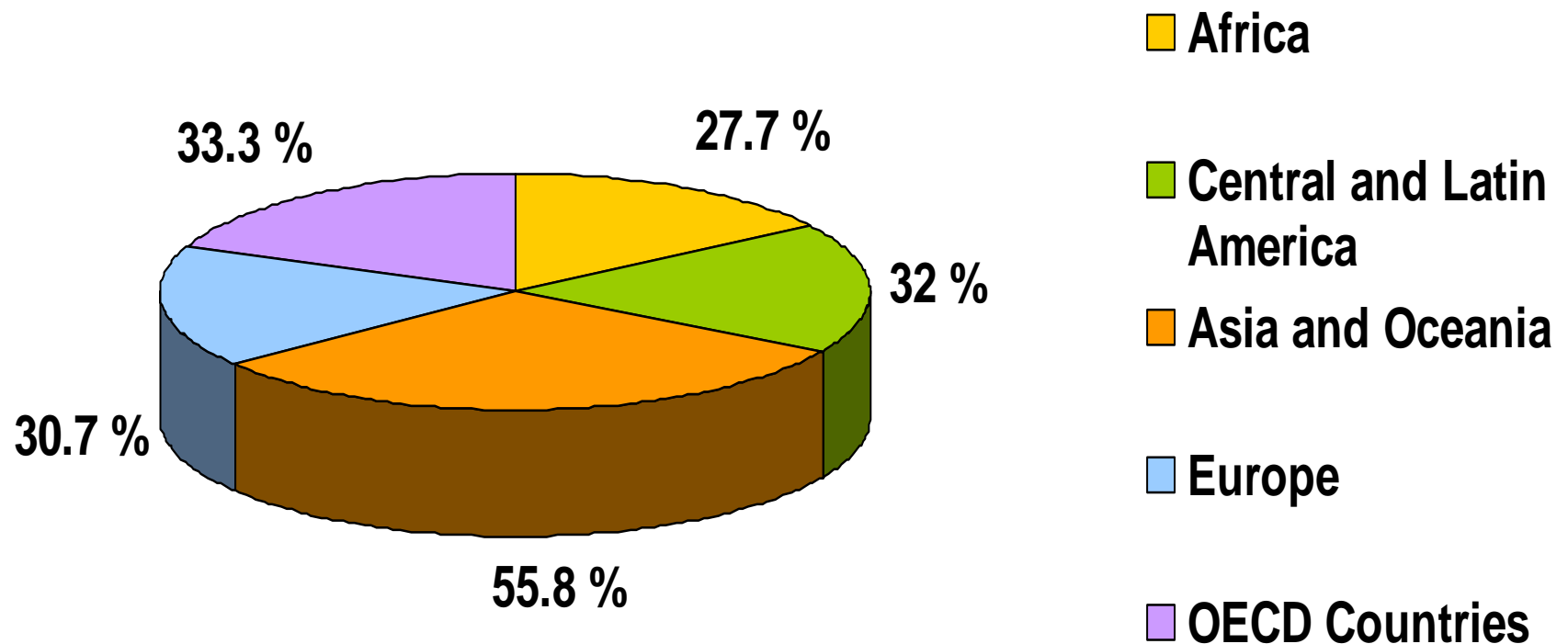
Compulsory Licenses (correct patent abuse)



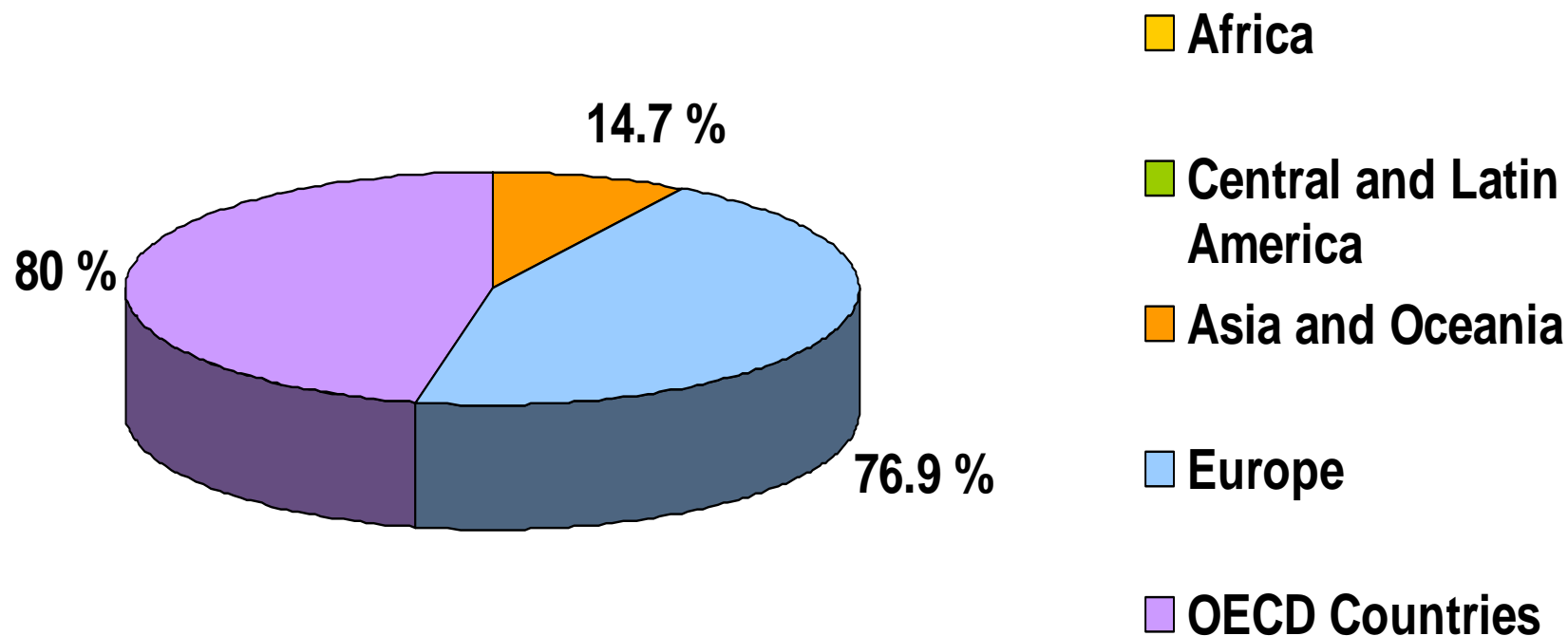
Compulsory Licenses (public interest)



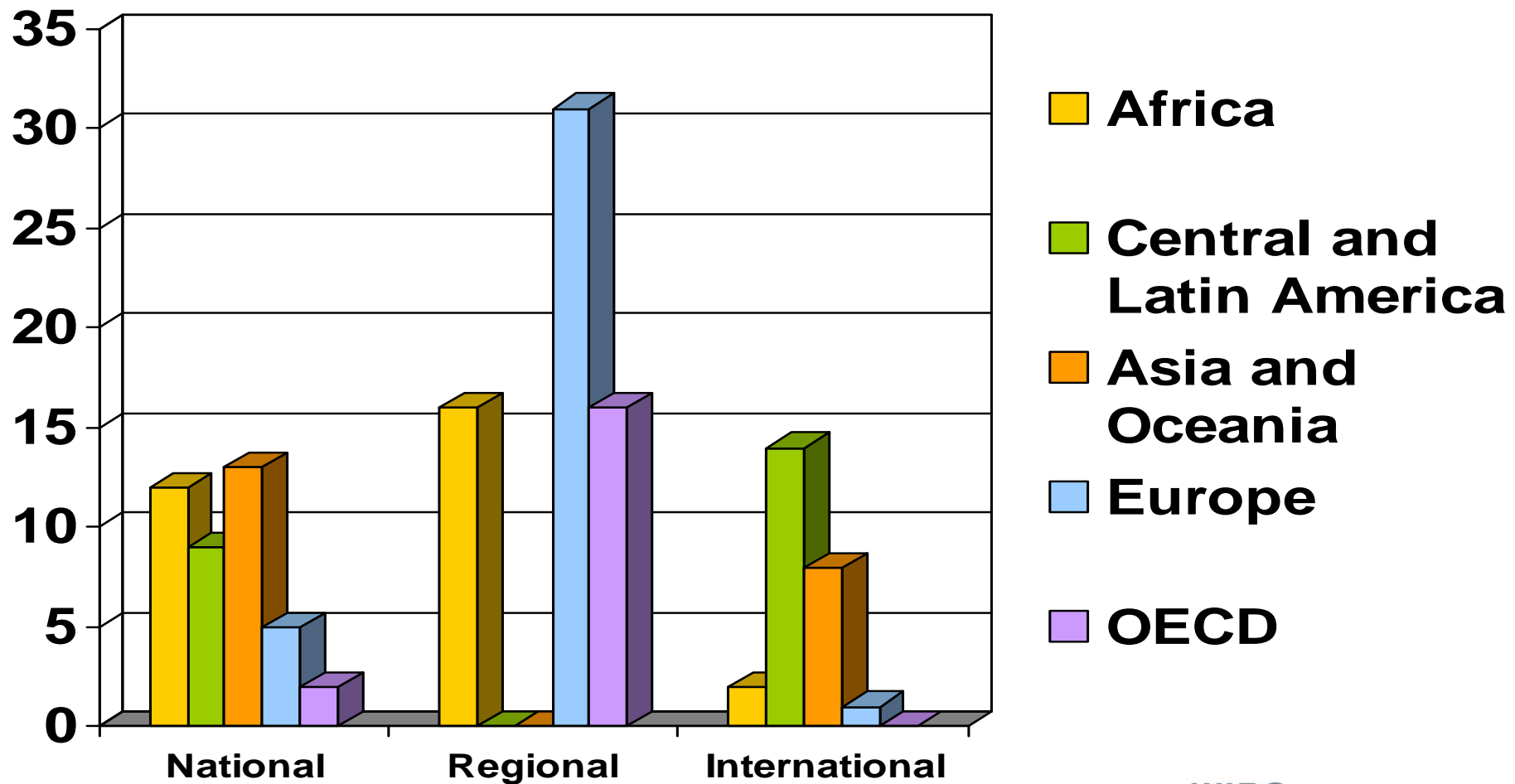
Compulsory Licenses (Government use)



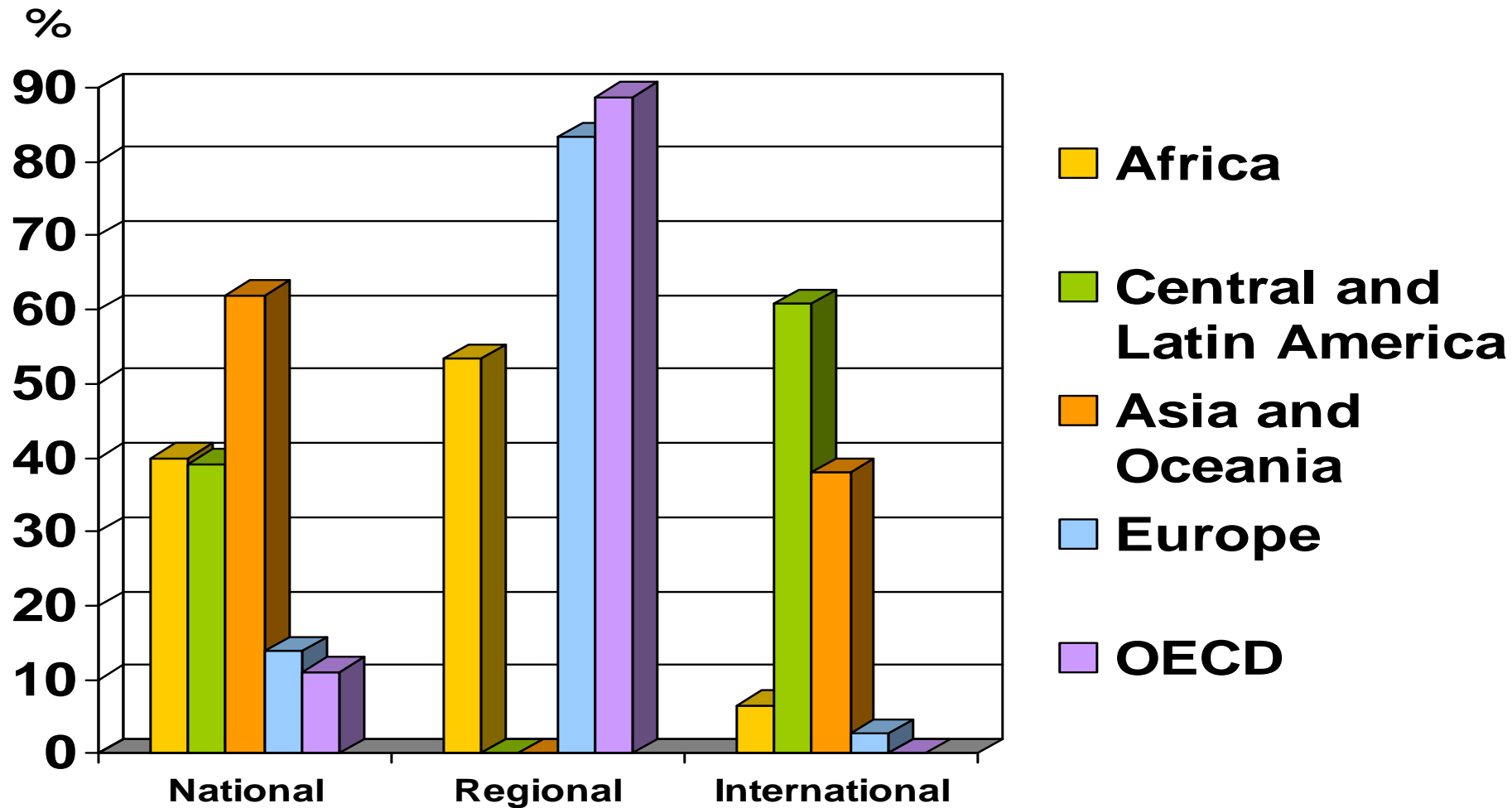
Implementation of the Decision of the General Council of August 30, 2003 (Paragraph 6 Decision)



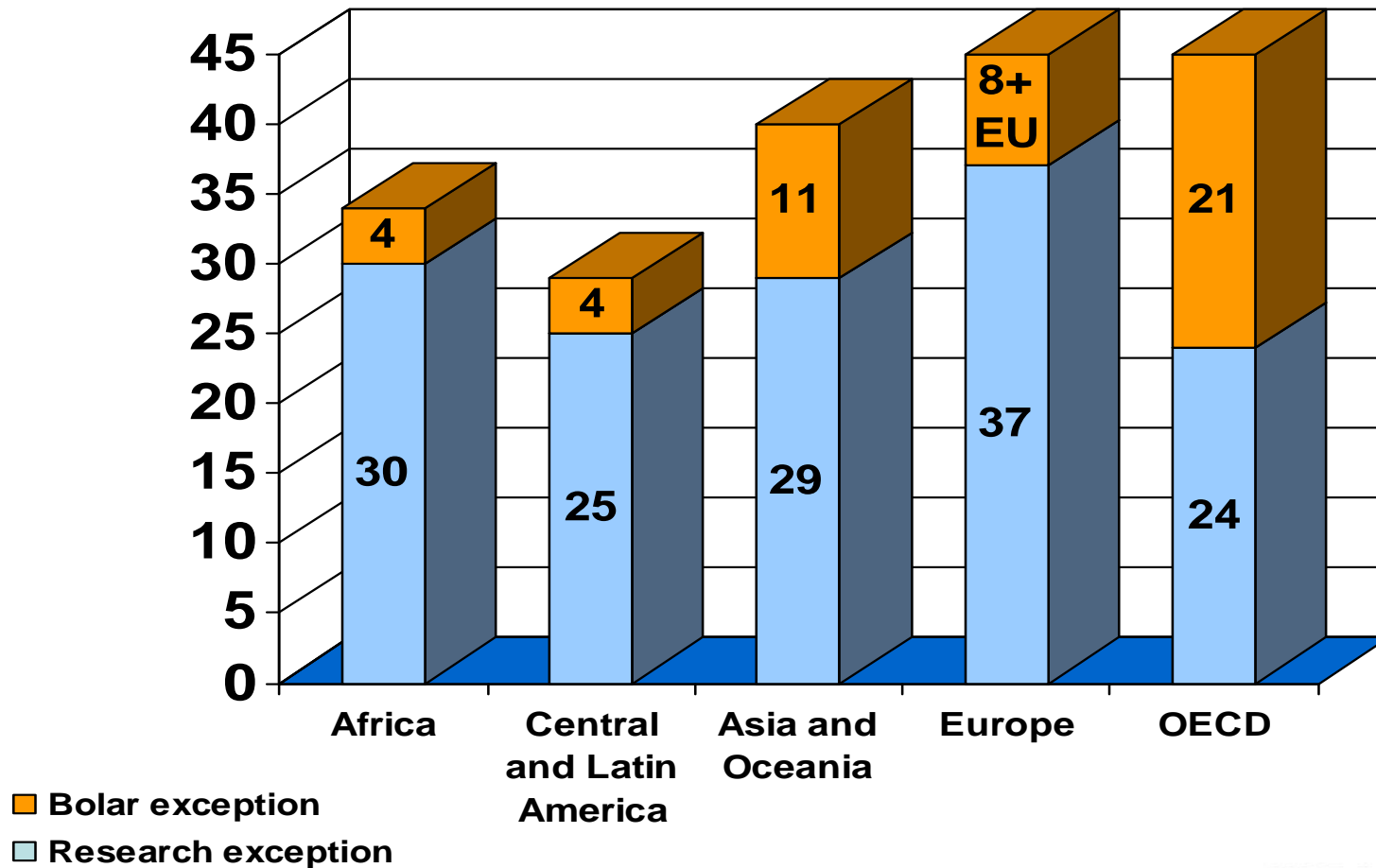
Exhaustion



Exhaustion



Countries analyzed: Research and regulatory exception



DA Project DA_19_30_31_01

- Project entitled “Developing tools for Access to Patent Information”

- Patent landscape of the antiretroviral Ritonavir prepared in cooperation with Medicines Patent Pool and published on the WIPO website.

http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html

A dedicated website providing information on the ongoing work and links to patent landscape reports established by other institutions and published on the Internet was created.

- Patent landscape of the antiretroviral Atazanavir completed (in cooperation with the Medicines Patent Pool).
- Patent landscape of vaccine manufacturing completed (in cooperation with WHO).
- Patent landscape of HIV diagnostics under discussion with UNITAID. Patent landscape of Neglected diseases under preparation (in collaboration with DNDi).

DA Projects relating to technology transfer

■ [DA_19_25_26_28_01](#): Intellectual Property and Technology Transfer: Common Challenges Building Solutions

A range of activities that will explore possible initiatives and IP-related policies for promoting technology transfer, the dissemination and facilitation of access to technology for development, particularly for the benefit of developing countries, including LDCs

■ [DA_10_03](#) : Innovation and Technology Transfer Support Structure for National Institutions

The Project will create and test or, where they exist, update and improve, a series of modules and materials relating to managing IP rights (particularly patents) by academic and research institutions, including on the setting up and running of technology transfer offices at public research organizations, exploring technology transfer mechanisms (in particular, licensing agreements) and enhancing the capacity to draft patents

Thank you

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