



DEPARTMENT OF INTELLECTUAL
PROPERTY
MINISTRY OF COMMERCE



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

***Topic 3: Patent Related Flexibilities in the Multilateral Legal
Framework and their Legislative Implementation at the
National and Regional Levels***

**Bangkok, Thailand
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Summary

- I. The Multilateral legal framework of patents
- II. The implementation of Multilateral Treaties on Patents
- III. Classification and meaning of Flexibilities
- IV. Some examples of flexibilities

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 manoeuvre left to the national legislator

III. Definition of flexibility

- « 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

Definition (2)

The term “**flexibilities**” means that there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and TRIPS provisions and principles are complied with



III. Classification (1)

- Flexibilities related to transition period and substantive flexibilities
- More elaborate classification:
 - Subject-matter which qualifies for protection
 - Scope of the protection
 - Modes of IP enforcement
 - Matters of administration

Classification (2)

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



IV. Identification of some flexibilities

- Compulsory licenses and Government Use
- Research exemption
- Regulatory review (*Bolar*) exception
- Utility models



Compulsory licenses

- MALAYSIA : Section 49 of the Patents Act No. 291 of 1983 as last amended on 2006

Application for compulsory licences. (1) At any time after the expiration of three years from the grant of a patent, or four years from the filing date of the patent application, whichever is the later, any person may apply to the Registrar for a compulsory licence under any of the following circumstances:

- (a) where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason;
 - (b) where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet public demand without any legitimate reason.
- (2) A compulsory licence shall not be applied for unless the person making the application has made efforts to obtain authorization from the owner of the patent on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.
- (3) The application for a compulsory licence shall be in compliance with such regulations as may be prescribed by the Minister.

Research Exemption

- INDONESIA : Article 16 (3) of the Patent Law No. 14 of 2001

Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder.

Regulatory review (Bolar) 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;
- (d) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.

Utility models

- THAILAND : Sections 65 bis and 65 decies of the Patent Act B.E. 2522 of 11/03/1979 as amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542

A petty patent may be granted for an invention in respect of which the following conditions are satisfied:

- (1) the invention is new;
- (2) it is capable of industrial application.

Countries analyzed: Compulsory licenses

Region	Compulsory license
Africa	36
Central and Latin America	25
Asia and Oceania	34
Europe	39 + EU
OECD countries	30

Statistics: compulsory licenses (1)

Region	C.L. for non-working
Africa	91,6 %
Central and Latin America	80%
Asia and Oceania	85.2 %
Europe	92,3 %
OECD countries	90 %

Statistics: compulsory licenses (2)

Region	C.L. for dependent patent
Africa	75 %
Central and Latin America	84 %
Asia and Oceania	67,6 %
Europe	87,1 %
OECD countries	83,3 %

Statistics: compulsory licenses (3)

Region	C.L. to correct patent abuse
Africa	13,8 %
Central and Latin America	76 %
Asia and Oceania	55,8 %
Europe	30,7 %
OECD countries	30 %

Statistics: compulsory licenses (4)

Region	C.L. for public interest
Africa	72,2 %
Central and Latin America	92 %
Asia and Oceania	70,5 %
Europe	79,48 %
OECD countries	86,6 %

Statistics: compulsory licenses (5)

Region	Government use
Africa	27,7 %
Central and Latin America	32 %
Asia and Oceania	55,8 %
Europe	30,7 %
OECD countries	33,3 %

Statistics: compulsory licenses (6)

Region	Implementation of the Decision of the General Council
Africa	0 %
Central and Latin America	0 %
Asia and Oceania	14,7 %
Europe	76,9 %
OECD countries	80 %

Countries analyzed: Research and Bolar exception

Region	Research exception	Bolar exception
Africa	30	4
Central and Latin America	25	4
Asia and Oceania	29	11
Europe	37	8 + EU countries
OECD countries	24	21

Statistics: Research and Bolar exception

Region	Research exception	Bolar exception
Africa	96,7 %	12,9 %
Central and Latin America	100 %	16 %
Asia and Oceania	90,6 %	34,37 %
Europe	97,6 % (without EU)	81,3 % (with EU countries)
OECD countries	82,7 %	72,4 %

Countries analyzed: Utility Models

Region	Utility Models
Africa	43
Central and Latin America	22
Asia and Oceania	→ 19
Europe	25
OECD countries	19



Thank you!

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