



DEPARTMENT OF
INTELLECTUAL
PROPERTY
MINISTRY OF COMMERCE



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

Topic 12: Which are Valid Grounds for a Compulsory License

**Bangkok, Thailand
March 29 to 31, 2011**

Jose Maria A. Ochave

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

MARCH 30, 2011 | BANGKOK, THAILAND

VALID GROUNDS FOR THE EXERCISE OF COMPULSORY LICENSING



OUTLINE

Valid Grounds for the Exercise of Compulsory Licensing

1. Introduction
2. The Importance of Clear Patent Policy Objectives – The Indian Example
3. The Variety of Grounds for the Exercise of Compulsory Licensing
4. CL as Remedy of Last Resort *or* Why the Private Sector is Not Sufficiently Interested
5. Points for Further Discussion

- License granted by a judicial or administrative body to a third party to exploit an invention without the consent of the patent holder
- Not a new concept as it is provided for even in the Paris Convention of 1883
- TWO TYPES:
 1. Predominantly for domestic market, under Art. 31.
 2. For export to an “eligible importing Member”, under Para. 6 of the Doha Declaration.

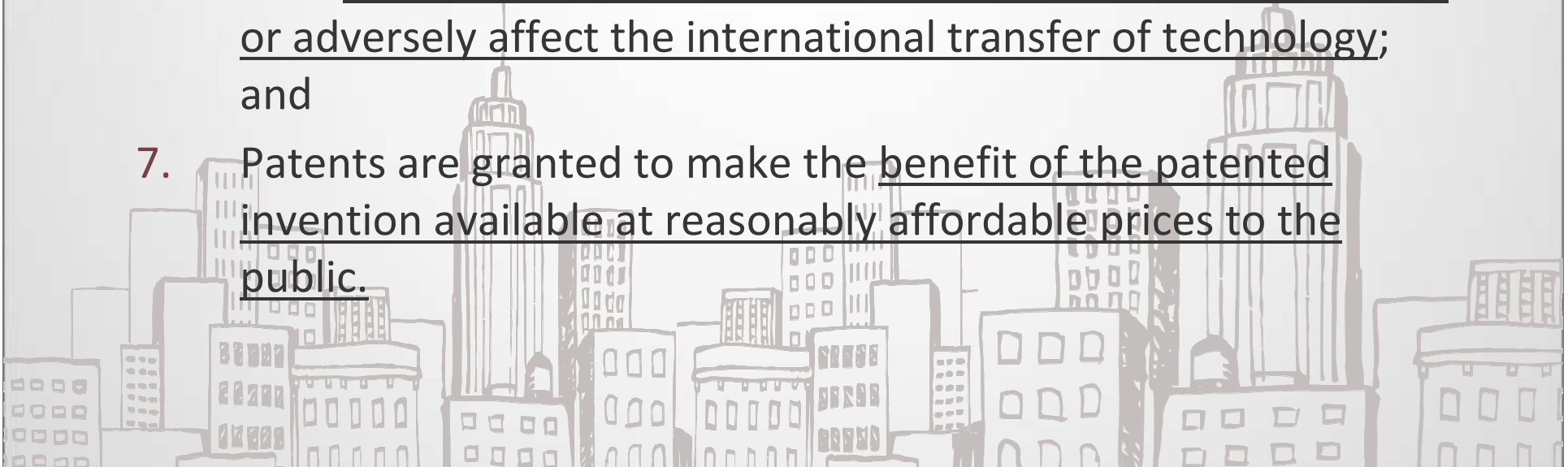


Section 83, Patent Act No. 3 of 1970 as last amended by the Patents Amendment Act No. 15 of 2005

General Considerations:

1. Patents are granted to encourage inventions and to secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without any undue delay;
2. They are not granted merely to enable the patentees to enjoy a monopoly for the importation of the patented article;
3. Protection and enforcement of patent rights contribute to the promotion of technological invention and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economical welfare, and to a balance of rights and obligations;

4. Patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
5. Patents granted do not in any way prohibit central Government in taking measures to protect public health;
6. Patent right is not abused by the patentee or person deriving title or interest on patent from patentee, and the patentee or a person deriving title or interest on patent from patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;
and
7. Patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.



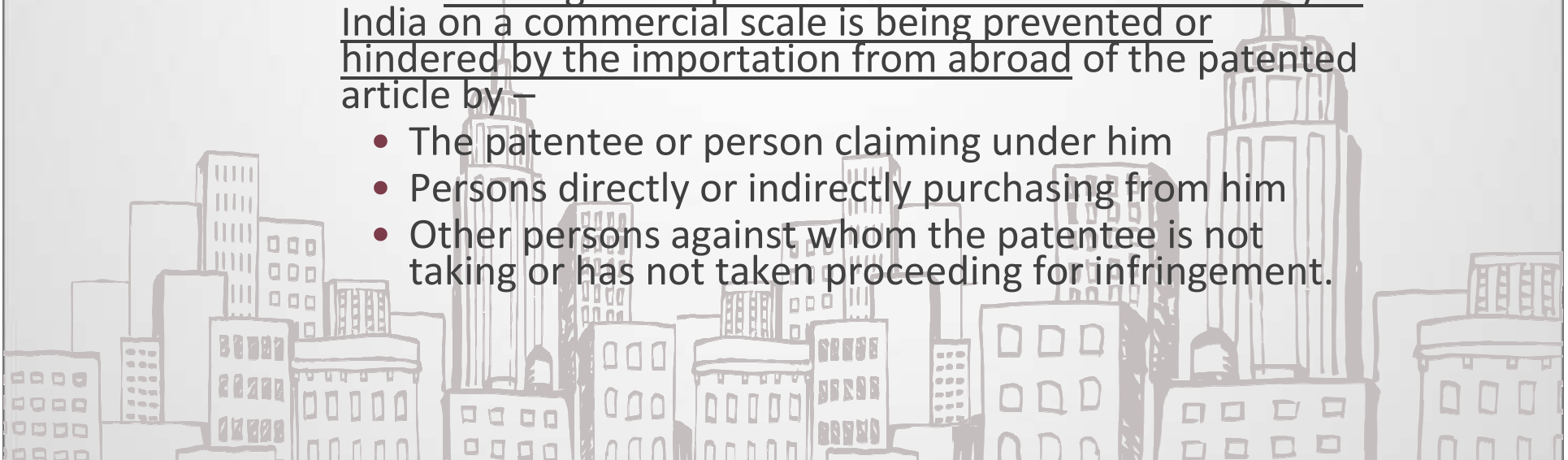
GROUNDS FOR USE OF COMPULSORY LICENSING

India:

Three years after grant of patent

- Reasonable requirements of the public with respect to the patented invention have not been satisfied.
 - If because of refusal to grant licence on reasonable terms:
 - Existing trade or industry or its development or establishment of new trade or industry in India or industry of any person or class of persons trading or manufacturing in India is prejudiced
 - Demand for patented article has not been met to an adequate extent or on reasonable terms
 - Market for export of the patented article manufactured in India is not being supplied or developed
 - Establishment or development of commercial activities in India is prejudiced

- If by reason of conditions imposed by patentee upon grant of licence or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced;
- If the patentee imposes a condition upon grant of licences to provide exclusive grant back, preventions to challenges to validity of patent or coercive package licensing
- If the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being worked to the fullest extent that is not reasonably practicable
- If the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by –
 - The patentee or person claiming under him
 - Persons directly or indirectly purchasing from him
 - Other persons against whom the patentee is not taking or has not taken proceeding for infringement.



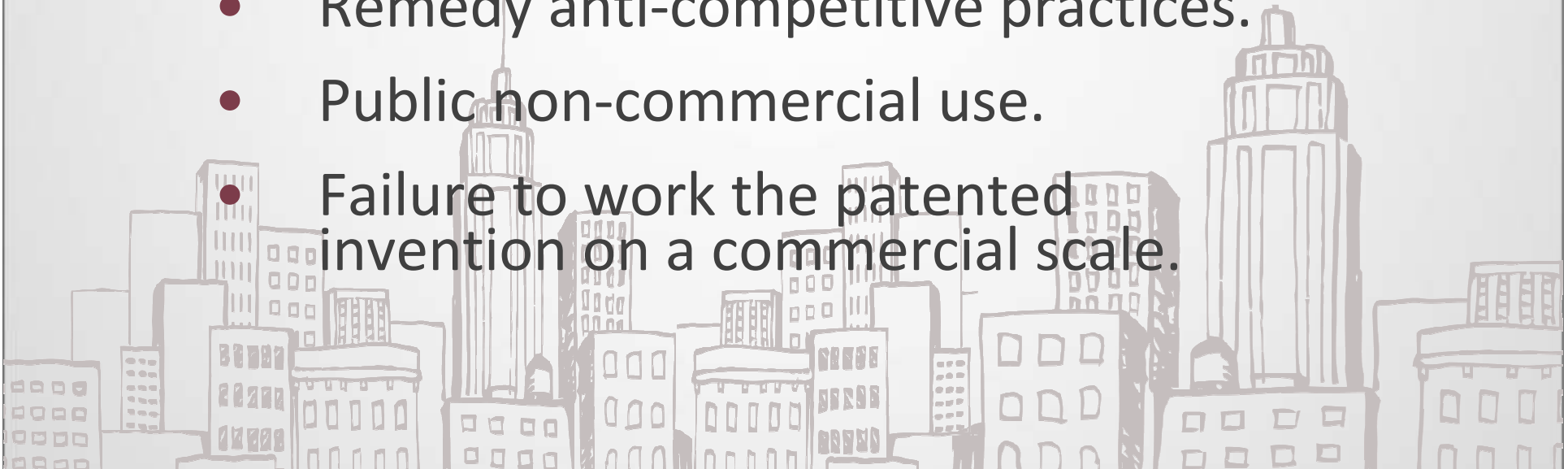
- Patented invention not available to the public at a reasonable price.
- Patented invention is not worked in the territory of India.



GROUNDS FOR USE OF COMPULSORY LICENSING

Philippines:

- National emergency or other circumstances of extreme urgency.
National security, nutrition, health or development of other vital sectors of the economy.
- Public interest requires.
- Remedy anti-competitive practices.
- Public non-commercial use.
- Failure to work the patented invention on a commercial scale.



GROUNDS FOR USE OF COMPULSORY LICENSING

Indonesia:

- Relevant patent has not been implemented or only partially implemented by the Patent holder.
After 36 months from grant of Patent.
- Implemented by Patent holder or licensee in a form and manner that contravenes public interest. Anytime after grant of patent.
- Government itself may exploit if important for conduct of defense and security of the State.

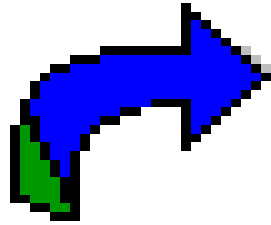


COMPULSORY LICENSING AS REMEDY OF LAST RESORT

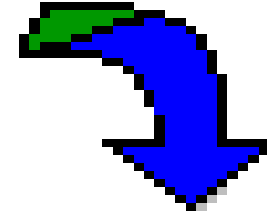
Why the Private Generic Sector is Not Using It:

1. Determination of the ground for CL is essentially political. High transaction cost.
2. Legal uncertainty due to protracted legal process. Possibility of injunction.
3. Voluntary licensing is the preferred mode. It does not close the door to future alliances.
4. The diseases for which there is strong legal and political mandate for CL use (i.e., malaria, TB and HIV-AIDS) have non-patented or off-patent medicines or have no significant market.
5. Foreign generic companies are not in a position to obtain CL. Local companies may not have capability to manufacture or source the product or are in a business relationship with the patent owner.

The Virtuous Cycle

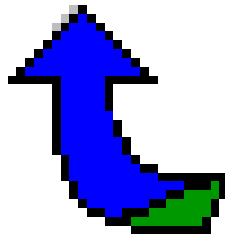


Drug Discovery

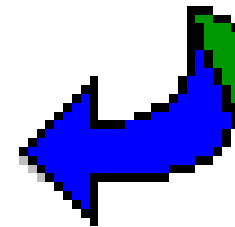


New Drug

**cheaper therapeutically
equivalent generics**



**Recovery of R&D
Investment**



**Patent
Expires**

**Patent
Protection**



**Valid Grounds for the Exercise
of Compulsory Licensing**

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Thank you.

