




# INTRODUCING TRIPS PLUS STANDARDS

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- WTO ACCESSION
  - FREE TRADE AGREEMENTS
  - TRAINING



# TRIPS FLEXIBILITIES

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- Patentability requirements

# UN High Commissioner on Human Rights

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- The requirements under the TRIPS Agreement for the grant of patents - novelty, inventive step and industrial applicability - are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, **the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge...**

**The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner, E/CN.4/Sub.2/2001/13, 27 June 2001,**



# Max Planck Institute-Patent Law Declaration

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- States have latitude to determine how the patentability requirements are interpreted and applied.



# Multilateral initiatives

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- WIPO's harmonization of patent law
- Substantive Patent Law Treaty (SPLT)

# Patentability standards in FTAs

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- **CAFTA, US-Morocco, TPP...**

- ...a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.

# TPP

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- Patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product.





## Second uses-Eli Lilly olanzapine

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- 1995-1998: 16 patent applications on the treatment of , inter alia, fungal dermatitis, bipolar disorder, sexual dysfunction, insomnia, anaesthetic agent, nicotine withdrawal, tic disorder, anorexia, depression, autism and mental retardation, pain, migraines, dyskinesia, addictive substance withdrawal, and Alzheimer's disease

# TRIPS-plus through training (1)

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- 'Swiss claims': use of X to manufacture a medicine for treatment of Y

# OBJECTIONS TO SECOND PHARMACEUTICAL INDICATIONS

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- Novelty of the use, not of the product
- No technical effect, industrial applicability
- Equivalent to a method of treatment



# TRIPS-plus through training (2)

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- Selection patents

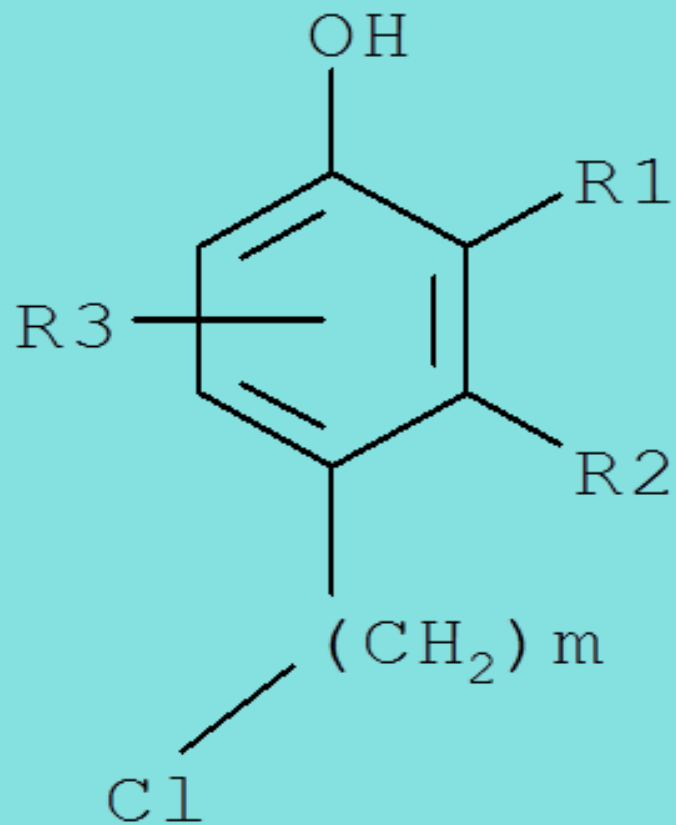
# Generic v. Specific disclosure

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C<sub>1</sub>—C<sub>4</sub>

# Markush claims


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## Patent CA 1,075,687 (1975)

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- 15 trillion compounds “useful in the treatment of mild anxiety states and certain kinds of psychotic conditions such as schizophrenia”
- Olanzapine one of the “most preferred compounds”

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- Developing national criteria on patentability



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- Section 3(d) India's Patent Act
  - Examination Guidelines (e.g. Brazil, Argentina, India)
  - Patent offices policies (e.g. Ecuador)
  - Courts' interpretations

# The role of patent offices

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- The patent office should function ‘as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power...
- Federal Trade Commission (2003), To promote innovation: the proper balance of competition and patent law policy, available at <http://www.ftc.gov>, p. 14.



# Novartis v. Gov. India

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- The claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.



# Novartis v. Gov. India

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- ...a monopoly is granted to a private individual in exchange of the invention being made public... To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.