Implications of Poverty, Inequalities and Trade Liberalization for Access to Health Technologies: An Evaluation of India's Legislative Response

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Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India

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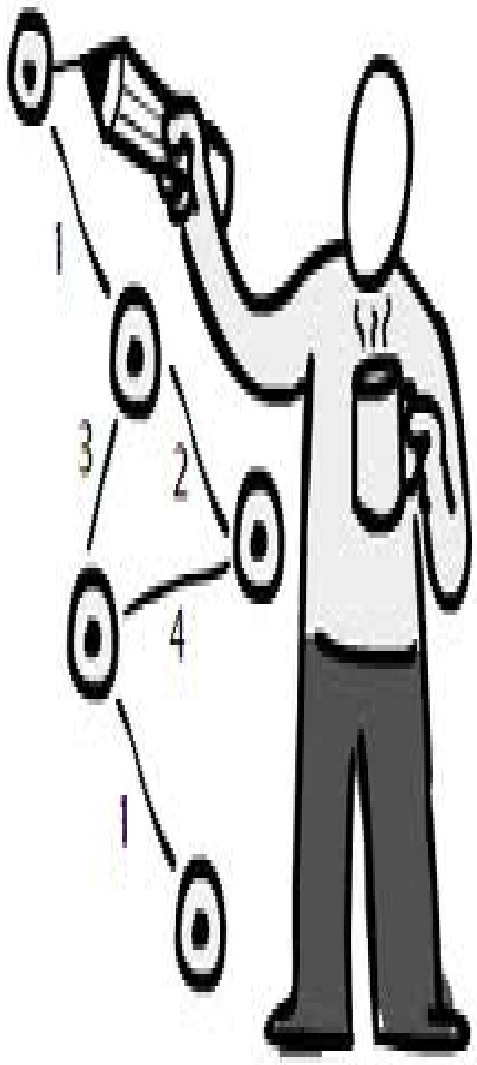
Presentation Overview

I. A Brief Overview of the Issue of Access to Medicines
II. India's Use of TRIPS' Public Health Flexibilities
A. Compulsory Licensing of Patents
B. Patentability Criteria and Patent Opposition
C. Parallel Importation



Patents as Barriers to Access

- Patents are private exclusive rights that allow patent holders to control whether, and on what terms, the protected items can be used by third parties.
- Patent protection conflicts with reverse-engineering and manufacturing of patented drugs and vaccines if such activities are carried out without the right holder's consent.
- Patents, therefore, provide the desired tool to patentee corporations to dominate the market and derive maximum profits by excluding others during the term of the patent (20 years from the date of filing).

India's Exemplary Use of TRIPS Flexibilities

- India accounts for the largest number of people living below the international poverty line, with 224 million people living under $1.90 a day.
- The TRIPS Agreement included a number of **public health flexibilities** in order to provide latitude to the Member States to tailor their national patent laws to fit their individual needs.
- While amending the Patents Act, India took a lead role in terms of **enacting TRIPS flexibilities** in its national laws in order to minimize the effects of a TRIPS-compliant regime.
- The Patents Act included special provisions, like sections 3(d) and 2(ja), which narrowed down the scope of patentable inventions in the pharmaceutical sector.
- India provided safeguard mechanisms like compulsory licensing of patents, parallel importation of patented drugs, and patent opposition procedures.

A. Compulsory Licensing of Patents: Indian Provisions

- First, **section 84** of the Act provides for ordinary compulsory licensing provision.
- Second, **section 92** of the Act provides for the special provision of compulsory licenses on notifications by Central Government in situations of “national emergency” or “extreme urgency” or “public non-commercial use”.
- Third, **section 92(A)** of the Act provides for special fast-track compulsory licensing provisions to allow the Indian generic manufacturers to make legally valid copies of patented drugs for export to poorer countries with no drug manufacturing capacity of their own.

B. Patentability Criteria and Patent Opposition

- To control the number of drug patents, India designed a well thought out patent opposition model.
- India used TRIPS flexibility (under Art.27.1) to define patentability criteria and raised the substantive threshold standards for patentability under s 3(d) and s 2(ja) of the Patents Act.
- India used another TRIPS flexibility (under Art.41.2) to design patent opposition model and linked s 3(d) and s 2(ja) with its patent opposition proceedings.

Why not pre-grant opposition?

- The WTO TRIPS Agreement did not provide any specific guidelines on patent opposition. [Arts. 62(2) and 41(2)]
- WTO Member States enjoy a wide discretion to choose only pre-grant or post-grant opposition procedures or a combination of both or no opposition procedures at all.
- WTO Member States should consider crafting pre-grant opposition procedures as well because preventing the grant of questionable patents is a superior policy option as compared to revoking the granted patents.

C. Parallel Importation

- The legal doctrine of exhaustion provides legality to the practice of parallel importation.
- Once rights are exhausted, it becomes legal for anyone to sell the goods they have purchased within the region of application. Because such transactions occur outside the distribution system of the original intellectual property rights owner.
- National exhaustion preserves right holders right to prevent importation from other jurisdictions.
- International exhaustion allows parallel importation from other jurisdictions.
- **Under section 107A of the Patents Act, India embraced international exhaustion of the rights of a patent owner.**

Why not international exhaustion?

- The TRIPS Agreement left exhaustion of rights to the discretion of its Member States.
- The footnote to **Art. 28(1)(a)** of the TRIPS Agreement clearly indicates that the patent holder's right to control import is subject to **Art. 6** of the TRIPS Agreement.
- Art. 6 mentions 'exhaustion' but leaves it unregulated: 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.
- By not imposing any specific conditions, the TRIPS Agreement recognizes the right of the Member States to determine the exhaustion regime according to their domestic needs.

- India's purposefully designed patent model has a clear public health objective.
- The Indian legislature tried to balance India's mandatory obligations under TRIPS with its national interests and constitutional obligation of providing good healthcare to citizens.
- Other WTO Member States, especially resource-poor countries, need to learn from India's reasonable approach and make wise policy choices to overcome public health challenges.

Thank you so much for your time and patience.