

# Intellectual Property Rights and Public Health Post TRIPS: Lessons from Abroad for Mexico to Ensure Sustainable Access to Medicines

*“Prices, Patents and Policies: Access to Priority Medicines for Mexico”*

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# TRIPS Implementation by Developing Countries

Few countries made full use of the transitional period in TRIPS for implementing protection for pharmaceutical product patents:

Country	Year of Implementation
Mexico	1991
Brazil	1997
Thailand	1999
Pakistan	2000
India	2005



## A Comparative Look at TRIPS Implementation and Public Health Safeguards in Developing Countries

Safeguards	Mexico	Brazil	India	Philippines	Thailand
Scope of Patentability	Invention defined broadly - no specific legislative safeguard  (see Art. 15 & 16)	No specific definition/ legislative safeguard (see Art. 8,10 & 11)  Potential safeguard with health agency ANVISA reviewing patents	Safeguard against secondary patenting/ use of known substances that do not show enhanced efficacy  (see s3(d))	Safeguard against secondary patenting/ use of known substances that do not show enhanced efficacy  (see s22 & 26)	No specific definition/ legislative safeguard (see s 5 & 9)

# A Comparative Look at TRIPS Implementation and Public Health Safeguards in Developing Countries

Safeguards	Mexico	Brazil	India	Philippines	Thailand
Observation/ Opposition Mechanisms	<p>Right to bring an invalidation action after grant of patent</p> <p>(see Art. 78)</p>	<p>Interested parties can file evidence (see Art 31)</p> <p>Third parties can apply to nullify a patent</p> <p>(see Art. 51)</p>	<p>Right to file opposition prior to grant of patent and after grant with hearing</p> <p>(see ss 25(1) &amp; (2))</p> <p>Right to revoke a patent</p> <p>(see s64)</p>	<p>Observation against applications permitted (see s47)</p> <p>Right to cancel a patent after grant if (see s61)</p>	<p>Any person can file an opposition before grant of a patent (see s31)</p> <p>Any person can file to cancel a granted patent (see s54)</p>

# A Comparative Look at TRIPS Implementation and Public Health Safeguards in Developing Countries

Safeguards	Mexico	Brazil	India	Philippines	Thailand
Compulsory License (CL) and Government Use (GU)	<p>Available 3 years after grant of patent. CL not permitted where patent holder is importing the product</p> <p>One year grace period for patentee to make use of patent before CL kicks in.</p> <p>National emergency provision in cases of serious disease decided by GHC</p>	<p>Patent is used in abusive manner.</p> <p>Non-working of patent in Brazil</p> <p>Patentee not meeting market needs</p> <p>National emergency/ public interest</p>	<p>-Automatic CL</p> <p>-Requirements of public not met</p> <p>-Not available at reasonable price</p> <p>-Non-working in India</p> <p>-Anti-competitive practices</p> <p>-Public non-commercial use</p> <p>-National or extreme urgency or public health crises e.g HIV, TB, malaria and other epidemics</p> <p>-For export</p> <p>-GU before/after grant of patent</p>	<p>GU for health purposes where:</p> <p>-anti-competitive</p> <p>-national emergency</p> <p>-Requirements of public not met</p> <p>CL for all the above grounds and for non-working</p>	<p>-Non-working</p> <p>-Product not made available</p> <p>GU for national emergency, including to relieve drug shortage</p>

# A Comparative Look at TRIPS Implementation and Public Health Safeguards in Developing Countries

Safeguards	Mexico	Brazil	India	Philippines	Thailand
Parallel Importation	Not permitted under NAFTA	Permitted after compulsory license issued	Subject to legal interpretation	Permitted	N/A
Data Exclusivity	Undisclosed/ confidential data subject to exclusivity	Only data protection - no exclusivity	Only data protection - no exclusivity	Only data protection - no exclusivity	Only for new chemical substances - but the Thai FDA appears to practice data protection and not exclusivity

## Scope of Patentability

- Implementation of India's efficacy standard
- Lack of definition of “evergreening” and lack of parameters for the term “efficacy”
- Decisions: Gleevec and Setting Efficacy Standard
- High Court decision influencing patent offices: concept of therapeutic efficacy
- Decisions: Trend of decisions illustrated by Nevirapine HH, particle size stability deemed to be storage
- Unique application of efficacy standard thus far to “mailbox” drugs, as Philippines and other countries follow suit, defining parameters is critical



## Pre-Grant Patent Oppositions

Objectives (of all public participation mechanisms, e.g. post grant, reexamination, observation, revocation and invalidity):

- improvement of patent quality
- increased public participation
- expert input increases efficiency of examination process
- ensures patents do not unnecessarily prevent other legitimate competitors from entering the market



## Pre-grant Patent Oppositions (Cont)

Arguments against mechanism:

- Potential for flooding patent offices with frivolous oppositions

- \*200 opposed out of 9000 pharmaceutical patent applications (2%)

- Lack of certainty and undue delay

- \* Generally resolved expeditiously

Dual Objectives of Addressing Information Asymmetry: Public Participation and the Integrity of the Patent System



# ARV Patent Oppositions and Going Forward

- Abacavir Sulfate and Combivir
- Tenofovir DF (case study for patent quality and access)
- Lopinavir/Ritonavir
- Atazanavir

## Going Forward:

- Maraviroc, Raltegravir, Etravirine
- US Patent Reform



## Compulsory Licensing

- Antiretroviral CLs in Thailand and Brazil - Political dimensions
- India CL applications - present debate on the right to a hearing
- “Automatic” Compulsory Licensing - India’s safeguard for public health
- Open Area for Research: What constitutes a national emergency? Indian injunctions case defining health crisis or health need.



# Concluding Thoughts

Irrespective of NAFTA, Mexico has taken a 'TRIPS Plus' approach to IP whereas other developing countries are more 'TRIPS Just'.

Potential options to help improve access to medicines which would comply with NAFTA/TRIPS:

- Improving patentability criteria and examination at patent office level
- Resolving information asymmetry around pharmaceutical patents
- Opposition/observation mechanisms to improve patent quality e.g. pre-grant observations by third parties
- Improving compulsory licensing provisions to include anti-competitive practices, meeting market needs and making patents available at reasonably affordable prices

Political and economic factors critical to considering these options

Further research:

- Measure technology flow and FDI to Mexico as result of stronger IP;
- Patent filing trends in pharmaceutical sector and correlation with stronger patent laws

