

An Evaluation of TRIPS Implementation and Public Health Safeguards: Re-visiting the Innovation-Access Dichotomy

**Global Governance of HIV/AIDS:
Intellectual Property and Access to Essential Medicines
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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
China	1992
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) & (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 (s11A(7)) - permits continued generic production</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> <ul style="list-style-type: none"> -anti-competitive -national emergency -Requirements of public not met <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

- Countries have chosen to limit the scope of what is patentable in different ways.
- In 2005, India introduced the efficacy standard into its national legislation:

Section 3(d) The following are not inventions within the meaning of this Act, –

(d) – the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.



Scope of Patentability

- Three years later, there remains a lack of clarity around how to define the term efficacy, and how the provision should be implemented.
- The Philippines has followed suit and enacted an efficacy standard into its patent statute. It remains to be seen how the Philippines will define efficacy.
- In India thus far, the efficacy standard has been applied to drugs applied for between 1995-2005 (known as “mailbox drugs”). Since time has lapsed, data relating to efficacy may be available. How will the efficacy standard be applied to new applications where no time has elapsed, with no data available? As the Philippines and other countries adopt the efficacy standard, this issue requires further thinking.



Scope of Patentability

- Judicial Decisions: the *Gleevec* case and setting efficacy standard
 - High Court recommended limiting efficacy standard to therapeutic benefits
 - *Gleevec* appeal at Patent Office, on the merits of the patent application, is pending
- Administrative Decision: Initial application of efficacy standard illustrated in application for Nevirapine Hemi-hydrate
 - particle size stability deemed to be a storage benefit
 - decision sets out that efficacy standard requires therapeutic benefit



Pre-grant Patent Oppositions

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

1. Improves patent quality
2. Increases public participation
3. Promotes efficiency of examination process by allowing for third-party expert input
4. Ensures patents do not unnecessarily prevent other legitimate competitors from entering the market



Pre-grant Patent Oppositions (Cont)

Arguments against public participation:

1. Potential for flooding patent offices with frivolous Oppositions
 - 200 opposed out of 9000 pharmaceutical patent applications (2%)
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



I-MAK Patent Oppositions on ARVs in India

Drug	Drug Type	Status
Abacavir Sulfate	Salt	Withdrawn
Nevirapine HH	Pediatric formulation	Rejected
Lopinavir/Ritonavir	LPV polymorph RTV polymorph Soft-Gel Combination Capsule Heat-Stable Combination Tablet	Pending Pending Abandoned Pending
Tenofovir DF	Ester Formulation	Pending Pending



Patent Oppositions: New Generation of HIV Drugs

- New ARVs such as Maraviroc, Raltegravir, Etravirine granted patents in India
- These patents not been opposed by generic suppliers or civil society groups because:
 - pricing structure for these ARVs is yet to be determined
 - are also not yet recommended by WHO for national treatment programmes
- Once patients require this new generation of drugs, civil society groups and generic suppliers may have more incentive to engage in post-grant opposition or revocation proceedings



Compulsory Licensing

- “Automatic” Compulsory Licensing in India - in practice thus far this issue has not been contested. In some cases e.g Abacavir and Combivir, the originator company (GSK) has withdrawn the patent application, so generic production has continued uninterrupted and without royalty payment.
- ARV CLs in Thailand and Brazil - Political will required to issue CLs in other developing countries, including India.
- Continuing issue: What constitutes a national emergency/public health need?
 - India CL applications for export to countries with no/insufficient manufacturing countries- NATCO and the debate on the right to a hearing and effectiveness of Doha Declaration provision.
 - Indian court bases its decision on *public interest needs* for affordable cancer drug Erlotinib to deny injunction to the originator company and allow for continued generic production.



Revisiting the Innovation Access Paradigm

- Innovation and access have been in conflict:
 - Health advocates argue that patents impede access.
 - Pharmaceutical companies argue that without patents there are no incentives to innovate
- Not only is access suffering, so is innovation:
 - Seeing fewer new NDA filings for NMEs (U.S GAO Report 2006). Companies appear to rely more on the low hanging fruits of the innovation scale.
 - More poor quality patents being detected that unduly prevent competition and innovation



Prescription for Improving Access and Innovation Within the Current Patent System

- Strengthen patentability criteria - to improve patent quality
- Increasing public participation in patent examination:
 - requires rectifying information asymmetry
 - strengthening patent challenge procedures pre and post grant
- Predicating patent terms on quality

