

# **TRIPS Compliance – the Legal, Economic & Public Health Concerns**

**A Presentation made at the  
The Retreat for the Honorable Justices of  
the Supreme Court of India  
The National Judicial Academy, Bhopal**

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# The Objectives

**The objectives of this presentation are  
to highlight some of the:**

**legal,**

**economic &**

**public health**

**implications of India's TRIPS  
compliance**

# Public Health Implications

## Propositions

- (1) Introduction of Product Patent Regime has raised public health concerns. Some sections argue that patents for proprietary drug molecules can lead to abuse of monopoly and increase in drug price. Accordingly, it is argued, that even essential drugs will not be available to poorer sections of people at affordable prices.
- (2) The counter argument by the pharmaceutical industry (primarily the research-based pharma industry) is that patents act as incentives for new chemical entity research that leads to quality medicines for emerging diseases.

## **These Propositions lead to the following questions:**

- (1) Does the TRIPS compliance amendment to the Patents Act, 1970 (introducing product patents for inventions relating to 'food, drug and medicines') strike a balance between access to health of India's rural poor and availability of quality medicines for new and emerging diseases?
  
- (2) Is there a link between product patents and drug price? Will the product patent regime affect Indian generic pharmaceutical industry and access to cheaper drugs?

# Questions on TRIPS & Public Health

- (3) Can 'Compulsory Licensing', as envisaged in the amended Patents Act, be used as an effective tool to check possible abuse of monopoly by product patentees?
- (4) Would it be possible for India to attract R&D investments in NCE research and Contract Research Outsourcing (CRO) without providing for product patents and data exclusivity?
- (5) And finally, what would have been the consequence of India not fully complying with the TRIPS Agreement as on January 01, 2005.

# The Legal Implications

## Propositions

- (1) Arguably, TRIPS r/w Doha Declaration on Public Health allow Member Countries like India to read further limitations into the substantive obligations – like product patents for pharmaceuticals.
- (2) A conflicting viewpoint is that the Patents 3<sup>rd</sup> amendment does not make the national law TRIPS compliant.

# the legal questions

- (1) If the message of Doha Declaration is to give primacy to 'Public Health' as against trade interests, then arguably India can exclude non-NCE pharma inventions and a certain types of biological subject matters from the scope of patentability. If not done carefully, this could make India face stringent retaliatory measures.
- (2) There is no empirically tested position on the question of patentability of computer software. While it could be in India's interests to extend the scope of patentability to newer areas like Information technology (reference to computer software), the approach has to be formulated based on a ground level assessment of the domestic industry's IPR preparedness. This has not been done.

# gaps in the law

- (1) There exists many grey areas in the Patents Act (as amended by the Patents Bill, 2005).
- (2) Some of these areas cannot be fully legislated, as for example the grounds for Compulsory Licenses (though specified), 'reasonableness of royalty' etc. leaves scope for Judicial Intervention.
- (3) Some other amendments are self-defeating in nature. As for example 'Inventive Step' has been redefined. The new definition, arguably, dilutes this stringent test of patentability.

## to fill in the legal gap

- (1) Judicial Intervention may be an appropriate method to fill in the existing gaps in the national patent law with respect to certain foundational norms (like novelty, inventive step etc).
- (2) In many jurisdictions in the world Judiciary has been filling the legislative vacuum by formulating 'public interests' perspectives in the patents law ?
- (3) Also it may be worth considering to set up a specialized patent court to deal with patent infringement actions?

## **Briefly ..**

India has to work within the framework of WTO and the global trade order. As such, TRIPS compliance is a reality. What can be done is to make best use of the flexibilities within the TRIPS and to be cautious when moving forward to TRIPS Plus.

# Briefly ..

We, as a nation, needs to strike a balance when it comes to crucial issues like public health. One can easily see that the perspectives of multinational pharma companies and local generics are the same when it comes to profit making.

Otherwise, why there is such a negligible R&D spending by local generics (except a few) in the last 10 years, despite knowing that by 2005 India will have to have a product patent regime?

Why no Indian pharma company is on drug discovery for poor man's diseases like the Malaria?

Why so many patent applications of Indian generic companies on diabetes?

# Briefly ..

When amending the national laws, we must be cautious in not making it self-defeating.

The Patents Act as it stands now has several legal gaps.

# Briefly ..

Judiciary has the difficult task of striking a fine balance in interpreting the national patents law provisions.

**Thank You**