

Intellectual Property Rights

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Intellectual Property Rights in Preferential Trade Agreements

- Many Preferential Trade Agreements (PTAs) adopted since the turn of the millennium, especially those involving the United States and the European Union, have ratcheted up the norms and standards of protecting intellectual property
 - They go beyond those provided in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
- The US and the EU had initiated this trend
- In recent years, several developing economies have also joined this trend
 - China, ASEAN members, Chile, Peru and Costa Rica

Conflicting Positions of Countries on IPRs

- Until the previous decade, there was a clear division in the positions of the developing and the developed countries on the framework for intellectual property protection in PTAs
 - Developing country position
 - Use of flexibilities within the Agreement on TRIPS
 - Developed countries
 - Inclusion of TRIPS-plus provisions
- In recent years, some developing countries are also agreeing to include TRIPS-plus provisions in the PTAs they are parties to

Essential Differences in the Two Positions

- Typical developing country position
 - IPRs regime should not just focus on the immediate interests of the right holders, but should also consider putting in place relevant instruments to protect public interest
- Developed countries' argument
 - Stronger protection to intellectual property (IP) would incentivise creativity, which will eventually contribute to economic welfare

Focus of This Presentation

- Will deal with the most common for IPRs, namely patents
- This, however, does not imply that the issues concerning the other forms of IPRs are any less relevant in the context of the PTAs

A Balanced IP Regime: An Avowed Objective

- “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations” (“Objectives” of the TRIPS Agreement – Article 7)
- Patent law plays an important role in the property rights regime essential to a well-functioning competitive economy (US Federal Trade Commission)
- “[F]ree competition” is “the baseline” on which “the patent system’s incentive to creative effort depends.” By limiting the duration of a patent, “[t]he Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’” (US Supreme Court - *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989))

Setting Boundaries on the Exercise of IPRs

- Limiting the exercise of the rights to serve public policy objectives
 - The rights of governments to issue compulsory licenses is important part of the patent regime
- Article 5 of the Paris Convention
 - “Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”
- Doha Declaration on TRIPS
 - TRIPS Agreement does not and should not prevent Members from taking measures to protect public health
 - Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted



PART I: Using TRIPS-Flexibilities

Balancing the Interests of Rights Holders and Users of Proprietary Technologies

- Intellectual property laws conform to the globally accepted standards established by the Agreement on TRIPS
- Laws provide the flexibilities necessary to respond to the critical development challenges
 - Access to affordable medicines
 - Providing the mechanisms for protecting traditional knowledge

Doha Declaration on TRIPS Agreement and Public Health, 2001

- Recognised the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics
- Stated that “TRIPS Agreement **does not and should not prevent** Members from taking measures to protect public health” (emphasis added)
- Affirms that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all

Features of the Declaration on TRIPS Agreement and Public Health(cont..)

- Affirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose
- “Each Member has the right to **grant compulsory licences** and the freedom to determine the grounds upon which such licences are granted”
- Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency
- Addressing the problem that countries with insufficient or no manufacturing capacities in the pharmaceutical sector face in making effective use of the compulsory licensing system to produce affordable medicines

Protecting Traditional Knowledge: The Rationale

- Traditional Knowledge (TK) is a “living body of knowledge” that has to be treated at par with the formal knowledge system
 - Promotes sustainable use of the world’s resources
 - Contributes to the preservation of natural habitats
 - Supports livelihoods of a large share of the population in many developing countries
- Increasing evidence of misappropriation of TK
 - Surfeit of “fakes”
 - Grant of patents and other forms of intellectual property rights (IPRs) on TK-based products and processes, e.g. “bad patents”

Using the Patent Regime to Protect TK

- Due diligence in the examination of patent applications to prevent misappropriation of TK
- Excerpts of the relevant provisions in the Intellectual Property Chapter of the Trans Pacific Partnership
 - The Parties recognise the relevance of intellectual property systems and traditional knowledge associated with genetic resources to each other, when that traditional knowledge is related to those intellectual property systems
 - The Parties shall endeavour to pursue quality patent examination, which may include
 - that in determining prior art, relevant publicly available documented information related to traditional knowledge associated with genetic resources may be taken into account
 - an opportunity for third parties to cite, in writing, to the competent examining authority prior art disclosures that may have a bearing on patentability, including prior art disclosures related to traditional knowledge associated with genetic resources



TRIPS-Plus Provisions

Strengthening of the Rights of the IP Holders

- Using the TRIPS framework
 - Data Exclusivity
 - Patent linkage
 - Patent term extension
- Pushing the contours of IP protection
 - Treaties under the World Intellectual Property Organization
 - Mega-regional trade agreements: Trans Pacific Partnership, Transatlantic Trade and Investment Partnership
 - Harmonising the IP laws further, leaving little room for individual countries to design their laws in keeping with the realities in their respective countries – “one size fits all”
- Initiatives like the Anti-Counterfeiting Trade Agreement

Data Exclusivity: Where has this issue come from?

- Article 39 of the TRIPS Agreement : Protection of Undisclosed Information
 - Protection justified on the grounds that unfair competition needs to be curbed
 - Protection must be applied to information that is
 - Secret
 - Has commercial value because it is secret
 - Has been subject to reasonable steps to keep it secret

Protection of Undisclosed Information and Access to Medicines

- Relates to the data generated during clinical trials, the submission of which is required by governments for approving marketing of pharmaceuticals – data exclusivity
- TRIPS Agreement requires that this data must be protected against “unfair commercial use”
 - Leaves it to the WTO member states to determine the best way of protecting the data
- US and EU provide 5-10 years data exclusivity, a period during which no new entrants are allowed into the markets for the products in question
 - This is sought to be made the global practice

Patent Linkage

- Makes regulatory approval for a pharmaceutical product dependant on whether or not the said product is under patent protection
 - Delays introduction of generic versions of the pharmaceutical products
- PTAs formalised by the United States were the first to include “patent linkage” provisions
 - Korea amended its patent act after the KORUS FTA was enforced

Patent Term Extension

- “The effective period of patent protection for inventions of new chemical entities is much less than the full 20 years, because a large part of that period will have expired before marketing approval is obtained from the public health regulatory bodies.
- For this reason, most of the major developed countries have introduced systems whereby a prolonged period of protection can be obtained to compensate, at least in part, for this loss of the effective period of protection.”

Source: WTO, Pharmaceutical patents and the TRIPS Agreement (accessed from: https://www.wto.org/english/tratop_e/TRIPs_e/pharma_ato186_e.htm#fntext1)

What are the Emerging Trends?

- Most of the PTAs that are currently on the table (including the TPP), include a combination of the two perspectives on IPRs
- The critical issue is whether the framework for protection of IPRs adopted in the PTAs would evolve into a more inclusive, wherein the balance between the producers and users of intellectual property



Thank you

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