IP Protection:

Plurilateral or Multilateral?

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Basic Facts

- WTO is a major landmark in Multilateralism
- Bilateral/Regional Trade Agreements result in fragmentation of trade
- However, the number of such agreements have been increasing sharply
  - Pre WTO: 1984-1994: 124 RTAs
  - Post WTO: 510+ RTAs
- One of the key reasons is slow pace of WTO Negotiations

Present IP Protection Regime

- *Multilateral level*
  - Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

- *Plurilateral or Bilateral Level*
  - *IPR provisions as a part of the RTAs /PTAs eg. NAFTA, EFTA, Trans-Pacific Partnership Agreement, Transatlantic Trade and Investment Partnership (TTIP) (currently under negotiation)*
  - *Plurilateral attempt by few nations to enhance the IP protection regime: Anti –Counterfeiting Trade Agreement (ACTA)*

TRIPS: Recap

- Coverage:
  - Copyright
  - Trademarks
  - Patents
  - Geographical Indications
  - Industrial design
  - Layout designs
  - Undisclosed information, including trade secrets

- Main Principles:
  - Only provides **minimum level of protection** for each of the above
  - Non discrimination (national treatment and MFN treatment)
  - Enforcement through WTO Dispute Settlement
  - Effective procedures and remedies for enforcing IPRs

RTAs/PTAs under the WTO Framework

- Legal Basis for RTAs under WTO found in **Article XXIV:5 of GATT** and **Article V** of **GATS**
- These recognize that preferential arrangements in case of trade in goods and economic integration in services can take place, provided certain conditions are fulfilled.
- However, **no corresponding provision found under TRIPS**
- So, what is the implication of this?

RTAs/PTAs and TRIPS

- Since TRIPS does not contain an exemption for RTA/PTA, the principle of MFN will apply to RTAs/PTAs as well
- For eg: If the US and a developing country member negotiate an RTA, MFN will force the developing nation to make the same IP concession it accepted in the RTA available to all nations.
- Remember: TRIPS only provides a minimum standard of protection. Countries free to go beyond TRIPS. But any additional concession/obligation taken under an RTA/PTA would have to be *MFNised* and made available to all.
- Thus, these **TRIPS Plus** provisions have far reaching implications and is gradually leading to higher level of IP protection than that was envisaged originally.

Reasons for the Rise of TRIPS Plus Provisions

- Stronger IPR protection has been the driving agenda of the major developed countries, particularly the US.
- Having failed to achieve all they sought in the TRIPS negotiations, these nations have shifted their focus to RTAs and PTAs
- Post TRIPS and following the failure of the Seattle Ministerial in 1999 – while many developing countries were still struggling to implement their obligations under TRIPS, developed countries were already raising the level of IPRs through RTAs/PTAs

IP Protection: Cycle of Multilateralism and Plurilateralism

- However, this is not the first time, that countries have resorted to IP protection at a plurilateral or Bilateral level. Cycle of multilateralism and bi / plurilateralism evidenced from the beginning of IPRs

- Early Bilateral commercial **Friendship, Commerce and Navigation (FCN) agreements in 1800s** contained IPR provisions

- Later, plurilateral attempts seen resulting in the culmination of the **Paris Convention (1883, patents, trademarks and industrial designs); Berne Convention (1886, copyright)**

- In 1967, **WIPO** created under the aegis of UN to oversee and administer these treaties and other IP related treaties
- In 1970s, following the failure of GATT 1947 to cover topics under **Bilateral Investment Treaties (BITs)** the FCN treaties, countries shifted to protect a range of private rights like IPRs: Return of Bilateralism

- Existing WIPO: available multilateral forum was seen as a developing country dominated institution and hence not acceptable to the developed countries

IP Protection: Cycle of Multilateralism and Plurilateralism…*contd*.

- However, with the failure of BITs to effectively protect IPRs and realization on part of developed countries that counterfeits goods were costing the nations a huge amount (USD 43-61 billion in case of the US) led to search for other forums

- The developed countries, especially the US had by the **early 1980s** attained **comparative advantage in IP**, while losing in other areas namely manufacturing: thus it became an international policy priority

- Thus, the US shifted away from multilateral forum and negotiated NAFTA and linked IPRs to its GSP program granting preferential access to the US market.
- The forum shifted back to multilateralism when the US with backing of EU, Switzerland and Japan, managed to get IP on the negotiating agenda in the **Uruguay round**: resulting in the adoption of TRIPS

- However since late 1990s, US and other developed countries wanted to negotiate higher standards of protection but with a prolonged Doha Round, **attention is back to bilateral/plurilateral fora**.

Why the current shift away from multilateral forum?

- Multilateral gains are always, to some extent, small and resemble the **least common denominator** due to large number of countries with varied opinions:
  - Thus, when the developed countries are unable to gain concessions through multilateral negotiations, they simply shift the parameters and sidesteps these impediments through RTAs/PTAs
- Also, multilateral agreements like the TRIPS contain **special and differential treatment and other opt-out clauses**, and hence the developed countries find it easier to shift to bilateral/plurilateral fora
- It has also been opined that by changing the forum and reducing the number of negotiating parties, countries like the US can provide side payments that it would not be able to offer in a multilateral forum.
- This may also prevent the LDCs from reopening the TRIPS negotiations with a better bargaining position.
- Thus, the developed countries are raising the minimum standards by progressively building upon the level of IP protection through development of RTA / PTA models or prototypes

Forms of TRIPS Plus Provisions

- Most bilateral regimes require the trading partners to implement TRIPS plus provisions in the following for:
  - Inclusion of new areas of IPRs
  - Implementation of more extensive levels or standards of IP protection than is required by TRIPS; or
  - Elimination of an option or flexibility available under TRIPS
- Practice of negotiating TRIPS-Plus provisions is not limited to RTAs with developing countries, but can also be found in agreements between developed countries like in the case of the US-Australia FTA
- In case of the US, it is seen that most TRIPS Plus provisions and resulting standards are designed to best protect US domestic interests and such provisions are identical to its domestic law.

TRIPS plus provisions - Examples

- Grant patents on plants, plant varieties and/or animals
- Accede (or commitment to accede) to the UPOV Convention for the Protection of New Plant Varieties (not mentioned in TRIPS)
- Conform with the 'highest international standard' of IP protection, which by implication mean that if there is a TRIPS-plus international standard, the contracting party would have to adhere to such agreement
- Narrower grounds for Compulsory Licensing
- Stricter border control measures – based on suspicion alone
- Extension of period of protection

TRIPS Plus: Linking Market Approval To The Patent Status Of A Drug

- Several RTAs (US-Chile, US-Morocco) have introduced provisions which prevent national drug regulatory authorities from registering generic version of a drug that is under patent in the country without the consent of the patent holder.

- Significant shift from traditional operating standards where the market approval of a drug that is the regulatory approval granted to a product which proves its **safety and efficacy** has not been linked to a drug's patent status.

- Potential infringement of a patented drug by the applicant generic manufacturer has never had a bearing on the decision of a national drug regulatory authority.
- Thus if a patent holder believes a generic manufacturer is infringing its patent, it traditionally has the responsibility to enforce its rights.
- The newly delegated role of the regulatory authority as an enforcer of a private right: significant benefit to the rights holder

TRIPS Plus: Linking Market Approval To The Patent Status Of A Drug…*contd*.

- Not only will these provisions delay access to generic drugs, but may also impediment a country from taking advantage of the TRIPS recognized flexibility of a compulsory license

- Unclear whether compulsory license can be issued to provide entry of generic drugs where the law does not allow registration prior to patent expiry
  - A manufacturer granted authority to produce under CL must be registered with the national drug authority
  - Thus – if the regulatory authority prevented from registering generics till patent expiry, CL will be prevented from coming into force.

TRIPS Plus: Data Exclusivity Period

- Before marketing a product, marketing approval from national drug regulatory authority required to ensure drug is safe, effective and of sufficient quality
- Results of clinical trials and other tests conducted by the applicant is submitted to the authority
- When a later applicant i.e. generic manufacturer seeks registration of the same drug, it need not re-conduct the same trials but prove the new drug
  - Has the same quality
  - Is therapeutically equivalent to previously approved drug
- The generic drugs save time and money this way
- TRIPS: does not explicitly oblige members to provide any period of data exclusivity
- Article 39.3 states the need to protect 'undisclosed data or other data' from 'unfair commercial use' and 'disclosure'
- Recent US FTAs seek five year period of data exclusivity
- Thus data exclusivity can act as a de facto monopoly preventing competition
- Where drug protected by patent, even compulsory license meaningless if fresh clinical trials have to be conducted for the drug

TRIPS Plus: Patent term extension

- TRIPS requirement: patent protection for **at least** 20 years
- No obligation on members to compensate patent holders for unreasonable delays in approving patent or registering the product by extending the patent term
- However, several RTAs, especially ones entered into by the US provide for compensating the companies for an 'unreasonable' delay caused by regulatory authorities
- Concern among developing countries as to what is 'reasonable', especially from a public health perspective given the constraint on national drug regulation authorities
- Extra years granted to patent as a way of compensation may have serious health implications in developing countries and LDCs

TRIPS Plus: Limits on Compulsory License

- CL is recognized by TRIPS and is subject to fulfillment of certain conditions.
- It is also recognized as an important public health safeguard allowing government to temporarily override a patent and authorize the production of generic versions of a patented product
- The restrictions on CL is imposed through:
  - Data exclusivity provisions
  - Direct restrictions limiting the grounds on which CL issued (by listing the specific cases eg. Remedying anti-competitive practice, national emergency, other emergency etc)

ACTA – TRIPS PlUS

Recent Plurilateral IP Protection attempt: **ACTA**

- National governments and stakeholders -- including right holders, competitors, consumers and the public generally -- have important interests in the nature and effects of intellectual property protection
- The accomplishment of public policy objectives may dictate stronger or weaker IPRs protection and enforcement mechanisms
- Traditionally enforcement of IPRs is the responsibility of right holders proceeding in civil courts before judges and jurors

Recent Plurilateral attempt: **ACTA**-Intention of Proponents

- TRIPS Agreement (1995) perceived by OECD industry groups as initial step in extension of higher IPRs standards
  - Developing countries preserved substantial flexibilities
- Subsequent efforts to strengthen protection at the multilateral level unsuccessful because of developing country resistance (WTO, WIPO, WHO, etc.)
  - Developing countries generally sought to preserve TRIPS flexibilities, and in public health arena to expand them

Shift to “second-best” solutions

- Incorporation of IPRs chapters in bilateral and regional free trade agreements (FTAs), focusing on patent and data exclusivity for pharmaceutical industry, protections in digital environment, strengthening enforcement standards
- EU initially did not focus on IPRs, but this changed
- From IPRs industry group standpoint FTAs largely accomplish objectives, but are politically cumbersome and inefficient

Changing global sourcing of innovation

- 15 year period since TRIPS Agreement reflects substantial shift in global economic balance, accompanied by gradual shift in sourcing of innovation
- Major emerging market economies playing a key role in global economic growth
- Substantial increases in R&D and branding expenditures by enterprises based in emerging markets, accompanied by increased interest in IPRs from local perspective
- IPRs protection not solely of OECD stakeholder interest

Where does ACTA fit?

- Intended by OECD IPRs-dependent industry groups to provide alternative forum to WTO, WIPO, etc., initially through World Customs Organization
  - Substitute for individualized FTA/EPA negotiations
- Shifted to self standing "plurilateral" negotiating forum
- Early drafts of ACTA represented "**wish list**" of IPRs-dependent industries, largely unconstrained by pre-existing IP laws
- Predominant objective to **move locus of enforcement from civil courts to customs authorities**
- ACTA mainly involves a group comprising the US, Japan, EU, Australia, Mexico, Morocco, New Zealand, Republic of Korea, Singapore, Canada and Switzerland.
- Initiated by Japan and US in 2006. Other countries joined later

Pushback constrained results

- Publication of draft texts resulted in forceful pushback by NGOs (consumer and public- oriented groups), European parliamentarians, developing countries in WTO TRIPS Council (India, China, Brazil, etc.)
- Would have been inconsistent with US patent law, including remedies, requiring amendment of domestic patent law and remedies
- Draft texts foresaw mandatory border enforcement regarding patents, data exclusivity and other IPRs, including seizure of goods in transit – patents and data exclusivity removed from border measures section; extension to other IPRs ambiguous
- Early drafts would have dramatically expanded liability of Internet Service Providers (ISPs) for copyright-protected content – effectively eliminated in final text

Entry into force remains in doubt – but should not be ruled out!

- Rejected by the European Parliament on July 2, 2012. However, ratification by only 6 parties required for ACTA to come into force.
- USTR is taking position that agreement does not require Congressional approval, but may be concluded as "sole executive agreement"
  - Very questionable basis under US constitutional law
  - Congress has power to regulate trade with foreign nations, to adopt IP law and to approve international agreements that affect those laws
  - USTR is taking position that ACTA requires -- and will require – no changes to US law
- This would not be first time that stakeholder industries have pursued result beyond existing standards resulting in rejection in political process (see Multilateral Agreement on Investment)

TRIPS Agreement Baseline: Civil Enforcement

- TRIPS Agreement generally requires availability of **civil enforcement** mechanisms allowing IP holders to enforce rights

- Civil remedies to include injunction and damages adequate to remedy injury in cases of knowing infringement, but **no specific damages formulas** or requirement for injunctions; judicial authorities shall have authority to order removal of goods from stream of commerce, and destruction if allowed by constitution

TRIPS Agreement Baseline

- Judicial authorities may order production of evidence following submission of supported case, and may in appropriate situations require production of **evidence regarding third-party** participants in production and distribution

- **Preliminary injunctions** must be available to prevent entry into the stream of commerce, including *inaudita altera parte* (without prior hearing of the other side) where threats imminent, subject to notice and right to respond, and termination of injunction within prescribed period if proceedings on merits not initiated

TRIPS Agreement Baseline

- Mechanisms must be available at **border** to prevent importation of trademark counterfeit and copyright pirated goods. Optional to maintain mechanisms for other forms of IP, and for exports. May exempt parallel trade.
- Requires presentation of **adequate evidence by right holder** to establish *prima facie* case.
- Right holder may be required to post security. Other than for trademark and copyright, accused may obtain release on posting of bond or security.
- **Time limit** of 10 working days (with possibility of 10 working days extension) for right holder to initiate proceeding on merits, or goods released. Notice must be provided to accused infringer.
- No *ex officio* action required. If authorized, subject to protections of accused, customs authorities may be exempted from liability only for actions in good faith.
- May exempt small noncommercial consignments and luggage.

TRIPS Agreement Baseline: Criminal liability

- Must provide criminal penalties for willful trademark counterfeiting and copyright piracy "on a **commercial scale**", including imprisonment and/or fines sufficient to constitute a deterrent.

- Seizure and destruction of infringing goods may be ordered, as well as implements predominately used in creation.

- Optional to provide criminal penalties for other IPRs infringements, in particular willful on commercial scale.

ACTA Key elements: Civil Enforcement

- Initially applied to all IPRs, but final text allows exclusion of patents and undisclosed information
  - US negotiators recognized inconsistencies with domestic law

- Designed to increase damages awards, e.g., damages may be based on "**suggested retail price**" of goods; **valuation and lost profit** presumptions in favor of right holders

  - Initially proposed to require losing party to pay attorneys fees, but eliminated by final text providing that judges shall have such authority.
  - Essentially reduces evidentiary requirements for establishing damages.

Key elements: Civil Enforcement

- Broad authority to order **provision of information** to right holders concerning supply and distribution chains
  - Subject to national rules on privacy and confidentiality protection, or may otherwise contravene existing standards

- Provisional measures (**temporary injunctions**) also extends to **third parties**, and *does not include protections of accused incorporated in TRIPS Agreement*, including the right of party to be heard after *inaudita altera parte* measures at the review stage (TRIPS 50.4), or mandatory termination of injunction if judicial proceedings on merits not initiated by right holder been prescribed time limit (TRIPS 50.6).

Key elements : Border measures

- Scope expressly **excludes patents and undisclosed information** (i.e. data protection)
  - Drafts through October 2010 would have extended scope to all IPRs
- Ambiguity introduced as to extent of scope, referring to "manner that does not discriminate unjustifiably between intellectual property rights"
  - EU demanded border protection for geographical indications, US resisted, outcome uncertain
- Extends to "goods of a commercial nature sent in small consignments"
  - May not permit exclusion of trademark prescription drugs for individuals, different than TRIPS Agreement
- Border measures must be applied to exports as well as imports
  - Application to goods in transit discretionary, but approved

Key elements : Border measures

- Requires that customs authorities be permitted to **act *ex officio***, and private applications available for all forms of covered IPRs
  - For ex officio action, refers to "suspend the release of suspect goods", but does not define basis of suspicion
  - Since right holders have express obligations to provide "adequate evidence", **absence of standards for customs** authorities problematic
- Includes no requirements for **notification** of accused infringer, or **time periods** for necessary action by customs authorities
  - Compare, e.g., Article 55 of TRIPS Agreement, requiring release of goods within 10 working days, or 20 working days with extension, unless case on merits initiated by right holder

Key elements: Border Measures

- Allows **right holder posting of bond** as security for potential liability, and does not permit posting of bond or other mechanism for securing release of goods by accused infringer, **other than by judicial order**
- Provides that competent authorities "may determine, within a reasonable period after the initiation of the procedures…, whether the suspect goods infringe an intellectual property right"
  - **Does not require any action or release of goods**
- In earlier drafts authorized customs to order destruction of materials used in production, but eliminated in final text
- Requires customs authorities to provide substantial information to right holders, including regarding the manufacture of goods, but limited by national privacy laws.
- Authorizes administrative penalties by customs authorities in addition to civil damages.

Key elements: Criminal enforcement

- For trademark counterfeiting and copyright piracy, **significantly reduces threshold of criminal liability**, overruling interpretative decision by WTO panel in *China-Enforcement* case (no longer requirement of commercial "scale")

- Establishes criminal liability for importation and use of labels or packaging bearing protected mark

- Must permit seizure of assets deriving from criminal activity, going beyond the direct assets used in commission of offense

Institutional development

- Establishes IP protection institution outside existing multilateral system
  - Collaboration among World Customs Organization (WCO), Interpol, right holder interest groups, etc.
- May impose additional requirements in “accession agreements” for new members
- May propose new rules
  - Presumably subject to legislative approval processes, but USTR position regarding approval raises some new doubts

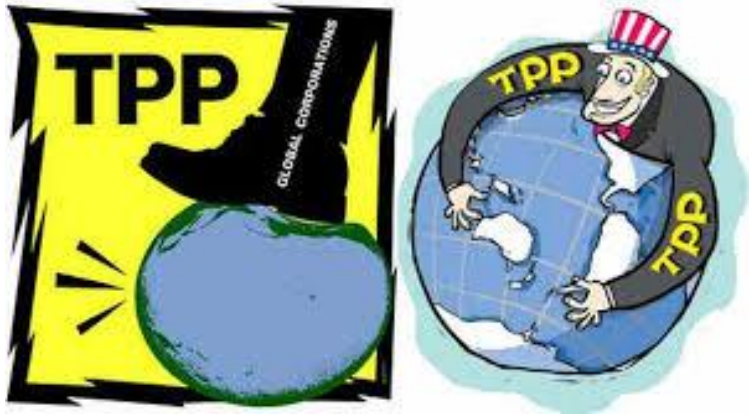
New focus on “border measures” mechanisms

- Distinction between IPRs and traditional border measures
  - Tariffs applied by government authorities with relative transparency; quotas and related measures internal governmental matters applied by customs
  - Customs authorities have limited capacity to identify potential infringements, to determine validity of underlying registrations, or to assess the legitimacy of requests for application of measures
- Mere initiation of border measures detention places exporter in financial and temporal difficulty

ACTA not an isolated phenomenon

- ACTA is not an isolated effort, but must be considered along with FTA/EPA phenomenon
  - Much of what is in the ACTA already appears in bilateral and regional agreements
- Raises broader questions concerning extent to which industrial policy relating to IPRs should be governed at the national or international level

Trans Pacific Partnership Agreement:
Trips Plus Plus?



TPP Negotiations

- The Wikileaks from the ongoing TPP negotiations have indicated the TRIPS Plus Plus proposals in the IPR chapter of the draft text. Some of which are:

- Broadening the scope of patentability – The US proposal makes it easier to patent new forms of old medicines that offer no added therapeutic efficacy for patients. Thus their proposal states that "**Patents shall be available for new uses or methods of using a known product**."

- TPP proposal specifically mentions that countries cannot have a provisions on lines of Section 3(d) of India's Patent Act, 1970 which states that the following is not 'invention':
  - "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 of 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."

TPP Negotiations

- *Making diagnostic, therapeutic and surgical methods for treatment of animals and humans patentable* -The TRIPS Agreement allows countries to exclude methods of surgical treatment from patentability. On account of this flexibility hospitals and medical professionals are not required to pay royalties on the standard of care.

- *Restrictions on pre-grant patent oppositions: the U.S. wants to make it harder to challenge unjustified patents* - The TRIPS agreement allows countries and third parties (including generic companies and civil society organizations such as patient groups) to file an opposition to the granting of a patent - either before it has been granted (pre-grant opposition) or after (post-grant opposition). (Original US proposal. New leaked draft shows this may have been done away with)

TPP Negotiations

- Imposing new forms of IP enforcement to allow customs officials to seize shipments of drugs on mere suspicion of IP infringement and to increase damages for IP infringement -The TRIPS agreement allows for governments to have considerable flexibility when designing the mechanisms that the country will allow for the enforcement of IP rights.

- However, the U.S., through the TPP and other tools (e.g. ACTA), is demanding that countries enforce IP rights with new forms of enforcement beyond what TRIPS requires.

- For example, the U.S. is requesting that TPP countries grant customs officials the ex officio right to detain shipments of medicines at the border, even in transit, if the goods are suspected of being counterfeits or if they are considered "confusingly similar" to trademarked goods.

- "Confusingly Similar" is a broader category

TPP Negotiations

- Expanding data exclusivity: US proposal for 5 years
- Requesting patent linkage: the U.S. is seeking to turn drug regulatory authorities into 'patent police'. Similar to ACTA

- **Copyright**
  - Term of Protection of a work (including a photographic work, performance or phonogram – life + 70 – 100 years being proposed.
  - In case of infringement: Countries have the option to provide additional damages which may include exemplary or punitive damages
  - Imposes legal regime of IP liability beyond DMCA standard
  - Includes text of controversial US/Korea side letter on shutting down websites.
  - Requires criminal enforcement for technological measures beyond WIPO Internet Treaties, even when no copyright infringement – for unintentional infringements of copyrights, related rights and trademarks too.

Discussion Points

- Which is the better way forward for IP protection: Multilateral or Bilateral/Plurilateral?

- Which of these gives the developing countries/LDCs the opportunity to bargain for a fairer position?

Recommendations for negotiating positions in RTAs

- Give serious consideration, before committing to a TRIPS-plus provisions in sensitive areas
- If there is a pressing requirement, then evaluate and understand implications in terms of domestic law and policy
  - Will the provisions require change of existing law and enforcement mechanisms?
  - Is such a change feasible?
  - What are the economic and political implications?
- Evaluate how the RTA partner has negotiated with other countries
- Is technical and financial assistance required?
- Need for capacity building?
- Negotiate for a phased approach
- Ensure to the extent possible, that these provisions are non-binding provisions

Thank You