UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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Local Pharmaceutical Production and the Trans-Pacific Partnership Negotiations: Intellectual Property Provisions

Typical TRIPS-plus Provisions
In Preferential Trade and Investment Agreements

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What is TRIPS and TRIPS-Plus?

- The Agreement on Trade-Related Aspects of Intellectual Property Rights
- Establishes minimum standards of protection for various categories of IPRs
- Standards that are stricter than the minimums established by TRIPS are called TRIPS-plus
- Why is it important for pharmaceutical manufacturers
  - Defines what is generic and what is not
  - Generic workspace can be wider if national law takes advantage of existing flexibilities
  - Existing flexibilities can be curtailed through preferential trade and investment agreement

What are ‘Flexibilities’?

- The concept of ‘flexibility’ and ‘policy space’
- Why some treaties are vague in their language
- Interpretive tools relevant to public health and local pharmaceutical production
  - Doha Declaration on TRIPS and Public Health
  - WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Flexibilities Typically Affected by TRIPS-Plus

- Exclusions from Patentability
- Pre-Grant Opposition
- Exceptions to Patent Rights
  - Regulatory Review Exception
  - Research and Experimentation Exception
- Compulsory and Government Use Licenses
- Border Measures
- Patent Linkage and Patent Term Extensions
- Test Data Protection
- Investor-State Dispute Resolution

Pre-Grant Flexibilities

Exclusions from Patentability

- Patents are available for inventions that are novel, involve an inventive step and are industrially applicable.

- TRIPS permits exclusion of:
  - Discoveries
  - Substances Existing in Nature
    - Plants (provided some regime for plant variety protection exists)
    - Animals
  - New Uses of a Known Product
  - Variations and Minor Modifications (derivatives)
  - Public interest exceptions

- Status under US-Chile and US-Peru FTAs?

  US-Chile: Requires a reasonable effort to develop legislation to make patents available for plants

  US-Peru: Best efforts to make patents available for plants, no roll backs if patents permitted on plants and animals

Pre-Grant Opposition

- *What is it?* Provides third parties with possibility to submit evidence to the patent office that could help to prevent granting of poor quality patents before a decision has been taken by the patent office. Opposition procedures require the patent office to hear the arguments advanced by the opposing party and to take them into account in its decision regarding pending patent applications.

- *Why do we need it?* Patent examiners may be making decisions on applications based on incomplete information. Opposition can support disclosure, including disclosure of origin requirements. 'Evergreening' a problem for pharmaceuticals.

- *Status under US-Chile and US-Peru FTAs?*

  US-Peru: permitted

  US-Chile: permitted

- Permitted under TRIPS, US-Morocco FTA eliminates pre-grant opposition. Australia has pre-grant opposition.

Post-Grant Flexibilities

Exceptions to Patent Rights under TRIPS

The Regulatory Review ('Bolar') Exception

- *What is it?* Permits generic competitors to use a patented substance during the patent term in order to prepare marketing approval applications of a generic equivalent to the national drug regulatory authority.

- *Why do we need it?* Without it, generic competitors could only start to work on the development of a generic equivalent of a patented product after the patent term expires, thus delaying significantly and *de facto* extending the term of the patent.

- *Status under US-Chile and US-Peru FTAs?* Permitted.

  - "Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

  - In the US-Chile FTA, export by a generic manufacturer of a product which is otherwise covered under the exception is only permissible for purposes of registration in the country from which the export emanates, forcing tests and production of quantities necessary for marketing approval to be done country by country in the event of export.

Exceptions to Patent Rights under TRIPS

The Regulatory Review ('Bolar') Exception (continued)

Why does the exception not unreasonably conflict with a normal exploitation of the patent?

- Does not affect the term of the patent, simply permits a generic competitor to enter the market asap after patent expiry.
- Recognized exception to patent rights under WTO Dispute Settlement: *Canada-Patent Protection of Pharmaceutical Products* (2000) ruled that the Bolar exception falls within the room for exceptions under Article 30 of the TRIPS Agreement
- Most OECD countries have Bolar exceptions, including the US. US and Canada were the first countries to include the exception in their domestic legislation (named after *Roche Inc. v. Bolar Pharmaceutical Co.*, 1984). Many developing countries also have introduced regulatory review exceptions into their laws, including Brazil, China, Egypt, India and Kenya.

Exceptions to Patent Rights under TRIPS

The Research and Experimentation Exception

- *What is it?* Permits the use of a patented product or process without the consent of the patent owner for certain research and experimentation activities.

- *Why do we need it?* Allowing the patent owner to prevent experimental use during the patent term would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public allowing other to come up with better products or processes.

- *Status under US-Chile and US-Peru FTAs?* Permitted

> "Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

Exceptions to Patent Rights under TRIPS

The Research and Experimentation Exception (continued)

Why does the exception not unreasonably conflict with a normal exploitation of the patent?

- Recognized exception to patent rights under WTO Dispute Settlement*: Canada-Patent Protection of Pharmaceutical Products* (2000)
- WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, adopted by the WHA in 2008, specifically recognizes that a research exception could help to address public health needs in developing countries. Interpretive value – sets the exception clearly within the ambit of the Doha Declaration on TRIPS and Public Health (2001).
- Recognized exception worldwide to promote technological innovation as well as the transfer and dissemination of technology.

Some Nuances: Differences in Policies between Countries

- Commerical v. Non-Commercial (untenable distinction, see *Duke v. Madey* (2002))
- Research "with" v. Research "on" the patented product/process

Compulsory and Government Use Licenses

- *What is it?* Refers to the practice by a government to authorize third parties to use the subject matter of a patent without the authorization of the right holder for reasons of public policy. A government use license grants that authorization to a government entity.

- *Why do we need it?* Compulsory licenses are sanctioned when public need outweighs the right of the patent owner to control access to and use of the technology in question during the term of the patent. Has been exercised numerous times by governments in the case of pharmaceuticals, including in Thailand, Indonesia and India.

- Status under US-Chile and US-Peru FTAs? Not specifically mentioned, but…

  Status arguably questionable under US-Chile. Article 17.10(c) of the US-Chile agreement says countries may "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent holder."

  With respect to US-Peru FTA, addressed through a communication directed to Peru in which the United States confirmed that the IP Chapter subject to 2001 Declaration on TRIPS and Public Health.

Global Status of CLs

- permitted, various procedural rules apply, and is subject to payment of royalty
- integral part of the solution under para. 6/draft Article 31bis
- developed countries have used it – cipro/anthrax in US

Border Measures

- *What is it?* Border measures permit a right holder to prevent the entrance of goods suspected of infringing IP rights before they enter the country. Countries differ in burden of proof (BoP) to be met for customs authorities to stop importation/seize at the border.

- *What is the significance of border measures?* Could potentially allow patent owner to block legitimate parallel imports or medicines in transit.

- *Status under US-Chile and US-Peru FTAs?*

US-Chile: Includes border measures for suspected counterfeit trademark or pirated copyright goods, subject to evidence constituting *prima facie* showing of infringement (BoP on right holder)

US-Peru: Includes border measures for suspected counterfeit or confusingly similar trademark goods or pirated copyright goods, subject to adequate evidence to establish *prima facie* infringement (BoP on right holder)

Patent Linkage and Patent Term Extensions

- *What is it?* Drug Regulatory Authorities (DRAs) are obliged to prevent marketing approval during the patent term. In some Free Trade Agreements (FTAs), extends patent term for delays in marketing approval process and applications for marketing approval notified to patentees during the patent term. Term extensions can also be granted for delays in the patent application process.

- *Why is linkage potentially problematic?* Utilizes DRAs to enforce patent law, while their mandate is public health. Erodes potential benefit of Bolar exception.

- *Status under US-Chile and US-Peru FTAs?*

US-Chile – Prevents marketing approval except by permission of the patent holder. Extension of patent term for DRA delays and notification that another person is seeking to market an approved pharmaceutical product during the patent term. Extension of term for patent application delays.

US-Peru – Notification that another person is seeking to market an approved pharmaceutical product during the patent term; Provide enough time for patent holders to seek remedies. Extension of term for patent application delays.

Test Data Protection

- *What is it?* TRIPS does not contain language that would prohibit reliance by DRA on originator data (Article 39). Considers clinical test data submitted to a DRA as trade secret. Typical provisions in FTAs prohibit DRAs from making use of originator data for a certain number of years.

- *What is the significance of border measures?* Forces generic companies to either wait until the exclusivity period has run in order to seek marketing approval of a generic equivalent even if the patent has expired, or to conduct its own trials during this period.

- *Status under US-Chile and US-Peru FTAs?*

  5 years data exclusivity for pharma products (current US-Vietnam FTA = 5 years)

Investor-State Dispute Resolution (ISDR)

- *What is it?* Normally, disputes concerning provisions of treaties are brought by countries against other countries that are party to a treaty. Under ISDR, investor companies are permitted to bring claims against governments utilizing the dispute resolution mechanisms specified in the treaty.

- *What makes ISDR potentially problematic?* While it is thought to make a country more attractive to potential investors, it opens up a country to potential commercial liability. 2012 cases: Occidental Petroleum v. Ecuador (US-Ecuador BIT - 1.77 bil USD plus interest); Eli Lilly v. Canada (NAFTA -Eli Lilly's challenge to Canadian court for revoking patent based on lack of utility).

- *Status under US-Chile and US-Peru FTAs?*

Includes provisions that permit investors to sue governments for actions that violate investment treatment standards.

Investor-State Dispute Resolution (ISDR) (continued)

- *Trends in ISDR among Developing Countries*

  - South Africa – no new BITs and will try to get out of existing ones
  - Australia – no ISDS in any new BITs
  - India – reviewing its BITs, especially the ISDS provisions
  - Brazil – opted not to sign any BIT
  - Ecuador, Bolivia, Cuba, Nicaragua, Domincan Republic, St. Vincent and the Grenadines and Venezuela – 7 country coalition to counter BIT suits, set up regional arbitration center. Establish an international observatory of ISDS cases.

Lesson- don't just look at the IP Chapter!

Any Questions?

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