WIPO Sub-Regional Workshop on Patent Policy and its Legislative Implementation

Topic 11: The scope of the patent right. Minimum standard of protection and related flexibilities, namely, exceptions and limitations

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The Scope of the patent right. Minimum standard of protection and related flexibilities: exceptions and limitations

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New Framework IPRs

- TRIPS /TLCs/ Bilateral IP & Investment Treaties/Regional Agreements
- Interaction with other social and political areas:
  - Food and Agriculture
  - The protection of the environment, biodiversity & traditional knowledge
  - Public health
  - Competition
  - Human Rights

New IPRs framework and economic structure of States

- Economic structure of the party to TRIPs as well as FTAs/Bilateral Treaties and/or Regional Agreements shall be considered when it comes to enact the implementing legislation and select policy options.
- Different degree of incentives to enhance IP protection: (i) Countries with demand and market for IP goods; (ii) countries with no demand but a market for IP goods; (iii) countries with demand but no market for IP goods; (iv) countries with no demand and no market for IP goods.

Patents and Exclusive Rights

- **Exclusive Exploitation Rights**
  - *(a)* to exploit the patented invention;
  - *(b)* to assign or transmit the patent;
  - *(c)* to conclude license contracts.
- **Exclusive exploitation rights** which gives the patent holder the right to prevent third parties to exploit the patent without his/her consent.
- If the **subject matter is a product** such rights covers the following acts:
  - Making the product
  - Selling or offering the product for sale
  - Use
  - Importation

Patents and Exclusive Rights

- If the **subject matter is a process** the patent holder has the right to prevent third parties to carry out the following third parties without his/her consent:
  - Selling, offering for sale, making or importing the product directly resulting from the protected process.

Exploitation forms of a patent

- Local effective exploitation vs. importation? TRIPS includes importation among the exclusive rights to be ensured by Member States
- Direct exploitation: manufacture of the subject matter through a subsidiary.
- Licensing the patented subject matter (manufacturing through a local independent party)
- Importation
- Brazil (1996) and India (2005) special exploitation requirements

Experimental use exemption

- **Use for academic or experimental purposes widely accepted**
- Different interpretations under domestic laws
- Research done for the purpose of developing and improving a patented invention (new scientific insight)
- Experimental activities may cover improving or modifying the invention
- Research for obtaining marketing authorization
- Research done for both (developing or improving an existing invention).
- Does the exemption [in the country concerned] cover clinical trials done for all these purposes but with the final goal of subsequently seeking a marketing approval (e.g., clinical trials not only using the patented product to obtain an authorization to market the product once the patent expired but use focusing on obtaining a new product, a new formulation, a new use or better dosage)?

Experimental use

- A common possible background interpretation or understanding in many countries is that “experimental” activities (or uses) are not solely confined to experimental purposes: to a different degree **it is accepted that the research may be conducted with a view to ultimately commercializing the end-products of the experimentation** (but not to cover acts aimed at commercializing the invention)

Experimental use

Andean Community (Decision 486/2000):

A patent owner may not exercise the exclusive rights arising from a patent “with respect to the following acts:

- a) acts carried out in a private circle and for non-commercial purposes;

- b) **acts** carried out exclusively **to experiment** with the subject matter of the patented invention;

- c) acts carried out exclusively for the purposes of teaching or scientific or academic research;

Experimental use

- Brazil:

  The provisions on exclusive rights of the patent holder do not apply:

  - I. to **acts carried out by unauthorized third parties**, privately and **without commercial purposes**, provided these acts do not prejudice the economic interests of the patent holder;
  - II. to acts carried out by unauthorized third parties for **experimental purposes**, in connection with scientific or **technological** studies or researches;

Experimental use

- Argentina:

The right conferred by a patent shall have no effect against:

- *(a)* a third party who privately or in an academic environment and **without gainful intent**, conducts scientific or **technological research activities for purely experimental**, testing or teaching purposes, and to that end **manufactures or uses** a product or applies a process **identical** to the one patented";

Experimental use

Trinidad and Tobago:

"42. The rights conferred by a patent shall not extend to—

(a) acts done privately and for non-commercial purposes;

(b) acts done **for experimental purposes** relating to the subject matter of the relevant patented invention

Experimental use: summary and conclusions

- An exception **that prohibits** -or may be deemed with a reasonable degree of certainty that it bans- **commercial use** [leaving aside indeed acts of a third party aimed at commercializing the patented invention] **may be duly restrictive and would not duly take advantage of the existing permissive framework under comparative and international law** (e.g. TRIPS Agreement).

Regulatory or “Bolar” type of exemptions

- Flexibilities (under TRIPS) do not impede countries to allow completion of R&D and other additional acts (including the purchase or manufacture of the patented product) necessary to register a “generic” product prior to the expiration of an originator patent.
- This flexibilities are or has been incorporated to domestic laws in many countries (Andean Community, Brazil, Israel, Argentina, etc.)
- In the absence a generic producer “early using” a third party´s invention to the develop a bioequivalent drug is making use of the patent in a way that might be considered as an commercial act and thus an infringement.

Bolar Exemption

Brazil: introduced the exemption in 2001to 1996 IP Law) specifically for the marketing authorization for generic drugs providing that exclusive rights do not apply with regard to:

- "to **acts** performed by non-authorized third parties, regarding patented inventions, **which aim exclusively the production of information, data and test results directed to procure commerce registration**, in Brazil or any other country, to allow the exploitation and commercialization of the patented product"…after the expiration of the patent (Section 43, VII of the 1996 IP Law).

Bolar Exemption

Argentina:

- Incorporated this exemption in the Law on the Protection of Confidential Information in 1996.
- With regard to a product or process protected by a patent, **any third party may use the invention prior to the expiration of the patent for experimental purposes and to gather information required by the competent authorities to obtain a marketing approval of a product or process** in order to commercialize them after the expiration of the patent.

Bolar Exemption

CAFTA AGREEMENT:

- 3. A 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** [TEXT THAT USES THE WORDING OF TRIPS ART. 30 ON EXCEPTIONS].

- 5. Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, **that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires**, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.

Bolar exemption

- What is the scope of this exemption and how may be it interpreted?
- Narrow or strict interpretation implies that:
  - it applies only to studies and trails for obtaining marketing approval for truly or genuinely generic medicinal products covered by a patent;
  - It does not cover the use of the patented product/ingredient/compound for developing new products and obtaining their approval thereafter (France, UK, Netherlands)

Bolar exemption

- Wide (r) interpretation of the exemption:
  - use of patentable product (or compound) in research (or clinical trials) to develop a new and innovative product tented compound falls not only under the research exemption but also under the Bolar exemption
  - Bolar exemption covers studies or trials for producing a generic product but extends to innovative products and their marketing approval (e.g., Germany)

Wide Interpretation of the Use and Bolar type Exemptions

- Experiments conducted prior to obtaining a compulsory license to see if the applicant could make the protected product economically and on a batch basis may fall under the research exemption (e.g., this was accepted by the Supreme Court in Canada in: *Micro Chemicals Limited et al v. Smith Kline& French Inter-America Corporation* (1971), [1972] S.C.R. 506
- Experiments to determine the best form of drug administration (using one patented compound in a new manner to improve the effect of another drug when exposed or is in the human body).

OMC Expert Group decision validating the Bolar Exemption

- In 2001 in a case confronting the **European Community vs. Canada** regarding the regulatory exemption under the domestic law of the latter, the Expert Group (EG) endorsed the lawfulness of this exception as being TRIPS consistent.
- Canadian law (analyzed by the EG) on the matter establishes:

  -**55.2 "**(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product".

OMC Expert Group decision validating the Bolar Exemption

- **The EG was prepared to acknowledge a narrow scope to the exceptions in the light of its interpretation art. 30 of TRIPS.** This interpretation is even narrower than case law in some developed countries (e,g, the two Clinical Trials cases rendered by the Supreme Court in Germany).

- Focusing analysis on the basis of the scope of the exceptions under the triple test of art. 30 of TRIPS rejected Canada's view that any exception is limited and thus TRIPS consistent as long its preserves the exclusive right of the patent holder to commercialize the patented product during the term of the patent.

- The EG deemed an exception be "limited" due to the few restrictions imposed upon the exclusive rights granted under article 28 of TRIPS. An exception is only valid so far as it is limited to the conducts necessary to comply with the regulatory requirements of a marketing approval process; the scope of the acts non-authorized by the patent holder that may be permitted under the exception shall be small and circumscribed.

Compulsory Licenses

- TRIPS focuses on the basic conditions that the different types of compulsory licenses shall comply with thereby acknowledging different possibilities:

  - Refusal to deal (can this be an independent ground?)
  - Lack of exploitation
  - Anti-competitive conducts
  - Dependant patents
  - National Emergency, public health, security reasons

Compulsory Licenses

- Incorporated in many legislations
- Not used or scarcely used in developing countries (Brazil, South Africa, Thailand, Philippines, etc.).
- Recent regulations in Ecuador and Colombia on the “public utility declaration”
- Pro-competitive tool that may serve to persuade or deter patent holder from abusive conducts (excessive prices)
- There is a need to complement patent regulation with adequate procedures.

Exhaustion and parallel imports

- **Types of exhaustion**:

  - automatic or optional (implied license theory in Great Britain and some commonwealth countries)

  - National (territorial), regional or international (freedom to opt for any system under TRIPS and the Doha Declaration)

  - Advantages and disadvantages depending on the country and the sector involved.

  - Price discriminations, regulated markets, price controls.

Exhaustion and parallel imports

- What could be the effects of non-having an exhaustion mechanism in the domestic laws?
- What are the likely effects from moving from national exhaustion to international exhaustion?
- What are the likely effects from moving from international exhaustion to national in an regional or bilateral agreement? (MFN clause of TRIPS applies and the benefit national of all TRIPS member States)

Guidance for interpretation in FTA's of bilteral treaties

- Non-derogation clauses as an interpretative tool to maintain flexibilities under TRIPS,
- Chile-US FTA: "Nothing in this Chapter concerning intellectual property rights **shall derogate from the obligations and rights of one Party** with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO)" (Section 17.1 (5) of the IP Chapter).
- The "rights" of a Party can bee understood of making use of the flexibilities, specially with regard to those that were not expressly contemplated in the FTA's.

Guidance for interpretation in FTA's

- Neutralizes any possible "non-violation" claim (based on non-compliance with the aims of the Treaty in the field of IP).
- Such claims may be based when a Party considers that the other one, affects – although without committing an unlawful act- the accomplishment of the objectives or expectations of the treaty (FTA) with regard to IPRs.

Final Remarks

- There is a need to combine pro-competitive legislative actions, tools and interpretations to achieve an adequate balance of interests.
- THANK YOU! Andrés Moncayo von Hase

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