Superintendencia de Industria y Comercio

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Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 6: Flexibilities Related to the Definition of Patentable Subject Matter

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Patent-Related Flexibilities in the TRIPS Agreement

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I.

Overview of Relevant TRIPS Provisions

General Provisions: Objectives and Principles

- Overall objective: balance of rights and obligations, between innovation incentives and use of existing inventions/creations
- Right to take TRIPS-consistent measures necessary to protect public health, to promote public interest and to prevent abuse of IPRs
- Doha Declaration: each TRIPS provision to be read in light of the agreement's object and purpose

→ **General flexibility to adapt protection at domestic level to meet social & developmental goals**

TRIPS Provisions on Patents

- Patentability Criteria
- Optional exclusions
- Disclosure requirements
- Permissible exceptions, including experimental use and “Bolar”-type provisions
- Compulsory licensing (see presentation under Theme 12)

Patentability: TRIPS Requirements

- "Invention" not defined
- But: three criteria apply cumulatively to qualify as an invention:
  - novelty
  - inventive step (non-obvious)
  - industrial applicability (useful)
- Additional substantive condition: disclosure of the invention

Patentability: Flexibilities in TRIPS (1)

- Criteria not further defined at international level, but generally understood as:
  - novelty: not previously disclosed to the public
  - inventive step: sum of differences represents sufficient, not trivial, advance in relation to state of the art
  - industrial applicability: susceptible of practical use in any kind of industry (not abstract theory/speculative notion)
- Definition of key terms and application left to national law, jurisdiction, practice

  → considerable degree of flexibility
- Allows for sector-specific considerations to be built into decisions on patentability (e.g. public health)

Patentability: Flexibilities in TRIPS (2)

- **Results in considerable divergence in implementation at country level:**
  - **patentability of new use or method of using existing product treated differently**
    - **examples: Section 3(d) Indian Patent Act 2005, Philippines "Universally Accessible Cheaper and Quality Medicines Act" 2008**
  - **varying landscape of patents for the same product: granted / rejected at country level**
    - **examples: Viagra (US-UK), tenofovir (US-Brazil/India)**
- **Explains calls for common definition across all jurisdictions (see AIPPI Resolution Q217 of 2011)**

Patentability: Optional Exclusions

- Available even when substantive and formal conditions for patents are met
- TRIPS contains exhaustive list of three possible grounds for exclusion:
  - protection of *ordre public* (i.e. general security, core values of society) or morality
  - methods of treatment - does not extend to related medical devices
  - plants, animals and essentially biological processes for their production
- Inherent recognition of different societal and ethical values
  - CJEU C-34/10: exclusion from patentability where invention requires prior destruction of human embryo / its use for scientific research

Provisions on Patentability in RTAs

- **Patentability criteria:**
  - interpretation of some or all of the criteria (see fn.5 TRIPS)
  - mandatory availability of patents for new uses or methods of using a known product
  - application of disclosure requirement: sufficiently clear if information provided allows invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date
- **Exclusions:**
  - Flexibility under TRIPS to exclude certain inventions from patentability suppressed

    → mandatory patentability of life forms

Limited Exceptions

- TRIPS establishes general principles, not an exhaustive list of permissible exceptions
- Application of "three step test"
- Interpretative guidance: "Canada – Patent Protection of Pharmaceutical Products" (DS114)
- Measures at issue:
  - regulatory review exception
  - stockpiling exception
- Alleged violation of Art.28 and 27.1
- Defense based on Art.30
- Panel found that:
  - stockpiling exception is not limited and therefore does not fall under Art.30
  - regulatory review exception meets all three conditions and qualifies as Art.30 exception
- Repeal of stockpiling exception by Canada

Exhaustion of Rights

- Choice between national – regional – international exhaustion determinant factor for parallel imports
- According to TRIPS:
  - no obligation to adopt particular regime
  - DS mechanism does not apply
  - non-discrimination must be respected
- Doha Declaration: confirmed freedom to establish regime which best fits domestic objectives
- But:
  - contractual obligations (Note: possible link to competition law)
  - few RTAs confirm right of patent owner to limit parallel imports through licensing contracts

Current Transition Periods for LDCs

- **Until 1.7.2013: TRIPS implementation, including patent section**
- **Until 1.1.2016: protection and enforcement of patents and test data in the pharmaceutical sector**

II.

A Concrete Example: Patent-Related Flexibilities and Public Health

Doha Declaration: Content

- **Confirmations:**
  - importance of IP protection for the development of new medicines, but concerns about its effects on prices
  - TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
  - TRIPS can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and, in particular, to promote access to medicines for all
- **Clarifications:**
  - compulsory licences
  - exhaustion

Doha Declaration: Achievements

- Shaped framework for multilateral cooperation on IP and public health
- Helped governments to make use of TRIPS flexibilities
- Reinforced understanding that TRIPS supports a balanced and flexible IP framework responsive to broader policy agenda
- Led to adoption of new flexibility ("Paragraph 6 System")
- Extended LDC transition period in pharmaceutical sector

WHO-WIPO-WTO Study

- Trilateral study on "Promoting Access and Medical Innovation: Intersections Between Public Health, IP and Trade"
- Aims at assisting decisionmakers by providing information on:
  - legal and policy options (IPRs: particular focus on options/practices regarding patents)
  - interplay between trade, IP and health rules
  - empirical data
- Illustrates the need to adopt a holistic approach:
  - from research and discovery to delivery
  - encompassing health, trade and IP dimensions
- Forms an integral part of technical co-operation offered by WHO/WIPO/WTO
  - in response to growing and diversified demands
  - strengthening policy coherence

III.

Some Final Observations

The WTO's Contribution

- Making available a forum for debate upon request by Members
- Responding to WTO Members' increasing demands for capacity building with respect to policy options available in TRIPS
- Collecting empirical data to facilitate informed debate and decision-making
- Solving disputes (ex: scope of exceptions, DS114)
- Collaborating with key IGOs, in particular in public health sector:
  - towards an effective partnership, recognizing complementary roles: trilateral coordination, joint symposia, trilateral study
  - guided by Doha Declaration, WIPO Development Agenda and WHO Global Strategy and Plan of Action

⇒ Note: WTO Secretariat has no mandate to interpret TRIPS provisions / assess use of TRIPS flexibilities

Conclusions

- TRIPS and its flexibilities as part of wider national and international action (see Doha Declaration)
- Part of solution next to other important factors: procurement policy, pro-competition safeguards, tariffs, infrastructure, sector-specific aspects (e.g. regulation to ensure safety and quality of medicines, national health systems), etc.
- Importance to preserve carefully negotiated balance
- Use of TRIPS flexibilities, in particular compulsory licences, not to be considered an end in itself
- Need for each country to consider policy options and to take the necessary steps at national level to avail itself of flexibilities