The TRIPS Agreement and Patentability Criteria

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Trilateral Cooperation: To Build Capacity, To Ensure Coherence

- Essentially among WHO, WIPO, WTO
- “Traditional” fields of cooperation, in particular capacity building activities
- Series of joint technical symposia
- WHO/WIPO/WTO study on “Promoting Access and Medical Innovation: Intersections Between Public Health, IP and Trade”:
  - Aims at assisting decision-makers by providing information and data
  - Illustrates the need to adopt a holistic approach
WTO’s Role

- Making available a forum for debate
- Raising awareness through workshops
  - Example: Workshop on Trade and Public Health (since November 2014)
- Providing factual / technical information
- Facilitating informed decision-making
- Solving disputes
- The WTO’s mandate is NOT
  - to interpret provisions of any of the WTO agreements, including the TRIPS Agreement
  - to assess implementation/use
Intersections between health, IP and trade

Mapping the policy intersections: key areas of law and policy for innovation and access

- Public Health
- Innovation & access
- Intellectual Property
- Trade
- Priority medical technologies
- Human rights dimension
- Affordability, pricing policy & financing
- Regulation for quality, safety and efficacy
- Innovation systems & technology diffusion
- Integration
- Patent system
- Test data protection
- Trade marks and nonproprietary names
- International trade agreements
- Tariffs and non-tariff measures
- Competition policy
- Procurement policies

Patentability Criteria
Interaction IPRs - public health

- Individual deals, projects, partnerships
- Policies & strategies for IP management at institutional level
- National policy settings for public-funded/public-interest research
- National legal framework & innovation policy
- International legal framework & cooperation
Patents: Search for A Balanced Approach

- Patents: Search for A Balanced Approach
  - Patentable Subject Matter (Art.27.1)
  - Exclusions (Art.27.2+3)
  - Patent Application
  - Disclosure (Art.29)
  - Exclusive Rights Conferred (Art.28)
  - Exhaustion (Art.6, Doha)
  - Protection: 20 years from filing (Art.33)
  - Exceptions (Art.30, 31, Doha)
  - Enforcement
  - Various optional provisions
TRIPS: Cumulative Application of Five Patentability Criteria

- Patentable subject matter
- Novelty
- Inventive step or non-obviousness
- Industrial applicability
- Disclosure of the invention
What TRIPS Says and Does Not Say (1)

- Article 27 covers “patentable subject matter”
- Article 27.1, 1st sentence makes availability of patents mandatory for:
  - Inventions: regarding both products and processes
  - In all fields of technology
  - Which are new, involve an inventive step and are capable of industrial application
- Inherent flexibility (footnote 5 to Art.27):
  - Inventive step = non-obvious
  - Capable of industrial application = useful
- In addition - key terms not defined:
  - What constitutes an “invention”
  - When is an invention new, inventive and capable of industrial application
  - No guidance by Paris Convention
What TRIPS Says and Does Not Say (2)

• Article 27.1, 2nd sentence: no discrimination as to place of invention, field of technology and whether products are imported/locally produced:
  – WTO jurisprudence on non-discrimination principle in DS114 (Canada – Protection of Pharmaceutical Products)
  – Rejects de jure and de facto discrimination of regulatory review exception - concentration of effects on pharmaceutical industry is no sufficient evidence of discriminatory purpose

• Disclosure requirement under Art.29:
  – Limited guidance as to what and how to disclose
  – Optional: best mode and information regarding foreign applications and grants
  – Silent with respect to disclosure of genetic resource or traditional knowledge

• Note: LDCs currently exempted from TRIPS obligations, except for national treatment and MFN
Optional Exclusions

- Available even when substantive and formal conditions for patents are met
- Art.27.2 and 3 TRIPS contain exhaustive list of three possible grounds for exclusion:
  - Protection of *ordre public* (i.e. general security, core values of society) or morality, provided that prevention of commercial exploitation is necessary to do so
  - Methods of treatment - does not extend to related medical devices
  - Plants, animals and essentially biological processes for their production
- Flexible framework: inherent recognition of different societal and ethical values
Patentability: Selected Key Issues (1)

• Material existing in nature
  – Patentability of biotechnological inventions is subject to longstanding and ongoing debate
  – See Proposal in TRIPS Council review of Art.27.3(b) to exclude patents on life forms
  – Examples from WTO Members:
    • EU Directive 98/44/EC and CJEU jurisprudence
    • recent jurisprudence in the US (Myriad; Mayo)

• First and second medical indications
  – Patentability not addressed by TRIPS
  – Countries take different approaches, e.g.:
    • Excluded by Andean Community Decision 486
    • Permitted under EPC
  – Typical example for debate on access and incentives to innovate
Patentability: Selected Key Issues (2)

- **Incremental and adaptive innovation**
  - **Examples:**
    - new dosage forms increasing compliance / improving efficacy
    - new formulations with improved storage characteristics
    - new forms of delivery
  - **Concerns voiced:** patenting delays access to medicines and innovation
  - **Challenge:** distinguish between innovations that confers real improvements and those that do not offer any therapeutic benefits

- **Disclosure:**
  - Proposal to amend TRIPS to require the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge in patent applications (TN/C/W/52 of July 2008)
Issues Raised in Recent TPR Reviews (1)

- **Patentable subject matter**
  - **Human gene sequence / biological material**
    - Human gene sequence extracted and/or isolated from its natural environment / synthetic DNA is patentable, provided a practical use is disclosed for the sequence (Australia, 2015)
    - Mere discovery of living material directly isolated from nature does not constitute patentable invention, but applications for processes of isolation can be considered (India, 2015)
    - No patents for plants and animals other than micro-organisms (India, 2015)
  - **Traditional knowledge (TK)**
    - Technical invention based on or developed using TK may be protected by patents provided that patentability requirements are satisfied (Hong Kong, China, 2014)
    - Substantive patentability criteria apply to patent applications being developed from Australian genetic resources and TK; submissions from third parties and third countries can be considered (Australia, 2015)
  - **Second medical use claims**
    - Not considered to be patentable products or processes (Viet Nam, 2013)
Issues Raised in Recent TPR Reviews (2)

• Patentability criteria in general
  – Interpretation
    • No move towards more liberal interpretation that could explain increase in patent grants (Japan, 2013)
  – In FTAs
    • No patentability of modifications and new uses of pharmaceutical inventions sought in FTAs concluded with developing countries (EU, 2013)

• Inventive step/obviousness
  – “Enhanced therapeutic efficacy” in Section 3(d) Patent Act does not introduce additional patentability criterion, but implies inventive step and applies to all fields of technology (India, 2015)
  – Raising the Bar Act of 2012 removes restrictions on information and background knowledge taken into account in assessing inventiveness (Australia, 2015)
Issues Raised in Recent TPR Reviews (3)

• **Industrial applicability/usefulness**
  – No intention to amend Patent Law to reflect “promised utility” doctrine in jurisprudence - courts seek to protect patent system against patent applications based on speculation (Canada, 2015)
  – To raise patent quality, 2012 Act bolsters usefulness requirement: invention to work as indicated by patent and explanation how it works (Australia, 2015)

• **Disclosure**
  – No measures envisaged to relieve applicant’s disclosure obligation; to ensure that inventors do not “hide” relevant prior art (US, 2014)
  – High standards for disclosure to ensure granted patents are not broader than disclosed inventions (Australia, 2015)

• **Collaboration**
  – With SIPO to support substantive examination of patentability criteria (Hong Kong, China, 2014)
Issues Raised in WTO Accession Negotiations

• Exclusions from patentability:
  – Inventions violating social interests or humanitarian and moral principles: confirmation that Art.1349 of Russia’s Civil Code would be interpreted and applied in compliance with Art.27.2 and 27.3 TRIPS (Russian Federation, WP Report of Nov. 2011)
  – Inventions contrary to public interest, humanitarian principles and morality: confirmation of law amendment to replace terms by reference to ordre public and morality (Kazakhstan, WP Report of June 2015)
Extracts from Country Reports 2015

• **Brazil**
  - Under way: Law Bill 5.402/2013 in Congress to implement TRIPS flexibilities
  - Proposed measures include stricter patentability criteria and explicit prohibition to grant patents for second uses

• **Seychelles**
  - Recommendation to restrict patentability of new uses and new indications under consideration

• **Trinidad and Tobago**
  - Possibility of patenting plants and animals
  - But: exclusions regarding discoveries effectively limit patentability to new varieties that can only be obtained by transgenic engineering and not by naturally occurring breeding
Patentability Criteria in Trade Agreements: Selected Examples

• TPP - see leaked text of October 2015
  – Provision on patentable subject matter based on Art.27.1, and exclusions in Art.27.2 and 3 TRIPS
  – Confirms that patents are to be made available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product; optional limitation of such processes to those that do not claim the use of the product as such
  – Confirms availability of patents for inventions derived from plants

• TTIP – EU position paper of March 2015
  – IPR chapter could recall “established practices on patent procedures and patentability criteria, including regarding secondary use or incremental innovation; …”
Conclusions

- Key terms not defined in TRIPS:
  - Considerable policy space left to patent offices and courts to interpret and apply patentability criteria at national/regional level
  - Allows for sector-specific considerations to be built into decisions on patentability

- Results in considerable divergence in implementation at country level:
  - Patentability of new use or method of using existing product treated differently
  - Varying landscape of patents for the same product: granted / rejected at country level

- Comprehensive, holistic reflection needed:
  - At country level: how can patentability criteria best assist in achieving policy objectives – need to define and to ensure implementation
  - In general: preserve TRIPS as is or need to harmonize further?