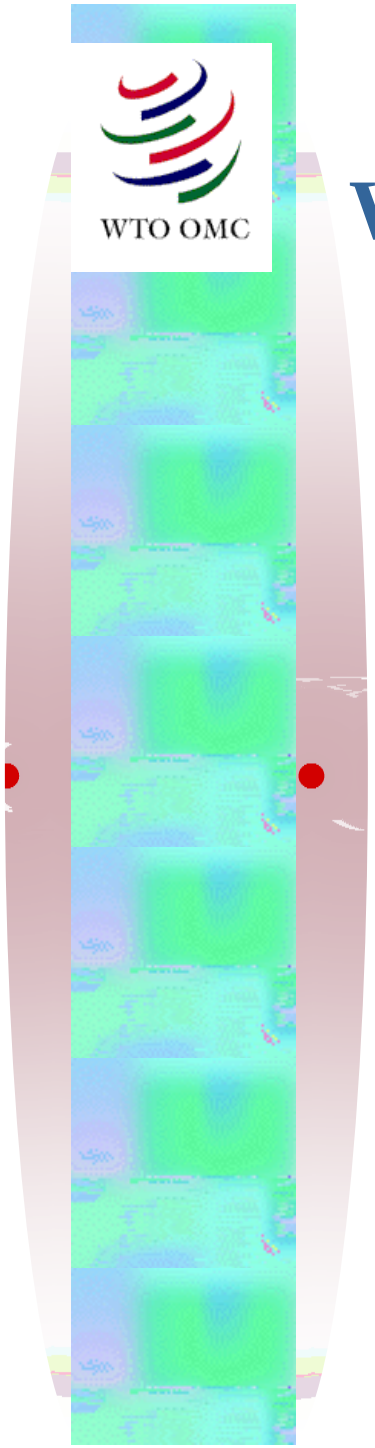


WHO-WIPO-WTO Technical Workshop on Patentability Criteria Geneva, 27 October 2015

The TRIPS Agreement and Patentability Criteria

Roger Kampf

WTO Secretariat

Trilateral Cooperation: To Build Capacity, To Ensure Coherence

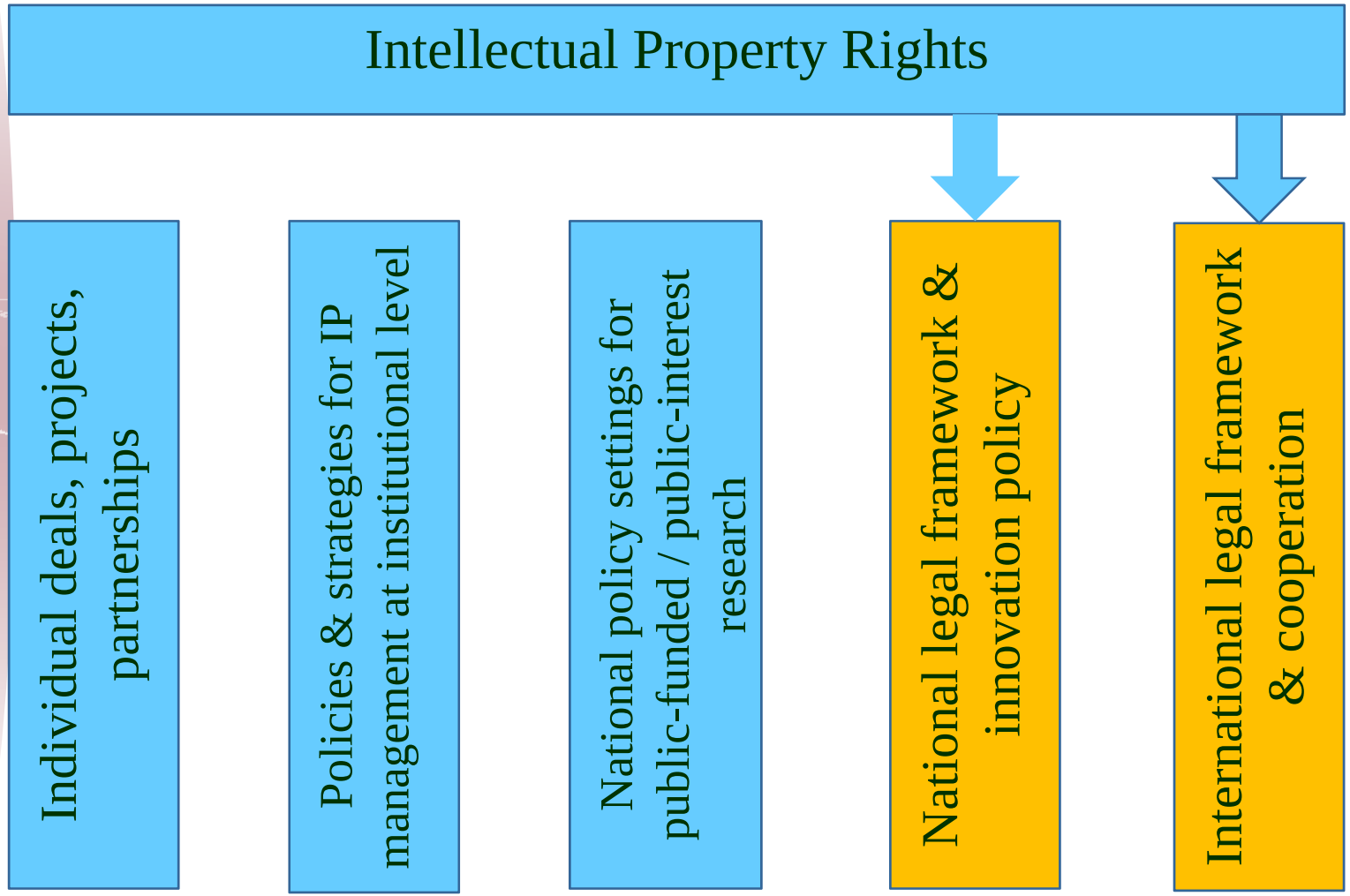
- Essentially among WHO, WIPO, WTO
- "Traditional" fields of cooperation, in particular capacity building activities
- Series of joint technical symposia
- WHO/WIPO/WTO study on "Promoting Access and Medical Innovation: Intersections Between Public Health, IP and Trade":
  - Aims at assisting decision-makers 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 trad

Interaction IPRs - public health



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

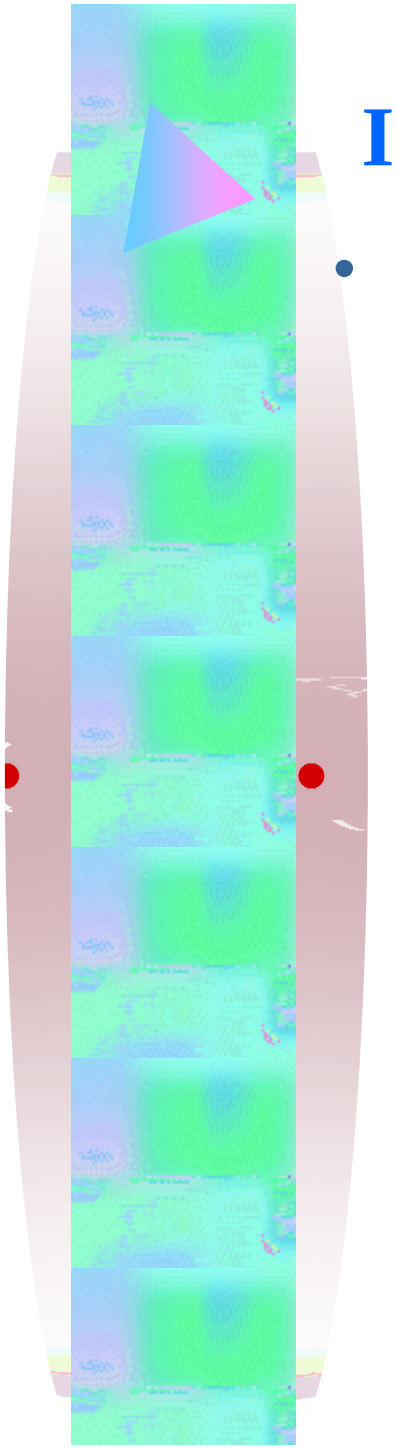
- Available even when substantive and formal conditions for patents are met
- Art.27.2 and 3 TRIPS contain exhaustive list of three possible grounds for exclusion:
  - Protection of *ordre public* (i.e. general security, core values of society) or morality, provided that prevention of commercial exploitation 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)**
    -

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)**
  - **Micro-organisms and non-biological processes: patentability clarified in new Law on Patents (Saudi Arabia, WP Report of November 2011**