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

The TRIPS Agreement and Patentability Criteria

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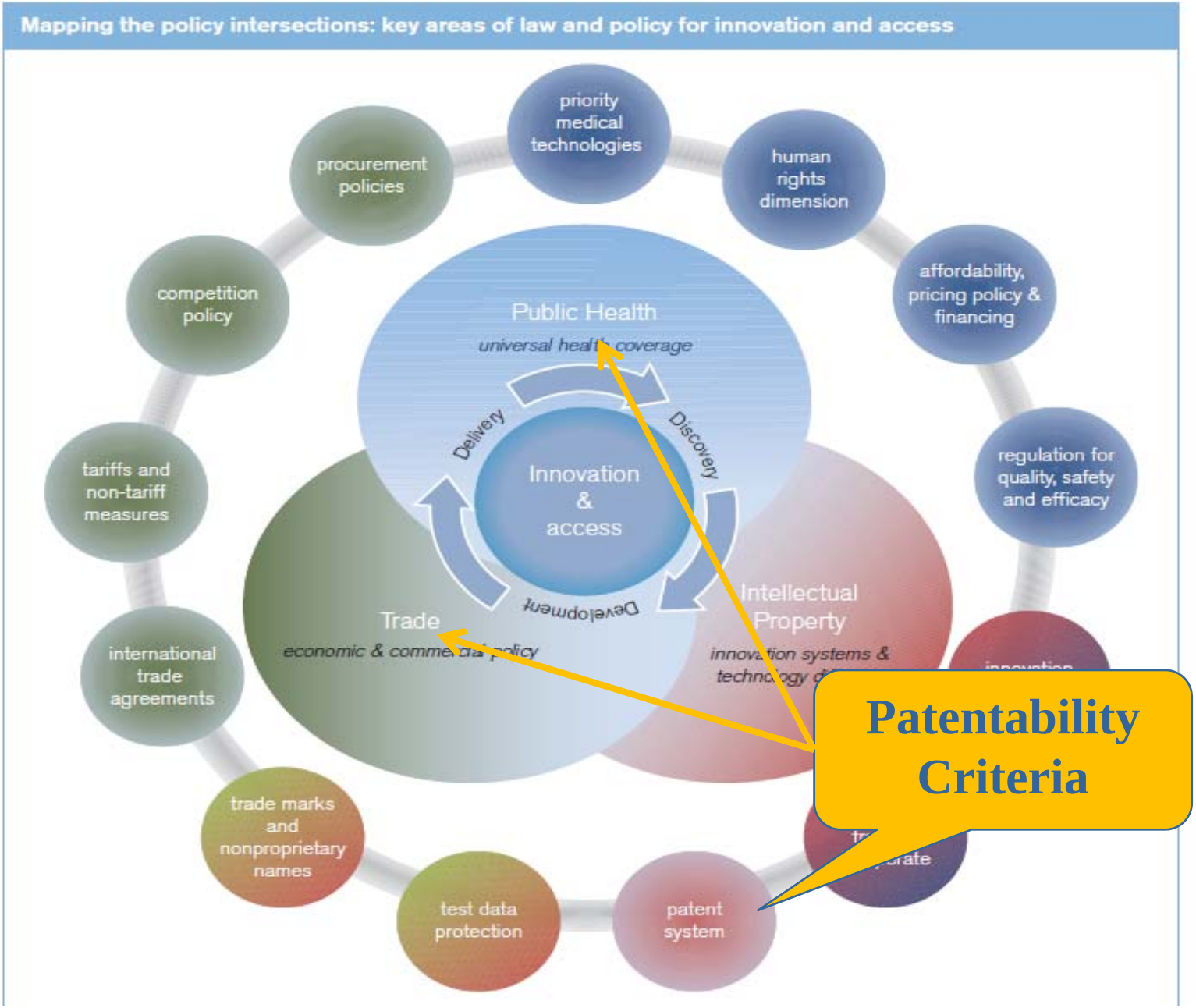
Trilateral Cooperation: To Build Capacity, To Ensure Coherence

- 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

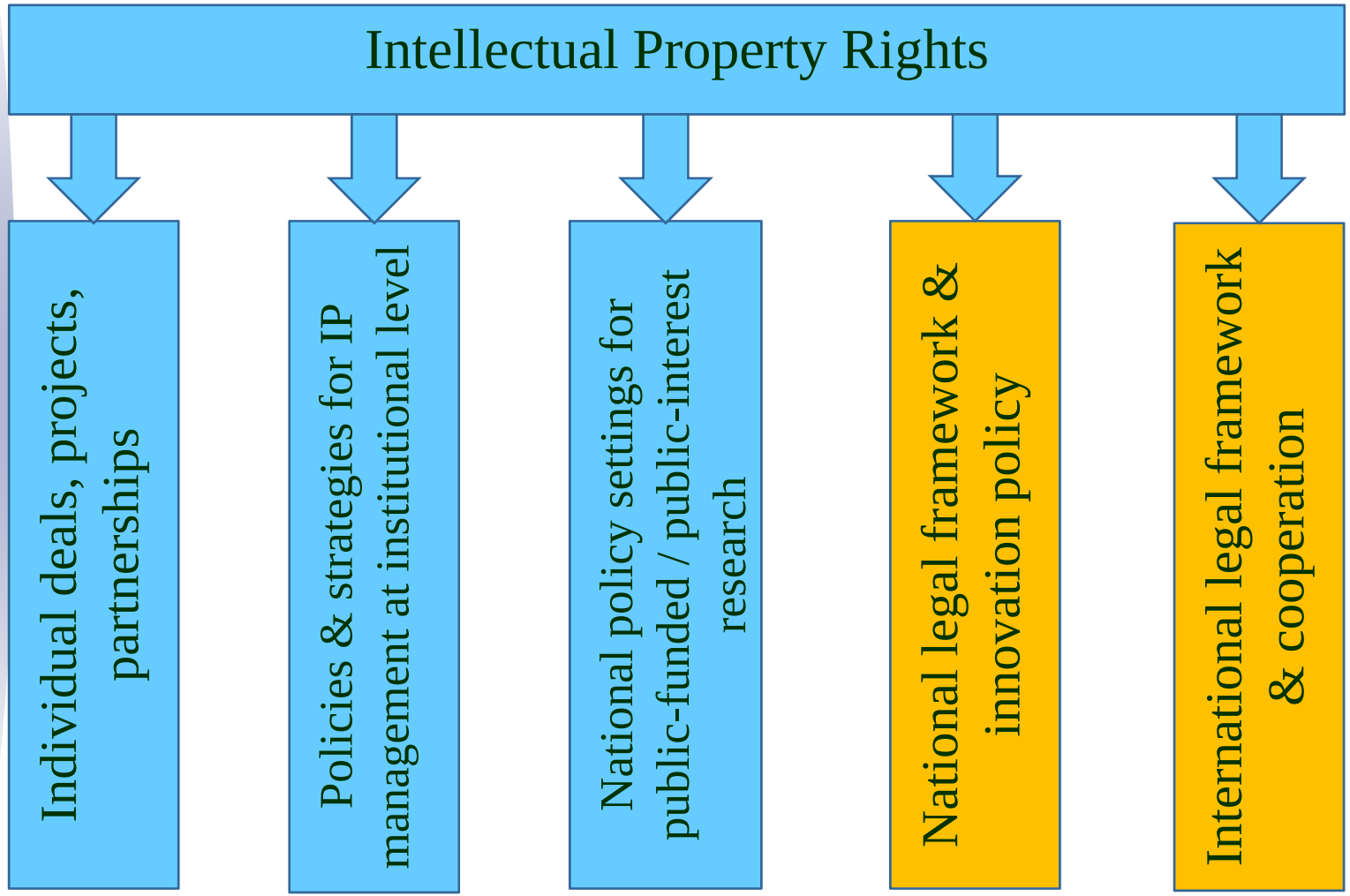
WTO's Role

- 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

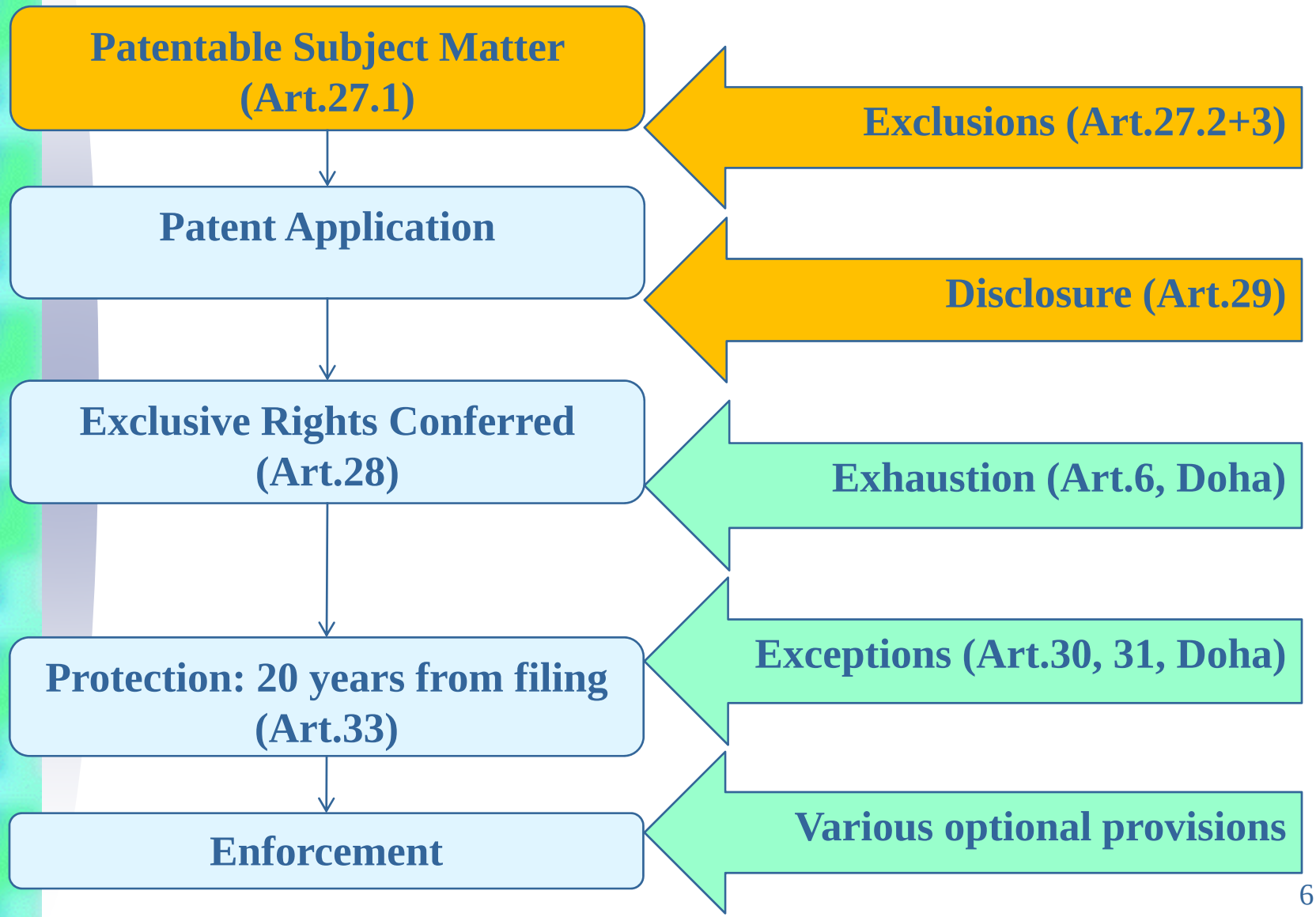
Intersections between health, IP and trade



Interaction IPRs - public health



Patents: Search for A Balanced Approach



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)

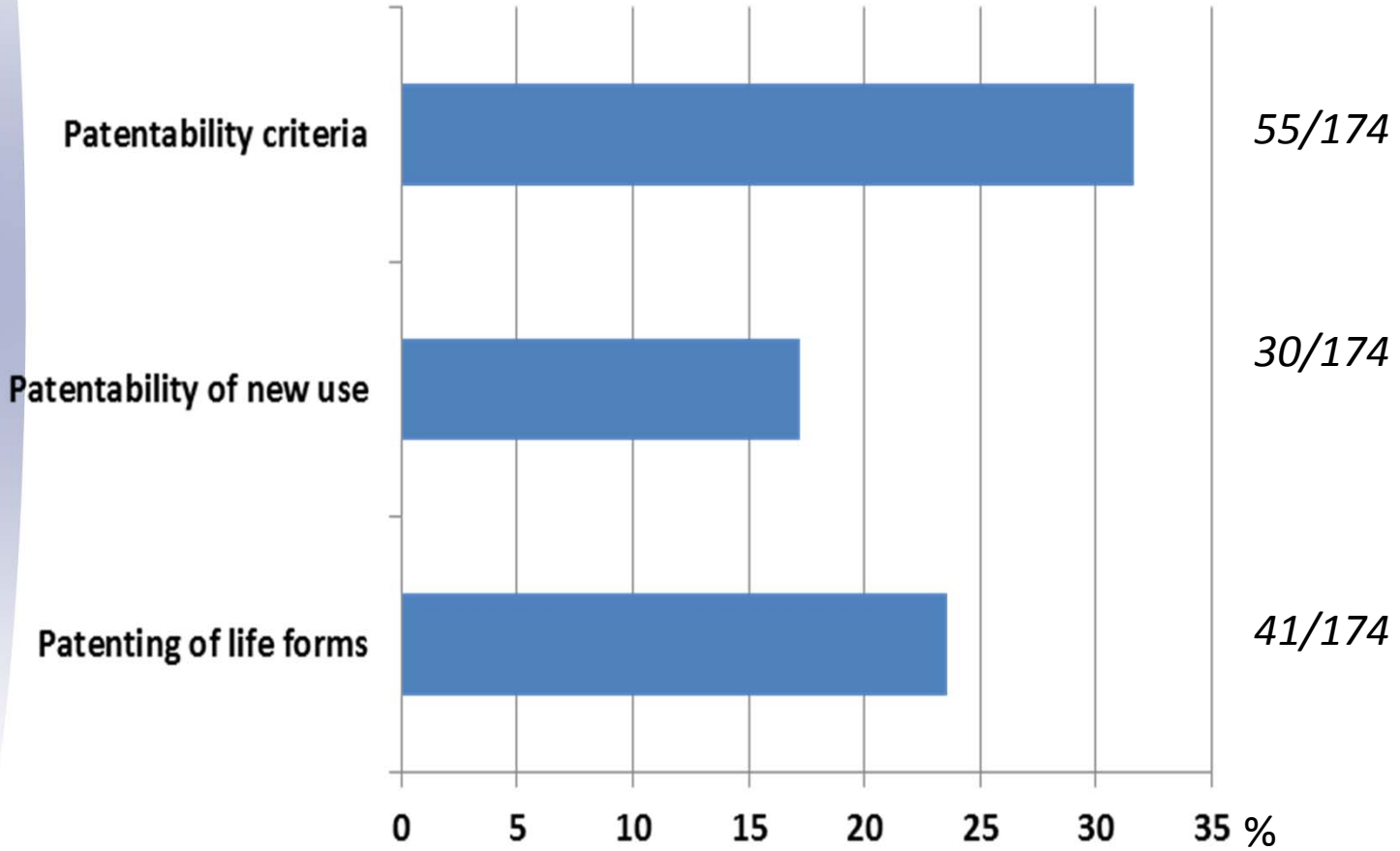
Issues Raised in WTO Accession Negotiations

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

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 Provisions In Trade Agreements With IP Provisions (Notified to the WTO By Feb.2014)



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?