USE AND ABUSE OF PATENT FLEXIBILITIES IN THE TRIPS AGREEMENT

Marco M. ALEMAN
Director, Patent Law Division, WIPO

Bogota, March 9 and 10, 2018
Outline

- Definition of flexibilities and examples thereof
- Flexibilities v. Trips Plus
- Illustrative examples of the legislative implementation of flexibilities and equivalent provisions that provide for a more extensive protection
- Constrains faced by developing countries in the implementation of flexibilities
- Final comments
The Concept of Flexibility

The term “flexibility” in TRIPS (paragraph 6 of the preamble and Article 66.1)

Carolyn Deere: “a range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPS Agreement”  *The Implementation Game*, Oxford University Press (2009), p.68.

Elena Ghanotakis: “There were several flexibilities inherent in the TRIPS Agreement. All of those measures, consistent with the TRIPS Agreement, reduce prices and increase the affordability of medicines, without negatively affecting future R&D”.


The term “TRIPS flexibilities” means that there are different options through which treaty commitments can be transposed into national law, thus, national interests are accommodated and yet TRIPS provisions and principles are complied with.
The Doha Declaration. Paragraph 4. “Members reaffirmed their right to use..., the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The Doha Declaration, in paragraph 5, clarifies that these flexibilities include the right to Members to: applying the customary rules of interpretation of public international law when interpreting the TRIPS Agreement; the right to grant compulsory licenses and the freedom to determine the grounds; to determine what constitutes a national emergency or other circumstances of extreme urgency; to leave each Member free to establish its own regime of exhaustion.
“Flexibilities” as a mechanism to consider national policies

Flexibilities go beyond health issues, since this concept is not technology-oriented

- CLs
- Utility models
- Patent prosecution (examination, publication, opposition)
- Disclosure related matters

Some examples of flexibilities that play a role in promoting access to medicines

- Transition period
- Exhaustion
- Patent term of protection
- Exclusions from patent protection
- Exceptions and limitations
Maximum standards
(more extensive protection)

patent restoration term,
national exhaustion, exclusion of plant varieties
protection to naturally occurring micro-organisms,
Narrow down exceptions and limitations

20 years of protection period,
international exhaustion, exclusion of plants and
genetically-modified micro-organisms,
bolar type exc., research exc.,
further grounds for CL

Flexibilities

TRIPS
Minimum standards

further protection (TRIPS violation)

Trips Plus
To waive
Flexibility

Below (TRIPS violation)
TRIPS Agreement implementation. 
Art. 27 and some of its flexibilities

Explicit obligation to give protection
- Inventions -whether products or processes- in all fields of technology.
- Micro-organisms

Explicit permission to exclude from patent protection
- Plants and animals
- Diagnostic, therapeutic and surgical methods

Implicit permission not to give protection
- Discoveries
- Substances existing in nature
- Incremental innovation
TRIPS Agreement implementation. Art. 27 and more extensive protection

<table>
<thead>
<tr>
<th>Explicit obligation to protect</th>
<th>Explicit permission to excluded</th>
<th>Implicit permission not give protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inventions, whether products or processes, in all fields of technology (to renounce to a transition period)</td>
<td>• Plant and animals (not to exclude or only exclude plants varieties and animal races)</td>
<td>• Substances existing in nature (allow protection when isolated and purified)</td>
</tr>
<tr>
<td>• Micro-organisms (comprehensive definition)</td>
<td>• Diagnostic, therapeutic and surgical methods (not to exclude or limit the concepts to allow protection under certain circumstances)</td>
<td>• First and Second medical use (allow protection via modify requirement of novelty/type of claims)</td>
</tr>
</tbody>
</table>
Countries exercise their right to choose options made available in international treaties to meet their domestic policy objectives.

Once the government transposes options in the international agreements to the national level, various individual stakeholders use the national legal framework.

- A government makes choices from the various options and implements those choices under the national legislation.
- There is public expectation that adequate use of the national legal framework by each stakeholder would lead to the attainment of the public policy goals, such as public health and access to medicines.
CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs

Constraints encountered by governments at the stage of national implementation of flexibilities

- Constructive ambiguity of international treaties
- Complexity of practical implementation
- Operation of law and administrative framework
- Institutional capacity
- National governance and internal coordination
- Extrinsic influences

Constraints faced by various stakeholders in using a national legal framework that has implemented policy options

- Ambiguity and uncertainty of national law
- Technical and technological capacity
- Identifying relevant patents and their status
- Other aspects that affect the use of compulsory licenses
- Other challenges where use of flexibilities has not led to intended policy outcomes
Final comments

- In implementing flexibilities into their national laws with a view to access to medicines, governments seek to strike a right balance among diverse interests, namely, to ensure access to both existing and future medicines and to promote innovation.

- The debates related to “full use of flexibilities” takes place at two levels: (i) Government choice and transposition of international law and (ii) use of national provisions by individual stakeholders.

- An appropriate use of flexibilities available at the multilateral level shall not compromise the adequate implementation of those treaty commitments.

- The use of the expression flexibilities referring to a given feature of a patent law, namely, when it is used as an equivalent concept of compulsory license, or exhaustion or any other given provision of a national patent law might be misleading.
MANY THANKS !!!

marco.aleman@wipo.int