



**BOGOTÁ**  
2018



# ■ USE AND ABUSE OF PATENT FLEXIBILITIES IN THE TRIPS AGREEMENT

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**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”

Access to Medicines for Developing Countries’, *Journal of World IP* (2004), vol . 7, issue 14.

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.

# TERMINOLOGIES – Patent flexibilities

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.

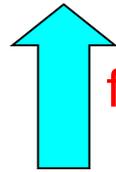
# “Flexibilities” as a mechanism to consider national policies

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



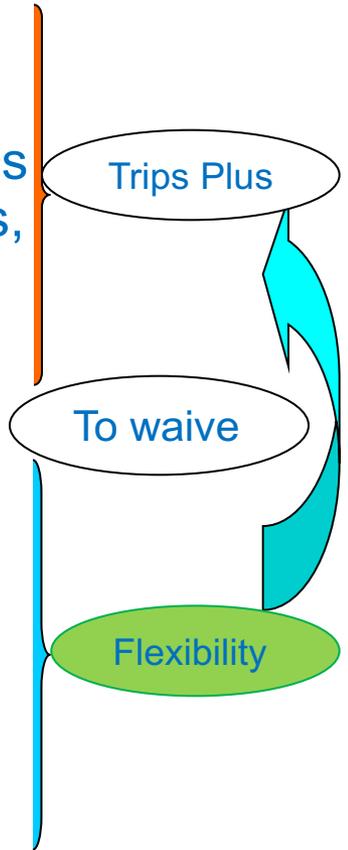
further protection (TRIPS violation)

Maximum standards  
(more extensive protection)



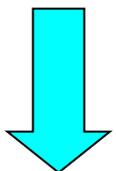
patent restoration term,  
national exhaustion, exclusion of plant varieties  
protection to naturally occurring micro-organisms,  
Narrow down exceptions and limitations

Flexibilities



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

TRIPS  
Minimum standards



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

Explicit obligation to protect	Explicit permission to excluded	Implicit permission not give protection
<ul style="list-style-type: none"><li>• Inventions, whether products or processes, in all fields of technology (to renounce to a transition period)</li><li>• Micro-organisms (comprehensive definition)</li></ul>	<ul style="list-style-type: none"><li>• Plant and animals (not to exclude or only exclude plants varieties and animal races)</li><li>• Diagnostic, therapeutic and surgical methods (not to exclude or limit the concepts to allow protection under certain circumstances)</li></ul>	<ul style="list-style-type: none"><li>• Substances existing in nature (allow protection when isolated and purified)</li><li>• First and Second medical use (allow protection via modify requirement of novelty/type of claims)</li></ul>

# TERMINOLOGIES – Full use of patent flexibilities

Countries exercise their right to choose options made available in international treaties to meet their domestic policy objectives

- a government makes choices from the various options and
- implements those choices under the national legislation

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

- 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 !!!**

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