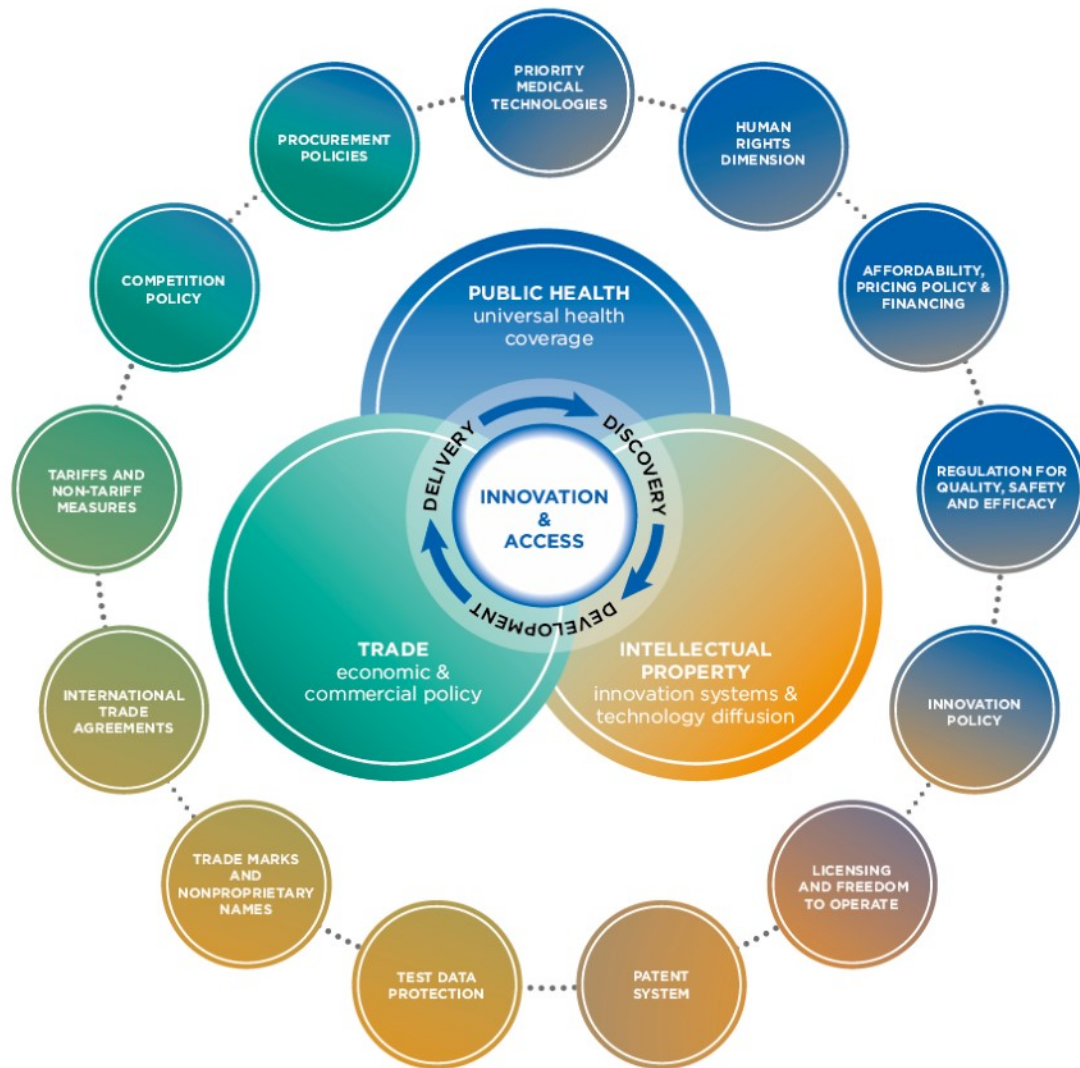


Health-Related IP Provisions in RTAs

Josefita Pardo de León
Intellectual Property, Government Procurement
and Competition Division
World Trade Organization

5 August 2021.

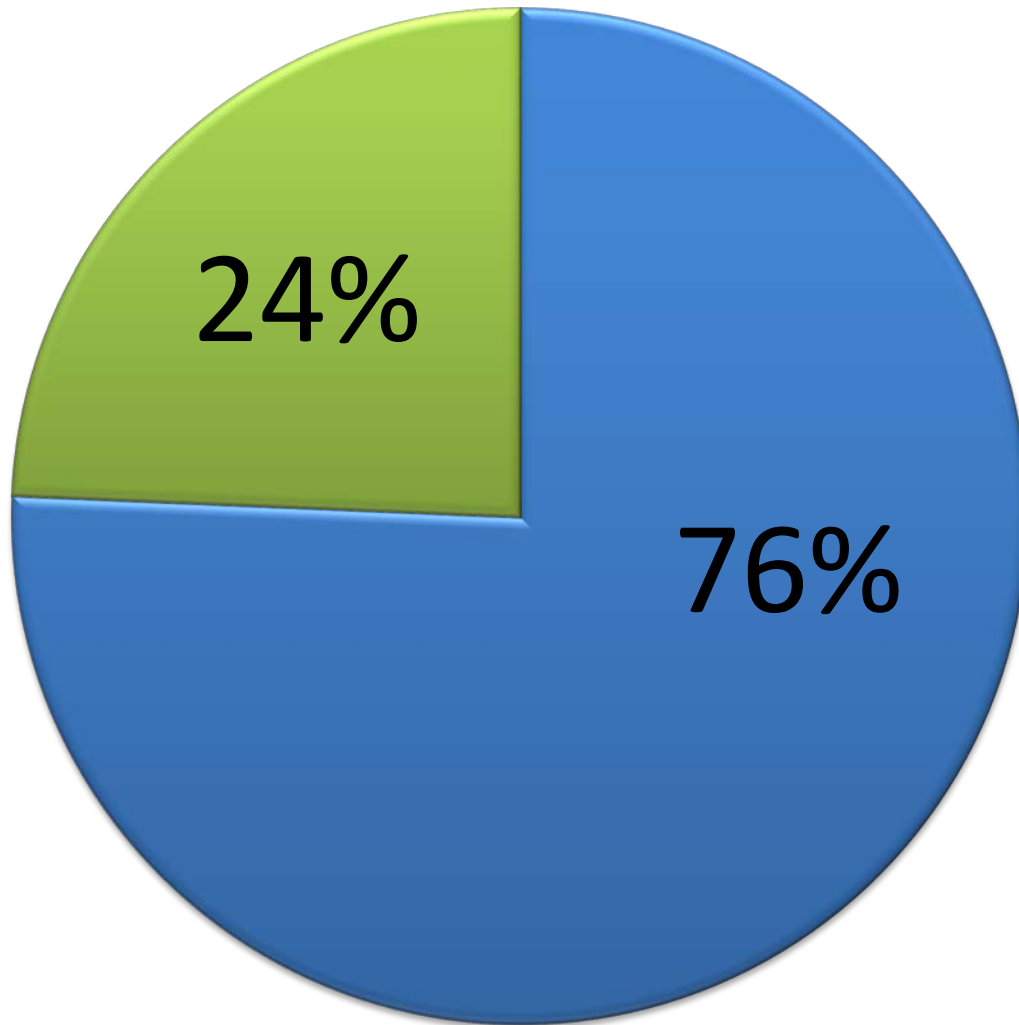




Source: [WHO-WTO-WIPO Trilateral Study, 2nd Edition \(2020\)](#)



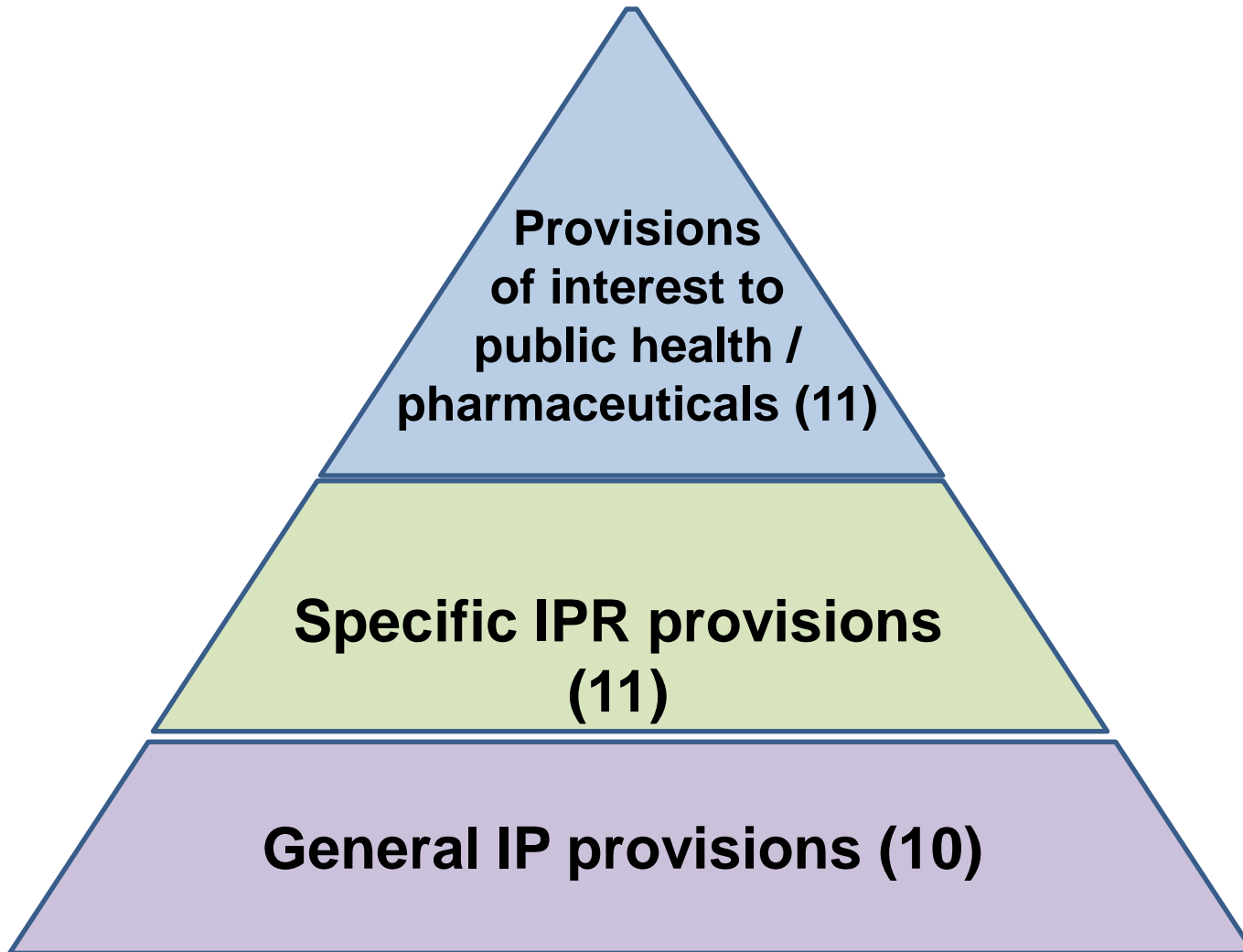
MAPPING IP PROVISIONS



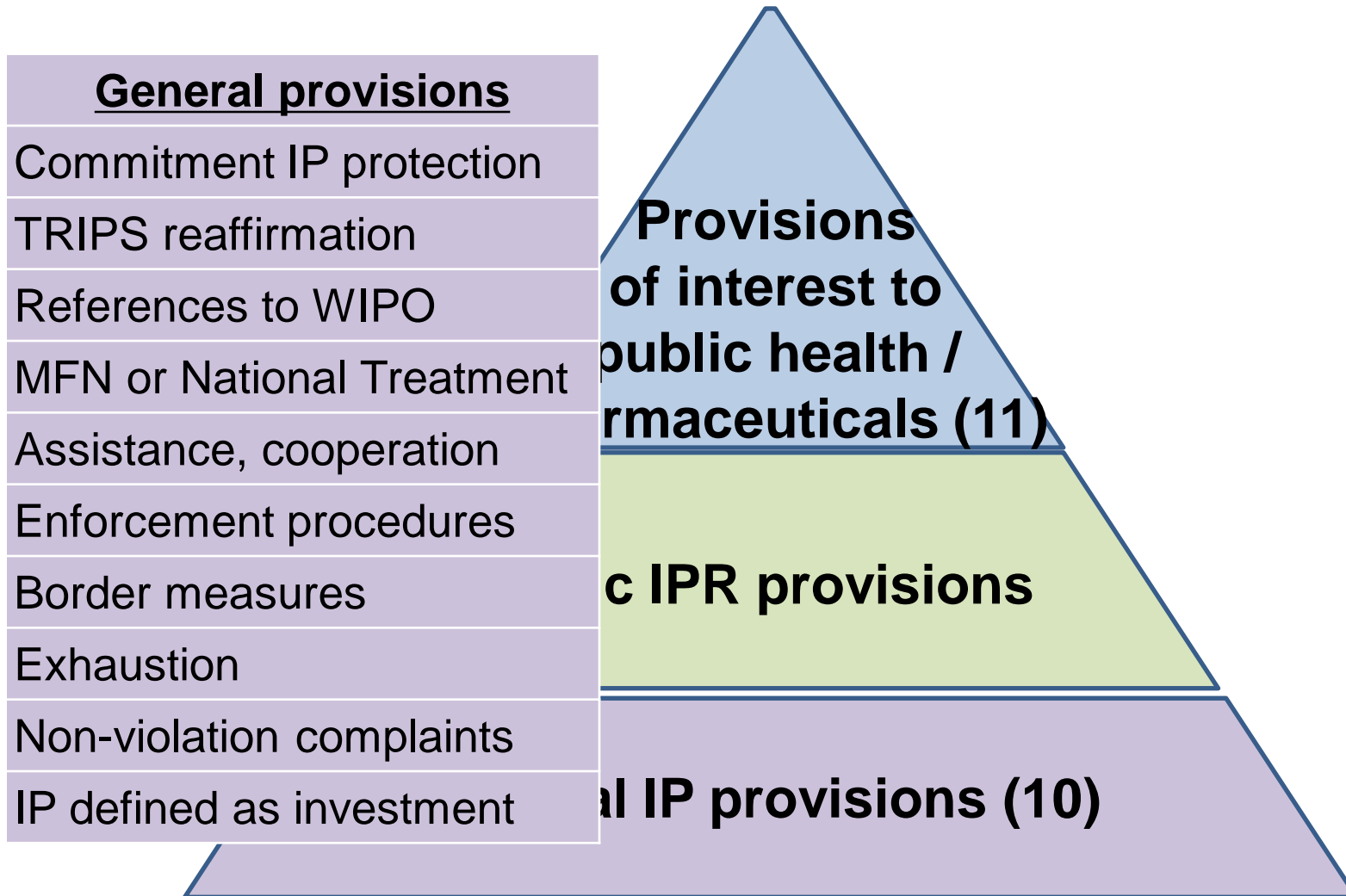
■ IP Provisions ■ No IP Provisions

**FTAs in
force
&
notified
to WTO**

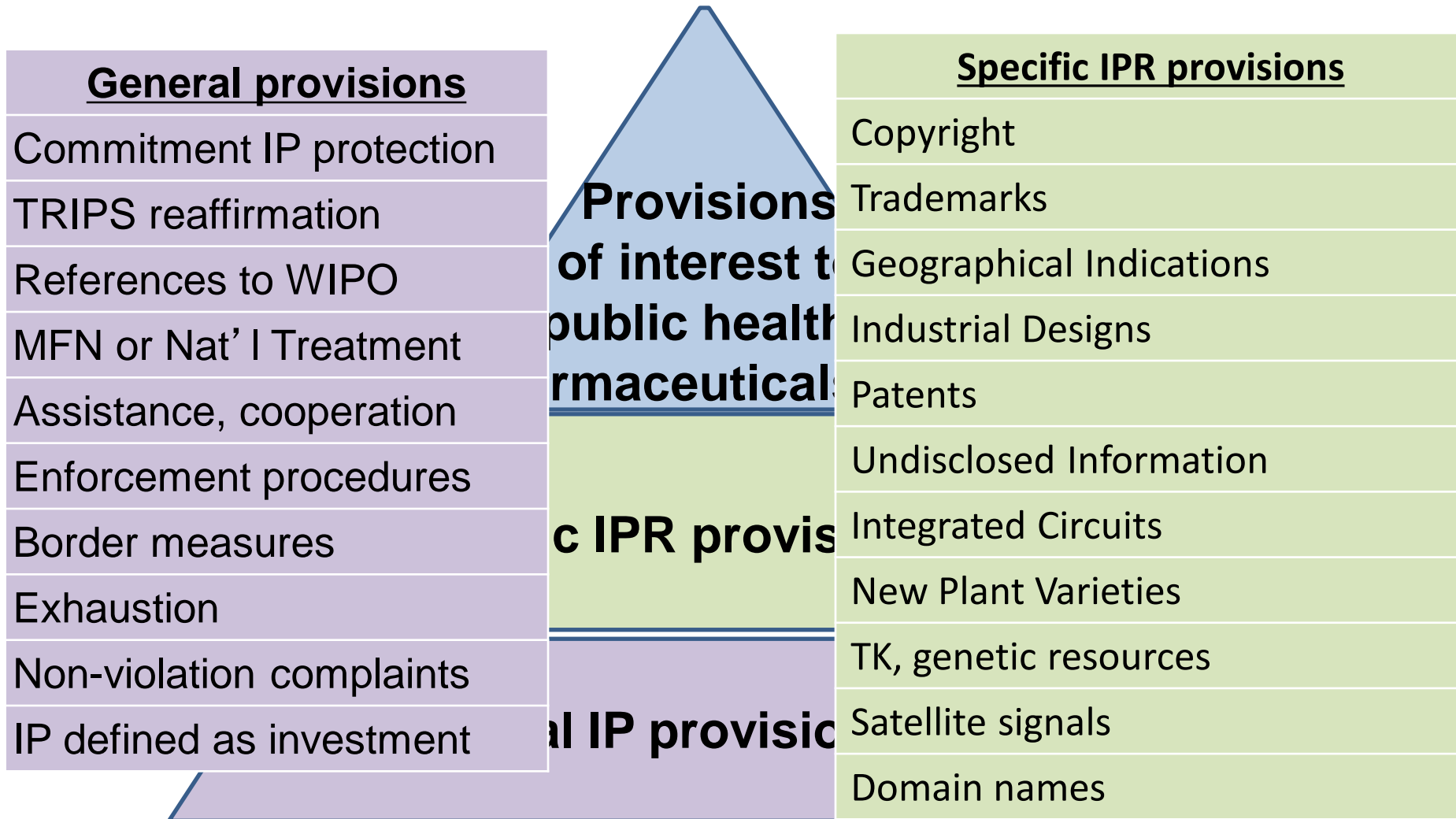
IP provisions in FTAs



IP provisions in FTAs



IP provisions in FTAs



IP provisions in FTAs

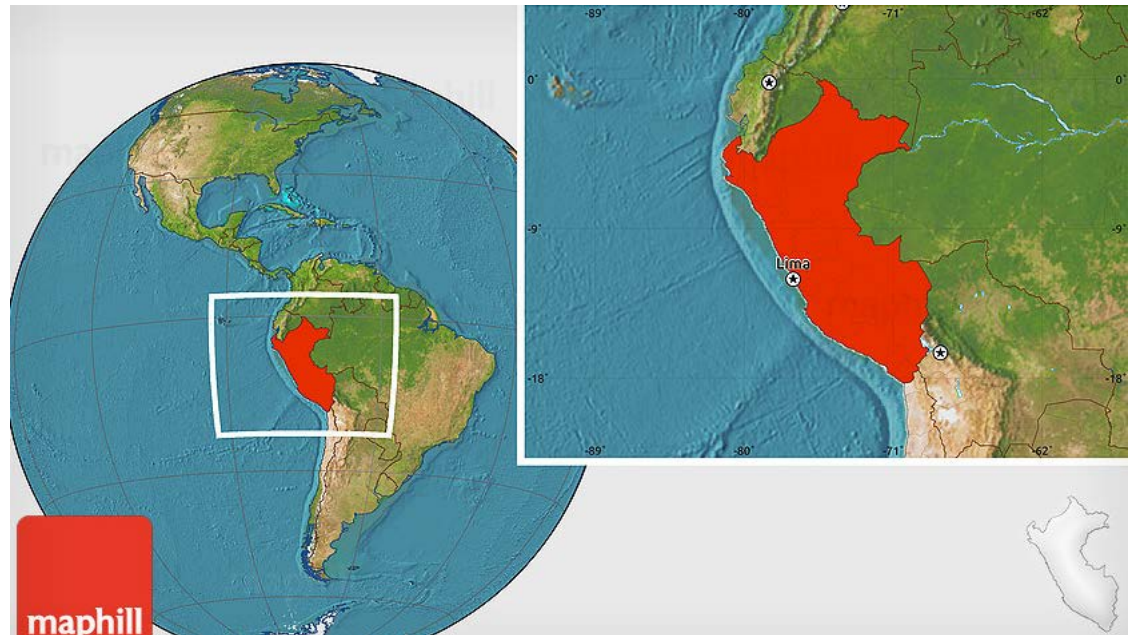
“Health-related” IP Provisions

<u>General</u>	1) Patentability criteria or patent subject matter	<u>Provisions</u>
Commitment	2) Patentability of new use	
TRIPS	3) Patenting of life forms	
Reference	4) Patent linkage	
MFN or	5) Exceptions/exclusions to exclusive rights	
Assistance	6) Data protection provisions	
Enforcement	7) ... Specified period of data protection	
Border	8) Term extensions of patent protection	
Exhaustion	9) Compulsory licensing of patents	
Non-violation	10) Compulsory licensing on investment	
IP definition	11) Safeguarding of a trademark's function	

Real-life Example: Peru

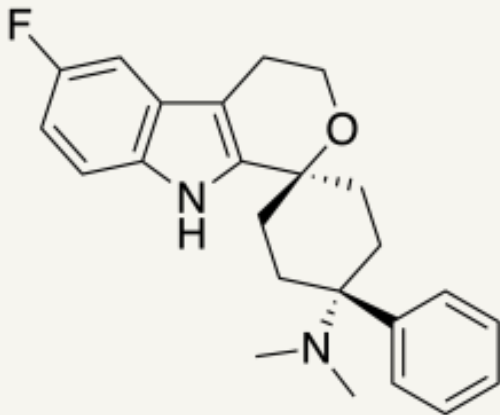
Peru's international obligations on data protection:

- [Decision 486 of the Andean Community](#)
- TRIPS Agreement
- [FTA with the United States](#)
- [FTA with EFTA](#)
- [Association Agreement with the European Union](#)
- [CPTPP](#)



Peru: National Implementation

- Definition of “test data”
- Definition of “new chemical entity”, including exceptions
- Period of Protection:
 - First application for marketing approval in Peru is also the first one worldwide - 5 years.
 - Approval by reference - The term begins to count from the moment the first marketing approval was granted worldwide and not from the grant in Peru.
 - Unjustified delays of the regulatory authority - 5 years after the "complete" file is submitted.



See: “Test data for Pharmaceutical products. Analysis of Peruvian Legislation and Applicable Treaties” by Maritza Reátegui Valdiviezo

<https://revistas.pucp.edu.pe/index.php/derechoysociedad/article/view/19884/19923>

Amended TRIPS Agreement: Special Compulsory Licenses for Export

- Article 31*bis* – creates a new legal avenue to export pharmaceuticals produced under compulsory licence.
 - Objective: Assist countries that lack manufacturing capacity
- Only requirement: Notification to the TRIPS Council
 - One page, templates available online, cost free.
 - See <https://e-trips.wto.org/>
- System has only been used by Rwanda and Canada
- 2017 WHO “study shows that TRIPS flexibilities have been used more frequently than is commonly assumed and have proven effective for procuring generic versions of essential medicines, particularly for treating HIV infection. The System has been utilized in negotiations with providers. (see “Medicine procurement and the use of flexibilities in the TRIPS Agreement, 2001–2016” by Ellen ‘t Hoen https://www.who.int/bulletin/online_first/BLT.17.199364.pdf)



11 May 2021

(21-4027)

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**Council for Trade-Related Aspects of
Intellectual Property Rights**

Original: Spanish

NOTIFICATION UNDER THE AMENDED TRIPS AGREEMENT

**NOTIFICATION OF NEED TO IMPORT PHARMACEUTICAL PRODUCTS
UNDER THE SPECIAL COMPULSORY LICENSING SYSTEM**

Notifying Member(s)	PLURINATIONAL STATE OF BOLIVIA
Product(s) needed	An estimated 15 million doses of COVID-19 vaccines. In particular, the intention is to import the vaccine, Ad26.COV2.S, a replication-incompetent adenovirus type 26 (AD16) vectored vaccine encoding a stabilized variant of the S protein of SARS-Cov-2. The Plurinational State of Bolivia reserves the right to import other vaccines.
Establishment of no or insufficient manufacturing capacities in the pharmaceutical sector	<input checked="" type="checkbox"/> Member currently has no manufacturing capacities in the pharmaceutical sector. <input type="checkbox"/> Member has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for the needed pharmaceutical product(s).
Information on how the lack of (sufficient) manufacturing capacity in the pharmaceutical sector was established	The Plurinational State of Bolivia has found that it has no manufacturing capacities in the pharmaceutical sector for COVID-19 vaccines, including the Ad26.COV2.S vaccine.
Is/are the product(s) needed protected by patent in the territory?	<input type="checkbox"/> No. <input type="checkbox"/> Yes. <input checked="" type="checkbox"/> To be determined. Should the patents for the products needed have been applied for or granted, the Plurinational State of Bolivia intends to grant compulsory licenses, in accordance with Articles 31 and 31bis of the TRIPS Agreement.
Submission date of notification	10 May 2021

National Implementation

- Implementing measures in at least 56 Members and 1 Observer (July 2020):
 - 37 industrialized country Members
 - 3 transition countries
 - 13 developing countries
 - 3 LDCs (including Samoa)
- Cover more than 85% of world's export markets
- For transparency purposes: notify relevant laws and regulations to TRIPS Council
- See [2015 Staff Working Paper](#)

Food for thought:

- What is needed to implement the key features of the Special CL into your national law?
 - What is the most straightforward measure?
 - How would authority be delegated for effective decision making?
- How could it be integrated as a tool of medicines' procurement processes?
- Compare with approaches taken by other Members.
- Notify measures when adopted for transparency purposes.

Waiver Proposal

- October 2020: Initial proposal for a waiver from certain provisions of the TRIPS Agreement by India and South Africa ([IP/C/W/669](#)).
- May 2021: Revised proposal co-sponsored by over 64 delegations, ([IP/C/W/669/Rev.1](#)).
- June 2021: EU communication on urgent trade policy responses to the pandemic ([IP/C/W/680](#))
- [Report from 27-28 July TRIPS Council](#)

COVID-19 and TRIPS-related Measures

- [Non-exhaustive list of measures](#) compiled by the WTO Secretariat.
 - $\frac{3}{4}$ are administrative measures to ease procedural requirements in IP Offices during lockdowns and development of online services.
 - $\frac{1}{4}$ are substantive measures aimed at promoting innovation or facilitating access to COVID-19-related health technologies and normally require the enactment of government decrees or amendments to existing legislation. Most have been duly notified to the TRIPS Council.

WTO Sources of COVID-19-related Information

- [Information Note on the TRIPS Agreement and COVID-19](#)
- [Developing and Delivering COVID-19 Vaccines Around the World](#)
- [Trade-related bottlenecks and trade-facilitating measures on critical products to combat COVID-19](#)

Some food for thought...

- Deep RTAs have the objective of regulatory convergence and protection of IPRs is important for innovation and business environment (see [World Bank Handbook of Deep Trade Agreements](#))
- Potential for duplication and overlap?
- Need for coherent, practical approach in negotiations and implementation.
- Global Value Chains
 - [World Development Report](#)
- [WHO-WTO-WIPO Trilateral Study, 2nd Edition \(2020\)](#)



Guan Chenchen of China earned the gold medal on the balance beam. Source: NY Times.

Credits: Photographs by Bedel Saget; composite image by Larry Buchanan

Food for thought: The balance of rights and obligations is a dynamic equilibrium that evolves over time, how can the international system respond and find practical solutions for different countries?

Thank you!

josefita.pardodeleon@wto.org

