Compliance Issues on TRIPS: Public Health Perspective

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Dr Socorro Escalante

WHO Country Office for Viet Nam

The TRIPS agreement does not and should not prevent members from taking measures to protect public health

The TRIPS agreement should be interpreted and implemented in a way that supports public health by promoting both access to new medicines and the development of new medicines

Presentation Outline

1. TRIPS: Public health related provisions
2. Public health sensitivity of patent legislation
3. Country examples
4. Questions to ponder

TRIPS: Public Health Relevant Provisions

TRIPS: Public health related provisions

Table 1. **Definitions of the framework's TRIPS flexibilities and their corresponding articles**

Flexibilities of public health interest	TRIPS Agreement articles	Definition
Transition period for granting pharmaceutical patents	65, 66 and paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration)	A transition period of ten years (until 2005) is specified for a developing country that did not grant patents for pharmaceutical products and processes before January 1995; least-developed countries that did not grant such patents before January 1995 have until 2016 to make this transition.
Parallel imports	6	Products imported into a country without the authorization of the patent holder in that country when the product is put on the market abroad by the patent holder or a third party with the patent holder's consent.
Experimental use	30	Use of the patented invention for scientific purposes.
Bolar exception (early working)	30	This allows a company to complete all procedures and tests required to register a generic product before the original patent expires.
Compulsory licensing	31	This refers to authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patent holder.
Health ministry participation in analysing pharmaceutical patent claims	8 (implicit)	Pharmaceutical patent claims are submitted to health ministry professionals for analysis and approval.

Source: ref. 16, 17.

Adopted from: Cahves, G and Oliveria, MA, *A proposal for measuring the degree of public health legislation in the context of the WTO-TRIPs Agreement* Bulleltin of the World Health Organization, January 2007, 85 (1)

TRIPS-plus: Public health related provisions

Table 2. **Definition of framework's TRIPS-plus provisions**

TRIPS-plus provision	Definition
Extension of patent term (beyond 20 years)	FTAs propose patent term extension as established in TRIPS Agreement article 33.
Linkage between drug marketing approval and patent status	Establishes a link between market approval for generic medicines and patent status, making it impossible for manufacturers to obtain market approval for generic versions of patented products.
Exclusivity of data submitted for registration of pharmaceuticals	This provision makes it impossible to obtain market approval for generic medicines based on safety and efficacy data the originating company submits to the Drug Regulatory Authority. Tests that prove safety and efficacy of a new molecular entity are performed in phase I, II and III clinical trials on humans. The presentation of clinical trial data is mandatory to request marketing approval for a product composed of a new molecular entity.

Source: ref. 30–35. FTAS = free-trade agreements.

Adopted from: Cahves, G and Oliveria, MA, *A proposal for measuring the degree of public health legislation in the context of the WTO-TRIPs Agreement* Bulleltin of the World Health Organization, January 2007, 85 (1)

Public health sensitivity of patent legislation

The contents of the slides under this section are derived/adopted from the publication: ***A proposal for measuring the degree of public health legislation in the context of the WTO-TRIPs Agreement*** by Gabriela Cost Chaves and Maria Auxiliadora Oliveira
Published in the Bulleltin of the World Health Organization, January 2007, 85 (1)

How do countries fare?

Table 5. **Analysis of selected countries' patent legislation**[a]

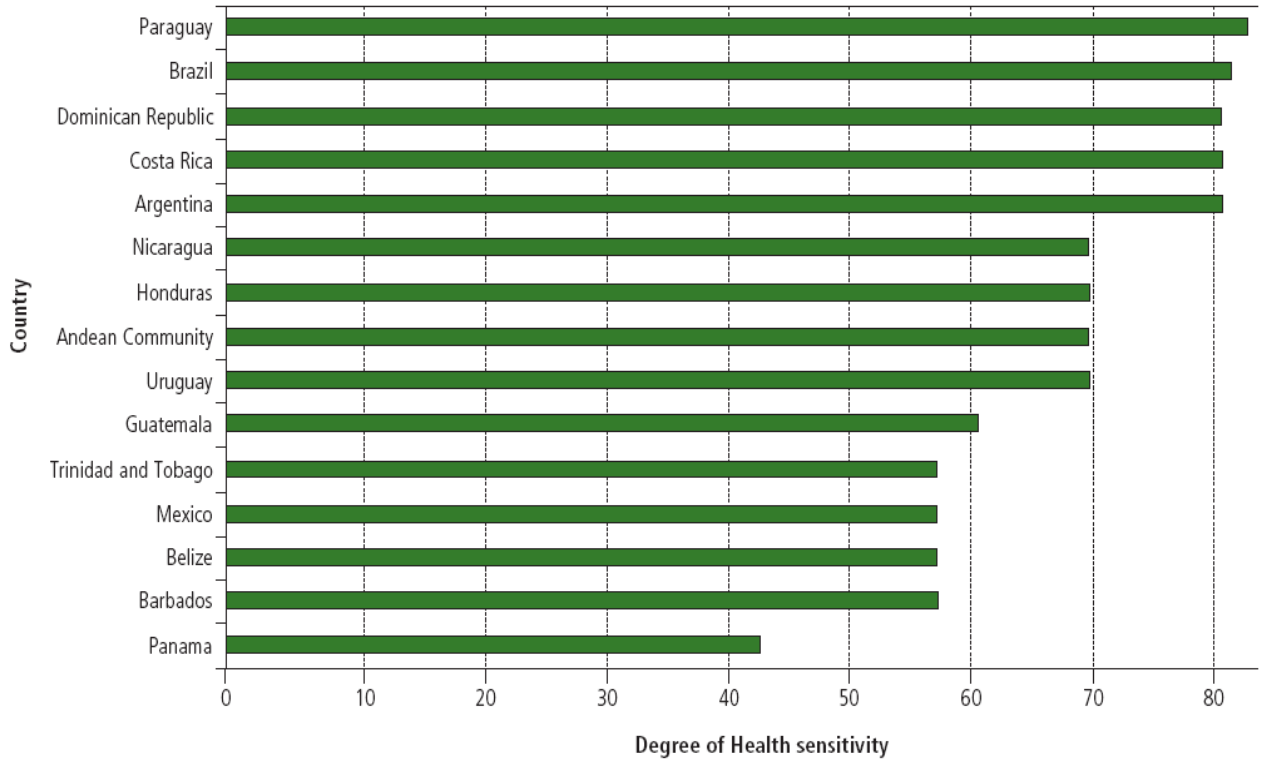
Legal provision	AR	BAR	BZ	BR	CA	CR	GUA	HON	MEX	NIC	PAN	PG	DR	TRI	URU
Flexibilities related to public health protection															
Compulsory licence	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+
Health ministry participation in analysing pharmaceutical patent claims	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-
Parallel imports	+	-	-	+	+	+	+	+	-	+	-	+	+	-	+
Bolar exception (early working)	+	-	-	+	-	+	-	-	-	-	-	+	+	-	+
Experimental use	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Transition period for granting pharmaceutical patents	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
TRIPS-plus provisions															
Does not include extension of patent term (beyond 20 years)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Does not include linkage between drug marketing approval and patent status	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Does not include exclusivity of data submitted for registration of pharmaceuticals	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-

Label: + when the provision is in the legislation; - when the provision is not in the legislation; NA when does not apply.

[a] Country abbreviations: AR – Argentina; BAR – Barbados; BZ – Belize; BR – Brazil; CA – Andean Community; CR – Costa Rica; GUA – Guatemala; HON – Honduras; MEX – Mexico; NIC – Nicaragua; PAN –Panama; PG – Paraguay; DR – Dominican Republic; TRI – Trinidad and Tobago; URU – Uruguay.

How do countries fare?

Fig. 1. **Health-sensitivity of patent legislation in selected countries, 1996–2005**



How do countries fare?

Key results in the analysis

- In some cases, the provisions existed but disagreed with the definitions

Example: Brazilian Patent Legislation Law (279/96)

- Includes parallel imports but applied for only one year and limited in situations in which imports are necessary to implement a compulsory license

How do countries fare?

Key results in the analysis

Some contain Bolar provisions, but with wide degree of variation

Examples:

- Paraguay: 30 days before the patent expires
- Uruguay: limited to one year before the patent expires

How do countries fare?

Key results in the analysis

- TRIPs plus provisions may not be contained in the legislation, but in FTA's and subsequent circulars

Examples:

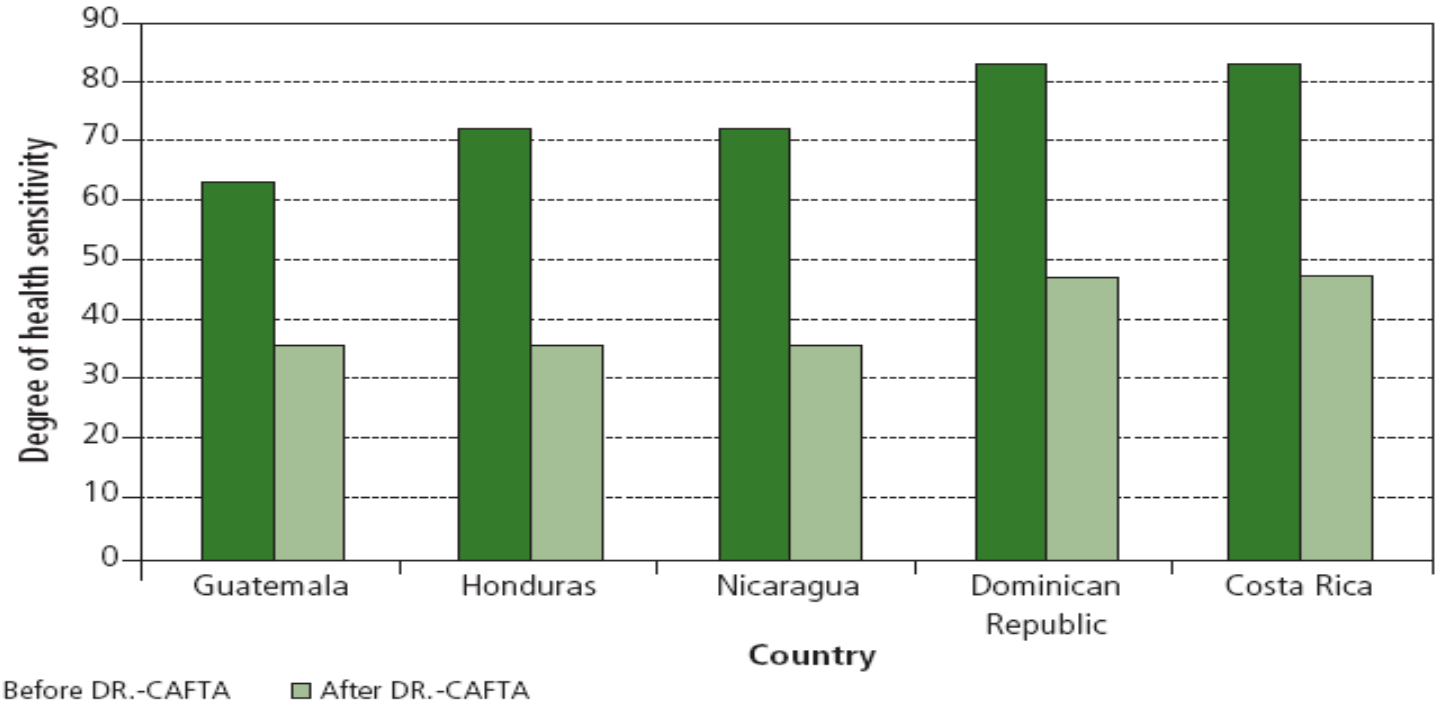
Mexico: no data exclusivity in patent legislation, but protects data for five years as established in the NAFTA (Article 1711, Trade secrets)

Colombia: data exclusivity are established in subsequent Decrees (677 and 2085)

Impact of FTA's on health sensitivity of patent legislation

- **The scenario of the IPR legislation changes for countries that have signed FTA's**

Fig. 2. **Degree of health-sensitivity of patent legislation in the Dominican Republic, Honduras, Guatemala, Costa Rica and Nicaragua, before and after the DR-CAFTA**



Country Examples

Country Examples

Argentina: Test Data

Case:

- Drug registration in Argentina is categorized into two scenarios:

1. Authorization for a drug that has not been authorized in Argentina or in any country with a high level of health surveillance
2. Authorization for a drug that have received prior authorization in Argentina or a country with high level of health surveillance

Country Examples

Argentina: Test Data

Requirement for safety data:

Scenario 1: Require clinical trials that demonstrates safety and efficacy

Scenario 2: Use data of reference drug that has been previously authorized. The applicant can invoke pharmaceutical similarity. Exemption from clinical trial is granted

Country Examples

Argentina: Test Data

- The Argentine regime does not grant exclusive rights to the undisclosed results of clinical trials presented to ANMAT or to regulatory authorities of other countries by the applicant
- Protects data presented to ANMAT only against unfair competition

Country Examples

Argentina: Test Data

- The Argentine regime has contributed to the preservation of a competitive market
- In 2006, it granted 1610 marketing authorizations: 89% were approved by similarity; 10% from countries with high level of surveillance and 1 % underwent clinical trials

Source: Local Production of Pharmaceuticals and Related Technology Transfers in Developing Countries, A series of case studies by the UNCTAD Secretariat, UN, 2011

Country Examples

Argentina: Test Data

Dispute:

- MNC's and the US questioned the granting of marketing authorization of drugs by similarity
- US initiated 2 separate consultations with DSU at the WTO in 1999 and 200
- Ground: Decree No. 150/92 and Law No. 24 766 were inconsistent with Article 39.3 of the TRIPS Agreement

Source: Local Production of Pharmaceuticals and Related Technology Transfers in Developing Countries, A series of case studies by the UNCTAD Secretariat, UN, 2011

Country Examples

Argentina: Test Data

Dispute:

- On June 22, 2002, Argentina and US notified WTO that they have reached a mutually agreed solution
- MNCs challenged the regime in the domestic forum
- 13 law suits were filed to challenge the constitutionality of the decrees
- The plaintiffs also filed preliminary injunctions to suspend marketing authorization of several drugs. Argentine courts denied the request
- One of the 13 claims have been dismissed, the rest of the 12 are still under resolution

Source: Local Production of Pharmaceuticals and Related Technology Transfers in Developing Countries, A series of case studies by the UNCTAD Secretariat, UN, 2011

Questions to ponder

Questions to Ponder?

1. Is there a way to measure compliance of FTA's to the Doha Agreement principles?
2. Will there be a mechanism for countries to assess their compliance to the Doha Principles?
3. What accountability can we attach to FTA's that do not comply with the Doha principles?
4. By whose accountability shall the imposition of TRIPs-plus provisions be placed?
5. Will non-compliance of the Doha principles and the imposition of TRIPs plus provisions a ground for complaints and dispute?
6. Is there a mechanism for transparency on TRIPs-plus provisions in FTA's during the negotiation process? Can countries be provided help/guidance in dealing with them?

Thank you