Compliance Issues on TRIPS: Public Health Perspective

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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.

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