
A GLOBAL FRAMEWORK FOR INTELLECTUAL PROPERTY RIGHTS: TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT

It has often been alleged by consumer activists and some representatives of international organizations that provisions within national patent laws and/or bilateral free trade agreements impose obligations beyond the requirements of the TRIPS Agreement (so-called “TRIPS-Plus” provisions). A good example of such allegations comes from a draft report from a multiparty Working Group addressing the UN Millennium Goals on Access to Healthcare:

“In Uganda, new patent law legislation has been drafted that would make it harder to access generic medications—a key component of differential pricing. This includes: legal provisions that criminalize patent infringement; granting data exclusivity to prevent the registration of generic versions of a medication for a specified length of time; linking patent status with drug regulatory authority approval; and granting patent protection for new uses of previously patented products. The proposed legislation goes beyond what is required by the TRIPS agreement.”

In examining this statement, it must be recognized that the TRIPS Agreement is a minimum standard, not a maximum level of intellectual property protection. Furthermore, national governments are within their sovereign rights to enhance their intellectual property protection if they judge it to be in their country’s interest, including as part of an overall package of trade issues which make up a bilateral free trade agreement.

In addition to the matter of principle noted above, it is also important to examine if the provisions often referred to as “TRIPS Plus” are actually beyond the requirements of the Agreement. In reality, the provisions in question are fully within the current TRIPS requirements, not beyond them.

1) Data exclusivity—Art.39(3) gives no maximum nor minimum duration for data exclusivity. The practice to date is that 5 years is a minimum. Therefore, FTA provisions specifying a period of data exclusivity of 5 years or more are clearly within TRIPS, not “TRIPS-Plus” (See Table 1 for data exclusivity periods in Developing Countries).

2) Market linkage—TRIPS Art.28(1)(a) clearly gives the patent holder the right to prevent unauthorized third parties from “offering for sale, selling, or importing” the patented product. Thus, government regulations which prevent unauthorized copies of a patented product from being marketed in a country are fully compliant with the spirit and effectiveness of the TRIPS agreement.

3) “Secondary use” patents—innovation is protected under TRIPS 27(1). There is no differentiation between “breakthrough” and “incremental” innovation in the Agreement, as both kinds of innovation lead to public benefits. “Secondary patents” are thus also within the TRIPS Agreement, not “TRIPS-Plus”.

4) Restrictions on parallel trade—Paragraph 5(d) of the Doha Declaration on TRIPS and Public Health says that each Member is free to establish its own regime for international or national exhaustion without challenge. This means that, if a country decides that it is in its national interest to establish a regime of national exhaustion and thus limit parallel trade, it can do so without challenge. Such provisions are not only not “TRIPS Plus”, but they are also within the provisions of the Doha Declaration on TRIPS and Public Health.

For these reasons, it is often inaccurate and misleading to say that provisions in national laws or bilateral free trade agreements which enhance intellectual property rights and their enforcement are “TRIPS Plus”. In reality, these provisions are fully within the TRIPS Agreement as it stands. Furthermore, it must be recognized that national governments are free, in principle, to implement national policies which enhance IPRs and their protection, given that TRIPS is a minimum, not a maximum, set of standards.

**TABLE 1
DATA EXCLUSIVITY IN DEVELOPING COUNTRIES/EMERGING MARKETS¹**

Developing Country/Emerging Market	Period of Data Exclusivity (in years)
Mexico	5
Costa Rica	5
El Salvador	Unspecified
Guatemala	5 or 10 years
Honduras	Unspecified
Nicaragua	Unspecified
Panama	10
Trinidad&Tobago	Unspecified
Bolivia	5
Brazil	5
Chile	5
Colombia	5
Ecuador	5
Peru	5
Venezuela	5
Bulgaria	6 or 10
Croatia	Unspecified
Czech Republic	6 or 10
Estonia	6 or 10
Hungary	6 or 10
Latvia	6 or 10
Lithuania	6 or 10
Poland	6 or 10
Romania	6 or 10
Slovakia	6 or 10
Slovenia	6 or 10
Egypt	5
Jordan	5
Saudi Arabia	Unspecified
South Africa	Unspecified
China	6
Hong Kong	Unspecified
Korea	6
Pakistan	Unspecified
Singapore	5
Thailand	Unspecified

¹ IFPMA. "A review of existing data exclusivity legislation in selected countries." Third revised edition. January 2004.