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THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH

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Introduction

Over the past ten years, an increasing number of countries are initiating, negotiating and agreeing new trade agreements between two countries or amongst a group of countries. These are commonly known as free trade agreements or "FTAs"[1], and they are promoted as providing significant economic benefits to signatory countries through the removal or reduction of barriers to trade in goods and services. Many political leaders have indicated that they would prefer to remove or reduce trade barriers through the multilateral system in a way that benefits all countries belonging to the World Trade Organization. Nevertheless, given that the "Doha Round" of negotiations is taking longer than initially anticipated to be concluded, bilateral and regional FTAs are often seen as a way to move forward the trade liberalization agenda in the meantime.

[1] "free trade agreements" (FTAs) also have different names – for instance investment treaties, trade development and economic partnership agreements, regional association agreements.

TRIPS and Access to Medicines

All WTO Members are obliged to provide patent protection to pharmaceuticals under the WTO Agreement on Trade-related Aspects of Intellectual Property Rights, known as the TRIPS Agreement, signed in 1994. Least developed countries (LDCs) have been granted a general exemption from the TRIPS Agreement until July 2013,[2] and a waiver from having to grant pharmaceutical patents until January 2016 subject to further extension.[3] Before the TRIPS Agreement came into operation, as many as 50 developing countries and LDCs did not provide patent protection for pharmaceutical products.

The LDC waivers are among the important flexibilities available in the TRIPS Agreement to WTO Members. Others include the liberty to:

- determine the grounds for issuing compulsory licences and when to order government use of the licensed products;
- allow various forms of parallel imports;[4]
- apply general exceptions, such as early working to facilitate generic entry of pharmaceutical and agro-chemical products upon expiry of a patented product or experimental use exceptions.

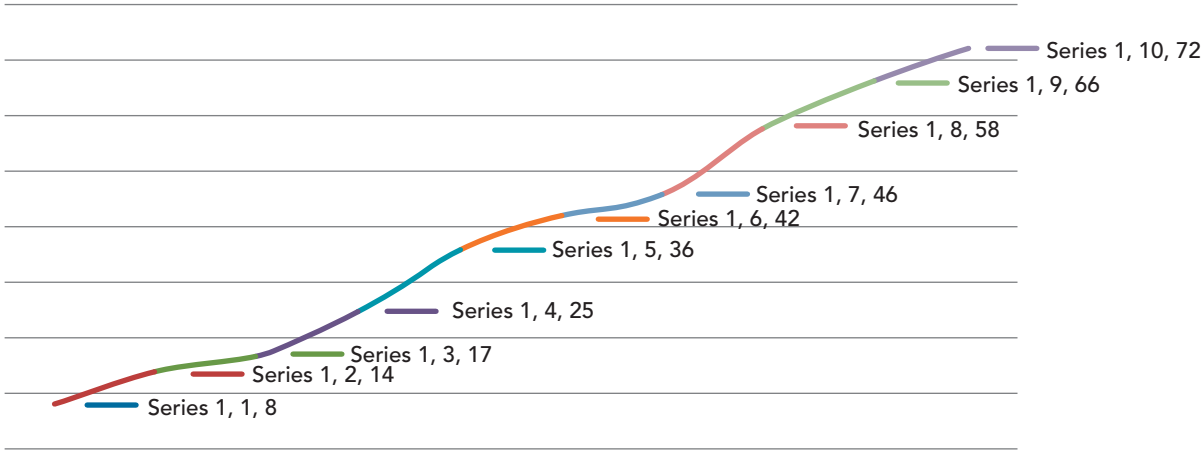
Retaining the flexibility to adapt intellectual property law and policy to meet national development objectives[5] has facilitated the development of robust generic industries among major global manufacturers such as India and Brazil.[6] Generic competition, primarily from Indian pharmaceutical manufacturers,[7] has been one of the key factors in the dramatic decrease in prices of first generation antiretroviral (ARV) medicines for HIV treatment. These prices fell from over US$ 10,000 per person per year to as little as US$ 116 for WHO pre-qualified first-line antiretroviral medicines in less than a decade. The price reductions have been instrumental in the significant scaling up of the international response to HIV over the past decade. The number of people in low- and middle-income countries on ARV treatment has risen from 300,000 in 2002, to more than 6.6 million on treatment by the end of 2010.

[2] As agreed at the WTO TRIPS Council Meeting of 29 November 2005. See document IP/C/40.
[3] This 2016 waiver may be extended further by agreement among WTO Members. In November 2011, Bangladesh, on behalf of the LDC Group submitted a request for extension of the LDC waiver.
[4] Companies often charge lower prices for a medicine in one country than in another, taking into account a range of market factors. This means that a country with limited resources can sometimes afford more of a patented medicine by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price. Parallel importing is possible under Article 6 of TRIPS.
[5] In 2001, WTO members reaffirmed the primacy of public health over trade, by the WTO Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration).
[6] In 1970, Brazil and India passed intellectual property laws that did not allow the patenting of pharmaceutical products.
[7] A 2010 study found that Indian generic pharmaceutical companies account for at least 80% of ARVs purchased by low and middle income countries with 91% of paediatric ARVs being produced by Indian generic companies.

Free Trade Agreements and TRIPS-Plus Provisions

A number of proposed and concluded bilateral and regional trade agreements contain clauses on intellectual property that exceed the minimum standards required by the TRIPS Agreement (generally referred to as "TRIPS-plus").

Number of FTAs with IP Clauses Announced to the WTO in the period 2001-2010



Source: www.wto.org

TRIPS-plus provisions that can limit the flexibilities available to countries to facilitate access to medicines include:

1. **Broadening Patentability:** There have been efforts to introduce provisions that allow patenting of new forms and new uses of known substances, which create the threat of "evergreening" of pharmaceutical patents. Evergreening extends patent protection by introducing modifications on the molecules that do not significantly improve the therapeutic effect of medicines, or, in the case of new uses of known substances, demand patent protection for discovery of new uses, rather than actual invention. The TRIPS Agreement does not require patent protection of new uses, or new forms of known substances.[8]

2. **Restricting Patent Oppositions:** Patent oppositions are a tool used to prevent patent applications that do not fulfil the requirements in national legislation for granting the patents. According to TRIPS, inventions must be new, involve an inventive step and be capable of industrial application. Patent oppositions have been successfully used in Thailand and India to prevent the granting of questionable patents on essential medicines. Some FTAs restrict the ability of countries to provide for pre-grant patent oppositions.[9]

3. **Extending Patent Duration:** Extension of patent duration is a TRIPS-plus provision that prolongs the patent monopoly and further restrains the entrance of generic competitors to the markets. A number of FTAs have resulted

[8] Gaëlle P. Krikorian and D. Szymkowiak. Intellectual Property Rights in the Making: the Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicines. *Journal of World Intellectual Property*, 2007, 10(5): 388-418, at 394.

[9] For example, the US-Bahrain FTA, Article 14.8 (4) states: Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent.

in the extension of patent terms beyond the 20 years required by TRIPS.[10]

4. **Introducing Test Data Exclusivity and a Patent-Registration Linkage:** Article 39.3 of the TRIPS Agreement does not require test data exclusivity[11], while it protects undisclosed data from unfair commercial use. However, some FTAs have required countries to adopt and implement such measures.[12] Some FTAs also contain a provision on patent-registration linkages, which would prevent the approval of new medicines by national drug regulatory authorities if they could potentially infringe existing patents. With such provisions, national regulatory authorities will be discouraged from registering new medicines and may be forced to deregister medicines, even when there is no proof that a patent has actually been violated. There is growing evidence that this trend exerts a negative impact on public health.[13] The detrimental effect of patent linkage has been established in countries with high HIV prevalence, for instance, Ukraine.[14]

5. **IP Enforcement Requirements:** A number of recently concluded FTAs contain provisions on intellectual property enforcement that exceed the minimum prescribed under the TRIPS Agreement[15]. A practical example of how increased intellectual property enforcement can impede treatment access is the seizure of essential medicines from India to various developing countries[16] by European customs authorities on at least 17 occasions while in transit through the EU in 2008-2009. The seizures took place on the suspicion that medicines violated fictional patent and/or trademark rights even though the medicines were lawfully produced in India and could be lawfully sold and consumed in destination countries. One of the shipments seized was a 49 kilogram consignment of abacavir sulfate tablets (an antiretroviral drug) purchased by UNITAID[17] destined for Nigeria.[18]

There is growing evidence that TRIPS-plus provisions may adversely impact medicine prices and consequently, access to treatment. A recent study estimated that the TRIPS-plus provisions in the US-Colombia Trade Promotion Agreement would increase expenditure on medicines in Columbia by US$ 919 million by 2020 or, alternatively, such measures would lead to a reduction in medicine consumption by 40%.[19] Assertions are often made about the advantages of TRIPS-plus protection but there has been little evidence of the beneficial effects of TRIPS-plus measures either in the form of increased foreign investment or increased innovation.[20]

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[10] For example, the US-Bahrain FTA, Article 14.8 (7), provides: When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other territory.

[11] Data exclusivity prohibits drug regulatory authorities from accepting applications from generic producers that refer to the existence of data of the originators on file with the authorities and claim bioequivalence. This prevents the registration of generics in a market regardless of patent status.

[12] See: United States Trade Representative (USTR). *2008 Special 301 Report*. USTR, Washington, D.C, 2008, www.ustr.gov/about-us/press-office/reports-and-publications/archives/2008/2008-special-301-report For an FTA example, see Annex V, Article 4 of the EU–Lebanon AA where data exclusivity must be provided for a period of at least six years from the date of approval.

[13] A recent study in Thailand projected that if a 10 year patent extension was granted as proposed under the Thai-US FTA, the following negative consequence will accrue over the next 20 years: a 32% increase in the price index for medicines; spending on medicines would increase from baseline to approximately USD 11,191 million; the domestic industry would lose USD 3,370 million. See Kessomboon N. Limpananont J. Kulsomboon V. Maleewong U. Eksaengsri A. and Paothong P. Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA. *Southeast Asian Journal of Tropical Medicines and Public Health*, 2010, 41(3): 667-677, at 637-638.

[14] UNDP, The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities, 2010. http://www.undp.org.ua/images/stories/IPRandAEM_Kyiv/BackgroundPaperFinal_ENG.doc

[15] Requiring countries to spend significant public financial, administrative and personnel resources on enforcing IPRs, which are private rights.

[16] Including Mexico, Brazil, Nigeria, Peru, Colombia and Ecuador.

[17] UNITAID is an international facility for the purchase of medicines used to treat HIV/AIDS, tuberculosis and malaria, established in 2006 by the governments of Brazil and France, it is hosted by the World Health Organization.

[18] A statement by UNITAID condemning the seizure of the medicines in transit by the Dutch authorities is available at: http://www.unitaid.eu/en/20090304156/News/UNITAID-statement-on-Dutch-confiscation-of-medicines-shipment.html.

[19] Gamba M. *Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia.* Mission Salud-Fundacion Ifarma, Bogota, Columbia, 2006, at: http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf

[20] Oxfam. *All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines.* Oxford, Oxfam Briefing Note, March 2007. The Oxfam study examined the Jordanian pharmaceutical market since the US-Jordan FTA came into effect in 2001. It stated that there had been "nearly no foreign direct investment by drug companies into Jordan since 2001 to synthesize or manufacture medicines in partnership with local generics companies."

[21] UN 2011 Political Declaration on HIV and AIDS, Paragraph 71 a.

[22] UNAIDS, UNDP and WHO, Policy Brief: Using the TRIPS Flexibilities to Improve Access to Treatment, 2011, http://content.undp.org/go/cms-service/stream/asset/?asset_id=3259398

[23] GFATM, Report of the Market Dynamics and Commodities Ad Hoc Committee 2011, http://www.theglobalfund.org/documents/board/23/BM23_09MDC_Report_en/

Conclusion

TRIPS flexibilities were implemented and endorsed by the global community as methods to mitigate the impact of WTO Agreements on access to affordable, quality pharmaceuticals. The potential public health implications of FTAs are recognized by the international community and are part of the discourse on improving access to treatment. For instance, the 2011 UN Political Declaration on HIV/AIDS recognizes the role public health related TRIPS flexibilities can play in increasing access to treatment and calls on UN members to *"ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities"*.[21] In a Joint Policy Brief on using the TRIPS flexibilities to improve access to treatment, UNAIDS, UNDP and WHO expressed concern about the detrimental effects TRIPS-plus intellectual property measures in FTAs may have on access to HIV medicines. They reiterated the call in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property asking countries to "take into account… the impact on public health when considering adopting or implementing more extensive intellectual property protection than [required by the TRIPS Agreement]".[22]

In its 2011 Market Shaping Strategy, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) also expressed its concern about the potential impact of the proposed EU-India FTA on prices of and access to HIV treatment. It emphasized that countries should use TRIPS flexibilities to achieve the lowest possible prices for products of assured quality.[23] To retain the benefits of TRIPS Agreement flexibilities, countries, at minimum should avoid entering into FTAs that contain TRIPS-plus obligations that can impact on pharmaceuticals price or availability. Where countries have undertaken TRIPS-plus commitments, all efforts should be made to mitigate the negative impact of these commitments on access to treatment by using to the fullest extent possible, remaining public health related flexibilities available.

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