



Excessive intellectual property protection for HIV (and other) treatments: the momentum for reform

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Overview

- The global environment for access to medicines
-How does IP affect access?
- The TRIPS Agreement and public health flexibilities
-Are the flexibilities sufficient to meet need, including for developing countries?
- Patent creep
-The spirit of TRIPS moves well beyond its original scope
- Reform
-Where to from here?



Access to medicines

- Despite the progress made in tackling a number of major global health challenges, millions of people have been left behind.
- **Disease and poor health remain major barriers to sustainable development in many countries.**
 - HIV, TB, malaria and viral hepatitis continue to kill more than 5 million people globally every year, with most of those deaths occurring in low- and middle-income countries.
 - The 17 neglected tropical diseases (NTDs) prioritized by WHO are endemic in 149 countries and affect more than 1.4 billion people, costing developing country economies billions of dollars every year



Access to medicines

- Treatment for other conditions remains largely unaffordable in rich and poorer countries alike
Examples include:
 - sofosbuvir used to treat chronic hepatitis C (HCV),
 - and treatments for many non-communicable diseases (NCDs), especially cancer



Non patent factors

- Recognize other factors, like:
 - Slow registration of medicines
 - Inefficiencies in procurement and budgeting
 - The presence or absence of a viable generics industry
 - Human resources constraints
 - Wider health system capacity
- *But, IP is a key determinant for access*



What is a patent?

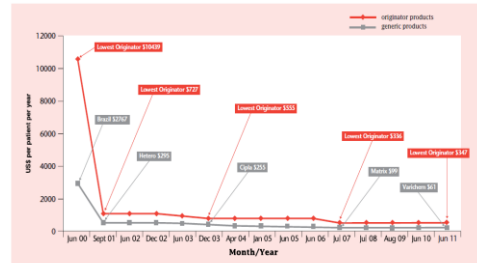
- A type of intellectual property
- Social contract between inventor and society
- Gives the inventor the *temporary* and *exclusive* right to make, use, export or market an invention in the country where the invention is patented.
- Is territorial (national)



How do patents affect access?



- 2 ways:
 - by creating protections on existing drugs, which give patent holders exclusive control to licence, manufacture and distribute their product.
 - by influencing the kind of innovation which is undertaken in the first place.



GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.
The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



The Current Regime: TRIPS



- Long title: *Agreement on Trade-Related Aspects of Intellectual Property Rights*
 - agreed 1994, entry into force 1995.
 - A WTO agreement setting minimum standards of IP protection for countries to follow.



How did TRIPS change things?



Before the TRIPS Agreement, a patchwork of regulatory frameworks:

- Up to 50 countries did not grant patents for pharmaceutical products
- Brazil & India changed colonial laws to exclude pharmaceutical products from being patented, stimulating innovation
- Many developed countries only began to grant pharmaceutical patents after their industries developed e.g. Switzerland 1977, Italy 1978

As a result of TRIPS

- TRIPS prescribes minimum standards for IP protection & enforcement
- Article 33 requires WTO Members to provide a 20 year minimum period of patent protection



TRIPS Agreement Objectives (Article 7)



*“The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to **the transfer and dissemination of technology knowledge** and in a manner **conducive to social and economic welfare**, and to balance of rights and obligations ”*



TRIPS Agreement Principles (Article 8)



1. “Members may, in formulating or amending their laws and regulations, **adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development**, provided that such measures are consistent with the provisions of this agreement
 2. “**Appropriate measures**, provided that they are consistent with the provisions of this Agreement, **may be needed to prevent the abuse of Intellectual Property Rights (IPRs) by the right holders...**”
- Granting of IPRs is the conferring of a monopoly which can be abused, and remedies are recognised as needed



The TRIPS Flexibilities at a Glance



Type	Examples
Preventative: Ensure that patents do not hinder access. Easier, faster, less politically sensitive	<ul style="list-style-type: none"> • Exclusion from Patentability: new use of known substances, methods, processes (Articles 27.2 and 27.3) • Patentability Criteria: Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1). • Patent Opposition: Pre-grant and post-grant • Waiver for LDCs: until 1 January 2016
Remedial: Preventative flexibilities cannot always be used	<ul style="list-style-type: none"> • Compulsory Licences and Government Use Orders (Article 31 (a) – (j)) • Compulsory Licences for Export - WTO 30 August, 2003 Decision. • Parallel Import (Article 6) • Exceptions: Bolar, research and experiments, individual use (Article 30) • National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)
Enforcement: Part III TRIPS sets minimum standards for IPR enforcement.	<ul style="list-style-type: none"> • No border measures for suspected patent infringement (Article 51) • No criminalization of patent infringement (Part III, Section 5)



Are the flexibilities enough?

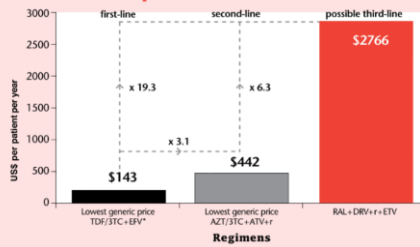


Growing sustainability pressures :

- Today, most of the adults and children on ART receive first line treatment
- Because of resistance, switch to second generation ARVs: some under patent, 3.4 times more expensive, 3rd generation up to 23.4 times more expensive
- India currently provides more than 80% of generic ARVs used in LMICs
 - 2005 Indian Patents Amendment Act to comply with TRIPS Agreement, allows patenting of pharmaceutical products
- Patenting of new medicines will affect availability of future ARVs in developing countries



Price comparisons of first-line, second-line and possible third-line



It's not just about HIV



- LMICs bear nearly 80% of the burden from NCDs like cardiovascular disease, diabetes, cancer and chronic respiratory diseases
 - More than two thirds of all cancer deaths occur in LMICs
 - Projections indicate that the burden of NCDs in LMICs will be greater than that for communicable diseases, by 2020
- Today, all WTO Members (including India) and except LDCs must provide patent protection to medicines under TRIPS. The future of affordable medicines is at stake.



'Creep' of international IP norms beyond TRIPS



- 'TRIPS-plus' provisions of FTAs.
- Trade and investment dispute resolution provisions
 - investor-state dispute settlement (ISDS) mechanisms.
- Proposed Trans Pacific Partnership (TPP) Agreement
 - Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam.



TPP, continued



- Leak texts reveal worrying possibilities that the TPP will (*inter alia*):
 - Broaden patentability
 - Extend the term of patent protection
 - Provide exclusive rights to test data
 - Create barriers to medicines registration by 'linking' IP to marketing requirements.



Calls for reform



- “We agree that the TRIPS Agreement **does not and should not** prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement **can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.**”

WTO Ministerial Declaration ‘Doha Declaration on the TRIPS Agreement and Public Health, paragraph 4 WT/MIN(01)/DEC/2



Calls for reform



- “[The Human Rights Council] [c]alls upon States, at the international level, to take steps, individually and/or through international cooperation, in accordance with applicable international law, including international agreements, to ensure that their actions as members of international organizations **take into due account the right of everyone to the enjoyment of the highest attainable standard of physical and mental health**, and that the application of international agreements is supportive of public health policies that **promote broad access to safe, effective and affordable medicine**”

Human Rights Council resolution A/HRC/12/L.23 of 25 September 2009



Calls for reform



- “*We must continue to remedy the policy incoherence current in modes of international governance in matters of trade, finance and investment on one hand, and our norms and standards for labour, the environment, human rights and sustainability on the other.*”

The road to dignity by 2030: ending poverty, transforming all lives and protecting the planet. Synthesis report of the Secretary-General on the post-2015 development agenda. 4 December 2014



Calls for reform



The Economist, Aug 2015

- “Today’s patent regime operates in the name of progress. Instead, it sets innovation back. Time to fix it.”
- Patent system is expensive
- Patents should reward those who work hard on big, fresh ideas, rather than those who file the paperwork on a tiddler.



Some interim remedial measures being implemented by UNDP et al



- identifying the need for public health sensitive intellectual property legislation,
- providing technical and policy support to governments in drafting such legislation and regulations,
- developing the capacity of governments to implement best practice intellectual property policies,
- providing the technical and policy support to promote awareness of the impact of TRIPS plus provisions and to build capacity for evidence-based assessments of regional and bilateral free trade agreements,
- Providing leadership on the need for global reform (e.g., Global Commission on HIV and the Law).



Where to from here?: Global Commission on HIV and the Law



- **Recommendation 6.1:**
 - The UN Secretary General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors.
- Watch this space...

