UNAIDS 2016 | REFERENCE

Intellectual property and access to health technologies

Questions and answers

Contents

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How do intellectual property rights affect access to HIV medicines and other health technologies?

This document provides a review of key issues related to intellectual property policies and their potential impact on access to HIV and other medicines. It is intended as an introduction to the issues for civil society engaged in the response to HIV and other health concerns.

By the end of 2015, almost 16 million people living with HIV were accessing antiretroviral therapy. The world would never have reached this historic achievement had it not been for the dramatic decline in the price of antiretroviral medicines over the past two decades—from just over US$ 10 000 per patient per year in the late 1990s to around US$ 100 per patient per year in many sub-Saharan countries in 2015. This drop in price was the result of sustained advocacy on the part of countries and communities affected by HIV to increase the availability of quality-assured generic antiretroviral medicines, in part by addressing intellectual property rights (IPR) issues.

Access to medicines as part of the right to health has emerged as a major public health issue. Even today, significant challenges remain in securing affordable access to medicines and other health technologies for many populations. In 2015, the World Health Organization (WHO) launched HIV treatment guidelines recommending antiretroviral therapy for everyone living with HIV, irrespective of CD4 count, thus increasing the number of people eligible to initiate treatment from 28 million people

to all 37 million people living with HIV. Newer antiretroviral medicines are far more expensive than existing medicines: costs for second- and third-line antiretroviral therapy are, respectively, 2 and 15 times higher than the cost of first-line therapy *(1)*, making these drugs inaccessible to many patients in the developing world.

The current intellectual property system presents various challenges to access to medicines:

- Duration of intellectual property-related protection for pharmaceuticals: the World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS) requires 20-year patent protection for all products, including pharmaceuticals, which reduces opportunities for competition within the health sector.
- Limited use of TRIPS flexibilities: in many contexts, national intellectual property laws have not incorporated all the flexibilities provided in the TRIPS Agreement, restricting the policy and legal spaces for countries to manage intellectual property from a public health perspective. In practice, developing countries are either not fully aware of the options available to them, or face pressure not to make use of TRIPS flexibilities to protect public health.
- TRIPS-plus provisions: regional and bilateral free trade agreements often include intellectual property provisions that go beyond the minimum standards required by TRIPS. These TRIPS-plus provisions generally include: extended patent terms ("evergreening"); requirement for extended data exclusivity provisions over clinical data submitted to drug regulatory authorities; introduction of minimum market exclusivity (monopoly) periods; tougher border and enforcement measures; patent linkage measures (associating the patent and marketing approval processes); curbing the circumstances under which a patent may be revoked or contested and limiting the ground for compulsory licensing; and limiting generic production or importation by signatories. For example, in October 2015, 12 Pacific Rim countries concluded the negotiations of the Trans-Pacific Partnership (TPP) deal, which includes many TRIPS-plus provisions that may impact access to affordable medicines. The Indian Patent Act, which enables Indian companies to supply cheaper generic products for other developing countries, is being challenged by free trade agreements.

Developments in making HIV medicines affordable

Pre-1994: before TRIPS—before 1994, countries were free to set their own patent protection scope and to exclude entire classes of product. As many as 50 countries did not grant patents on pharmaceutical products and processes, in some cases because it was considered a sector for industrial development or to ensure the provision of health care.

1995—the TRIPS agreement constituted one of the WTO founding core agreements, requiring all

members to grant at least 20-year patent protection to any inventions, including pharmaceuticals and diagnostics.

Late 1990s: the first generic antiretroviral medicines faced opposition from patent-holding pharmaceutical industries and some governments—in 1998, numerous manufacturers brought a court case against South Africa's Government over amendments to its Medicines Act aimed at making medicines more affordable and allowing importation of less expensive medicines (parallel importation), although they ultimately abandoned the case. When Brazil and Thailand produced generic antiretroviral medicines at 25% of the cost of originator medicines, they faced substantial challenges from companies and trade pressures from other governments.

2001: the Doha Declaration on the TRIPS Agreement and Public Health was adopted by WTO Member States—affirming the primacy of public health, the Doha Declaration highlighted the right to make use of flexibilities provided within TRIPS to enhance access to medicines for countries with low or no pharmaceutical production capacity.

2001: the first generic combination antiretroviral therapy regimen—Indian manufacturer Cipla stunned the world by offering the first generic fixed-dose triple-combination antiretroviral therapy regimen to nongovernmental organizations (at US$ 350 per patient per year) and African governments (at US$ 600 per patient per year). Costing less than US$ 1 per day (less than half the cost of the three originator drugs), the Cipla single-pill generic medicine revolutionized HIV care in the developing world by simplifying treatment and kick-starting a process of expanding access to antiretroviral therapy through further price reductions in developing countries.

2005—because of India's obligations as a WTO Member, India amended its Patent Act in 2005 to become fully TRIPS compliant, granting patents to pharma-ceutical products. Nevertheless, India preserved the most important flexibilities provided within TRIPS, securing the capacity of its industry to produce and export affordable non-patented drugs *(2)*.

2008—based on the recommendations of the WHO Commission on Intellectual Property Innovation and Public Health report, launched in 2006, the sixty-first World Health Assembly adopted the WHO Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health, which provides WHO with a mandate to support countries in managing intellectual property rights using a public health perspective. One outcome of the global strategy was the establishment of the Consultative Expert Working Group on R&D Financing and Coordination (CEWG), which is assessing demonstration projects on alternative models to finance innovation within the pharmaceutical sector.

2013—the WTO TRIPS Council approved the extension of the transition period (TRIPS exemption) for the least developed countries until July 2021.

October 2015—negotiations were concluded around the establishment of TPP, a free trade agreement that will likely elevate global standards

of patent protection for pharmaceutical and other products far beyond its signatory countries, reducing the policy options for developing countries to access affordable health products.

November 2015—the WTO TRIPS Council adopted an extension of the TRIPS exemption over pharmaceutical products for the least developed countries until January 2033.

November 2015—the United Nations Secretary-General announced the establishment of a high-level panel on intellectual property and health technologies to recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of improving access to health technologies. The panel was formed following the recommendation of the Global Commission on HIV and the Law.

TRIPS flexibilities: balancing trade and human rights obligations

Although the TRIPS Agreement requires countries to provide at least 20 years of patent protection for pharmaceuticals, it also provides legal safeguards ("flexibilities") to balance public interests and human rights obligations (including protecting and promoting health) and the private, commercial interests of companies, such as intellectual property claims.

In 2001, based on a recognition that intellectual property protections may hinder access to health in developing countries, WTO Members unanimously adopted the Doha Declaration on TRIPS and Public Health, affirming that TRIPS "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".

The key TRIPS flexibilities include those below.

Stricter patentability criteria
TRIPS specifies that "patents may be granted only to inventors who show that their creation *(1)* is novel, *(2)* embodies an 'inventive step' and *(3)* is 'capable of industrial application'". Countries have the option of defining those terms sufficiently narrowly to prevent frivolous patents designed primarily to extend patent terms via minor changes to existing drugs (that is, to prevent evergreening). Countries, for example India, have also adopted a pre-grant and post-grant opposition system to prevent granting of illegitimate patents or to revoke such patents.

Compulsory licensing
WTO Members may license third parties to produce generic medicines without the consent of patent-holders in the pursuit of public interests. Contrary to a popular misconception, TRIPS is clear that the use of compulsory licensing is not limited to emergency situations. Rather, TRIPS states that in these and other urgent situations, the normal precondition of having to first attempt to secure a licence voluntarily from the patent-holder within a "reasonable" time period on "reasonable commercial terms and conditions" may be waived. The Doha Declaration

affirmed that countries are entirely free to determine the grounds upon which compulsory licences may be issued.

A further unanimous decision by WTO Members in August 2003 affirmed that WTO Members are permitted, within certain parameters, to issue compulsory licences of products for export to eligible importing countries (this is important because many developing countries lack sufficient manufacturing capacity). The mechanism for doing so, set up by WTO members in 2003, has been widely criticized as unnecessarily cumbersome and restrictive, and indeed has been used only once after years of effort, leading to calls for it to be redesigned.

Government use
As with compulsory licences, under certain circumstances, such as public health emergencies, governments may license a patented product without the consent of the patent-holder.

By 2010, 17 low- and middle-income countries (including Brazil, Ecuador, Indonesia and Thailand) had issued compulsory licences for government use of antiretroviral medicines.

Parallel imports
As per Article 6 of the TRIPS agreement, a country can import a generic version of a patented drug by using a compulsory license, and the government has the freedom to determine the grounds upon which such licences are given.

Transition periods
The TRIPS Agreement provided an initial transition period whereby some developing countries were exempted from adopting the bulk of TRIPS provisions until 2000. Countries that did not grant patents before TRIPS (1994) had another five years to integrate TRIPS provisions into their laws, as India did in 2005. There are two relevant transition periods that the least developed countries may continue to rely on:

- In 2013 the TRIPS Council agreed to extend the deadline for least developed countries to comply with the bulk of the TRIPS Agreement until 1 July 2021.
- In February 2015 the Least Developed Countries Group requested that WTO Members extend the period before which the least developed countries are obliged to grant patents and other intellectual property standards under TRIPS to pharmaceuticals until such a time that countries graduate from least developed country status *(3)*. On 6 November 2015 the TRIPS Council accepted the request but limited its scope until January 2033.

What about voluntary licences?

Another way of promoting the affordable supply of health technologies is through voluntary licensing agreements, whereby the patent-holder allows another party to use the patent rights under certain conditions, often, but not always, in exchange for payment of an agreed royalty. Many pharmaceutical companies have entered into voluntary licensing agreements for HIV treatments through the Medicines Patent Pool (MPP), created with the

support of UNITAID in 2010. Originator companies can choose to license products to MPP, which in turn makes sub-licences available to qualified generics manufacturers, which pay royalties on sales in developing countries. Some paediatric formulations have been licensed without royalties. In addition to lowering prices and improving access to generic versions of newer medicines, MPP aims to foster formulations that respond to the needs of the developing world, such as fixed-dose, paediatric and heat-stable formulations. MPP has made public the full text of licences and has recently expanded its mandate to include medicines to treat hepatitis C and multidrug-resistant tuberculosis.

One of the primary concerns with voluntary licences, whether executed bilaterally or via MPP, is their territorial limitations, the extent to which some middle-income countries are often excluded, despite the significant and growing disease burdens in such countries. For example, tuberculosis accounted for an estimated 1.5 million deaths in 2013 (up from 1.3 million in 2012) in middle-income countries; by 2020 the majority of people living with HIV will likely reside in middle-income countries; and the majority of people living with hepatitis C currently live in middle-income countries.

Initiatives aimed at getting patent-holding companies to license patented technologies voluntarily are one important part of an overall approach for securing and increasing access to affordable medicines, but it is important to note that such initiatives should not and need not be the only approach used by countries. TRIPS flexibilities, including compulsory licensing, remain elements of a balanced approach.

What are the risks of free trade agreements?

Increasingly, trade agreements between two countries, or among groups of countries, include stringent TRIPS-plus provisions that exceed the minimum protections required by TRIPS. These often further limit access to affordable health technologies. The central concern levelled at these types of TRIPS-plus provisions is that they offer patent holders additional opportunities to prolong the life of their patents or delay the entry to market of competitors, ultimately driving up prices (or at a minimum impeding opportunities to achieve price reductions as products come off patent).

For example, the TPP text *(5)* released publicly in November 2015 and signed by its members in February 2016 contains TRIPS-plus provisions and other restrictions that could put at risk the supply of less expensive generic antiretroviral medicines in low- and middle-income countries. UNAIDS and other stakeholders have stressed that TRIPS-plus provisions will stand in the way of reaching the 90–90–90 treatment targets, whereby 90% of people living with HIV know their HIV status, 90% of people who know their HIV-positive status are accessing treatment and 90% of people on treatment have suppressed viral loads *(4)*. The under-negotiation European Union–India free trade agreement is likely to have an adverse impact on the Indian generic pharmaceutical industry's ability to continue to be a major supplier of affordable HIV medications throughout the developing world.

Various calls have been made by the international community to resist incorporation of TRIPS-plus measures, including in the 2012 report by the Global Commission on HIV and the Law *(6)*, and by the United Nations General Assembly, which in the 2011 Political Declaration on HIV and AIDS recognized the importance of the TRIPS Agreement flexibilities and called on United Nations Member States to "ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities".

Is the current intellectual property system addressing public health needs?

The rationale of the current, dominant innovation model underpinned by patent protection relies on the assumption that higher profits afforded by temporary patent monopolies permit pharmaceutical manufacturers to recoup the costs of researching and developing new medicines and therefore create incentives for such innovation. The concern is that the high resulting prices prevent many people from accessing medicines and may not incentivize innovation in the technologies needed to address the pressing health needs of low- and middle-income countries.

Monopolies can permit manufacturers to set prices as high as the market will bear, and innovative products reach only the people who can afford them. Although enforcement of intellectual property protection may be one approach to incentivize research and development, critics argue that this not only leads to high prices and rationing but also fails to incentivize products targeting populations that do not represent a commercially attractive market, such as paediatric HIV formulations and other neglected diseases highly prevalent in low- and middle-income countries.

From a public health perspective, the challenge is to maximize human welfare by providing sufficient incentives for products that would not otherwise be brought to market, while keeping prices low enough to enable access by the people who need them. Alternative proposals to incentivize innovation based on public health priorities aim to de-link the prices of marketed products from research and development, so that research and development costs can be recouped without resorting to the high prices supported by the current patent system. These incentives may include prize funds, pooled financing, public–private partnerships and an international treaty on research and development for health.

How can countries and communities advocate for expanded access to generic medicines?

Intellectual property policies are among the most challenging issues facing advocates for universal and equitable access to antiretroviral medicines and other health technologies. Civil society advocates need financial and other support to help them work effectively with governments and multinational institutions to ensure IPRs don't undermine access to medicines, therefore enabling an end to the HIV epidemic as a public health threat.

Civil society advocates play a crucial role in opposing intellectual property policies that impede

access to HIV, and other, medicines. Advocates work directly with parliamentarians and the media, issue analysis and research papers, demonstrate, and build alliances with advocates in other sectors.

Although minimum standards of intellectual property rules are regulated at the international level by the TRIPS Agreement, how they are implemented and applied at the national level varies. Constant vigilance and advocacy are needed to ensure that increased patent protections do not erode competition and affordable medicine prices, particularly as newer medicines come on to the market. In a policy brief published in 2011, UNAIDS, WHO and UNDP urged countries to retain existing legal flexibilities (e.g. under TRIPS) and to expand public health safeguards to ensure continued access to more affordable, generic medecines *(7)*. Recommended measures include the following:

- **National patent law reform that is sensitive to public health concerns:** significant patent law reform is under way in several key countries, including South Africa, still the home of the largest number of people living with HIV in the world, and India, from which manufacturers supply the vast majority of generic antiretroviral medicines used in the developing world. Both South Africa and India are facing substantial pressures from high-income countries and international pharmaceutical manufacturers to adopt more restrictive intellectual property provisions and practices. It is imperative that new laws retain and even expand legal flexibilities that have important public health safeguards.
- **Incorporating and using TRIPS flexibilities:** low- and middle-income countries often face significant pressure not to use the TRIPS flexibilities, most often from governments that are host to multinational patented pharmaceutical companies and trading partners. To date, relatively few countries have taken advantage of existing options, particularly compulsory licensing. For middle-income countries, exercising TRIPS flexibilities, or sometimes simply announcing a credible commitment to do so, remains the best option for lowering prices.
- **Resisting TRIPS-plus provisions in free trade agreements:** it is critical that countries seeking to join regional or bilateral free trade agreements reject the inclusion of TRIPS-plus provisions that weaken public health safeguards by imposing stricter IPRs. TPP signatory countries should seriously consider not ratifying internally the agreement, since it contains provisions that will harm access to medicines.
- **Exploring alternative funding models for research and development:** countries should make greater use of models for incentivizing pharmaceutical research and development in ways that do not rely on intellectual property enforcement. Collectively, countries should consider a range of strategies to spur innovation in accordance with public health priorities.
- **Using complementary enabling laws, such as competition law:** another useful but less widely recognized branch of law, and one of the more

rarely discussed flexibilities under the TRIPS Agreement, is competition law. For instance, in the event of anticompetitive practices a compulsory licence may be issued more easily (without any requirement for attempting prior negotiation with the patent-holder for a possible voluntary licence). Calls have been made to make greater use of competition law, including by the Global Commission on HIV and the Law, an independent body tasked with interrogating the relationship between human rights, law and public health in the context of HIV. It recommends that, "Countries must proactively use other areas of law and policy, such as competition law and policies, price control policy and procurement law which can help increase access to pharmaceutical products" *(8)*.

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UNAIDS
Joint United Nations
Programme on HIV/AIDS

20 Avenue Appia
1211 Geneva 27
Switzerland

+41 22 791 3666

unaids.org