



THE PROBLEM WITH PATENTS

**ACCESS TO
AFFORDABLE
HIV TREATMENT
IN MIDDLE-INCOME
COUNTRIES**



ABOUT FRONTLINE AIDS

Frontline AIDS wants a future free from AIDS for everyone, everywhere. Around the world, millions of people are denied HIV prevention, testing, treatment and care simply because of who they are and where they live.

As a result, 1.7 million people were infected with HIV in 2018 and 770,000 died of AIDS-related illness.

Together with partners on the frontline, we work to break down the social, political and legal barriers that marginalised people face, and innovate to create a future free from AIDS.

ABOUT MAKE MEDICINES AFFORDABLE

Millions of people die unnecessarily each year because life-saving medicines are over-priced. Make Medicines Affordable (MMA) believes it is every person's right to access the treatment they need. We work to bring down the price of HIV, TB and Hepatitis C medicines in middle-income countries where there is the most significant treatment gap.

The campaign is led by the International Treatment Preparedness Coalition (ITPC) with civil society partners from over 20 countries.

www.makemedicinesaffordable.org

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INTRODUCTION



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The introduction of combination antiretroviral therapy (ART) in 1996 was one of the most significant interventions in the history of the HIV response. Combination therapy today means that in many parts of the world, AIDS is no longer seen as a death sentence. However, in the early days of the AIDS epidemic, very few people could access this treatment. People living with HIV led efforts across the world to improve access to treatment including campaigning to reduce the prices of HIV medicines. In 2018, over 23 million people were accessing ART¹ but the struggle to ensure affordable access to treatment for all is not over.

At the end of 2018, there were nearly 38 million people living with HIV and the majority of them lived in middle-income countries². While overall treatment costs have fallen dramatically, there are wide disparities, with people in middle-income countries in particular still facing exorbitant prices for treatment of HIV and of common co-infections like tuberculosis (TB) and Hepatitis C (HCV). At the same time, as countries graduate to 'middle-income' status, they face the withdrawal of overseas development assistance by international donors, and increasing expectations to enforce international patent rules, hampering their ability to access affordable generic medicines.

This paper focuses on the need to address the issue of patents and their impacts on drug prices in middle-income countries, in order to make progress towards the goals of health for all and ending AIDS. It calls on governments and civil society in middle-income countries to step up efforts to ensure affordable access to medicines for all, and urges global health and development agencies to prioritise the issue of patents and drug prices. This is especially important now as they commit to a new Global Action Plan which will define how international organisations can "better collaborate to accelerate progress towards the health-related targets of the Sustainable Development Goals (SDGs)"³.

CONFUSING CLASSIFICATIONS

HOW ARE MIDDLE-INCOME COUNTRIES DEFINED?

WORLD BANK CLASSIFICATION

The most common way of classifying countries is the World Bank's classification by gross national income (GNI) in US dollars. For 2019, low-income economies are those with a GNI per capita, of \$995 or less in 2017; lower middle-income countries (LMICs) are between \$996 and \$3,895; upper middle-income countries (UMICs) are between \$3,896 and \$12,055; and high-

income countries (HICs) are those with a GNI per capita of \$12,056 or more. According to the World Bank, this income-based classification is "a useful and easily available indicator...closely correlated with...nonmonetary measures of the quality of life, such as life expectancy at birth, mortality rates of children, and enrollment rates in school."⁴

UN'S LIST OF LEAST DEVELOPED COUNTRIES

Several Least Developed Countries (LDCs) feature as middle-income countries in the World Bank's classification. The LDC list, prepared by the UN Committee for Development Policy is based on low income, human resource weakness and economic vulnerability.⁵ It is reviewed every

three years⁶ and transition strategies are a key part of the graduation process.⁷ There are 47 countries in the LDC list: 36 are members of the World Trade Organization (WTO); 13 are listed as LMICs by the World Bank.

UNDP'S HUMAN DEVELOPMENT INDEX (HDI)

UNDP's HDI was "created to emphasize that people and their capabilities should be the ultimate criteria for assessing the development of a country, not economic growth alone."⁸ HDI is based on health as assessed by life expectancy at birth, education as measured by mean years of schooling for adults aged 25 years

and more, and expected years of schooling for children of school entering age; and standard of living as measured by GNI per capita. UNDP acknowledges that even the HDI "captures only part of what human development entails. It does not reflect on inequalities, poverty, human security, empowerment, etc."⁹

WORLD TRADE ORGANISATION (WTO) COUNTRY GROUPINGS

WTO categorises countries as developed, developing or least developed. While LDCs are categorised based on the UN classification, there is no methodology to classify developed and developing countries. Countries choose their own classification in this regard.



1 PATENTS, PRICES AND THE RIGHT TO HEALTH

Access to antiretrovirals (ARVs) and other HIV-related treatment in middle-income countries can be impeded by a range of factors. Organisational barriers can include poor administration of treatment services, supply chain disruptions and stock-outs, and lack of trained healthcare workers. Physical barriers include long distances from treatment facilities, expensive transportation and lack of decentralised care and treatment. Social barriers include stigma and discrimination, and lack of privacy and confidentiality.¹⁰ Lastly, financial barriers include user fees, high out of pocket expenses and the costs of the ARVs themselves. **One of the most critical barriers that has existed since treatments for HIV were first developed relates to patents.**

WTO, TRIPS and patents on medicines

The global impact of patents on access to medicines is a relatively recent phenomenon emerging with the establishment of the World Trade Organization (WTO) in 1995. The WTO is based on several international agreements signed by all members, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Under TRIPS, all WTO members are obliged to introduce intellectual property laws, including providing for patents. A patent grants the patent holder of *any* new product or process exclusive rights over the invention, allowing them to prevent any other person from (1) making; (2) using; (3) selling; (4) offering for sale and (5) importing it without the permission of the patent holder for 20 years. Before TRIPS, several developing countries did not allow patents on medicines and other health technologies or restricted their enforcement, recognising their obligations to protect public health.¹¹

In theory, patents are meant to serve a public good: to benefit society by encouraging inventors to disclose their research and incentivise further research through exclusive rights. In practice, patents on pharmaceuticals often make them more expensive and less available by either preventing competition from companies manufacturing generic medicines¹² during the patent term, or restricting countries where generics may be available. This is most evident in the context of the HIV epidemic.

TRIPS and access to generic HIV treatment

When HIV was first discovered there was no known treatment. By the late 1990s, the advent of triple combination therapy (also known as Highly Active Antiretroviral Therapy or HAART) revolutionised HIV treatment and offered the hope of a long, healthy life to millions. However, the medicines comprising HAART were protected by patents and the resulting high prices kept treatment out of reach for most people living with HIV outside of high-income countries. A UN-backed initiative for donations made little headway and even the best discounted price offered by patent holders for HAART - approximately US \$10,000 per person per year - was impossible to sustain in developing countries. Then in 2001 an Indian generic manufacturer offered a price of less than a dollar a day. In countries like India, generic manufacture unhindered by patent barriers also led to the introduction of fixed dose combinations which dramatically simplified HIV treatment. By 2010, 80% of people living with HIV who were on treatment were using generic medicines.¹³

The Doha Declaration

By 2001 it was clear that developing countries were struggling to balance their obligations to protect patent holders under the TRIPS Agreement with their public health obligations, including ensuring access to affordable ARVs. South Africa amended its law on medicines to enable importing of generic ARVs and was sued by 39 pharmaceutical companies.¹⁴ Global outrage at the

South African litigation resulted in all WTO members adopting the Doha Declaration on TRIPS and Public Health in 2001 which stated that "the (TRIPS) 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".¹⁵ What the Doha Declaration highlighted was that countries could use safeguards in the TRIPS Agreement, also known as 'TRIPS flexibilities' to ensure access to medicines.

SDGs re-affirm TRIPS flexibilities

Since 2005, all developing countries that are WTO members have been granting patents on medicines including ARVs.¹⁶ As patenting of medicines in these countries increases, the use of TRIPS flexibilities is now even more important. The SDG target 3.b explicitly recognises this, committing governments to "support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."¹⁷

TRIPS FLEXIBILITIES

WHAT ARE THEY?¹⁸

Since the Doha Declaration, country experience has shown that there are a range of TRIPS flexibilities (safeguards) that can be used to ensure access to affordable medicines. These include:

PRE-GRANT FLEXIBILITIES

- Strict patentability criteria: TRIPS requires that patents must be granted if a product or process is new, inventive and capable of industrial application, without defining these terms. Several developing countries like India, the Philippines, Argentina, Indonesia have adopted strict patentability standards to prevent unnecessary patenting or evergreening i.e. the practice of patent holders applying for multiple, overlapping patents on existing medicines.
- Patent exemptions: Several developing countries do not allow patents on methods of treatment, traditional medicines or substances found in nature that haven't been modified or altered.

POST-GRANT FLEXIBILITIES

- "Bolar" provision is a research exemption in patent law that allows generic manufacturers to undertake the research and testing to prepare for regulatory approval of the medicine before the patents related to it expire, are revoked or a compulsory license is issued. This allows generic medicines to enter the market immediately after the patent barrier is removed.
- Parallel imports allow for imports of a patented product from another country where it can be sold at a lower price by the patent holder, their licensee or under a compulsory license.
- Compulsory and government use licenses are issued by a government body or court, and allow the production, supply, import or, in certain circumstances, export of generic versions of patented products before patents expire. Compulsory licenses issued in cases of national emergency, extreme urgency or for public non-commercial use, do not require prior negotiations with a patent holder. This is in contrast to a voluntary license, where the patent holder gives a license themselves and usually includes geographic and other restrictions.

PATENT OPPOSITIONS

These allow challenges to patent applications and/or granted patents by third parties such as civil society groups or generic competitors. These oppositions provide much needed scientific, technical and legal assistance to over-burdened and under-resourced patent offices

ENFORCEMENT RELATED FLEXIBILITIES

Several flexibilities exist in patent enforcement. For instance, TRIPS does not require criminal enforcement of patent infringement. It allows personal imports or small consignments of generic versions of patented medicines. In patent infringement proceedings, courts are now considering public interest before ordering injunctions.

LDC TRANSITION PERIODS

LDCs enjoy two transition periods under TRIPS: they are not required to comply with TRIPS before 2021 and are not required to grant or enforce patents

and data protection for pharmaceuticals until 1 January 2033. LDCs are entitled to further extensions of these transitions.

2

HOW PATENTS IMPACT ACCESS TO TREATMENT IN MIDDLE-INCOME COUNTRIES

There is growing recognition of the gross income inequalities existing in middle-income countries.¹⁹ These countries also have a large and growing share of HIV infections. According to the 2019 UNAIDS Epidemic Update, "the annual number of HIV infections has increased in three regions: Eastern Europe and Central Asia (29% increase), Middle East and North Africa (10% increase) and Latin America (7% increase)."²⁰ Two of these regions have extremely low rates of treatment access: 38% in Eastern Europe and Central Asia and 32% in the Middle East and North Africa.²¹

Huge pricing disparities

There is a growing disparity in drug pricing and treatment coverage between low- and middle-income countries, particularly those outside of sub-Saharan Africa. As global health agencies shift their focus away from middle income countries, actual prices being paid in upper-middle income countries are not readily available. The most recent pricing figures come from two 2014 WHO reports that confirm the massive price disparities,²² including²³:

- **First-line treatment regimens:** While average generic prices were \$115 per person per year (ppy), China, Cuba, Ecuador, Thailand and Ukraine paid in excess of \$300 while Brazil, Kazakhstan and the Russian Federation paid more than \$1000. The higher prices were a result of countries sourcing the drugs from originator companies when part or all of the treatment regimen was under patent.
- **Second-line treatment regimens:** While most countries could access generic second-line treatment for less than \$330 ppy, Brazil, China, Indonesia and Ukraine paid over \$500, Kazakhstan over \$1800 and the Russian Federation over \$4000. Evergreening patents (described below) on these medicines have been granted or are pending in these countries.
- **Third-line regimens:** The lowest prices (ppy) for third-line drugs that are widely patented were \$664 ppy for darunavir, \$439 for etravirine and \$553 for raltegravir; the lowest

combined prices were still in excess of \$1500. Outside sub-Saharan Africa, median prices for darunavir were \$5180. For salvage therapy (when standard treatment options no longer work), countries reported paying \$6072 for tipranavir, \$5190 for maraviroc and \$17,700 for enfuvirtide.

- **Paediatric formulations:** Kazakhstan, Russian Federation, Ukraine and China pay the highest prices for abacavir, zidovudine, lamivudine, nevirapine and lopinavir/ritonavir sourced almost exclusively from originator companies.

Treatment access for HIV co-infections – (HCV and TB - is also impacted by patents. New medicines for the treatment of Multi-drug Resistant TB (MDR-TB), which is of particular concern for people living with HIV,²⁴ i.e. bedaquiline and delamanid, are widely patented in middle-income countries. Neither drug has generic versions yet; researchers estimate that generic bedaquiline could be priced between \$48-96 for a six-month course while the best discount available to some countries is \$400 for the same course of treatment. Other countries pay tiered prices of \$900 (low-income), \$3,000 (middle-income) or \$30,000 (high-income).²⁵ It is unclear which countries can access which prices. The recent emergence of directly acting antivirals (DAAs) boasting 98% cure rates has transformed the HCV treatment landscape. Unlike HIV, HCV is mainly found in middle-

income countries and prices for the new medicines vary considerably. For instance, for sofosbuvir, while generic prices range from \$20-40 for a 28-week supply, Gilead offered Brazil a price of \$1399 and Malaysia a price of \$11,200 for a 28-week supply.²⁶

The impact of the high price of an ARV on a country's HIV or health budget can be dramatic. According to the All Ukrainian Network of People Living with HIV, in 2018 the Ukrainian government spent \$19 million to purchase AbbVie's lopinavir to treat 27,000 patients living in Ukraine. However, if instead of purchasing the originator medicines the government had purchased the generic version, prices would have been three times lower, bringing the government's spending down to around \$5-6 million, saving more than \$13 million on a yearly basis.²⁷

Widespread patenting and evergreening

Evergreening is a tactic used by pharmaceutical companies to extend their exclusivity over a medicine by applying for and usually getting multiple, overlapping patents on a single medicine. Most medicines are covered by several patents, known as patent 'thickets' and are used to delay or complicate generic production. In the case of ARVs, lopinavir/ritonavir sold as Kaletra by Abbott, is an interesting example. This second-line ARV is a combination of two existing

medicines both of which should be off-patent in most countries. Yet, they remain highly priced and free of generic competition in several middle-income countries thanks to evergreening patents. The example illustrates the extent of delay that evergreening can cause to generic competition. One study of the patents for lopinavir/ritonavir,²⁸ found 108 patents, which together could delay generic competition until at least 2028 - 12 years after the patents on the drugs' base compounds expired, and 39 years after the first patents on ritonavir were filed.

Decreased funding

Criticised for years of optimistic reporting on successes in addressing the HIV epidemic, in 2018 UNAIDS finally started acknowledging that progress was in fact slowing²⁹. Unfortunately, the years of poor messaging had already had an impact on donors. In 2018, UNAIDS reported

that investment in the HIV responses of low- and middle-income countries decreased by \$900 million in just one year.³⁰ As international funding for HIV has contracted, funding agencies and bilateral donors have tightened their policies to focus their shrinking funds. The World Bank's country classification is key to these adjusted policies. For example, the Global Fund's Eligibility Policy, revised in May 2018, states that upper-middle income countries must have at least a 'high' burden of disease to be eligible for financing.³¹ Another major funding agency, Unitaid, dedicates 85% of funds specifically to commodity purchase interventions in lower middle-income countries. In addition, bilateral donors (mostly developed countries) appear to be moving away from middle-income countries and focusing largely on sub-Saharan Africa.³² Civil society organisations are already raising the alarm about increasing death rates and the risk that countries may need to ration HIV treatment.³³

Changes in the income status of countries seldom reflect ground realities;³⁴ yet "graduation" to middle-income status often results in the immediate and simultaneous withdrawal of aid.³⁵ For countries like Venezuela and Argentina that have been see-sawing between middle-income and high-income status for the past few years, these changes leave their health programmes in an increasingly precarious position.³⁶

Increasing levels of resistance to HIV medicines

While the reporting of treatment coverage does not tell us how many people in middle-income countries need second- and third-line treatment or what percentage are able to access these treatments today, recent studies are also raising concerns over increasing HIV drug resistance. WHO's *HIV Drug Resistance Report 2019* also found high levels of pre-

Access to Dolutegravir: Lost in a maze of patents, prices and licenses



In July 2019, the WHO recommended dolutegravir (DTG) based regimens as preferred first-line treatment for HIV³⁷. The drug results in faster viral suppression, fewer side-effects and a strong genetic barrier to resistance. ViiV Healthcare has filed for, and been granted, multiple evergreening patents on DTG, claiming and extending their exclusive rights on DTG and DTG-based regimens in several countries until at least 2026, in some cases until 2031³⁸.

In 2014, ViiV Healthcare signed a bilateral voluntary license with a generic company covering 92 countries.³⁹ The same year they also signed separate voluntary licenses with the Medicines Patent Pool (MPP) allowing generic producers to manufacture adult and pediatric generic versions of DTG. The adult ViiV-MPP voluntary license covered all low-income, all least developed and all Sub-Saharan African countries. Exclusions from the pediatric license were more limited but still left out key upper-middle income countries⁴⁰.

In 2017, major donors announced a price deal of \$75 per person per year for a DTG based combination.⁴¹ The deal was restricted to the countries included in the ViiV-MPP licenses, thus excluding 49 upper middle-income countries.⁴² While the exclusions from the ViiV-MPP licenses follow the World Bank income groups, prices vary massively in the excluded upper middle-income countries. The lowest and highest prices of DTG varied by 268 times in upper middle-income countries. At present, 49 upper middle-income countries are excluded from the adult license and nine⁴³ from the pediatric license. DTG costs \$9656 ppy in Bulgaria compared to \$365 in Brazil and although their epidemic size and GDP per capita are similar to that of Brazil, Russia and China's prices (Russia \$1871; China \$3854) are more than 5- and 10-fold higher.⁴⁴

treatment resistance (over 10%) to two of the most commonly used first-line ARVs, efavirenz and nevirapine.⁴⁵ A 2018 study of people living with HIV in 10 countries in Africa, Asia, South America and the Caribbean who were followed from 2013 to 2015 found that third-line regimens were well tolerated but that worryingly, failure of second-line ART in resource-limited settings was common.⁴⁶ One study estimates that by 2025, 3.5 million people living with HIV will be on second-line treatment and 0.6 million on third-line treatment⁴⁷, which tend to be far more expensive than first-line treatment regimens and are more widely patented as well.

Exclusions from voluntary mechanisms

While funding cuts and restrictions influenced by World Bank classification impact the health budgets of middle-income countries, multinational pharmaceutical companies are increasingly excluding them from donations, decreased prices and/or voluntary licenses. Upper-middle income countries in particular bear the brunt of these exclusions in terms of ARVs. As far back as 2011, civil society organisations (CSOs) pointed out that price discounts for middle-income countries were being withdrawn. For instance, in 2011, Merck announced that it would no longer issue price discounts for 49 middle income countries for its new drug raltegravir.⁴⁸ ViiV Healthcare's Access to Medicines Policy (2018) states that voluntary licenses for adult HIV treatments will include, "all low-income, all least developed, all lower-middle income and all sub-Saharan African (SSA) countries as defined by World Bank Country Classifications."⁴⁹ This approach of excluding upper-middle income countries was reflected in ViiV Healthcare's voluntary license on dolutegravir with the Medicines Patent Pool. (See Box). In the case of voluntary licenses for HCV treatment, these kinds of exclusions have an even

greater impact with the HCV epidemic primarily impacting middle-income countries.

The Bristol-Myers Squibb -Medicines Patent Pool voluntary license for daclatasvir includes 112 countries covering approximately 65% of patients in need.⁵⁰ The bilateral Gilead voluntary license for sofosbuvir covers 105 countries.⁵¹ According to the WHO, "as of November 2017, a number of mostly upper middle-income countries, including Brazil, China, Colombia, Mexico, Kazakhstan and Turkey, which together are home to an estimated 14 million people living with HCV, were not included in the license agreements. Due to patent protection, they are not able to import or locally produce generic versions of the respective DAA medicines."⁵²

Legal and political pressure

Besides high costs and scarce funds, middle-income countries also have to contend with pressure from high-income countries and patent holders not to use TRIPS flexibilities. Patent holders often resort to lengthy, costly litigation. One of the earliest examples was in 2001, when 39 pharma companies sued South Africa for the inclusion of TRIPS flexibilities in their national medicines law. In 2006, Pfizer sued the Philippines for trying to register generic versions of medicines going off-patent.⁵³ In 2013, the Indian Supreme Court upheld the strict interpretation of India's patent law on evergreening, after an extensive seven-year battle fought by Novartis against the Indian government, cancer patients and Indian generic companies.⁵⁴ Brazil and Argentina are currently facing litigation by multiple pharmaceutical companies on their strict patent criteria.⁵⁵

Middle-income countries also face bilateral pressure from high-income countries. For instance, the United States Trade Representative annually lists countries it believes are not

adequately protecting US intellectual property, backed by threats of sanctions and investigations. In 2007, Thailand was elevated from the Watch List to Priority Watch List for issuing compulsory licenses.⁵⁶ In 2013 and 2014, the US International Trade Commission announced investigations into India's trade policies that included intellectual property law and policy.⁵⁷ In 2018, in response to the Malaysian compulsory license on sofosbuvir, the USTR announced an out-of-cycle review of Malaysia.⁵⁸

One of the most direct approaches to preventing the use of TRIPS flexibilities is to push for 'TRIPS-plus measures'. These require protection of intellectual property far in excess of TRIPS requirements, for instance, patent term extensions which require patents to be granted for periods much longer than the 20 years that is required under TRIPS. TRIPS-plus measures are typically pushed through bilateral or regional free trade agreements (FTAs)⁵⁹ and several studies have found that such measures result in higher medicine prices. A 2015 study concluded "the negotiated prices of branded antiretrovirals are, on average, 57% higher in countries with FTAs than they are in other countries."⁶⁰ UNAIDS recommends "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."⁶¹

FREE TRADE AGREEMENTS

A THREAT TO ACCESS TO MEDICINES

TRANS-PACIFIC PARTNERSHIP AGREEMENT (TPPA)

Rejected by US President Donald Trump, the TPPA negotiations featured some of the most aggressive TRIPS-plus measures ever seen in trade negotiations. After US withdrawal, the

provisions were suspended from the agreement. If the US re-enters the agreement, the TRIPS-plus provisions may be resurrected.⁶²

EUROPEAN UNION FREE TRADE AGREEMENTS (FTAs)

The EU has emerged as a major proponent of TRIPS-plus measures in trade agreements in the last 10 years. The text proposed by the European Commission in several FTA negotiations with

developing countries demand harmful provisions including longer patent terms, data exclusivity and TRIPS-plus enforcement measures.⁶³

REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP (RCEP)

These ongoing negotiations cover 16 countries in the Asia-Pacific region. The agreement will cover three significant generic producers – India, China and Thailand. The

presence of Japan and South Korea in these negotiations has brought TRIPS-plus demands on the table.⁶⁴



3

HOW CIVIL SOCIETY CAN MAXIMISE THE USE OF TRIPS FLEXIBILITIES

With such high costs and decreased funding, middle-income countries are increasingly struggling to provide universal access to medicines. The use of TRIPS flexibilities in such scenarios has been effective and successful, lowering prices and making medicines more available. Using one TRIPS flexibility can have a ripple effect on patent-holding companies who often cut prices in other countries or extend existing voluntary licenses to cover excluded countries. However, under pressure from high-income countries and facing the risk of litigation by multinational pharmaceutical corporations, middle-income countries hesitate to use these legal tools. This is where the role and expertise of CSOs has been so important in catalysing the use and protection of these flexibilities. Key examples include:

Patent oppositions

The TRIPS Agreement requires that patents must be granted where a product or a process is new, inventive and capable of industrial application. However, it does not define these standards. It is up to individual countries to decide whether they will apply these standards rigorously or not. For example, a patent application for a combination of two existing medicines should result in that application being rejected since combining medicines or making fixed dose combinations is a well-known technique in the pharmaceutical sector. Several developing countries like India, the Philippines, Argentina and Indonesia have adopted rigorous standards to prevent such patents from being granted. Networks of people living with HIV and CSOs, in India for example, have successfully used these provisions to challenge evergreening patent applications. Similar challenges are now being filed in China, Russia, Ukraine, Thailand and even in the European Union and the United States on applications related to HIV, HCV and TB medicines.

In Argentina, Fundación Grupo Efecto Positivo (FGEP) regularly files such patent oppositions. They start by getting copies of patent applications on key medicines which are then analysed according to Argentina's patentability requirements. When an application does not meet patentability criteria, they submit evidence of those shortcomings to the patent office. In 2015, FGEP challenged Gilead's patent application

for the combination of tenofovir and emtricitabine, that Gilead markets under the brand name Truvada. The government was paying Gilead approximately \$12 million a year at the time for this combination - 23% of the National AIDS Office annual budget.⁶⁵ In 2016, Gilead withdrew its application opening the way to generic access and huge savings for the country's AIDS budget⁶⁶.

Buyers' clubs

Although a patent holder can stop anyone from importing a generic version of their patented medicine, under the TRIPS Agreement countries *can* allow personal imports or small consignments of generic versions of patented medicines into the country. This is called the 'personal use exception'. This previously underused TRIPS flexibility has been put to good use by patients and activists to access affordable HIV and HCV treatment.

'Buyers' clubs' for medicines emerged in the US at the beginning of the HIV epidemic when ARV prices were exorbitant and led to people with HIV importing more affordable treatment from elsewhere.⁶⁷ In the early 2000s South Africa's Treatment Action Campaign bought boxes of affordable fluconazole in Thailand and flew into South Africa displaying the affordable pills at the airport and daring patent holder, Pfizer to sue them.⁶⁸ More recently buyers' clubs in high- and middle-income countries have been providing access to exorbitantly

priced HIV and HCV treatments at a reduced cost. In Indonesia, over 100 patients have accessed affordable generic HCV treatments through the buyers' club set up by the Indonesia AIDS Coalition, a community-based organisation of people living with HIV. Initially they began importing generic drugs for their staff through friends in India but soon realised many others could benefit. The buyers' club has faced challenges when medicine deliveries are delayed by customs agents and many patients cannot even afford the generic medications.⁶⁹ In many high-income countries, patients have imported active pharmaceutical ingredients for HCV treatments and had pharmacies prepare the medicines for them.⁷⁰

Compulsory licenses

A compulsory license is a government order allowing other people or companies to use, make, sell, offer for sale or import a patented product or process without the patent holder's consent. This is distinct to a voluntary license which is provided directly by the patent holder. The right of countries to issue compulsory licenses is well recognised in the TRIPS Agreement and was reiterated in the Doha Declaration. The latter also clarified that each country was free to determine the grounds on which compulsory licenses could be issued. TRIPS does set some conditions, for example, requiring negotiations with patent holders before one is issued. But this requirement is waived



World's first compulsory license for Hepatitis C treatment

In 2017, Malaysia made history by granting the first ever compulsory license on the HCV drug sofosbuvir. Gilead excluded Malaysia from its voluntary licenses on the drug in 2014 and entered protracted price negotiations with the government. The request for the compulsory license came from the Positive Malaysian Treatment Access and Advocacy Group (MTAAG+) and subsequently a joint coalition of CSOs like MTAAG+, Third World Network and the Malaysian AIDS Council supported the government with advocacy and evidence-based information for the case.⁷¹ As a result, Malaysia bought generic versions of sofosbuvir for as little as US \$33-35 per person per 28-day course.⁷²

The compulsory license has opened up access to generic sofosbuvir through several other suppliers, and provided a boost to research and development in HCV treatment. The Drugs for Neglected Diseases Initiative (DNDi) is conducting clinical trials in collaboration with the Malaysian Ministry of Health on a promising combination of sofosbuvir and ravidasvir. The compulsory license assisted DNDi's efforts to secure an affordable, pan-genotypic DAA combination to treat HCV at less than \$300.⁷³ It also benefitted countries outside of Malaysia as it forced Gilead's hand to include more countries in its sofosbuvir voluntary licenses to prevent others from following Malaysia's example.⁷⁴

in cases of national emergency, extreme urgency and for public non-commercial use. Compulsory licenses that are predominantly for export can also be issued but some procedural requirements must be met.

A compulsory license is not the same as tearing up a patent. Patent holders still have the right to be compensated for the use of their patent by competitors; generic producers have to pay a royalty on the sales of the generic versions of the medicines made under the license.

Nor are compulsory licenses only to be used as a last resort or in an emergency. There are no such restrictions on the use of them by governments. There are also no restrictions on the kinds of medicines or health technologies that compulsory licenses can be issued on or on the diseases or illnesses they are meant to diagnose or treat. There are numerous examples of countries issuing them, and in nearly every instance, CSOs have played a key role.

Reforming patent law

Recognising that the full range of TRIPS flexibilities may not be provided for in their national laws, many developing countries are amending legislation to provide for these flexibilities. For instance since 2011, CSOs in South Africa joined forces under the Fix the Patent

Laws (FTPL) campaign to demand that the government change its patent laws to include key TRIPS flexibilities.⁷⁵ According to FTPL, South Africa registers all patents with filed paperwork and fees paid for, instead of examining applications according to the patentability criteria.⁷⁶ Patented medicines in South Africa can cost up to 35 times more than in countries like India, where robust generic competition exists. In 2014, attempts by the multinational pharmaceutical industry to delay the patent law reform came to light and were widely condemned by activists across the globe.⁷⁷ In 2016, women with cancer picketed the pharmaceutical company Roche to highlight the excessive cost of life-saving breast cancer medicine. Roche is able to charge these prices as it holds multiple patents on the drug, blocking generic versions entering South Africa until 2033.⁷⁸ In 2018, the government finally released details of forthcoming patent law reform including patent examination and patent oppositions.⁷⁹

Protecting TRIPS flexibilities in Free Trade Agreement negotiations

As noted above, middle-income countries are under pressure to adopt TRIPS-plus measures through FTAs. Networks of people living with HIV and their supporters have been at the forefront of challenging this

trend. For example, in 2007 the EU-India bilateral trade and investment agreement negotiations started. Leaked negotiating text showed the EU was demanding ambitious TRIPS-plus measures including longer patent terms and new exclusive rights on medicines.⁸⁰ Activists led by networks of people living with HIV have persistently advocated against these measures, holding sit-in protests and marches. In 2012, they stepped up the pressure during the EU-India summit and mobilised global solidarity from activists across Asia, Africa, Europe and Latin America.⁸¹

As a result of this ongoing advocacy, the government consulted them and other CSOs on the proposed EU text. In 2013, The Prime Minister's Office issued a press release stating that nothing in the trade agreement would go beyond TRIPS or India's domestic law.⁸² As attempts to restart the negotiations on the agreement were made in 2017, people living with HIV networks once more protested outside the EU offices in Delhi highlighting their ongoing concerns. Although media reports indicate that negotiators from both sides are in regular contact in trying to progress with the talks, the exact status of the EU-India negotiations is unclear.⁸³

4

HOW GLOBAL HEALTH AGENCIES APPROACH TRIPS FLEXIBILITIES

While CSOs play a critical role in pushing for the use of TRIPS flexibilities at a national level, global health agencies also play an important role in providing technical assistance and guidance to governments.

What global health agencies say

Several global health agencies have been working on the issue of patents and prices and specifically on TRIPS flexibilities for several decades now. For the WHO, concerns around TRIPS and access to medicines were reflected in the 1996 World Health Assembly resolution on the Revised Drug Strategy, which asked the WHO Director General to report on the impact of the WTO on national drug policies and essential medicines.

In 2000, UNDP's Human Development Report highlighted concerns over the impact of TRIPS on medicines noting that, "in 1998 the anti-AIDS drug fluconazole cost \$55 in India for 100 tablets (150 milligrams) but \$697 in Malaysia, \$703 in Indonesia and \$817 in the Philippines."⁸⁴

UNAIDS first approached the problem of ARV pricing through the Drug Access Initiative attempting to bring big pharma to the negotiating table.⁸⁵ By 2000 UNAIDS was acknowledging the importance of countries turning to TRIPS flexibilities.⁸⁶

In 2002 the Global Fund to Fight AIDS Tuberculosis and Malaria was set up and in its resolution on procurement that year encouraged "recipients to comply with national laws and applicable international obligations

in the field of intellectual property including the flexibilities provided in the TRIPS agreement and referred to in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality."⁸⁷ In the 2004 Guide to the Global Fund's Policies on Procurement and Supply Management, the Fund expanded this encouragement to asking recipients to "apply the flexibilities" and reiterated this by stating further that, "in the event that a PR [Principal Recipient] does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may, using funds budgeted in the Global Fund grant, contract the necessary expertise."⁸⁸

UNITAID is committed in its Constitution to "base its price reduction strategy on market competition. Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable."⁸⁹

What global health agencies do

It is thus clear that using and promoting the use of TRIPS flexibilities forms part of the mandate of some key global institutions working on HIV and in this regard, several of these agencies regularly publish documents and policy briefs guiding countries on the use of TRIPS flexibilities⁹⁰. Many of them also participate in and hold meetings or have set up important commissions⁹¹ and high level panels⁹² to discuss TRIPS flexibilities. However, they often struggle to fully meet this mandate and in some cases there are concerns that the mandates have been diluted. CSOs have raised concerns that several global health agencies tend to encourage countries to negotiate prices, donations or voluntary licenses rather than use TRIPS flexibilities. The agencies' emphasis on voluntary mechanisms can be gauged by the time, effort and budget they expend on these mechanisms compared to that spent on the use and promotion of TRIPS flexibilities. In 2011, UNITAID funded the establishment of the Medicines Patent Pool, a voluntary licensing mechanism. In 2014, the Global Fund set up the blue ribbon task force to develop a global multi-tiered pricing framework for middle-income countries.⁹³ Since 2016, the WHO has convened various forums to discuss the concept of "fair pricing."⁹⁴

Pressure on global health agencies

Apart from UNITAID, few donors⁹⁵ continue to fund work related to the use of TRIPS flexibilities and, most importantly, fund CSOs to this end. This should be a key area of funding and work for the Global Fund, given the direct impact that the use of TRIPS flexibilities has in providing access to lower priced generic medicines. Indeed, until a few years ago this area was well resourced with Global Fund support and several countries almost routinely used TRIPS flexibilities in the procurement of ARVs through the Global Fund.⁹⁶ Around 2013 however, civil society started to voice concern that the Global Fund was moving away from this critical area of work.⁹⁷ Two years later, despite objections from civil society, the market dynamics team that worked on the use of TRIPS flexibilities was disbanded,⁹⁸ which had a major impact. Since then, there have been signs of a revival. The Global Fund's 2017 transition guidance note stated that technical support for procurement systems that were being transferred to national systems could include support for the use of TRIPS flexibilities.⁹⁹ The promotion of TRIPS flexibilities is key to transition strategies as increasingly countries face what is being called the "procurement cliff."¹⁰⁰ In 2019, the Fund issued an updated procurement guide that says recipients should use TRIPS flexibilities to achieve lowest possible prices.¹⁰¹ Despite these recent positive statements, it remains unclear the extent to which work on TRIPS flexibilities is actually being funded by the Fund.

Where agencies have focused on promoting TRIPS flexibilities, they have come under heavy criticism and pressure from big pharma and developed countries, and this pressure is becoming more overt. In 2016, the report of the UN Secretary General's High-Level Panel on Access to Medicines drew sharp criticism from the US government. In its statement, the US said that it was, "regrettable that the Panel worked under the presumption of "policy incoherence" between intellectual property rights, international trade liberalization, and human rights".¹⁰² Raising the pitch, in 2019 the Pharmaceutical Research Manufacturers Association (PHRMA) in its submission for the US Special 301 report targeted the WHO, UNDP, UNCTAD and UNITAID for their work on promoting the use of TRIPS flexibilities.¹⁰³



5

RECOMMENDATIONS

The recent Lancet Commission-International AIDS Society report, *Advancing global health and strengthening the HIV response in the era of the Sustainable Development Goals*, finds that not only is the HIV epidemic not on track to end but that the prevailing discourse on ending AIDS has bred a dangerous complacency and may have hastened the weakening of global resolve to combat HIV.¹⁰⁴ It warns that tens of millions of people will require sustained access to ARVs for decades to come.¹⁰⁵

As the world strives to make progress towards the 2030 goals, it is crucial to remember that without tackling the issue of patents and high prices of medicines, the goal of healthy lives and well-being for *all* will remain out of reach. This is particularly true for middle-income countries, which account for an estimated 70% of people living with HIV¹⁰⁶.



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Governments in middle-income countries

must lead efforts to make full use of TRIPS flexibilities to ensure sustainable access to affordable medicines. This will require them to work with and support CSOs, including meaningfully engaging them in negotiations on trade and investment agreements. Governments should review their patent laws and incorporate the full range of public health safeguards, seeking technical assistance from global health and development agencies as they review and draft intellectual property laws and policies. They should also take proactive steps to strengthen the patent examination process, in order to prevent evergreening. Finally, they must work together against political and legal pressure, including advocating for the use of TRIPS flexibilities at international and regional forums and platforms, and rejecting any TRIPS-plus measures that may impact access to medicines.



Global health and development agencies

must provide technical and political support to middle-income countries and actively encourage the use of TRIPS flexibilities as part of their efforts to expand access to affordable medicines. This must include specifically funding CSOs and enabling them to contribute their expertise. As the agencies collaborate to deliver on SDG 3 and better coordinate through initiatives such as the new *Global Action Plan for Healthy Lives and Well-being for All* coordinated by the WHO¹⁰⁷ they will also need to challenge any political or financial pressure that would undermine their full support for use of TRIPS flexibilities. Finally, given the importance of tackling the HIV epidemic in middle-income countries, global agencies should consider the public health-oriented basis for determining funding and health interventions instead of relying on income-based classifications.



CSOs and networks of people living with HIV

must continue to work in solidarity across countries and across diseases, to build on and amplify community experiences and to demystify and challenge patents and other intellectual property barriers to universal access to treatment. Working with legal aid organisations and others, they can and should play an active role in opposing patent applications that amount to evergreening, and should continue to use innovative approaches such as 'buyers' clubs' to maximise the 'personal use exception'. Civil society must also engage with their governments to advocate for the full incorporation of TRIPS flexibilities into national law, for proactive use of these flexibilities and for opposition to TRIPS-plus measures in FTA negotiations, to ensure affordable medicines for all.

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