



ANALYSIS

Medicines Patents, Access and Innovation

The growing challenges for people in low and middle-income countries to access new medicines

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Preface

Patent issues and intellectual property rights were seen in the past as the domain of specialists. Many people and organizations felt that the issues were too complex or not relevant enough for their daily work. This changed when treatment for HIV became more widely available. For countries of the Global South, it was clear that HIV treatment could only be rolled out, if there was access to affordable medicines. If the countries had to pay the high prices of the originator companies (10,000-15,000 USD per person per year), HIV positive people would not benefit from life-saving anti-retroviral treatment.

Partner organizations of Bread for the World, like the Treatment Action Campaign (TAC), therefore took a stance to fight for access to health over patent issues. TAC supported the South African Government against a court case which 39 pharmaceutical companies had brought upon South Africa on the basis of a Medicines Act of 1997. Pharmaceutical originator companies regarded this Act, which facilitated access to cheaper medicines, not to be in line with the requirements of the World Trade Organization (WTO). Due to TAC's involvement in the court case, the pharma companies saw their image tarnished as companies that cared more for their own profits than saving the lives of Africans. The companies withdrew the case in 2001.

Also from the late 1990s, African countries which had to deal with a high disease burden of HIV, malaria and TB demanded clarification within the World Trade Organization on the exemptions and flexibilities with regard to patents on medicines such as compulsory licensing or parallel importing. This led to the so-called Doha Declaration of November 2001 which clearly put the right to health over and above patent considerations and spelt out the flexibilities countries can use.

The World Trade Organisation was founded in 1995 and set out in its agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that 'innovation' had to be patented also with regard to medicines. However, countries can define what they regard as 'innovative' and worthy of protection. Whilst India has a very tight definition of 'innovation' and explicitly excludes slight molecular modifications of a substance as well as new use for a known substance, countries like South Africa so far have held on to a very wide definition of 'innovation' with the result that few medicines get patented in India whereas in South Africa few patent applications on medicines are rejected.

In recent years, patent issues have become the concern of many governments and physicians also in the Global North as the high prices charged for a new and effective hepatitis C treatment are also making it difficult for countries of the Global North to treat those who need the medicines. In addition, the price seemed in no way related to the manufacturing costs of this treatment and questions have been asked, about whether this patent system is the right system for making pharma products available to those who need them. Patents are one effective way for companies to hold a monopoly and to dictate prices. We see this very clearly with 'Sofosbuvir'. Sofosbuvir is an important new hepatitis C medicine which in conjunction with other hepatitis C medicines cures the disease within 12 weeks: a real breakthrough in the treatment of hepatitis C (HCV). Yet whilst this medicine is sold for 84,000 USD for the 12 week treatment in the USA and in Germany for 43,500 Euros, the actual cost of production for a 12 week treatment is between 68 and 163 USD according to a pharmacologist of Liverpool University. This disjunction of actual production costs with what companies can charge if they hold a monopoly has outraged many countries and organizations. Gilead, the company manufacturing Sofosbuvir, had not developed this medicine but bought up the firm which had developed Sofosbuvir for the price of 11 billion dollars, so the 'research and development costs' were mainly the take-over costs of the firm Pharmasset as well as medicine trials, the approval of the medicine and putting it onto the market. In 15 months, the firm recouped all the costs for bringing Sofosbuvir onto the market and it continues to make high profits on Sofosbuvir and the combination with another hepatitis C medicine.

Sofosbuvir has therefore caused Western countries to also open a debate on access to affordable medicines, which has been conducted for many years in countries of

the Global South. Whilst Sofosbuvir is a needed new medicine, much research and development by originator firms is not directed at medicines that are needed globally or in poorer countries but at life-style medicines of the Global North and slight modifications of already existing medicines. The World Health Assembly in its 69th Assembly in May 2016 also devoted time to health research and development and decided to establish a WHO Expert Committee on Health Research and Development to provide technical advice on the prioritization of health research and development for diseases which occur mainly or exclusively in the Global South and to take into consideration the research and development needs of developing countries.

This publication lays out the reasons why patents have been the problem and not the solution in providing needed and affordable medicines and why we need a paradigm shift with regard to research and development of new medicines. The author, Ellen 't Hoen, is a respected lawyer who has been working for development organizations as well as organizations that deal with intellectual property rights and is now working as a freelance consultant.

The publication is directed at development organizations including the partner organization of Bread for the World for their own advocacy work in-country, at political decision-makers in Germany and other countries, as well as interested individuals in the field of public health who are concerned about access to affordable treatment. We hope that this publication contributes to a long overdue debate of finding more appropriate solutions for developing the medicines we need at affordable prices.

ASTRID BERNER-RODOREDA
HIV Policy Advisor, Bread for the World

Chapter 1

Brief introduction to patents and medicines

Millions of people around the world do not have access to the medicines they need to treat disease or alleviate suffering. Strict patent regimes interfere with widespread access to medicines by creating monopolies that can lead to medicine prices well beyond the reach of the people who need them.

The magnitude of the AIDS crisis in the late nineties brought this issue to public attention, when millions of people in developing countries died from an illness for which medicines existed in Western countries, but which were usually not available or affordable elsewhere. Faced with a huge health crisis - 8,000 people worldwide dying daily - the public health community launched an unprecedented global effort that eventually resulted in the large-scale availability of quality assured generic HIV medicines and a steady scale-up of treatment programmes that provided access for many to those medicines. Today, 17 million people are on HIV treatment (UNAIDS 2016) leading longer, healthier lives as a result.

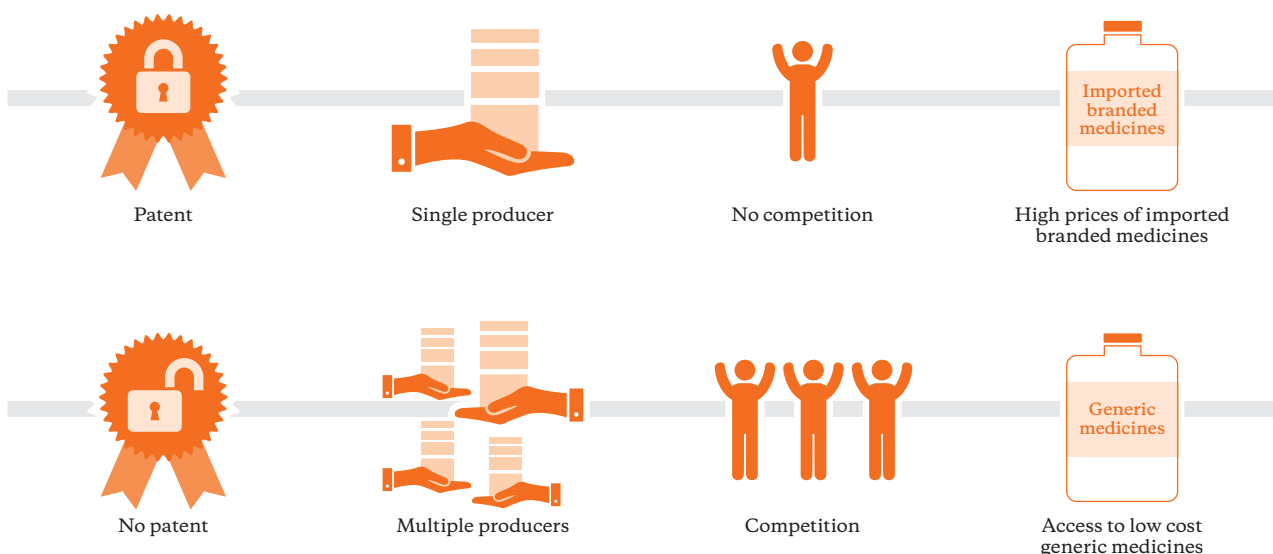
However, trends in international intellectual property law could impact many of the policy tools used to scale up HIV treatment. Developments in global health, and specifically policies designed to ensure access to medicines, are now at an important juncture. Impressive progress has been made in access to medicines for HIV and many lessons can be learned from that experience. But it is important to examine whether those lessons can be applied to

other new medicines, including medicines to treat HIV, that are high priced because, for example, they are not included in the Medicines Patent Pool (MPP). The Medicines Patent Pool was set up as a one stop shop for voluntary licences. The MPP negotiates licenses with patent holders, mostly pharmaceutical companies, which allow generic manufacturers to produce these medicines, including in combination with other products. This has facilitated generic competition in the market and access to lower priced treatments for HIV including fixed-dose combinations which are easier for people to take than single pills.

Today's pharmaceutical patent regimes affect almost all medicines developed since 1995 in most countries. The high prices of new medicines, such as for cancer, tuberculosis, hepatitis C, and HIV cause huge access challenges globally, in both developed and developing countries. While important progress has been made to increase access to HIV medication, dealing with high-priced patented anti-retrovirals (ARVs) that are only available from the patent holder remains a problem.

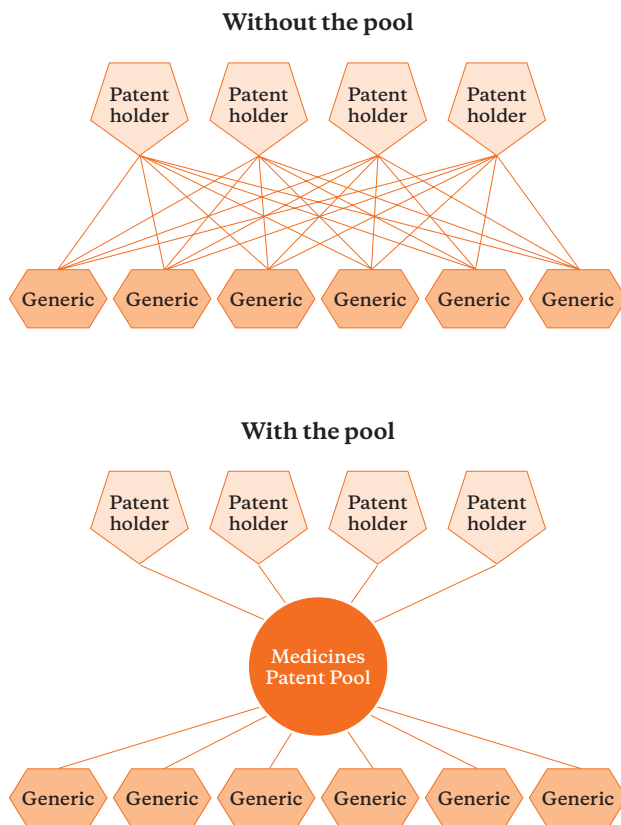
Why be concerned about patents?

Patents are a form of intellectual property (IP). IP refers to the legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields. IP



Patents create monopolies.

Source: Treatment Action Campaign: (2011): *Fix the Patent Laws Activist Guide*, p. 4



The Patent Pool dramatically simplifies interactions between patent holders and generics, lowering transaction costs for all involved.
 Source: Medicines Patent Pool (2011): Annual report 2010-2011, p. 13

has two branches: industrial property (e.g. inventions [patents], trademarks, industrial designs, geographical indications) and copyright (and related rights). IP law aims at safeguarding creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the use made of those innovations. In the case of medicines those that have invested in the development of a new medicine can recoup that investment because they are protected against competition from others who have not made such investment. Patents are relevant to access to medicines because they can increase the price of a medicine by blocking generic production for the duration of the patent.

The requirements for intellectual property protection are set out in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which gives a set of binding rules that were adopted in 1995 when the World Trade Organization was established.

Governments grant patents to people who invent something new, non-obvious and useful. Patents are usually granted at a national level, though some regional patent offices exist. A patent holder can prevent others from making, using, importing, or selling their invention for a certain period of time without his or her consent. In exchange, the public is meant to benefit from the sharing of scientific advances. The patent system is intended to strike a balance between incentivising innovation, protecting innovators, and ensuring maximum public benefit from innovation.

However, today's pharmaceutical patenting system is out of balance. It provides excessive financial rewards to patent holders, which are mostly large pharmaceutical companies. At the same time, pharmaceutical innovation to address important health priorities lags behind. Because the patent holder can prevent competition in the market, it is in a very strong position to set the price for a medicine. Competition in the market by multiple generic producers is the most effective way to bring medicines prices down. If such competition is lacking, medicines prices are often high, which excludes individuals and governments with limited resources from accessing the medicines.

The problem of access to medicines is no longer confined to developing countries. For example, the high price of hepatitis C treatments, which can cost up to USD 94,000 for a 12 week combination treatment course is leading to rationing of the medicine even by high-income countries.

In Europe and North America health professionals are ringing the alarm bell over prohibitive medicines pricing, for example, in the case of cancer. A group of over 100 physicians from six continents wrote in the journal *Blood* that by 2012 the price for imatinib, an essential medicine to treat leukemia, had climbed from USD 30,000 a year in 2001 to USD 92,000 a decade later (Experts in Chronic Myeloid Leukemia 2015). Imatinib has helped nearly double the survival rate of people suffering from this particular cancer. Generic imatinib, which is manufactured in India where the patent for imatinib was rejected, costs between USD 2,004-2,112 a year (t Hoen 2013). Today, medicines patents are causing problems also in wealthy nations, as we have seen with regard to hepatitis C and cancer medicines. The calls for government interventions to ensure access to new medicines are getting louder.

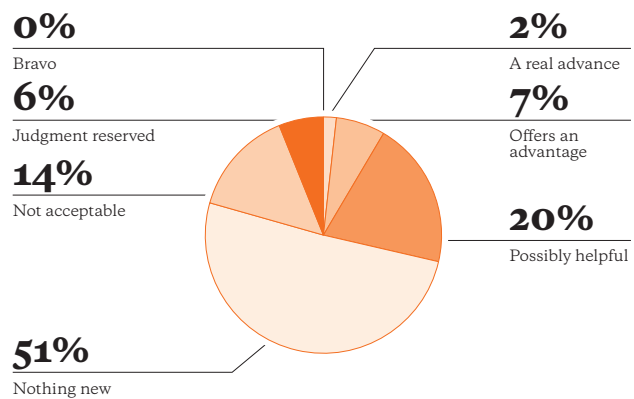
Chapter 2

Patents and innovation – does it deliver?

High drug pricing is justified by the pharmaceutical industry to compensate for the cost of research and development (R&D) of new drugs. Without patents pharmaceutical R&D will come to a standstill, they argue. Commercial companies will indeed not invest in the development of a new product, if it cannot generate significant profits. The huge profits the patent system sustains, however, affects priority setting in R&D by companies. Companies do not consider it profitable to invest in the development of medicines for people with limited or no purchasing power. The situation with the neglected diseases crisis first described by Médecins Sans Frontières in its 2001 seminal report “Fatal Imbalance: The Crisis in R&D for Neglected Diseases” (Doctors Without Borders 2001), has not much improved today despite the globalization of stronger intellectual property protection (Pedrique et al. 2013). Although there have been several new R&D initiatives launched over the past 10-15 years, progress has been largely incremental, such as in the field of neglected tropical diseases (NTDs) and is based on not-for-profit initiatives. A breakdown of 1,432 new drug approvals in Europe between 2000 and 2014 by La Revue Prescrire shows that there were no “real breakthroughs.” More than 51% of the new medicines were so-called ‘me-too’ products, which indicates that the pharmaceutical industry over-invests in products that are similar to what is already available on the market. These ‘me-too’ products may lead to new medicines patents for the company, but do little to expand the therapeutic arsenal (Prescrire 2015).

The lack of medical innovation and the lack of access to health tools (including medicines, diagnostics, and vaccines) to address global health needs are now well-documented and widely recognized. Some in the industry also recognize that the current innovation system is detrimental to dealing with global health needs. For example, in response to questions about the role of the pharmaceutical industry in dealing with the Ebola outbreak in West-Africa, Andrew Hollingsworth, policy manager of the Association of the British Pharmaceutical Industry, said: “Unfortunately, the standard economic model for drug development, in which industry takes all of the risk in R&D and gets a return on investment from successful products, does not work for diseases that primarily impact low-income countries and developing healthcare systems” (Kollewe 2014).

A meaningful discussion about the best way to finance pharmaceutical R&D is hampered by the lack of transparency on the cost of R&D. The pharmaceutical



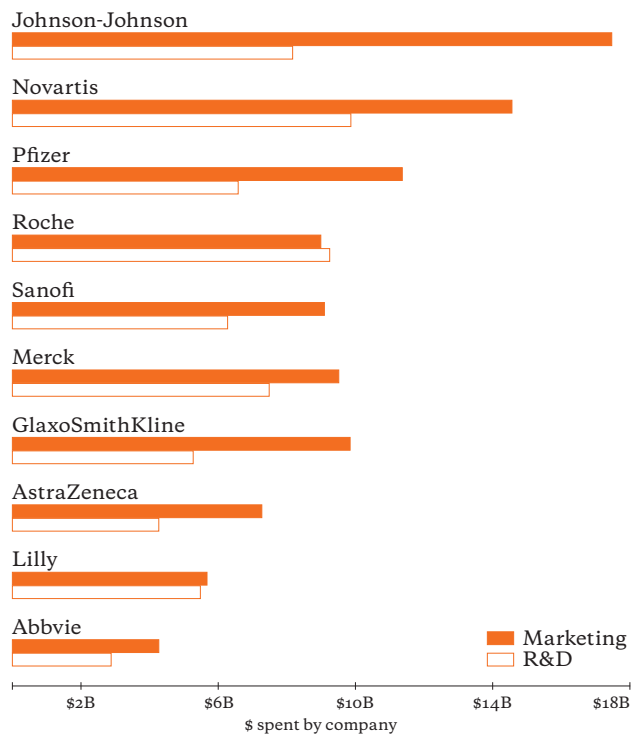
Prescrire's ratings 2000 to 2014 (Percentages per category, N = 1432)
Source: “L'Année du médicament” Rev Prescrire 2015; 35 (376):132-136.

industry claims that the development of a new medicine costs 2.6 billion USD (The Economist 2014). However not-for-profit development initiatives that have published data on their R&D expenditure show a different picture. The Global TB Alliance estimated costs of developing a new chemical entity (NCE) are approximately USD 76-115 million (The Global Alliance for TB Drug Development 2001). DNDi's cost for the development of an NCE is estimated to be € 100-150 million. These estimates are based on real cost for products that have been or are under development (DNDI 2014).

The inflated R&D cost projections by the pharmaceutical industry have been heavily criticised, including by some in the industry. For example, GlaxoSmithKline (GSK) Chief Executive Officer Andrew Witty called the USD 1 billion figure “one of the great myths of the industry” (Sell 2013; Weisman 2014). Still, these figures showing very high R&D costs are used by the industry to justify high medicines prices.

The negative effects of relying on high drug prices sustained by market monopolies as the main mechanism for funding medical innovation have become clear and are now a global issue leading to demands for “delinkage”. A joint WTO, WIPO, WHO study describes delinkage as follows:

“One important concept that evolved from this discussion is the concept of delinking price of the final product from the costs of R&D. This concept is based on the fact that patents allow developers to recoup the costs and make profits by charging a price in excess of the costs of production. This way of financing R&D is viewed as constituting a barrier to access to medicines in countries



Big Pharma Spending: Marketing vs. R&D
 Source: Randal S. Olson (2015): *Design critique: Putting Big Pharma spending in perspective.*

where populations pay out of their own pockets for medicines and thus cannot afford to pay high prices. The principle of delinking is based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided, other than through the price of the product” (WHO 2012).

International policy processes such as the UN High-Level Panel on Access to Medicines and the talks at the WHO on the recommendations for new global rules for medical R&D, as well as efforts to deal with the crisis of antimicrobial resistance and other global health crises, offer opportunities to translate the delinkage concept into concrete proposals that can offer an alternative to the patent system.

Chapter 3

Patents and access to medicines – key challenges

In the last decade and a half the price of medicines needed for the first-line treatment of HIV, the first medicines people with HIV receive when they start treatment, has plummeted from USD 15,000 per patient per year to around USD 140 per patient per year (MSF 2014). This price drop was a result of generic medicine production capacity that existed mainly in India resulting in market competition.

Many countries that had patents on ARVs but wanted to buy generic products from India could acquire them through the use of compulsory licensing or because voluntary licensing and non-assert statements were available – see box for further explanations. These mechanisms provided suppliers of generic medicines the confidence that they could sell the generic products without risking legal repercussions from the patent holder.

Compulsory Licence/Government Use: A compulsory licence is an authorisation by a competent government authority to use a patented invention by a third party without the consent of the patent holder, against a payment of “adequate remuneration”. A “government use” is a particular form of compulsory licence issued by the government for its own use.

Voluntary Licence: Patent holders can license the right to manufacture a pharmaceutical product it holds the patent for to others for example to one or more generic manufacturers. It can do this unilaterally or through the Medicines Patent Pool. To have the benefit of generic competition for lowering the price of a medicines it is important that licences are available to multiple generic manufacturers.

Non-Assert Statement: Non-Assert Statement is a statement by a patent holder, for example, a pharmaceutical company, that it will not enforce its patent in certain territories. In practice this means that in these territories generic medicines can be made or imported without the risk of patent infringement action by the patent holder.

Today, the world is facing a second wave of crises from high medicines prices. The legal space that allowed for the manufacturing of low-cost ARV drugs in the early 2000s has narrowed as key generics-producing countries such as India have implemented the World Trade Organization’s TRIPS Agreement. This agreement sets out minimum standards for the protection of intellectual property

India, the pharmacy of the developing world?

Since India is a key country in providing ARVs for Africa and other regions of the Global South it is often called ‘the pharmacy of the developing world’. India changed its Patents Act in 1970 to exclude among others product patents for medicines. Only process patents could be obtained. This meant that Indian firms could develop generic versions of medicines without infringing a patent right of a third party. As a result a vibrant generic industry developed in India which became well-equipped to produce medicines at a much lower price.

In 2005, India had to change its Patents Act to become compliant with the WTO TRIPS Agreement and introduced product patents. It also implemented a number of flexibilities set out in the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health. India introduced strict patentability criteria in an effort to prevent the granting of trivial patents and to limit ev-

ergreening (modification to a known compound in an attempt to extend its patent life beyond 20 years).

Section 3 (d) of the Indian Patents Act reads: “The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

Having strict patentability criteria is important to limit evergreening of patents and can reduce the number of patents granted. South Africa, for example which currently does not apply strict patentability criteria granted 2,442 patents related to medicines as compared to Brazil which granted 278 patents in the years 2003-2008 (Correa 2011).

rights. Countries that are members of the WTO, and these include India, can no longer exclude entire fields of technology, such as medicines, from patentability (see Article 27 of the TRIPS Agreement). Providing a minimum 20-year patent term for pharmaceutical products is obligatory. New essential medicines, be they ARVs, antivirals to treat hepatitis, medicines to treat tuberculosis TB or cancer will also be subject to patent protection in India.

The kind of generic competition that brought down the price of first line ARVs has become much harder to achieve. First line ARVs are the first anti-retroviral medicines HIV-positive people receive when they test HIV-positive. Over time, the regimen needs to change due to resistance or side-effects and HIV positive people are then

put on so-called second line ARVs. If second line anti-retrovirals do not work any longer, third line ARVs are needed. New medicines that are patented go to market with a very high price. Some of these medicines for third line HIV treatment, i.e. for treatment when the first and second line options no longer work because of resistance or serious side-effects, the treatment of HCV, cancer and drug-resistant tuberculosis (TB) have nevertheless been included in the WHO Model List of Essential Medicines (EML). These are medicines all country should strive to make available. These products are widely patented with expiry dates for those patents that stretch far into the future. Therefore, it will be very difficult to produce and supply generic versions of these products.

Medicine	Company	Primary patent number(s)	Expected date of expiry of the patent
TUBERCULOSIS			
bedaquiline (Sirturo)	Janssen	WO 2004/011436	July 2023
delamanid (Deltysba)	Otsuka Pharmaceutical	WO 2004/033463 WO 2005/042542	October 2023 October 2024
HEPATITIS C			
sofosbuvir (Sovaldi)	Gilead	WO2005003147A2 - base compound WO2008121634A2 - prodrug	April 2024 March 2028
simeprevir (Olysio, Galexos, Sovriad)	Janssen	WO2007014926A1	July 2026
daclatasvir (Daklinza)	Bristol-Myers Squibb	WO2008021927A2	August 2027
ledipasvir	Gilead	WO2010132601A1	May 2030
ombitasvir	AbbVie	WO2010132601A1	June 2030
CANCER			
bendamustine (Treakisym, Ribomustin, Levact and Treanda)	Marketed by Cephalon in the USA	WO2006076620	January 2026
Imatinib (Gleevec, Glivec)	Novartis	WO9509852 WO9903854 (secondary patent)	September 2014 2018
rituximab* (Rituxan, MabThera and Zytux)	Biogen Idec, Genentech, Roche, Chugai Pharma, Zenyaku Kogyo and AryoGen, depending on location	WO8804936 WO9411026	2008 November 2013 Several formulation patents - 2019–2020
HIV			
Lopinavir/ritonavir (heat stable)	Abbott	WO2006091529	2026

Primary patent expiry date of selected new medicines on the EML
Source: UNITAID 2016 and Medicines Patent Pool Patent Database

Chapter 4

Measures to overcome patent barriers to accessing medicines

In the late nineties and earlier 2000s a number of patent-related trade and legal disputes broke out around the supply of generic medicines. A much publicised dispute was the legal challenge mounted by 39 drug companies in 1998 against the South African Medicines Act, which the companies abandoned in 2001 after significant global public pressure (Swarns 2001).

Big Pharma vs. Nelson Mandela

In February 1998, the South African Pharmaceutical Manufacturers Association and 40 – later 39, as a result of a merger – mostly multinational pharmaceutical manufacturers brought a law-suit against the Government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (“Medicines Act”) violated TRIPS and the South African Constitution (Pharmaceutical Manufacturers’ Association of South Africa 1998). Provisions of the Medicines Act included generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines. The Treatment Action Campaign (TAC) mounted a successful global campaign to persuade the companies to drop their case. TAC’s co-founder Zackie Achmat said at the time: “This case is about life or greed. It is as simple as that: life or greed” (journeyman.tv).

Following an extensive public outcry and the disclosure that the most contentious section of the Medicines Act was based on a draft legal text produced by the WIPO Committee of Experts (Sidley 2001), the companies withdrew from the case in April 2001.

These events, together with the offer of the Indian drug manufacturer Cipla of a first-line triple anti-retroviral therapy (ART) for less than a dollar a day (Zimmerman/Pesta 2001), the global mobilisation around HIV and the plans for a global financing mechanism to pay for the treatment of HIV in low and middle income countries (LMICs) caused a shift in approach to intellectual property protection in the area of medicines (’t Hoen et al. 2011). In parallel, the WHO Prequalification of Medicines Program (PQP), established in 2003, provided the necessary regulatory framework to allow smooth international trade in generic ARVs (’t Hoen et al. 2014). The

PQP carries out quality assessments of medicines, which provides assurances to funders, of ARVs such as donor countries, NGOs and the Global Fund that their money is used to buy quality assured products.

Doha Declaration on TRIPS and Public Health

The developments around HIV were instrumental in the adoption of the Doha Declaration on TRIPS and Public Health at the World Trade Organization ministerial meeting in 2001. African countries which were heavily affected by HIV wanted to be assured in 2001 that they could provide generic ARVs without risk of provoking disputes around patents as in the case of South Africa. The Doha Declaration recognized the effect of intellectual property protection on medicines prices and the problems low and middle income countries were experiencing in accessing generic medicines. The Declaration affirmed the sovereign right of governments to take measures to protect public health, including, but not limited to, the use of compulsory licensing and parallel importation (Paragraph 4 of the Declaration).

Doha Declaration on TRIPS and Public Health, paragraph 4:

“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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The Declaration further extended the deadline of the transition period for least-developed country (LDC) Members from 2006 to at least 2016 for the implementation of pharmaceutical product patents and the protection of undisclosed test data (see entry “data exclusivity” in glossary). It also waived the obligation to enforce such rights until at least 2016. This waiver was important be-

cause many LDCs had already granted patent protection for medicines. This waiver has now been extended until at least 2033. In Doha, countries were further promised a solution to a serious problem that arose from the restriction TRIPS puts on the effective use of compulsory licensing by limiting it to the supply “predominantly for the domestic market” (TRIPS Article 31f). This export restriction caused problems for countries without sufficient production capacity that rely on importation for their supply of medicines to make effective use of compulsory licensing. Solving this problem became subject to a separate process at the WTO TRIPS Council leading to the adoption in 2003 of the so called “August 30 decision” setting out rules for compulsory licensing for export purposes. These rules allow the granting of a compulsory license for export purposes to a country that has indicated not to be able to produce the needed medicine. In principle this mechanism can help to maintain current production capacity in countries such as India.

From Declaration to Practice

Today’s recommended first-line ARV regimens are available from generic suppliers for USD 95-158 (Doctors Without Borders 2014). This price represents a steep decrease from the USD 10,000 to 15,000 a decade and a half ago and only a fraction of the price charged in high-income countries. What were the elements that made that possible?

First of all, the establishment of the early HIV treatment programmes in MICs such as Brazil and Thailand in the late 1990s and early 2000s were possible, in part, because key pharmaceuticals, including the first-line HIV drugs (such as lamivudine, nevirapine and stavudine) were not patent-protected and could be produced locally at much lower costs. Brazil’s purchasing power reduced the price of the active pharmaceutical ingredients (APIs) on the global market, which helped to create large-scale low-cost production of ARVs by Indian companies; the resulting economies of scale allowed for dramatically reduced costs and led to lower prices for medicines.

From 2001 onwards countries have used the provisions of the Doha Declaration on a wider scale than perhaps is generally known to access the generic supply from India. A study of the use of the Doha Declaration published in 2009 showed that between 2001 and the end of 2007, 52 developing and least-developed countries issued compulsory licenses, gave effect to government use

provisions or implemented the non-enforcement of patents (’t Hoen 2009). These measures almost all concerned ARVs and in some cases were geared to allow local production of ARVs. Pharmaceutical companies have also responded to these government measures by lowering their price or allowing generic copies of their patented products under a voluntary license agreement.

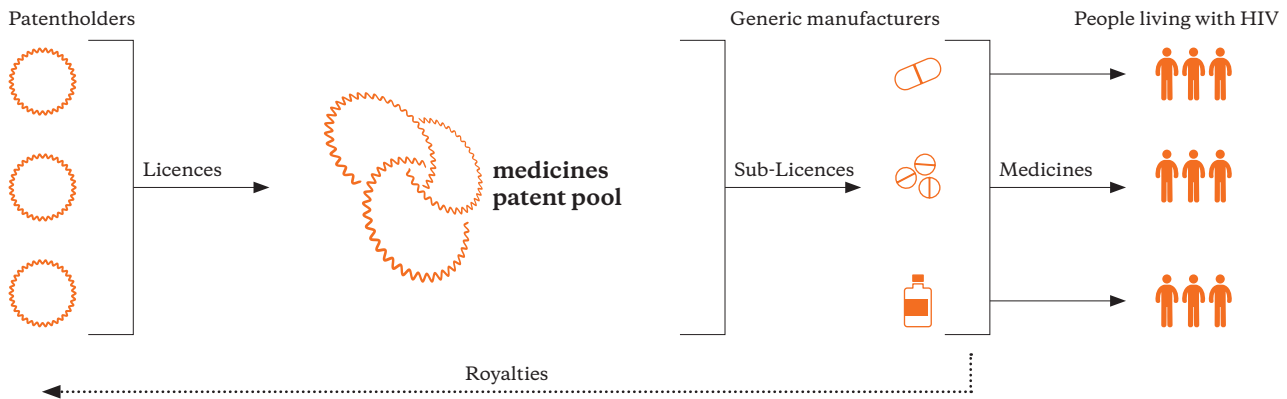
Between 2001 and 2010 at least 24 of the 34 WTO LDC member states have used the LDC waiver on enforcement of pharmaceutical patents in procurement of ARVs. This measure offered important legal certainty for procurement agencies which were reluctant to supply products that could infringe a patent (IDF 2015). This also explains why such agencies supported the request from LDCs to further extend the waiver’s deadline beyond 2016 until 2033 (Saez 2015). The Doha Declaration, however, includes additional options for LDCs and developing countries that have not been sufficiently explored (see box).

TRIPS regional waiver

The “WTO August 30th Decision” is largely viewed as an inefficient system because of its case-by-case procedure. However, it also created a regional waiver, which specifically allows exports under a compulsory license, without quantity restrictions, among countries that belong to a regional trade agreement, of which at least half of the members are LDCs. Most regional economic communities (RECs) in Africa have a majority of LDC members. While LDCs of these RECs may continue to make use of the special LDC waiver, developing countries of RECs can issue compulsory licenses to locally produce or import generics and export, or re-export, without quantity restrictions, within the REC, to harness economies of scale (Boulet/’t Hoen 2015).

One way forward - the Medicines Patent Pool

In 2010 the Medicines Patent Pool (MPP) was established with the purpose of creating predictable and sustainable licensing for new HIV medicines. The MPP negotiates licences with patent holders of essential HIV medicines, in order to ensure low-cost generic production and supply can take place without legal risks. It is especially useful



Medicines Patent Pool: a one stop shop for voluntary licences.
 Source: Medicines Patent Pool (2014): *The Future of HIV Treatment*.

for developing and producing fixed-dose combinations of molecules patented by different companies, which would otherwise not be possible without protracted negotiations. The MPP recently expanded its mandate to hepatitis C and tuberculosis. In November 2015, the first hepatitis C medicine was licensed to the Medicine Patent Pool. After more than five years of operation the MPP has proven to be a promising mechanism to ensure access to generic ARVs in a large number of low and middle-income countries (see box for details on achievements of the MPP). However, challenges remain for the countries that are excluded from the license agreements because the patent holder wants to maintain control of certain mid-

dle-income country markets. It should, however, be noted that the MPP licensees, the generic companies, can nevertheless supply generic products made under the MPP agreements as long as the importing country makes use of a TRIPS flexibility. If, for example, Peru, a country that can generally not benefit from MPP licenses because it is not included in the list of countries generic producers can supply, issued compulsory licenses for HIV medicines it wanted to buy from an MPP sub-licensee, there would be no barrier to it doing so. In fact, consumer groups in Peru are asking the government to issue a compulsory license to access lower-priced HIV medication produced under a license from the MPP (Silverman 2015).

Achievements of the Medicines Patent Pool (2010–2015)

Patent licenses and agreements (MPP 2015)

- Patent licences signed on 12 priority ARVs with six patent holders, and 59 sub-licences with 14 generic manufacturers
- One licence on a treatment for hepatitis-C for 112 LMICs
- One agreement to increase access to treatment of cytomegalovirus retinitis, an opportunistic infection in people living with HIV
- One agreement with the University of Liverpool for Solid Drug Nanoparticle (SDN) technology for the development of anti-retrovirals as nanomedicines, for use in all 135 LMICs and two HICs in Africa

Impact on production and supply

- Generic companies with MPP licences have supplied more than seven million patient years of WHO-rec-

ommended ARVs in 117 countries, including 41 countries that were previously unable to benefit from generic competition for such medicines

- MPP licences enable manufacturing and sale of generic adult ARVs to 87-93 per cent of people with HIV in the developing world. This includes all 34 low-income countries and 55-80 per cent of MICs
- MPP sub-licensees have supplied 4.3 million patient-years of tenofovir disoproxil fumarate (TDF) in the first six months of 2012 shortly after the agreement was reached.
- Financial savings
- MPP agreements have led to ARV procurement savings of USD 119.6 million
- In the coming years, further savings of USD 1.18 - 1.4 billion are expected (Burrone 2015)

Chapter 5

New essential medicines, new challenges and new trade agreements

In May 2015, the World Health Organization added several important medicines (WHO 2015), including those for the treatment of cancer, tuberculosis and hepatitis C, to its Model List of Essential Medicines (EML). The uniqueness of these medicines – aside from their value as treatments for devastating illnesses – is their high price. Now that the WHO has given these medicines the status of ‘essential’, they must be made both available and affordable. As innovative new medicines are increasingly patented around the world and thus are only available at monopoly prices that prevent widespread access, a public policy response is needed to address the intellectual property challenges associated with essential treatments (‘t Hoen/Mara 2016).

A huge threat to effective public policy to curtail high drug prices are the TRIPS-plus provisions contained in regional and bi-lateral trade agreements that are designed to strengthen the hand of patent holders and weaken measures governments can take such as compulsory licensing.

The following TRIPS-plus demands regularly feature on the wish lists of the US and/or the EU in trade talks. All of these TRIPS-plus features can delay the introduction of generic medicines and thereby affect access to medicines:

- *Patent linkage*: Prohibits granting of marketing approval by drug regulatory authorities during the patent term without the consent of the patent holder. These provisions effectively create a new function for

health authorities in the enforcement of patents on medicines;

- *Data exclusivity*: Prohibits for a certain period of time the use of pharmaceutical test data for drug regulatory purposes, which will delay the registration and thereby the marketing of generic medicines, including bio-similar products, regardless of the patent status of the product;
- *Extension of the patent term* for pharmaceuticals beyond the 20 years required by the TRIPS Agreement, which will further delay generic competition (EC 2012);
- *Extension of the scope* of patent protection to allow known substances to be patented for each “new use”;
- *Restrictions on the grounds for compulsory licensing*;
- *Restrictions to parallel importation*.

The recent Trans-Pacific Partnership (TPP) Agreement also has created concern among health advocates, not least because the agreement is cast as a model for future agreements. The TPP negotiations involved 12 countries (the US, Japan, Australia, Peru, Malaysia, Vietnam, New Zealand, Chile, Singapore, Canada, Mexico, and Brunei Darussalam) and were concluded in November 2015.

UNITAID, a financing mechanism for HIV, tuberculosis (TB) and malaria hosted by the WHO, which was established in 2006 by Brazil, Chile, France, Norway and the United Kingdom to speed up the availability of medicines and diagnostics, made the following statements on TRIPS-plus provisions in the TPP (UNITAID 2014):



People queuing at local pharmacy to buy medicines.

“TRIPS-plus provisions also limit or undermine developing countries’ policy options for legislating and using TRIPS flexibilities, even though safeguards and flexibilities were included in the TRIPS Agreement to enable governments to protect public interests, including access to medicines. This has led to concerns that TRIPS-plus provisions in free trade agreements will undermine public health safeguards and objectives – notably access to medicines. These concerns are particularly pertinent with regard to the negotiation of a Trans-Pacific Partnership Agreement, which has been positioned as a ‘model’ for the 21st century – implying that the same or similar provisions are likely to appear in future trade agreements, including those involving developing countries” (UNITAID 2014).

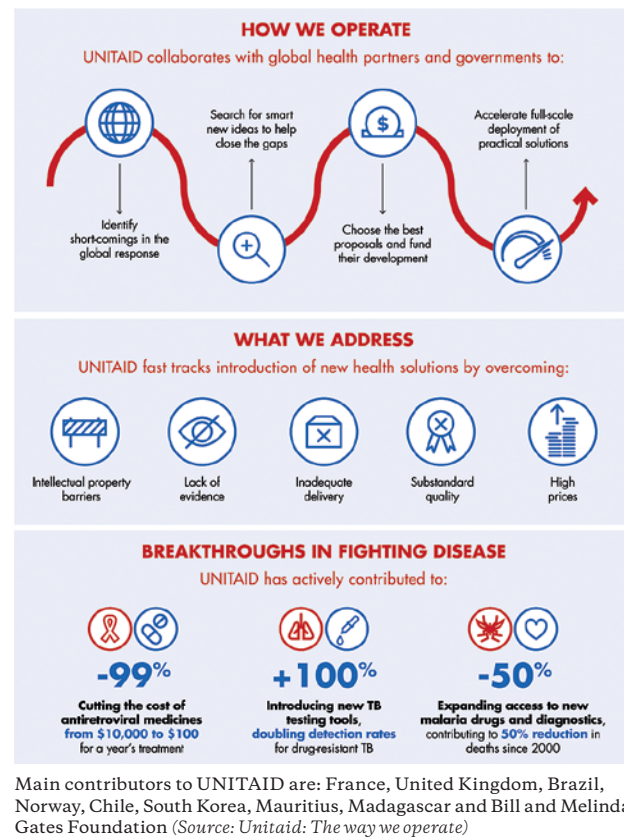
Some of the TRIPS-plus provisions of the TPP are (Baker 2016):

- Patent term extensions beyond the minimum requirement of 20 years in TRIPS;
- Introduction or expansion of data exclusivity for biologics leading to market exclusivity even in the absence of patents (Behsudi/Norman 2015), and resulting in a loss of diversity in data protection laws in TPP countries;
- Requirements for patentability criteria that allow for the granting of secondary and new use patents, a practice that can lead to evergreening of patents and which is currently legally not possible in a number of countries including India.

With regard to compulsory licensing the TPP includes the following provision: “The Parties understand that nothing in this Chapter limits a Party’s rights and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the Parties accept.”

This provision should protect countries’ abilities to use compulsory licensing effectively. However, some have pointed out that the investor-state dispute settlement (ISDS) provisions that give companies the right to sue a foreign government for losses when it considers that certain measures negatively affect their investment will have a chilling effect on the use of compulsory licensing (Shah 2015). ISDS are not imaginary. Currently the American company Eli Lilly is suing the Canadian government over losses resulting from Canada’s invalidation of secondary patents related to the previously known active ingredients atomoxetine (Strattera) and olanzapine (Zyprexa), drugs used to treat attention deficit hyperactivity disorder, schizophrenia and bipolar disorder (Public Citizen 2015). Eli Lilly is using the invest-

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UNITAID seeks faster, cheaper and better ways to prevent and treat
HIV, Tuberculosis and Malaria



ment chapter of the North American Free Trade Agreement (NAFTA) to support its suit.

The United Nations Conference on Trade and Development (UNCTAD) maintains a database of ISDS, which currently counts 608 cases (UNCTAD). In its 2015 World Investment Report, UNCTAD notes that developing countries “bear the brunt of these claims” and that most claimants (i.e. the companies) come from developed countries (UNCTAD 2015).

The purpose of TRIPS-plus provisions in trade agreements is to increase the prices companies can charge for their medicines: the stronger their position in the market the easier it is to keep competition out and demand a high price. Strong market positions depend on patents and other regulatory measures to maintain a monopolistic position. The trend to negotiate trade agreements in secret and outside the multilateral system comes with the increased risk that the public interest is made submissive to business interests.

Chapter 6

Conclusion - time for change: innovation for access

Based on today's knowledge of the challenges for both access to and innovation of the current pharmaceutical development system, we need to look at alternatives. We need to bring the price of new essential medicines down so they become affordable to the communities that need them. To deal with the patent barriers to affordable new medicines one could imagine an essential medicines patent pool backed up with an effective and easy to use compulsory licensing practice at a national level ('t Hoen/Global Health Law Committee of the International Law Association 2016). Equally important is ensuring that research and development for new essential treatments takes place.

New financing models for R&D can be promising when they provide the correct incentives for innovation while keeping drug prices low. This can be achieved when they are based on delinkage principles in which paying for the cost of R&D is delinked from the price; in other words, R&D would no longer be dependent on the ability to charge high prices. At its Assembly in May 2016, the WHO considered recommendations for an interna-

tional medical R&D agreement made by a group of experts convened by the WHO in 2012, it wants to prioritize health research and development for essential medicines that are neglected by commercial R&D efforts. (Moon/'t Hoen 2012; 't Hoen/Global Health Law Committee of the International Law Association 2016). The UN Secretary General in 2015 established a UN High-Level Panel on Access to Medicines to address the misalignment between the rights of inventors, international human rights law, trade rules and public health where it impedes the innovation of and access to health technologies. These international talks provide an opportunity for the medical community and development organisations to step up engagement with an issue that for too long has been exclusive to trade and business lobbies. The discussions could lead to rewriting the rules so needed innovations in health are financed and accessible to all in need. Pharmaceutical innovation and access to new medicines is no longer an issue for developing countries only, but affects all peoples the globe over.



Publicly funded research and development is needed.

Glossary

Active Pharmaceutical Ingredient (API): The part of a pill that provides the medical benefit. Other parts of the pill are inactive and may include the material in which the API is encased (e.g., a gel capsule) or suspended (e.g., a liquid).

Antiretroviral (ARV) and Antiretroviral Treatment (ART): A medicine for the treatment of HIV. There are several classes of ARVs, which all target a different phase in the reproductive cycle of the virus. ART is a treatment regimen composed of several ARVs (usually three).

Compulsory Licence/Government Use: A compulsory licence is an authorisation by a competent government authority to use a patented invention by a third party without the consent of the patent holder, against a payment of “adequate remuneration”. A “government use” is a particular form of compulsory licence issued by the government for its own use or for the use of a third party.

Data Exclusivity: Data exclusivity is the prohibition of use of pharmaceutical test data submitted to a regulatory agency by an originator company for the purpose of registering a generic drug. Generic companies rely on this test data to demonstrate the safety and efficacy of their bioequivalent drug. Delayed use of the data will therefore delay the registration and marketing of generic medicines, regardless of the patent status of the product.

Delinkage: A concept in public health wherein the cost of research and development on a new medicine is “delinked”, or independent from, the medicine’s final market price. There have been several ways discussed to achieve delinkage, including pooled funding for research and development and cash prizes.

Essential Medicines List (EML): The EML is a list maintained by the World Health Organization that contains the most important medicines that should be available and affordable to the communities and people that need them. The EML is a tool for governments and healthcare providers seeking to meet the health needs of their populations. The EML is updated periodically to detail the medicines a health system should seek to make available.

Evergreening: The practice of seeking secondary patents with the aim of extending market exclusivity beyond the patent term of the basic patent.

Fixed-dose Combination (FDC): A treatment combining several medicines in one pill (usually two or three). FDCs have been instrumental in scaling up HIV treatment by allowing for easier treatment, improved treatment compliance, and simplified distribution.

Intellectual Property: Intellectual property (IP) refers to the legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields. IP has two branches: Industrial property (e.g., inventions [patents], trademarks, industrial designs, geographical indications) and copyright (and related rights).

LDC Waiver: Least-developed countries (LDCs) have an extended transition period before they have to comply with the TRIPS agreement; that period is currently in force until 2021. A separate LDC pharmaceutical waiver allows LDCs not to grant or not to enforce existing IP rights on pharmaceutical products. This waiver will be in place until 2033.

New Chemical Entity (NCE): A drug that contains a chemical that has never before been approved by a medicines regulatory agency (such as the US Food and Drug Administration).

Neglected Tropical Diseases (NTD) are a group of diseases which predominantly occur in tropical and sub-tropical countries and affect

about a billion people. The WHO now recognizes 18 NTDs for which more awareness and research is required to develop better diagnostic methods, treatments and control strategies.

Non-Assert Statement: Non-Assert Statement is a statement by a patent holder, for example, a pharmaceutical company that it will not enforce its patent in certain territories. In practice this means that in these territories generic medicines can be made or imported without legal risks.

Parallel Importation: Parallel importation refers to the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country. Parallel imports take place when there are significant price differences for the same good in different markets.

Patent: A patent is a form of IP granted to an inventor for the creation of something new, non-obvious to a person who is knowledgeable in the field, and useful. Patents grant a temporary monopoly (usually 20 years), during which time the patent holder can prevent others from making, using, or selling their invention. A patent is national in nature, and inventors must apply under each country’s patent law in order to receive protection in that country. In international trade, however, a blocking patent in either the country of import or export could interfere. That means a patent in a country that produces generic medicines, such as India, can be enough to restrict access to those medicines in other countries relying on the first country’s exports, regardless of whether or not there is a patent in the importing country.

Prequalification of Medicines Program (PQP): Established by the World Health Organization in 2001, the PQP provides a stringent, straightforward way to validate the quality of generic medicines and formulations. It is relied upon by United Nations-based and several external medicines procurement bodies, and has been critically important in scaling up treatment. Initially focussing on medicines for HIV, tuberculosis and malaria, the PQP has been expanding to other disease areas and medical technologies.

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS): Administered by the World Trade Organization (WTO), TRIPS sets out minimum standards for the protection of several forms of IP that all WTO member countries need to implement. TRIPS also contains several important flexibilities to preserve the rights of nations to protect the public interest.

Triple therapy: The use of three different ARVs, of at least two different classes, in a treatment regimen in order to more effectively fight the virus. Different classes of ARVs act to inhibit different stages of the virus’ life cycle. See also ART, above.

TRIPS-plus: These are requirements for more stringent IP standards than those contained in TRIPS or that limit flexibilities inherent in TRIPS. They are often found in bilateral or regional trade agreements, and are a matter of concern for public health advocates.

Voluntary Licence: Patent holders can license the right to manufacture a pharmaceutical product it holds the patent for to others for example to one or more generic manufacturers. It can do this unilaterally or through the Medicines Patent Pool. To have the benefit of generic competition for lowering the price of a medicines it is important that licences are available to multiple generic manufacturers.

World Health Assembly (WHA): Attended by health ministers from World Health Organization (WHO) member states, the WHA is the most important WHO governing body, setting the direction and priorities for the organisation at its annual meeting.

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