

**Access to affordable medicines for  
HIV/AIDS and hepatitis:  
the intellectual property rights context**



**World Health  
Organization**

Regional Office for South-East Asia

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# Acronyms

CAMR	Canada's Access to Medicines Regime
DNDi	Drugs for Neglected Diseases Initiative
GATT	General Agreement on Tariffs and Trade
LDC	Least Developed Countries
PEPFAR	President's Emergency Plan for AIDS Relief
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

# 1. Introduction

Intellectual property rights, in particular patents, have been at the centre of the debate on access to affordable medicines for HIV/AIDS. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) – which came into effect on 1 January 1995 – is, to date, the most comprehensive multilateral agreement on intellectual property.<sup>1</sup>

The importance of public health has been recognized in the rules of the multilateral trading system since the time the General Agreement on Tariffs and Trade (GATT) – that metamorphosed into the WTO – was founded over 50 years ago. This explicitly recognizes the right of governments to enact trade-restricting measures whenever these are necessary to protect human life and health. The right to take measures for the protection of health is also included in other relevant WTO agreements, including the TRIPS Agreement.<sup>2</sup> With regard to access to patented products for public health, countries also make use of the flexibilities available under the WTO TRIPS Agreement.<sup>3</sup>

TRIPS sets minimum intellectual property standards, but nations can provide additional intellectual property protection. TRIPS requires nations to protect pharmaceutical and drug patents. Those nations that do not support the rules risk trade sanctions by WTO.<sup>4</sup> Before the TRIPs Agreement, nations had in place a wide variety of different patent regimes for drugs. Some granted patents for drugs, while others did not.<sup>5</sup> For example, the Indian Patents Act 1970 allowed only for process patents on pharmaceuticals. Product patents were not recognized and this enabled Indian industry to supply low-cost drugs. This is due to the difference between the high cost of discovering and testing new drugs and the low cost of reverse engineering of generic copies of existing drugs.<sup>6</sup> Pharmaceutical firms consider patents critical to their efforts to recoup research and development (R&D) investments, and this is much more so than in the case of firms in other industries.<sup>7</sup>



## 1.1 South Africa HIV/AIDS crisis leading to adoption of Doha Declaration for Public Health in WTO in 2001

The TRIPS provisions came into focus for public health when most of the substantive obligations of the Agreement for developing countries were enforced in 2000. In a landmark legal action, a pharmaceutical industry association and 39 affiliate companies filed complaints at the Pretoria High Court alleging, among other things, that South Africa's law on medicines allowed for parallel importation of (HIV/AIDS) medicines and was inconsistent with the TRIPS Agreement.

The law suit triggered an active campaign led by nongovernmental organizations (NGOs) and AIDS activists. During the court procedure, it was revealed that the South African law was based on a WIPO (World Intellectual Property Organization) model law, and in the end, the companies withdrew their complaints unconditionally in 2001. At the Fourth WTO Ministerial Conference in Doha, Qatar, on 14 November 2001, ministers adopted by consensus the Doha Declaration. This was in response to concerns expressed that the TRIPS Agreement should not undermine the legitimate right of WTO members to formulate their own public health policies to protect public health.<sup>8</sup>

Further, compulsory licensing and government use without the authorization of the patent holder are allowed under TRIPS, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31.<sup>9</sup> The compulsory licensing provisions of Article 31(h) offered little potential benefit to least developed countries (LDC) with no or insufficient manufacturing capacity in the pharmaceutical sector. Therefore, Article 6 of the Doha Declaration also directed the Council for TRIPS to report an expeditious solution to the domestic supply restraint (31(f)) by 2002. This resulted in the development of the Doha Declaration Paragraph 6 Waiver mechanism for supply of affordable medicines.

The Doha Declaration provides additional relief for LDCs. Article 66 of the TRIPS Agreement affords LDCs the right to not comply with the provisions of the agreement until 1 January 2006. This date was extended by the Doha Declaration on the TRIPS Agreement and Public Health (August 2003) till 1 January 2016.

It is to be noted that recently, the Council for TRIPS has provided for extension of the transition period for LDC Members by their decision of 11 June 2013 until 1 July 2021".<sup>10</sup>

## 2. Doha Declaration Para 6 Waiver in action

The Doha Declaration Paragraph 6 Waiver requires that developing countries notify WTO of their intention to become an eligible importing member. Countries must notify the products and quantities that they intend to import. Rwanda was the first Member State to notify the intent to use the Waiver in July 2007, stating that it “wanted to purchase 260 000 packages of a triple-drug antiretroviral (ARV) therapy, enough to treat 21 000 people for one year”.

Canada was one of the first countries to enact domestic legislation – Canada’s Access to Medicines Regime (CAMR) – for this purpose. The law became effective in May 2005. Before Canada can issue a compulsory licence, the law requires a generic company to obtain the permission, called a voluntary licence, from the patent holder. Once the company owning the patent grants a voluntary licence, the generic manufacturer must then obtain a compulsory license from the Canadian Commissioner of Patents. After these requirements are met, the generic manufacturer can formally begin a bidding process with the government of a developing nation.

For over a year, the Toronto-based generic drug manufacturer Apotex, Inc. sought to obtain a voluntary licence from manufacturers-GlaxoSmithKline, Shire and Boehringer Ingelheim, each of which owned patents on three components of a triple-fixed-dose, antiviral AIDS drug known as Apo-TriAvir that Apotex wanted to produce under CAMR. Despite efforts to negotiate, the pharmaceutical companies refused to give Apotex a voluntary licence. It was not until after Rwanda sent its notification to WTO that the companies consented to the use of their patented drugs. On 19 September 2007, the Canadian Commissioner of Patents granted Apotex a compulsory licence, and on 4 October 2007 Canada notified WTO. Finally, after meeting obligations under CAMR and TRIPS, Apotex was able to begin negotiations with Rwanda. On 7 May 2008, Rwanda accepted Apotex’s bid resulting in the dispatch of the “first shipment of seven million tablets, which will help save the lives of 21 000 people”.<sup>11</sup>

It is clear that CAMR is too complicated and imposes requirements that are too stringent. For example, the voluntary licence requirement permits the pharmaceutical patent holder to stop/slow the process at any time. The experience between Rwanda and Canada suggests that there are still steps that need to be taken under the Doha Declaration Paragraph 6 Waiver mechanism to improve the process and ensure that the goal of access to medicines is achieved.



### 3. TRIPS flexibilities and compulsory licensing

TRIPS flexibilities include “public health sensitive” provisions such as exhaustion/parallel imports (Article 6), experimental use and early working/“Bolar exception” (Article 30), and compulsory licensing (Article 31) in the TRIPS Agreement. Given the lengthy Doha Declaration Para 6 Waiver mechanism procedures required to obtain ARVs, it is not surprising that countries began to opt for using TRIPS flexibilities to obtain affordable medicines. Additionally, the flexibilities such as parallel imports in TRIPS create difficulties for Member States to find low-priced drugs from other countries.<sup>12</sup> The “Bolar exception” allows generic companies to use the patented invention to obtain marketing approval without the patent holder’s permission so that they can market their product as soon as the patent expires.<sup>13</sup> This presupposes that a generic company is willing to produce and market the drug, which may not always be the case. A compulsory licence is a licence granted by the government allowing the use of an intellectual property (IP) right without the holder’s consent. Compulsory licences require payment of certain amounts of royalties from licencees to IP holders and are granted under certain conditions such as “for public non-commercial use”, “to correct anti-competitive practices,” “for the demand of domestic market,” “national emergency” and “extreme urgency”.<sup>14</sup>

Due to the practical difficulties of using the TRIPS flexibilities of parallel imports and Bolar provisions, it is apparent that compulsory licensing has been adopted by most countries to promote access to medicines. In 2007, Thailand, after failing to negotiate a price for the HIV/AIDS drug Kaletra (lopinavir/ritonavir) with Abbott, invoked the legal mechanism of compulsory licence.<sup>15</sup> Thailand, upon issuing the compulsory licence, began manufacturing the medicine on its own at low cost.<sup>16</sup>

In 2002, Mozambique, Zambia and Zimbabwe issued compulsory licences for HIV/AIDS medications treatment, followed by Indonesia and Malaysia in 2004 and Brazil in 2007.<sup>17</sup>

In 2004, Malaysia issued a compulsory licence for HIV/AIDS medicines patented by GlaxoSmithKline and Bristol-Myers Squibb, after lengthy, failed price negotiations.<sup>18</sup> The pharmaceutical companies offered 30–40% discounts. The Malaysian government, however, chose to issue a compulsory licence to “meet the needs” of its national

HIV/AIDS treatment programme. Malaysia's use of this TRIPS flexibility expanded its programme's treatment capacity from 1500 to 4000 by reducing the cost of three patented medicines by 81%. However, this resulted in certain consequences. First, the patent holder pharmaceutical companies filed complaints with the Malaysian government prompting concerns about "negative implications for foreign investment." Second, though the Malaysian Ministry of Health offered 4% remuneration pursuant to TRIPS Article 31(h), the patent holders "refused compensation . . . for fear of creating an international precedent". Third, it took three years of "negotiations and discussions within governmental agencies" for Malaysia to increase its access to the medicines using the compulsory licensing mechanism. Finally, Malaysia's use of compulsory licensing led the United States of America to approach Malaysia directly – outside the collective WTO framework – and successfully discourage it from future compulsory licence issuance through a bilateral free trade agreement.

This fact reveals that the TRIPS compulsory licensing mechanism, and the domestic legal procedures that it requires, could be cumbersome and not expedient in a public health crisis.

Brazil has extensively utilized TRIPS flexibilities. In 2001, Brazil successfully used the threat of issuing compulsory licences to receive significant discounts for Merck & Co. and Roche medicines. In June 2005, Brazil threatened Abbott with compulsory licence issuance for the HIV/AIDS drug Kaletra. On the verge of Brazil actually issuing the compulsory licence, Abbott granted Brazil its requested price. Less than two years later, in May 2007 Brazil used the threat of issuing a compulsory licence again, this time against Merck & Co. for its HIV/AIDS drug efavirenz. Over the course of negotiations related to this transaction, Merck & Co. made significant price concessions. But Brazil ultimately demanded the price that had been offered a few years earlier to Thailand and finally Merck & Co. agreed to that price.<sup>19</sup>

## 4. Approaches to compulsory and voluntary licensing for access to medicines

The mechanisms proposed to secure affordable medicines and ARVs related to both compulsory and voluntary licencing. Universities Allied for Essential Medicines has proposed that universities adopt global access licencing policies and enable generic or low-cost production of the end product in less developed countries. Generic competition is a critical market force that has, for instance, driven down the price of HIV/AIDS treatments from more than US\$ 10 000 to less than US\$ 99 per patient per year today.<sup>20</sup> Brazil, in addition to issuing a compulsory licence on the AIDS drug efavirenz in 2007, negotiated discounts between 40% and 65% on nelfinavir, imatinib, efavirenz, tenofovir and lopinavir/ritonavir between 2001 and 2007 against the backdrop of threatening to issue compulsory licences<sup>21</sup>.

India had been a supplier of low-cost quality generic medicines and was able to reduce monthly medicine costs from US\$ 395 to US\$ 20. India had till 2005 to bring its domestic patent laws into compliance with TRIPS requirements. In this 10-year span since the TRIPS Agreement in 1995, Indian pharmaceutical companies produced significant amounts of generic HIV/AIDS medicines and provided them at low cost domestically and to various countries in Africa.

By 2005, India updated its domestic patent laws to comply with TRIPS requirements. One impact of these changes is that Indian pharmaceutical companies now have a narrower range of medicines that they may legally produce as generics. In particular, they may not produce generics of the newest “second- and third-generation” HIV/AIDS medicines, whose patents must now be respected. The net result of this is that the role Indian pharmaceutical companies have played since 1995 in reducing costs for the most needed HIV/AIDS medicines could be curtailed.

Several governments and international agencies have established or proposed pharmaceutical licensing royalty systems in recent years. A set of guidelines proposed by UNDP (United Nations Development Programme) suggested royalties from 0% to 6% of the price charged by the generic competitor. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity

set royalties at 0%–4% of the generic price, depending on the level of development of the importing country.

National, regional and international intellectual property rules require that a compulsory licence licensee must pay compensation to the patent holder. TRIPS Article 31(h) requires that a licensee must pay “adequate remuneration” to the patent holder “taking into account the economic value of the licence”. In recent years, a number of developing countries have issued compulsory licences on HIV/AIDS drugs. Indonesia set a royalty rate of 0.5%, Malaysia at 4% for such licences, Mozambique established a 2% royalty, and Thailand at 0.5% while Zambia set it at 2.5% royalty on the AIDS and heart disease medications it compulsorily licensed.<sup>22</sup>

In the pharmaceutical industry, voluntary licence rates range widely, generally 4–5%. The joint UNDP-WHO publication *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* notes the evidence of compensation for private, market-based licence arrangements and provides an important context for royalty and remuneration arrangements in cases of compulsory licensing. Reports from the pharmaceutical industry and others suggest that licensing fees for the pharmaceutical industry are at 4%–5%. The pharmaceutical company Gilead has provided voluntary licences to eight Indian generic firms to produce two important AIDS drugs for sale in 95 countries. The royalty rate in this agreement is set at 5%.

## 5. TRIPS flexibilities: Compulsory licensing for medicines other than ARVs

The success of countries in using compulsory licensing for ARVs has prompted them to use the same mechanism to obtain medicines other than those for HIV/AIDS. Thailand issued licences on four cancer drugs in January 2008.<sup>23</sup> Thailand asserted that they were necessary because cancer is currently the number one cause of death in Thailand; the most effective cancer treatments are patented and not covered on the Thai List of Essential Drugs due to their high cost; and thereby are inaccessible to Thai citizens.<sup>24</sup> Thailand asserted that cancer is no less serious than HIV/AIDS, accounting for 30 000 deaths a year with 100 000 new cases diagnosed each year. Moreover, Thailand noted that the licences were critical to prevent either severe economic hardship, including bankruptcy, or certain death, without treatment.<sup>25</sup>

In November 2005, Taiwan issued a compulsory licence pursuant to TRIPS Article 31 for the avian influenza drug “Tamiflu” manufactured by Roche. Taiwan claimed that the potential for an outbreak of bird flu constituted a national emergency and that it was necessary to ensure sufficient stockpiles of Tamiflu.<sup>26</sup>

## 6. Legal landscape changes and challenges

IP rights including patents are territorial in their application. This means that while minimum standards are outlined in the TRIPS Agreement, each country has its own patent law and thus may define the scope of patentability. For example, Section 3d of the Indian Patents Act prescribes a higher threshold of criteria for patentability for certain inventions: “the mere discovery of any new property of 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;” that has a profound impact on the grant of pharmaceutical patents in the country. Further, the Indian Patents Act provides for the grant of compulsory licences without prior attempt to obtain a licence from the patentee on reasonable terms and conditions in case of anti-competitive practices adopted by the patentee [Section 84.6(iv)], as well as the right to export any products produced under such licences, if necessary.

In April 2013, the Supreme Court of India ended a seven-year battle around the patentability of imatinib mesylate for the treatment of chronic myeloid leukaemia, marketed by Novartis under the tradename Glivec/Gleevec, and refused the grant of the patent. The Supreme Court rejected the patent application claim for a specific crystalline form ( $\beta$ -crystal form) of imatinib on the grounds that this form is not a new substance, was already known and does not show enhanced therapeutic efficacy. The Supreme Court points out that other positive characteristics, e.g. it being less hygroscopic, are not sufficient under Section 3d.

The situation in this case is particular: Novartis could not file the basic patent on imatinib in India, as at the time, India did not grant pharmaceutical product patents at all. Thus, even if the patent on the  $\beta$ -crystal form would have been granted in India, this would not have prevented generic version of other crystal forms. Imatinib mesylate has been considered for inclusion in the WHO EML by the 19th Expert Committee on the Selection and Use of Essential Medicines in April 2013<sup>27</sup> and is recognized to be a breakthrough in the treatment of leukaemias.<sup>28</sup>



There are changes in domestic laws of developed nations such as the United States that address encouraging affordability and generic medicines. On 16 September 2011, the Leahy-Smith America Invents Act (AIA) became law and this came into force on 16 March 2013.<sup>29</sup> Congress acted “to amend title 35, United States Code, to provide for patent reform” by adopting the first-inventor-to-file system (rather than the previously existing first-to-invent system).<sup>30</sup> However, the present bill already provides ample incentive for an inventor to enter the patent system promptly. The new law represents a comprehensive reform of the law of patentability and patent enforceability. In addition, AIA makes dramatic changes to the role of the public in the patenting process. In the future, most patent applications will not only be promptly published, but members of the public will have the opportunity to submit information relevant to patentability that the patent examiner must consider before making a decision to issue a patent.<sup>31</sup> This profound reversal in the patenting process – with the public’s role being transformed from blinded spectator to full participant – was made possible because of the manner in which the AIA rewrites basic rules for patentability of applications for patents and validity of patents once issued. Simply, the AIA limits patentability issues in a manner that renders the new post-grant patent challenge mechanisms administratively feasible.<sup>32</sup> Most importantly, the determination of whether a claimed invention is sufficiently different (i.e., novel and non-obvious) from previously existing technology (i.e., the “prior art”) to merit a patent has changed in fundamental ways.<sup>33</sup> Therefore, substantive legislation both in developed and developing countries is encouraging greater public scrutiny in patent applications that should result in eliminating practices such as “evergreening” of patents.

Furthermore, in the USA on 13 June 2013, in *Association for Molecular Pathology et al., Petitioners v. Myriad Genetics Inc. et al.*, the court held that isolated DNA involved a naturally occurring segment of DNA and was not patentable. Only synthetically created DNA known as complementary DNA (cDNA) that was not naturally occurring could be patented. In this case medical organizations, researchers, genetic counsellors and patients brought action against the patentee and United States Patent and Trademark Office (USPTO) challenging the validity of patents for isolated DNA sequences associated with predisposition to breast and ovarian cancers and for diagnostic methods of identifying mutations in those DNA sequences.<sup>34</sup> This shows that courts in the USA are also applying a stringent patentability standard for patents in public health.

In addition, in judicial decisions such as *AstraZeneca AB v. European Commission* in the European Court of Justice,<sup>35</sup> 6 December 2012, it is held that the pharmaceutical companies had abused their dominant position in the market by providing misleading information to various patent offices in the European Union in order to obtain supplementary protection certificates and keep manufacturers of generic products out of the market. This decision related to obtaining market authorization through misleading statements made by the pharmaceutical company. The Court observations related to parallel imports including patents and supplementary protection certificates for omeprazole-based products for gastrointestinal conditions called “Losec”. A fine of US\$ 52.5 million was imposed on AstraZeneca AB. Thus, it is clear that European courts are also rigorously scrutinizing patents from pharmaceutical companies.

## 7. Additional international legal facilitation for access to ARVs

Certain legal covenants in countries such as The United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act, 2003 aim to strengthen the effectiveness of the US response to certain global infectious diseases.

More specifically, the purpose of the Act was to:

- (1) establish a comprehensive, integrated five-year, global strategy to fight HIV/AIDS that encompasses a plan for phased expansion of critical programme and improved coordination among relevant executive branch agencies and between the United States and foreign governments and international organizations;
- (2) provide increased resources for multilateral efforts to fight HIV/AIDS;
- (3) provide increased resources for United States bilateral efforts, particularly for technical assistance and training, to combat HIV/AIDS, tuberculosis, and malaria;
- (4) encourage the expansion of private sector efforts and expanding public-private sector partnerships to combat HIV/AIDS; and
- (5) intensify efforts to support the development of vaccines and treatment for HIV/AIDS, tuberculosis and malaria.

This resulted in the development of the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003 to treat those infected with HIV/AIDS in countries facing the AIDS epidemic.

UNITAID is another global health initiative financed by a solidarity levy on airline tickets. Established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, it provides sustainable funding to provide medicines, diagnostics and prevention treatment for HIV/AIDS, malaria and tuberculosis in developing countries. This uses innovative financing to transform markets for products to test, treat and prevent HIV/AIDS, malaria and tuberculosis in less developed countries. Using resources from a levy on air tickets and long-term government contributions, UNITAID

invests in high-impact market interventions to make health products more affordable, readily available and better adapted for low-income populations.<sup>36</sup> UNITAID financed the Medicines Patent Pool in 2010 to promote licence agreements to expand access to affordable HIV medicines in developing countries.<sup>37</sup>

Patent landscapes can provide policy choices for strategic research planning and technology transfer. They may also be used to analyse the validity of patents, based on data about their legal status and form the basis of a freedom-to-operate analysis.<sup>38</sup>

## 8. New research and development models

WHO set up an independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH).<sup>39</sup> This report of 2006 made important observations on the status of innovation, IP and the pharmaceutical industry. These include promoting access to new and existing medicines and developing new diagnostics and vaccines to treat diseases that disproportionately affect developing countries. Based on recommendations of CIPRH, the Sixty-first World Health Assembly established an intergovernmental working group that developed the Global strategy and plan of action on public health, innovation and intellectual property (GSPA) in 2008.

GSPA outlined 108 specific actions across eight elements and 25 sub-elements. These elements are:

- (1) prioritization of research and development needs;
- (2) promotion of research and development;
- (3) building and improvement of innovative capacity;
- (4) transfer of technology;
- (5) application and management of intellectual property to contribute to innovation and promote public health;
- (6) improvement of delivery and access;
- (7) promotion of sustainable financing mechanisms; and
- (8) establishment and monitoring of reporting systems.

As a result of active community and civil society engagement, new research partnerships, such as the Drugs for Neglected Diseases Initiative (DNDi) of 2003, emerged. DNDi was created with the collaboration of Médecins Sans Frontières (MSF), Pasteur Institute, Oswaldo Cruz Foundation of Brazil, Indian Council of Medical Research, Kenyan Medical Research Institute, and the Ministry of Health of Malaysia. DNDi addresses R&D gaps and develops new treatments for neglected diseases such as leishmaniasis, sleeping sickness (human African trypanosomiasis, or HAT), Chagas disease, malaria, paediatric HIV and specific helminth infections.

A DNDi and MSF study reveals that from 1975 to 1999, of the 1393 new drugs brought into the market globally, only 16 (or 1.1%) were for tropical diseases including malaria and tuberculosis. This despite the fact that these diseases represented 12% of the global disease burden. During this same period, 179 (12.8%) new drugs were developed for cardiovascular disease, which represented 11% of the global disease burden. Government and not-for-profit/philanthropic funding for R&D for neglected diseases totalled only about US\$ 100 million.

Studies in 2012 showed that of the 756 new drugs approved between 2000 and 2011, 29 (3.8%) were indicated for neglected diseases, though their global burden is 10.5%. Of these, only four were new chemical entities (NCE), three of which were for malaria, and none for TB or neglected tropical diseases (NTD).<sup>40</sup> The study recognizes that the WHO Prequalification Programme, while not explicitly designed as an R&D enabling mechanism, has played a major role in facilitating regulatory approval of medicines in developing countries, thereby increasing access – including to adapted formulations for paediatric HIV drugs and fixed-dose combinations – for patients most in need. There is a clear need to closely monitor and assess these new mechanisms with regard to their impact both on innovation and access

Besides this, a number of new partnerships in public health have emerged in recent years that focus on specific programmes, such as the Program for Appropriate Technology in Health (PATH), International AIDS Vaccine Initiative (IAVI), Medicines for Malaria Venture, Malaria Vaccine Initiative (MVI), Global Alliance for TB Drug Development (TB Alliance), Aeras Global TB Vaccine Foundation (Aeras), International Partnership for Microbicides (IPM), Pediatric Dengue Vaccine Initiative (PDVI), Foundation for Innovative New Diagnostics (FIND) and Institute for One World Health (IOWH).

Additionally, a new initiative was announced on 3 April 2014 by the USPTO. This initiative, the Patents for Humanity Program, was launched to incentivize further research on humanitarian technologies. Applications are to be accepted in five categories: (i) medicine, (ii) nutrition, (iii) sanitation, (iv) household energy, and (v) living standards.<sup>41</sup> This was based on the 2013 Patents for Humanity pilot. The award winners had pioneered innovative business models to deliver much-needed HIV medicine, create more nutritious food products for the poor, and generate solar energy for off-grid villages, among others.<sup>42</sup>

The genesis of these recent new initiatives to promote public health was in no small measure the early HIV/AIDS prevention efforts that promoted access to medicines with the help of concerted advocacy and civil and community participation.



## 9. New models of cooperation

The pharmaceutical industry is also more responsive than before, and is developing new cooperation models. As reported in the WHO Global Partners' Meeting on Hepatitis in Geneva (27–28 March 2014), Gilead has offered to supply its newest treatment for the hepatitis C virus (HCV) to Egypt at 99% discount on the US price. In Egypt, the hepatitis C drug will now cost the equivalent of US\$ 900 for a 12-week treatment course, which is a fraction of US\$ 84 000 that is the cost for the same treatment in the US. The company's offer will supply sovaldi to Egypt, that has the highest prevalence rate of hepatitis C in the world.

Gilead says it also plans to license its new therapy to Indian generic manufacturers, which will then supply lower-cost versions of the drug to India. The company's two-pricing moves were made in order to help narrow the access gap for hepatitis C drugs among the world's poorer nations.<sup>43</sup> This opens up scope for development of new models of cooperation between "Big Pharma" (the originator drug companies) and generic pharmaceutical companies. This also leads to an acceptance and development of differential pricing models, i.e. pricing the drugs differently for developed and developing countries.

## 10. Conclusions: Array of options for promoting access to medicines

The goal of achieving access to affordable medicines for HIV/AIDS and hepatitis has contributed to exploring hitherto unknown mechanisms for securing the public health needs for all populations. These new mechanisms came from community and civil society advocacy that led to affordable medicines for HIV/AIDS. This has a similar potential for other communicable such as with the hepatitis C drug, as well as noncommunicable diseases such as for treatment of cancer.

The advent of the TRIPS Agreement of WTO led to harmonization of patent laws across the globe. However, the Council for Trade-Related Aspects of Intellectual Property Rights has provided for “Extension of the Transition Period under Article 66.1 for Least Developed Country Members by their decision of 11 June 2013 until 1 July 2021”, which is a waiver from TRIPS obligations for these countries.

The HIV/AIDS epidemic in South Africa led to the development of Para 6 of the Doha Declaration that emphasized the importance of using TRIPS flexibilities for public health purposes, and at the same time developing a new mechanism for the supply of affordable medicines. This Doha Declaration Paragraph 6 mechanism took a long time to implement in the Rwanda case. As a result the TRIPS flexibilities, particularly compulsory licensing, became the favoured option for securing affordable ARVs by developing countries.

The global response also included the development of certain legal covenants in countries such as the United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act, leading to PEPFAR that aimed to strengthen the effectiveness of the HIV/AIDS response.

Since intellectual property rights, including patents, are territorial in their application, a number of countries such as India defined a higher threshold of

patentability in their patent law so as to secure access to affordable generics. This may be done through local production or obtaining low-cost generics from supplier countries.

However, in the almost 20 years since the 1995 TRIPS Agreement in WTO, the legal landscape has evolved in patent laws in developed countries as well. The United States through the America Invents Act, 2013 has revised the patentability criteria and subjected the USPTO to greater public scrutiny in the grant of patents. Furthermore, court decisions in these countries have limited the scope of patents in certain cases.

Active government and community and civil society partnership was promoted through new research collaborations such as the Drugs for Neglected Diseases Initiative. This also resulted in the WHO response of setting up the Commission on Intellectual Property Rights, Innovation and Public Health to examine these issues and the resultant global strategy and plan of action. The WHO Prequalification Programme has also played a major role in facilitating regulatory approval of medicines in developing countries and increasing access.

At the same time, since 2006, UNITAID used innovative financing to transform markets for products to test, treat and prevent HIV/AIDS, malaria and tuberculosis in developing countries. Its Medicines Patent Pool promotes sub-licensing and product development of relevant patents for HIV/AIDS.

Other new and innovative initiatives down the line have encouraged the pharmaceutical industry to be more responsive than before, as evidenced in the Gilead-Egypt agreement for supply of hepatitis C drugs at hugely affordable costs.

Evolving trends in domestic legislation and recent legal pronouncements in developed countries open the field wider for newer options for affordable medicines for HIV/AIDS and other diseases.

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experimental use exception does not apply when the use is for commercial purpose. Since Bolar intended to sell its generic product in competition with Roche immediately after Roche's patent expired, the exception does not apply. The CAFC also held that the policy issue whether the public policy favoring the availability of generic drug immediately after patent expiration justifies Bolar's use should be decided by Congress, rather than by court. Shortly after the case, the U.S. Congress did pass the law, the Hatch-Waxman Act, to allow use of patented products in experiments for the purpose of obtaining FDA approval. The law was codified as Section 171(e)(1) of the Patent Act. It reads, "[i]t shall not be an act of infringement to make, use, offer to sell within the United States or import into the U.S. a patented invention ... solely for uses related to the development and submission under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological product."

In 1984, the U.S. Congress passed the Drug Price Competition and Patent Term Restoration or Hatch-Waxman Act to give generic companies considerable leverage in drug market competition and patent litigation by creating a "Bolar exception," which we will discuss later. As a balance, the Act also grants patent holders a period of additional market exclusivity by restoring the time lost during the regulatory approval. Specifically, it grants an extension up to five years, but the total patent term (including the restoration period) following FDA approval cannot be longer than 14 years. So when the regulatory review period for a new drug is five years, a five-year restoration period may be granted. However, if the remaining term of a patent is 10 years, only a four-year restoration period is allowed even if the review period is five years.

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This publication was prepared for Twenty-third Meeting of the National AIDS Programme Managers held in New Delhi, India, from 1 to 4 July 2014. The meeting focused on measures needed to further strengthen the health sector response to HIV/AIDS in the South East Asia Region. The successful pursuit of science to win against HIV infection has resulted in a vision of the end of AIDS. As antiretroviral treatment (ART) is scaled up, more people start ART earlier and for prolonged periods of time the consequences of drug resistance to HIV, costly second- and third- line treatments, increased health-care costs, and need for developing newer drugs are important issues.

Intellectual property (IP), in particular patents, have been at the centre of the debate on access to affordable medicines for HIV/AIDS. This publication traces IP developments from the inception of the South Africa HIV/AIDS crisis leading to adoption of Doha Declaration for Public Health in WTO in 2001 and the Doha Declaration Para 6 Waiver . The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) flexibilities including compulsory licensing and voluntary licensing options have been examined. Further, present legal landscape changes and challenges including new research and development models are discussed. A number of options for Member States for promoting access to medicines are described. A number of measures are suggested for achieving the goal of access to affordable medicines for HIV/AIDS and hepatitis and for securing the public health needs for all populations beyond 2015.

Access to affordable medicines for HIV/AIDS is linked to intellectual property rights, in particular patents. The lessons from the engagement for generic anti- retroviral drugs holds true for many medical products.



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