

Using TRIPS flexibilities | POLICY BRIEF to improve access to HIV treatment

Introduction

The right of every human being to access the highest attainable standards of health is now fully recognized by numerous national constitutions and legally binding international human rights treaties. Access to essential medicines is now established as a part of the right to health.¹ In the context of HIV, this includes access to antiretroviral drugs and other medicines essential for HIV care, including medicines for the treatment of opportunistic infections such as tuberculosis.

This paper reviews how countries can successfully use the flexibilities of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to increase access to HIV treatment. The Millennium Declaration set in 2001 the goal to achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it (Goal 6, Target 2). This was reaffirmed in the Political Declaration on HIV/AIDS highlighting the flexibilities of the TRIPS Agreement to improve access to treatment.² The World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property urges governments to “consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003” (WHO 2008b).

Context

Antiretroviral therapy significantly reduces morbidity and mortality among people living with HIV (Braitstein et al. 2006). As of December 2009, an estimated 5.2 million people living with HIV in low- and middle-income countries were receiving antiretroviral therapy, a 12-fold increase since 2003 (WHO 2010a). The new 2010 WHO HIV treatment guidelines for adults and adolescents recommend starting HIV treatment at a CD4 count of 350 cells/mm to reduce HIV-related mortality and to prevent opportunistic infections such as tuberculosis (WHO 2009). This change has increased the number of people estimated to be in need of antiretroviral therapy at the end of 2009, from 10.1 million to nearly 15 million (WHO 2010)³. The situation is even more urgent among children living with HIV: in December 2009, it was estimated that only 355 000 children under the age of 15 years living with HIV were receiving antiretroviral therapy (WHO 2010b). Despite progress, nearly 10 million of the estimated 15 million people needing antiretroviral therapy are without access to treatment, making it absolutely critical to accelerate programme delivery to reach universal access goals (WHO et al. 2010)⁴. In July 2010, UNAIDS and WHO launched the Treatment 2.0 platform, which aims to accelerate access to more effective and less toxic drug combinations and diagnostics and to start antiretroviral therapy earlier. Treatment 2.0 acknowledges the positive consequences of

1 See Universal Declaration of Human Rights: <http://www.un.org/en/documents/udhr/>. Article 25 provides that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”

See also the International Covenant on Economic, Social and Cultural Rights, Article 12. For a detailed interpretation, see *The right to the highest attainable standard of health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*. General Comment No. 14, E/C12/2000/4. Geneva, UN Committee on Economic, Social and Cultural Rights, 2000. <http://www2.ohchr.org/english/bodies/cescr/comments.htm>.

2 *Political declaration on HIV/AIDS*. General Assembly Resolution 60/262, Article 20. Geneva, UNAIDS, 2006. http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf.

3 World Health Organisation (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Children Fund (UNICEF), “Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report 2010,” Geneva, Switzerland, World Health Organisation, <http://www.who.int/hiv/pub/2010progressreport/en/index/html>.

4 Since 2002 the expanded provision of antiretroviral therapy in low- and middle-income countries has resulted in an estimated gain of 3.2 million life-years in people living with HIV.

treatment on reduced HIV transmission and aims to remove cost as a barrier to treatment (UNAIDS 2010). In the past decade, the annual price of first-line antiretroviral drugs has tremendously decreased from over US \$ 10 000 per person in 2000 to less than US \$ 116 for the cheapest WHO-recommended first-line antiretroviral regimen in the first quarter of 2010, a reduction of nearly 99%.⁵

Information on the prices of antiretroviral drugs from the WHO Global Price Reporting Mechanism shows that the prices of most first-line regimens decreased by up to 40% between 2006 and 2008⁶ and by up to 60% between 2008 and March 2010 (WHO et al. 2010). Although these reductions have contributed greatly to the wider availability of treatment, prices have remained high in most middle- and low-income countries in Europe, Asia and Latin America. The average price paid for second-line regimens continues to be high in both low- and middle-income countries in all regions (WHO et al. 2010; Waning et al. 2010).

Prices are influenced by a variety of factors – but whatever the reason, cost remains one of the barriers to increasing access to treatment and care services. The 2006 Political Declaration on HIV/AIDS commits United Nations Member States to “finding solutions to overcome barriers in pricing, tariffs and trade agreements, and to making improvements to legislation, regulatory policy, procurement and supply chain management in order to accelerate and intensify access to affordable and quality HIV/AIDS prevention products, diagnostics, medicines and treatment commodities.”⁷ One of these factors in the context of trade agreements relates to the potential impact of intellectual property rights on public health and the use of the flexibilities contained in the TRIPS Agreement and reaffirmed in the Doha Declaration on the

TRIPS Agreement and Public Health (Doha Declaration).

The Doha Declaration categorically states 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.”⁸

What is TRIPS and why does it matter?

In January 1995, when WTO was created, the TRIPS Agreement, building on the existing multilateral treaties administered by the World Intellectual Property Organization (WIPO), introduced minimum standards for protecting and enforcing intellectual property rights to an extent previously unseen at the global level, including new monitoring and dispute settlement mechanisms. Article 27.1 of the Agreement requires WTO Members to make patents “available for any inventions, whether products or processes, in all fields of technology”, which includes patents for pharmaceutical processes and products. The minimum term of protection that a country must make available under the TRIPS Agreement is 20 years from the filing date of a patent application. In 1986, at the start of the Uruguay Round, the eighth round of multilateral trade negotiations, countries were free to determine the duration of patents; about 50 countries did not grant patent protection for pharmaceutical products at all, while some also excluded pharmaceutical processes (UNCTAD & ICTSD). When TRIPS was introduced in 1994, it reduced the discretionary powers of WTO Members to customize key elements of their national intellectual property regimes.

5 See WHO global price reporting mechanism report, May 2010, at <http://www.who.int/hiv/amds/en/>.

6 See WHO global price reporting mechanism report, May 2010, at <http://www.who.int/hiv/amds/en/>.

7 Political declaration on HIV/AIDS. General Assembly Resolution 60/262, Article 20. Paragraph 42. Geneva, UNAIDS, 2006. http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf.

8 *Doha Declaration on the TRIPS Agreement and Public Health*. Paragraph 4. WTO document WT/MIN(01)/DEC/W/2. Geneva, World Trade Organization, 2001. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

The Declaration was adopted at the Fourth Session of the WTO Ministerial Conference in Doha, Qatar, on 14 November 2001.

Although intellectual property rights are an important incentive for the development of new health-care products, their protection and enforcement should balance the interests of the holder of the property rights and the interests of the consumer. Article 7 of the TRIPS Agreement states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

Even though the TRIPS Agreement marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important policy options,

flexibilities and safeguards, including the liberty to:

- determine the grounds for issuing compulsory licences (see Box 1) and for when to order government use;
- allow for various forms of parallel imports (see Box 1);
- apply general exceptions, such as early working for regulatory approval of generic pharmaceutical and agricultural chemical products (Bolar provisions; see Box 1) or experimental use exceptions;
- make use of transition periods for developing countries and a longer, extendible transition period for least developed countries in particular (see Box 1).

In addition, certain key terms relating to TRIPS obligations are not defined in the Agreement

Box 1: Important TRIPS Flexibilities

Compulsory licences: These are mechanisms used by public authorities to authorize use of a patent-protected invention by the government or third parties without the consent of the patent-holder. Patent-holders are to receive adequate compensation, usually in the form of a royalty. As clarified by the Doha Declaration, WTO Members are free to determine the grounds upon which compulsory licences may be granted. Practice shows that they may be issued on various grounds of general interest, such as public health, and are a common feature of patent law in both developed and developing countries. A government use order is a specific type of compulsory licence usually issued in the form of an order by a competent administrative or judicial authority, authorizing a government or a party acting on behalf of the government to exploit a patent provided that such exploitation is in the interests of the country in question.

Parallel imports: Companies often charge lower prices for a medicine in one country than in another, taking into account a range of market factors. This means that a country with limited resources can sometimes afford more of a patented medicine by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price. Many countries’ patent laws determine that once a patent owner sells its goods in any country, it has no right to control the resale of those goods (so-called “regime of international exhaustion”). In legal terms, the patent owner has “exhausted” its property rights in the product actually sold – it maintains the exclusive right to manufacture the product, but it cannot use its intellectual property rights to prevent resale of those units it sells. An intermediary could thus buy a patented medicine in one country at the lower price set by the company and then resell the medicine in another country at a price that is higher but still undercuts what the manufacturer is charging for its patented medicine in that country. This is called “parallel importing”.

Bolar provision/regular exception: This permits the use of a patented invention without authorization from the patent owner in order to obtain marketing approval of a generic product before the patent expires. This allows a generic product to enter the market more quickly after patent expiry, which in turn facilitates access to cheaper medicines.

Exemptions for least developed countries: In November 2005, before the WTO Hong Kong Ministerial Conference, the WTO TRIPS Council extended the transition period for least developed countries from mandatory compliance with the TRIPS Agreement other than the provisions providing for non-discriminatory treatment, until July 2013. With specific reference to pharmaceutical products, Paragraph 7 of the Doha Declaration, as implemented by a TRIPS Council Decision of June 2002, exempts least developed countries from having to grant patents and from providing for the protection of undisclosed information until 1 January 2016. These transition periods are subject to further extension upon duly motivated request, Article 66.1 TRIPS Agreement.

itself, including such essential patent law concepts as “invention”, “new/novel” and “involve an inventive step/non-obvious”, which leaves considerable discretion to WTO Members as to how to apply the three criteria of patentability – novelty, inventive step and industrial applicability – within their national laws. The use of these policy options and other flexibilities can directly or indirectly help to increase the supply and availability of necessary medicines. This should enable low- and middle-income countries to achieve a balance between intellectual property protection and specific developmental priorities, including the attainment of national public health objectives.

Although these flexibilities could be used by developing countries and least developed countries to facilitate access by reducing medicine prices, a political consensus about the right of these countries to use these flexibilities to protect public health was not articulated until the 2001 Doha Declaration. In addition to other provisions clarifying the nature of TRIPS flexibilities, the Doha Declaration extended the transition period for least developed countries to implement protection of patents and undisclosed information and their enforcement for pharmaceutical products until January 2016. These transition periods are subject to further extension upon duly motivated request, Article 66.1 TRIPS Agreement.

Although the importance of the Doha Declaration cannot be overstated, it left one issue unresolved: the application of Article 31(f) of TRIPS, which requires that countries issuing compulsory licences for the local manufacture of antiretroviral drugs do so only if the medicines are to be used predominantly in their domestic markets. This restriction potentially constrained the production of antiretroviral drugs under compulsory licences specifically for export. In turn, it meant that countries with no or insufficient manufacturing capacity could

not effectively use compulsory licensing as a source of affordable medicines. This obstacle was addressed by the 30 August 2003 WTO General Council Decision,⁹ which authorises WTO Members to grant compulsory licences for the production and export of generic medicines to developing countries and least developed countries with insufficient or no manufacturing capacity in the pharmaceutical sector. This so-called “Paragraph 6 solution” was formalized as an amendment to the TRIPS Agreement in 2005. However, whether this decision solves the problem, given the scope and procedural requirements, is currently the subject of a controversial debate in the WTO TRIPS Council.

The importance of competition

The increased availability of sources for generic medicines has drastically reduced the annual price of first-line antiretroviral drugs from over US \$10 000 per person in 2000 to less than US \$116 for the cheapest WHO-recommended first-line antiretroviral regimen in the first quarter of 2010, a reduction of nearly 99%.¹⁰ For the first-line stavudine-containing regimens – mostly used by low- and middle-income countries until 2009 – the procurement price dropped to between US \$64 and US \$122. These regimens were removed from the WHO recommendations in late 2009 and were replaced by new and improved first-line regimens that are more durable, efficacious and tolerable. However, not all patients will remain on first-line antiretroviral therapy. Some people living with HIV will need to switch to second-line therapy, which includes protease inhibitors that are currently still more expensive than first-line drugs. Despite these substantial price reductions, prices of first-line regimens that include zidovudine or tenofovir and of second-line regimens are still too high for many least developed countries, representing major challenges for antiretroviral therapy programmes.

9 WTO General Council Decision of 30 August 2003, WT/L/540 and Corr. 1, 1 September 2003.

10 See WHO global price reporting mechanism report, May 2010, at <http://www.who.int/hiv/amds/en/>.

In low-income countries the annual price per person for first-line regimens ranges from US \$136 to US \$243, and in lower-middle-income countries the price ranges from US \$116 to US \$667. For second-line regimens, the annual price per person ranges from US \$572 to US \$803 in low-income countries and from US \$818 to US \$1545 in lower-middle-income countries. In upper-middle-income countries, annual prices of first-line regimens range from US \$161 to US \$1033 and second-line regimens range from US \$3393 to US \$3647.¹¹

India is particularly important for the production of generic medicines, as it has a strong generic drug manufacturing sector and produces a high percentage of the medicines currently used for HIV treatment in low- and middle-income countries. For instance, in 2006 India supplied 70% of generic antiretroviral drugs, while South Africa supplied 7%, the United Kingdom supplied 6% and the United States of America supplied 4% (Chaudhuri 2008).

TRIPS flexibilities continue to be important, including for first-line antiretroviral drugs that are still under patent protection. The revision of WHO treatment guidelines in November 2009 will increase the number of people needing treatment, which could lead to serious financial constraints. Another result of the recent revision of the treatment guidelines is the recommendation to substitute stavudine with the less toxic tenofovir or zidovudine in first-line regimens, but first-line regimens that include tenofovir cost up to three times more than stavudine-based regimens. This, coupled with the need for second- and now third-line regimens, makes it even more important for countries to take all available measures to reduce prices and increase treatment access, including the incorporation of TRIPS flexibilities into domestic legislation and the use of these flexibilities where necessary and feasible.

The challenge of maintaining patients on treatment has been exacerbated by the global economic crisis, which is expected to decrease donor funding for HIV and to put current treatment programmes under increased strain because of reduced budgets and competing priorities. Lower prices are essential if governments and donor agencies are to meet commitments to keep patients on lifelong antiretroviral therapy while ensuring the sustainability of treatment programmes as the number of people in need of treatment increases.

Although this paper focuses on TRIPS flexibilities, it is important that countries explore all mechanisms available to reduce the prices of drugs, including using market information to negotiate lower prices with pharmaceutical companies, reducing import tariffs and taxes, and increasing economies of scale and bargaining power through joint procurement and price negotiations. For example, in 2002 the Organisation of Eastern Caribbean States¹² saved approximately 44% through joint procurement compared with the prices that individual countries paid (Kerry & Lee 2007).

Use of TRIPS flexibilities: selected examples and challenges

There are several instances in which the use of TRIPS flexibilities has led to reduced prices of drugs. Civil society has played a key role in raising public awareness of the implications of the current patent system and the TRIPS Agreement for access to HIV medicines. In some instances, such as seen recently in India, civil society organizations have catalysed the process by challenging specific patents.

Competition law in South Africa

The TRIPS Agreement recognizes that the protection of intellectual property and competition policy need to work harmoniously,

11 See WHO global price reporting mechanism report, May 2010, at <http://www.who.int/hiv/amds/en/>. See also *Untangling the web of antiretroviral price reductions*. Geneva, Médecins sans Frontières. <http://utw.msfaaccess.org/drugs>.

12 The Organisation of Eastern Caribbean States comprises nine countries: Anguilla, Antigua and Barbuda, British Virgin Islands, Dominica, Grenada, Montserrat, Saint Kitts and Nevis, Saint Lucia, and Saint Vincent and the Grenadines. Their combined population amounts to a total of approximately 550 000.

and this is an important component of the policy balance articulated in the Agreement. In South Africa, treatment activists successfully used competition law to increase the number of antiretroviral drug suppliers, resulting in increased competition and a lowering of essential medicine prices (Avafia et al. 2006). In a recent court case, the Competition Commission of South Africa found two pharmaceutical companies guilty of excessive pricing and referred the matter to the Competition Tribunal for ruling. Before a decision was rendered by the Competition Tribunal, both companies entered into a number of agreements with the Commission and the complainants, which allowed for the increased supply of more affordable generic versions of antiretroviral drugs still under patent in the country.¹³

Use of the "30 August 2003" mechanism by Rwanda

In 2006 the Government of Rwanda passed a law requiring generic medicines to be used for all treatment programmes when available (Open Society Institute, Access to Medicines Initiative, 2008). In July 2007 Rwanda became the first country to announce its intention to use the WTO 30 August 2003 decision to import a generic fixed-dose combination of zidovudine, lamivudine and nevirapine from a Canadian generic manufacturing company. The compulsory licence issued under the Canadian Access to Medicines Regime authorized the delivery of enough of this fixed-dose combination for 1 year's treatment of approximately 21 000 people living with HIV at the most affordable price globally of US \$0.19 per tablet. To date, Rwanda is the only country to have used this flexibility. The practicability and usefulness of the WTO 30 August 2003 decision as a long-term solution to increasing access to patented medicines is currently the subject of debate in the WTO TRIPS Council.

Price negotiations and compulsory licences in Brazil

The Government of Brazil demonstrated that legislation that provides for the effective and expeditious use of public health-related flexibilities can be a useful asset in negotiating lower prices for antiretroviral drugs (Abbott & Reichman 2007). Using the threat of compulsory licensing, the Brazilian Government negotiated significant price reductions of efavirenz and nelfinavir in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006. In 2007, after protracted negotiations, a compulsory licence was issued for efavirenz, an important antiretroviral drug used by a third of Brazilians on treatment through the national programme. After the licence was issued, the price dropped from US \$1.60 per dose to US \$0.45 per dose for the imported generic version of the drug. It is estimated that the Brazilian Government's policies, including the use of TRIPS flexibilities, saved approximately US \$1.2 billion on antiretroviral drug purchasing costs between 2001 and 2005 (Nunn et al. 2007).

Use of compulsory licences in Thailand

In late 2006 and early 2007 Thailand issued compulsory licences for a number of pharmaceutical products (see Box 2): efavirenz, lopinavir/ritonavir and clopidogrel (a drug used for heart disease). This decision prompted widespread protests from multinational drug companies, but by early 2008 the number of patients using lopinavir/ritonavir had tripled. In early 2008 the Thai Government issued additional compulsory licences for letrozole (a breast cancer drug), docetaxel (a breast and lung cancer drug) and erlotinib (a drug used for treating lung, pancreatic and ovarian cancer).

¹³ See *Fact sheet on settlement agreements*. Cape Town, Treatment Action Campaign, 2003. http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm.

Box 2: Dr Mongkol na Songkla, Minister of Public Health, Thailand, 2006–2008

“Essential drugs are humanitarian products and must be made universally accessible to everyone who needs them. We, of course, also need innovation to develop new pharmaceutical products, and someone has to pay the cost of research and development for new essential drugs.

When a government such as ours declares a “compulsory licence” to allow for public non-commercial use of patented products by the government for the greater public good, we are doing so to increase access to these essential, often life-saving, medications for the poor and marginalized members of our communities who were not consumers of these expensive, patented drugs. The more well-off members of our society continue to consult their own private physicians and continue to pay – out of their own pockets – the price of patented medications.

Thus, both the patent and compulsory licence for the same product can exist harmoniously side by side in a country such as Thailand, with maximum benefits for all. Those who have the capacity to pay the high market prices of patented medications – often through private medical facilities – continue to do so, and help to subsidize further pharmaceutical research and development costs through these prices. At the same time, action in the public interest through the governmental use of compulsory licensing allows poor and marginalized groups in our society to access and benefit from essential patented drugs that they would never otherwise be able to access or use. There does not need to be conflict in such a case; it can and should be a win-win situation for all.”

Patentability criteria in India

When revising its patent law to comply with TRIPS requirements that pharmaceutical products should be patentable, India adopted patentability criteria by introducing Section 3d to its Patent Act (Patents Amendment Act of 2005), according to which “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” is not considered an invention and is thus not patentable under the Indian Patents Act.¹⁴

In 2007 the Indian Patent Office, following an opposition filed by a patient organization, relied on this section in its refusal to grant a pharmaceutical company a patent for the cancer drug imatinib mesylate. The patent office considered the beta-crystalline form of imatinib mesylate to be a new form of a known substance without the enhancement in efficacy required under Section 3d and thus rejected the patent application under India’s revised Patent Act.¹⁵ The company filed two lawsuits. In one lawsuit the company challenged the decision of the Patent Office, claiming that imatinib mesylate fulfils the patentability requirements under the Indian Patent Act as it enhances the efficacy of a known substance. In a second lawsuit the company claimed that Section 3d does not comply with the TRIPS Agreement and violated the Indian Constitution. On 6 August 2007 the High Court in Madras rejected the constitutional challenge, decided that it was not the forum to address questions on compliance with the TRIPS Agreement, and upheld the validity of India’s 2005 Patents Amendment Act. On 6 June 2009 the Intellectual Property Appellate Board of Chennai rejected the lawsuit against the decision of the Patent Office. This judgment was appealed by the patent applicant and a decision is pending. The decision on whether a new form of a known substance can be patented has major implications for many drugs used in HIV care, now and in the future.

14 Patents Amendment Act 2005. The Indian Patent Act can be found at <http://www.patentoffice.nic.in/ipr/patent/patents.htm>.

15 Decision of the Patent Controller, Chennai, 25 January 2006. <http://www.lawyerscollective.org/hiv-aids/activities/legal-services-access-to-medicines-patents>.

Other countries that have used compulsory licences or government use for the local manufacture or importation of generic medicines in recent years include Indonesia, Malaysia, Mozambique, Zambia and Zimbabwe (Open Society Institute, Access to Medicines Initiative 2008; WHO 2008b; Martin et al. 2007; Ford et al. 2007; Oxfam International 2006; Musungu & Oh 2005).

Overall implementation of TRIPS flexibilities

Despite the opportunities provided by TRIPS flexibilities, many countries have yet to amend their laws to incorporate optimally the flexibilities, which is a precondition for their use. A UNDP study conducted in 2007 found that only six countries had a provision on the international exhaustion of rights in their legislation (UNDP 2007). Findings from a recent study conducted by WIPO within the framework of the implementation of the WIPO Development Agenda showed a diverse picture with regard to the incorporation of TRIPS flexibilities in national patent laws (see Box 3).

“TRIPS plus” provisions in bilateral and regional trade agreements

A number of countries are party to, or are in the process of negotiating, bilateral or regional free trade agreements containing “TRIPS plus”

provisions – that is, levels of intellectual property protection that go beyond the minimum standards required by the TRIPS Agreement. The WHO Global Strategy and Plan of Action urges Member States to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States.” Provisions that have been included in free trade agreements in the past and that may have an impact on public health or may hamper the use of flexibilities include:

- limiting the grounds and conditions under which compulsory licences may be issued;
- providing for the possibility of extensions of terms for individual patents beyond the 20 years required by TRIPS in order to compensate for delays in the patent-granting procedure or in marketing approval processes;
- requiring drug regulatory authorities, most of which have limited expertise in patents, to consider the patent status of medicines before granting marketing authorizations to generic manufacturers;
- requiring test data protection that restricts the use of clinical test data on pharmaceutical products by drug regulatory authorities for the approval of generic medicines for a certain period of time. This prevents generic companies

Box 3: WIPO study on patent-related flexibilities in 142 countries

The first step countries must take to make use of TRIPS flexibilities for public health purposes is to incorporate them into their national legal framework. The WIPO study “Patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels” provides relevant information on the integration of five selected TRIPS flexibilities into the legislation of 142 countries. For example:

- With regard to regulatory review (Bolar) exception, of the 95 countries with available information, only 56% had integrated it into their patent legislation. The percentage of countries integrating this flexibility varied from 0% (0/20) for least developed countries to 93% (25/27) for high-income countries.
- With regard to parallel imports, an analysis of the legislation of 112 countries showed that 29 (26%) have an international exhaustion regime, 36 (32%) have a regional exhaustion regime, thus allowing for parallel imports, and 42 (37.5%) have a national exhaustion regime (WIPO 2010).

from relying on these data for proving the efficacy and safety of their products and thus delays the entry of such drugs on to the market;

- limiting the grounds under which a patent may be revoked;
- requiring countries to loosen the criteria for patentability and to expand the scope of protection by allowing for the patenting of new uses or methods of using a known product;
- allowing patent-holders to restrict parallel imports, which may prevent developing countries from buying medicines from the cheapest global supplier.¹⁶

Public-health-sensitive patent examination

Patents should be of the highest quality and should reward only genuine innovations in order to prevent the so-called “ever-greening” of patents. According to the WHO Commission on Intellectual Property Rights, Innovation and Public Health, “ever-greening occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term” (WHO 2006). Providing for public-health-sensitive patent examination guidelines (Correa 2007) as well as pre- or post-grant opposition procedures can help to prevent the patenting of products and processes that lack innovation.

TRIPS flexibilities: what can be done?

The following actions are in line with the 2006 Political Declaration on HIV/AIDS and with the principles of the Doha Declaration and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Actions for high-income governments

- Countries with manufacturing capacity should consider implementing the “Paragraph 6” or “30 August 2003” mechanism in an administratively efficient and effective manner

in order to facilitate the export of generic medicines to countries without sufficient or any manufacturing capacity.

- High-income governments should ensure that free trade agreements with middle- or low-income countries comply with the principles of the Doha Declaration.
- High-income governments should encourage and facilitate where possible the transfer of technology between the global north and the global south for the production of antiretroviral drugs and other essential health products.¹⁷
- High-income governments should intensify efforts to protect gains in access to antiretroviral drug treatments in low- and middle-income countries and should maintain global commitment and financial resources to reaching universal access goals.

Actions for low- and middle-income governments

- Low- and middle-income governments should consider revising national intellectual property legislation in order to ensure that TRIPS flexibilities specifically geared to promote access to medicines are incorporated into national laws and regulations without delay.
- Parliamentarians should ensure that new trade agreements are not contradictory to the Doha Declaration.
- Least developed countries should consider taking the necessary legislative action, where appropriate, to use the transitional period and not to grant pharmaceutical patents until 2016, as provided for in the Doha Declaration.
- Low- and middle-income governments should encourage regional cooperation to:
 - develop intellectual property and trade policies that promote innovation, consistent with TRIPS, and that allow for the full use of flexibilities in order to promote access to affordable HIV medicines and other medicines essential for HIV care and the treatment of opportunistic infections for all who need them;

¹⁶ See examples provided by Fink & Reichenmiller (2005).

¹⁷ See TRIPS, Article 66.2.

- develop or strengthen the capacity of national regulatory authorities to ensure the quality, safety and efficacy of health products and to fast-track the registration of drugs that are prequalified by WHO;
- invest in regional and national production capacity in the pharmaceutical sector and in the development of local expertise.

Actions for international organizations

- International organizations should support national governments to increase access to treatment by providing technical assistance to implement TRIPS flexibilities in order to promote access to medicines in accordance with their respective mandates. They should address public health concerns in such crosscutting exercises as establishing intellectual property and development strategies, or identifying the needs of countries to implement the TRIPS Agreement.
- International organizations should promote the inclusion of flexibilities into legislation and should advocate for the exclusion of legal provisions that could negatively affect access to essential medicines in middle- and low-income countries.
- International organizations should monitor the development of intellectual property regulations and their impact on public health, including access to first- and second-line antiretroviral drugs.
- International organizations should monitor and participate in the debate on alternative models for stimulating innovation relevant to low- and middle-income country needs.
- International organizations should promote the exploration of all possibilities to reduce the cost of drugs.

Other possible measures

Although this paper focuses on TRIPS flexibilities, it is of course important to explore other mechanisms and measures available to increase access to medicines.

Pharmaceutical manufacturers should consider providing voluntary licences for the manufacture and sale of antiretroviral drugs in order to increase the availability of affordable antiretroviral drug products in low- and middle-income countries, for example through the Medicines Patent Pool.¹⁶

Countries should:

- invest in developing health-delivery infrastructure and encourage improving the financing of health products;
- encourage discussion and collaboration among all relevant government entities and all stakeholders, including civil society actors, with regard to intellectual property and public health issues;
- monitor and participate in the debate on alternative models for stimulating innovation relevant to the needs of low- and middle-income countries;
- develop and implement other mechanisms for reducing the price of medicines, including:
 - pooling procurement for the regional and subregional purchase of antiretroviral drugs and other essential medicines for HIV care and the treatment of opportunistic infections;
 - using relevant pricing information during procurement negotiations with pharmaceutical companies;
 - eliminating taxes and tariffs and controlling mark-ups where appropriate and where consistent with countries' broader strategic trade and industry policy objectives.¹⁷

¹⁶ In December 2009 the UNITAID board approved the establishment of a voluntary patent pool for antiretroviral drugs. A dedicated Medicines Patent Pool Foundation under Swiss law has recently been established. See <http://www.medicinespatentpool.org>.

¹⁷ For further measures, see WHO (2006). See also WHO (2008a).

Conclusion

In light of the above, it is clear that the flexibilities contained in the TRIPS Agreement and reaffirmed by the Doha Declaration provide important opportunities for WTO Members to reduce prices and expand access to HIV medicines. Countries revising their laws should use to the full the flexibilities contained in the TRIPS Agreement. WTO Members should in addition carefully consider

the public health implications when adopting or implementing more extensive intellectual property protection than is required by the TRIPS Agreement. International organizations should advocate for and support their national partners in the use of all these flexibilities and in all other actions consistent with the TRIPS Agreement to promote access to antiretroviral drugs, other HIV medicines and technologies related to HIV treatment.

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