DOHA+10
TRIPS FLEXIBILITIES AND ACCESS TO ANTIRETROVIRAL THERAPY: LESSONS FROM THE PAST, OPPORTUNITIES FOR THE FUTURE

UNAIDS / JC2260E (English original, November 2011)

Photo credits: UNAIDS / P. Virot / D. Walker/AFP

ISBN 978 92 9173 914 1 publications@unaids.org www.unaids.org
UNAIDS 20 avenue Appia CH-1211 Geneva 27 Switzerland T (+41) 22 791 36 66 F (+41) 22 791 48 35

Contents

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
CEWG	Consultative Expert Working Group on R&D: Financing and Coordination
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
DNDi	Drugs for Neglected Diseases Initiative
EAC	East African Community
EPA	Economic Partnership Agreement
EU	European Union
FDC	Fixed-dose Combination
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IP	Intellectual Property
IPRs	Intellectual Property Rights
LDC	Least-Developed Country
MDGs	Millennium Development Goals
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
OAPI	African Intellectual Property Organization
PEPFAR	President's Emergency Plan for AIDS Relief
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	UN Joint Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNGASS	UN General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
USA	United States of America
USTR	United States Trade Representative
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive summary

The transformation of HIV from almost certain death to a chronic condition for many people living with HIV in low- and middle-income countries is a significant public health achievement. By the end of 2010, 6.6 million people in low- and middle-income countries – 47% of the total number eligible – had access to antiretroviral therapy. This represents a dramatic increase from the 300 000 (2.7% of those eligible) on antiretroviral therapy in 2002. This remarkably effective scaling up of access to antiretroviral therapy has been, in large part, due to a drastic fall in antiretroviral drug prices during this period. In 2000, three-drug antiretroviral therapy combinations cost US$ 10 000–15 000 per person, per year. Today the price for a similar regimen is less than US$ 120 per person, per year in many countries; a 99% reduction in cost.

Generic competition in low- and middle-income countries has played a major role in the fall of antiretroviral prices in the past decade. This has enabled individuals, governments and international funding agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the United States President's Emergency Plan for AIDS Relief (PEPFAR), to be able to afford these treatments. Maintaining generic competition became increasingly complex as low- and middle-income countries were impacted by the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which required enforcement of patent protection for pharmaceutical products, including medicines and diagnostics.

While TRIPS did include flexibilities for access to essential medications, there was a lack of consensus over the meaning of, and methods for, utilizing those flexibilities. This hampered early efforts to widen access to antiretroviral therapy in low- and middle-income countries. In this context, the Doha Declaration on the TRIPS Agreement and Public Health, (adopted in November 2001 at the Fourth World Trade Organization (WTO) Ministerial Conference was a major milestone. The Doha Declaration clarified the scope of, and provided interpretive guidance for, the policy flexibilities embodied in the TRIPS Agreement that could be used to ameliorate the impact of patents on access to medicines. It also extended until 2016 the transition period before least-developed countries (LDC) must provide patent protection to pharmaceuticals. Of equal importance was the confirmation provided by the Doha Declaration that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement could be used to improve access to medicines.

In the decade since the adoption of the Doha Declaration, the vision and the clarifications it provided have been pivotal to increasing access to antiretroviral therapy in low- and middle-income countries. The Doha Declaration's impact has been widespread, affecting policy, legislation and procurement decisions considerably.

The Doha Declaration and the Doha-inspired public health decisions of the TRIPS Council include a number of components that have directly increased access to medicines in low- and middle-income countries. A sizeable number of low- and middle-income countries have proactively used TRIPS flexibilities to produce and purchase generic antiretroviral medications. The use of these flexibilities for introducing

generic competition has achieved a reduction in the prices of originator medicines. In addition, the Doha Declaration has also had a positive impact on high-income country intellectual property (IP) policies and access to medicines. Donor countries now permit the use of their funds to procure generic antiretroviral medications for low- and middle-income countries.

UNAIDS has strongly supported the use of TRIPS flexibilities and advocated for countries to make greater use of them in order to help achieve universal access to treatment. Other important international and multilateral institutions, including the United Nations Development Programme (UNDP), the World Health Organization (WHO), the WTO and the Global Fund, have adopted clear policies supporting the use of TRIPS flexibilities. Various UN agencies and international organizations have significantly increased their technical assistance programmes in support of TRIPS flexibilities. Civil society organizations have relied on the Doha Declaration for their advocacy campaigns and for procuring antiretroviral medications for their treatment programmes. Generic drug companies have increased their investments in antiretroviral production, including production of fixed-dose combinations. In addition, originator pharmaceutical companies have tempered their prior opposition to the use of TRIPS flexibilities.

The global community has good reason to be proud of the impact that the first decade of the Doha Declaration has had on access to antiretroviral therapy and other medicines but there is much more to do in the second decade. With only 47% of people eligible for treatment currently receiving antiretroviral therapy, the reiteration of commitments to achieving universal access in the June 2011 United Nations Political Declaration on HIV/AIDS will require the continued use and possible expansion of TRIPS flexibilities.

Action will also be needed to tackle a range of emerging challenges. One is the sustainability of generic production during a period of threats to HIV treatment budgets. The patent status for newer antiretroviral medications in countries such as India that are major generic antiretroviral suppliers also needs to be carefully monitored. It is critical that all available flexibilities are used by countries affected by HIV in order to encourage generic manufacturers to remain in the market. Bilateral and regional trade agreements are another area of concern, and IP enforcement initiatives may also raise barriers to access. Of equal importance is the need to enact key Doha-inspired decisions, such as 2002 plan that facilitates compulsory licensing by countries with insufficient or no manufacturing capacity in the pharmaceutical sector. So far only one country has utilized that system, raising concerns about its practical use. All concerned stakeholders need to convene and address its shortcomings.

The continued use of TRIPS flexibilities remains as critical today as it was in 2001 when the Doha Declaration was adopted. We cannot afford to be complacent. Determined efforts to use these flexibilities in the face of challenges, as well as taking innovative approaches to support the use of TRIPS flexibilities, including the Medicines Patent Pool, south-south cooperation initiatives and patent transparency initiatives, will provide options for maintaining and expanding the gains that the global community has made in equitable access to HIV treatment.

1. Introduction

The UN Millennium Summit in 2000 was a turning point in the provision of HIV treatment and care. The Millennium Declaration that emerged from it recognized the need for the global community to comprehensively tackle the HIV epidemic by expanding prevention, treatment and care.[1] World leaders committed to halt the expansion and begin to reverse by 2015 the spread of HIV, malaria and other major diseases. The leaders also committed to providing special assistance to children orphaned by HIV. Millennium Development Goal 6 made combating HIV central to the Millennium Development Goals (MDGs),[2] with target 6.B setting 2010 as the year by which universal access to HIV treatment should be achieved. In addition, under MDG 8, target 8.E commits the global community to providing access to affordable essential drugs in developing countries.

In 2001, the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) built on the momentum generated by the adoption of the MDGs. In the Declaration of Commitment on HIV/AIDS, adopted at UNGASS, participants unequivocally recognized that care, support and treatment were fundamental elements of an effective response.[3] The Declaration called for national strategies able to address factors affecting the provision of HIV-related drugs, such as affordability and pricing.

While the Millennium Declaration and UNGASS, along with international and national efforts including the work of UNAIDS[4] and the Médecins Sans Frontières (MSF) Access to Medicines campaign,[5] succeeded in placing treatment for HIV on the global health agenda, the situation in low- and middle-income countries remained dire. Although the technology and in some cases the capacity to make low-cost generic antiretroviral medications existed, originator medicines, costing more than US$ 10 000 per person per year for a full regimen, dominated the marketplace. As a consequence, antiretroviral therapy was only really available and affordable to people living with HIV in high-income countries. For people living with HIV in low- and middle-income countries, advancing immune suppression was a sign of imminent disability and death. In countries such as India, where some capacity for generic production existed, the challenge was to supply these generics to other developing countries. Patent restrictions in the importing countries, or lack of information regarding the patent status, had raised barriers. In some cases, even where there were no patents, it was erroneously assumed that the TRIPS Agreement somehow created an international patent.

It was in this context that the impact of IP protection (particularly patenting) on the pricing and affordability of antiretroviral therapy became a central issue. The debate focused on whether the IP rules set by the 1994 WTO's TRIPS[6] were restricting access to existing HIV medicines for low- and middle-income countries. The problem became apparent to the global community when 39 pharmaceutical companies sued the South African Government, citing violation of TRIPS[7] for parallel importation and other legislative provisions meant to facilitate access to medicines. In 2001, there was a bitter confrontation between low- and middle-income countries and a broad range of civil society organizations on the one hand, and high-income countries and originator pharmaceutical companies on the other. Low- and middle-income countries and civil society organizations argued that patents on pharmaceuticals used in the developing

world raised prices and thereby reduced access to life-saving treatment. Originator pharmaceutical companies and high-income countries argued that the larger problem in low- and middle-income countries was weak health service infrastructure. Patents, they argued, were needed to ensure innovation.[8]

The Doha Declaration on the TRIPS Agreement and Public Health (hereinafter "the Doha Declaration"), adopted in November 2001 at the Fourth WTO Ministerial Conference in Doha, Qatar, aimed to resolve this dispute. The Doha Declaration clarified the scope and interpretation of the policy flexibilities embodied in the TRIPS Agreement that could be used to improve access to patented medicines.[9] Importantly, the Doha Declaration confirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement could be used to improve access to medicines for all. Access to antiretroviral medications was a key issue in the debate and negotiations leading to the adoption of the Declaration. The HIV treatment access movement also galvanized global public opinion in support of the Doha Declaration.

The purpose of this document, which is the contribution by UNAIDS to the 10th anniversary commemoration of the Doha Declaration, is to evaluate the impact of the use of flexibilities under the WTO-TRIPS Agreement on access to antiretroviral therapy. Using lessons learnt, the possible future uses of TRIPS flexibilities to support universal access to HIV treatment are also analysed. An extensive review of policy documents and literature on the Doha Declaration and the use of TRIPS flexibilities in low- and middle-income countries was performed. This, along with interviews with key informants involved in negotiation of the Declaration, in antiretroviral therapy procurement and in HIV treatment programmes, forms the basis of this study.

This analysis begins with a brief outline of the policy and legal effects the Doha Declaration had on both the TRIPS Agreement and the actions of those involved in HIV treatment. In Chapter 3, the study assesses the impact of the Doha Declaration on the use of TRIPS flexibilities in low- and middle-income countries in different regions. It also uses case studies to examine policy processes and actions by international institutions and other stakeholders. In Chapter 4, the study discusses the opportunities for and the challenges inhibiting the use of TRIPS flexibilities to promote access to antiretroviral therapy in the next decade and beyond.

2. Intellectual property rights, the Doha Declaration and access to antiretroviral therapy

The relationship between patents and access to pharmaceutical products has been a central issue in the debate surrounding IP rights and public policy objectives for many years. It is therefore no surprise that the TRIPS negotiations on pharmaceuticals were so controversial.[10] This is also why a significant number of countries, including key developing countries such as Argentina, Brazil and India, did not grant patents for pharmaceutical products at that time.[11]

High-income countries, such as Canada, Australia and several in the European Union (EU), granted patents to pharmaceutical products, but also had (and continue to have) specially tailored policies to mitigate the negative effects of pharmaceutical patents. These policies include, among others, the regulatory exception in Canada, the price and benefits scheme in Australia, and regional parallel trade within the EU. Canada, several EU countries and the United States of America, also had and continue to use mechanisms, such as compulsory licensing and government use, to deal with public health and other public policy imperatives.[12] For example, between 1969 and 1992 Canada issued 613 compulsory licenses for the importation and local production of medicines.[13] The United Kingdom also used compulsory licensing (commonly referred to as 'crown use' in that country) to facilitate the provision of generic medicines to the National Health Service (NHS).

The TRIPS and public health debate was primarily about two underlying issues. Firstly, should public health considerations condition the manner in which IP rights are implemented? Secondly, should liberal or restrictive interpretations of the provisions of TRIPS be adopted when dealing with public health-related flexibilities? These are both fundamental issues. As the WTO Technical Note on Pharmaceutical Patents and the TRIPS Agreement states:

"Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is not always easy. Doing so at the international level is even more difficult than at the national level. Perhaps nowhere do these issues excite stronger feelings than in regard to pharmaceutical patents, where tension between the need to provide incentives for research and development into new drugs and the need to make existing drugs as available as possible can be acute."[14]

It is in this context that the adoption of the Doha Declaration was hailed a major success in the MSF Access to Medicines campaign.[15] The Declaration was seen as an important milestone in the efforts by low- and middle-income countries and key UN agencies and organizations, such as UNAIDS, UNDP and WHO, as well as civil society organizations to overcome IP-related barriers to access to medicines. The focus of the Declaration on the TRIPS flexibilities was particularly important since it is these flexibilities which guarantee the balance between the exclusive patent rights conferred under Article 28 of TRIPS and the interests of the public, consumers and competitors. Box 1 contains the basic definitions and key public health-related TRIPS flexibilities and their effect on availability and pricing of antiretroviral medications and other medicines.[16]

Box 1: Public health-relevant TRIPS flexibilities

Exhaustion of rights (parallel importation) (Article 6)
Exhaustion of rights under IP theory refers to the point at which the right holder loses legal control over a protected product by virtue of selling or otherwise releasing it into the channels of commerce. The rules on exhaustion determine whether the patent holder can prevent a third party from importing a pharmaceutical product where the patent holder or his licensee may have sold the product into another country where they also have a patent. A number of countries allow such imports, which are commonly known as parallel imports. These rules therefore address what is commonly referred to as parallel importation. In the context of medicines, parallel importation allows procurement agencies and treatment providers or third-party importers to import medicines from other countries where the prices are lower than the prices set in the local market by the patent holder or his licensees.

Patentable subject matter (Article 27)
The three criteria for patentability (novelty, inventive step and industrial application) are not defined under TRIPS. Each member is free to interpret their meanings, which can determine what is patented in the pharmaceutical sector. In addition, governments can refuse to grant patents for three reasons that may relate to public health, including inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2); diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a); and certain plant and animal inventions (Article 27.3b).

The key impact is that countries can ensure that only true inventions are patented, so that far fewer products will be under patent than would otherwise be the case if the patentability criteria were not carefully defined or where the power to refuse patenting in certain cases was not exercised. The impact is that a greater number of medicines can be available in generic forms in a competitive market, which has a positive impact on prices.

Research and experimental use exception (Article 30)
Under this exception, countries allow the use of a patented invention for research in order to understand the invention more fully and for other related purposes. The intent of this exception is to ensure that patents do not prevent scientific research that uses existing knowledge to generate new knowledge. The research exception is important for improving the effectiveness of products or the development of better-adapted formulations. This exception fosters pharmaceutical technological progress and innovation by exempting experimentation acts for purposes such as inventing around the initial invention, improving on the invention or evaluating the invention.

Regulatory (bolar) exception (Article 30)
This exception allows a potential competitor to use an invention to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term without the authorization of the patent holder. This exception is provided to

ensure that generic versions of the product are available on the market immediately, or within a reasonable time, after the expiry of the patent. More rapid introduction of generics into the market leads to more rapid competition and lowering of prices.

Compulsory licensing (Article 31)

A compulsory licence, also referred to as a non-voluntary licence, is a licence granted by an administrative or judicial body to a third party to exploit a patented invention, without the consent of the patent holder. Compulsory licensing is used in public health to address a variety of situations including: high prices of medicines; anti-competitive practices by pharmaceutical companies; failure by pharmaceutical patent holders to sufficiently supply the market with needed medicines; and in emergency public health situations. In practical terms compulsory licensing can be used to bring down the prices of medicines and to ensure a sufficient supply of medicines in the market in cases where the patent holder cannot, or will not, provide sufficient supplies at the right price. It is also a critical tool in emergency situations where the patent holder cannot respond to an urgent situation.

Public, non-commercial use (government use) (Article 31)

The TRIPS Agreement, although not specifically mentioning government use, recognises such use by its references to the concept of public, non-commercial use and of patents "used by or for the government". Where the state or a state agency uses patents without the consent of the patent holder, it is, like compulsory licensing, covered under Article 31. The distinction between government-use provision and compulsory licensing primarily relates to the nature or purpose of the use of the patent. In the case of government use, it is limited to "public, non-commercial purposes", whereas compulsory licences can also cover private and commercial use. As with compulsory licences, government-use orders can be used to bring down the prices of medicines, to ensure a sufficient supply, and address emergency situations.

Scope of pharmaceutical test data protection (Article 39.3)

Article 39.3 of TRIPS provides that members who require, as a condition of approving the marketing of pharmaceutical or other products that utilize new chemical entities, the submission of undisclosed test or other data, must protect such information or data against unfair commercial use if its generation involved considerable effort. In some jurisdictions, particularly the United States and the EU, this provision has been implemented by granting a time-limited exclusivity to the originator company. During this period the regulatory authorities cannot rely on the test data to register generic substitutes (commonly referred to as "data exclusivity"). The TRIPS Agreement does not, however, mandate data exclusivity as the only way to implement the provisions. Other countries allow national health authorities to rely on such test data to register generic substitutes based on bioequivalence, while prohibiting disclosure of the data to generic companies or other third parties.

An approach to test data protection, which allows regulatory authorities to rely on the data but not provide generic companies access to it, has important public health benefits. It ensures that generic producers do not need to conduct trials on compounds that have been proven to be efficacious, thus avoiding the imposition of additional costs that may be passed

on to the consumer. This approach may also be important for preventing unnecessary and unethical tests, such as repeated human trials for each version of the medicine.

Competition law (Article 40)

Under Article 40 of the TRIPS Agreement, it is recognized that licensing practices or conditions pertaining to IP rights that restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. Consequently, the TRIPS Agreement allows WTO members to specify in their legislation the specific licensing practices or conditions that may constitute an abuse of IP and have an adverse effect on competition in the relevant market. They may also adopt appropriate measures to prevent or control such anti-competitive practices. Countries that use this provision appropriately can ensure adequate and healthy competition in the pharmaceutical market, improving pricing and availability of needed products.

Transition periods (Articles 65.2; 65.4; and 66.1)

The TRIPS Agreement provides four transition periods for the implementation of its minimum standards. The first two sets of transition periods, those relating to developed countries and developing countries, lapsed in 1996 and 2000 respectively. The third, which lapsed in 2005, related to those developing countries that did not provide pharmaceutical patents when TRIPS came into force in January 1994. The fourth transitional period, that relating to LDCs, will remain in force for pharmaceutical patents and test data protection until at least 2016. It can be extended further. Hence, until 2016 or later, LDCs have no obligation to provide patent protection to pharmaceuticals, including medicines and diagnostics.

LDCs that take advantage of this transition period can achieve two broad goals. They can obtain medicines at generic prices since there will be no patents in their territories. Second, by not granting patents, LDCs can also foster the development of a generic industry to supply low-cost medicines.

The importance of the Doha Declaration should be judged for what it said and the implications of TRIPS Council decisions that derived from it (hereinafter "the Doha-inspired public health decisions").

The Declaration provided both general and specific interpretive guidance on the use of TRIPS flexibilities for promoting access to antiretroviral medications and other medicines. The key statements and points in the Declaration include the following:

- The TRIPS Agreement needs to be part of the wider national and international action to address public health problems faced by developing countries, especially those resulting from HIV, tuberculosis, malaria and other epidemics.
- While IP protection is important for the development of new medicines, such protection also has effects on medicine prices.
- The TRIPS Agreement does not, and should not, prevent WTO members from taking measures to protect public health and it can and should be interpreted and implemented in a manner supportive of members' rights to protect public health and, in particular, to promote access to medicines for all.

- WTO members remain committed to the TRIPS Agreement and its objectives.
- WTO members have the right to use to the full the provisions in the TRIPS Agreement, which provide flexibility (TRIPS flexibilities).
- There are a range of flexibilities under TRIPS that can be used by WTO members to protect public health and promote access to medicines for all, including:
  - The provisions of the TRIPS Agreement should be read in light of the objective and purpose of the agreement as set out in the objectives and principles in line with the rules of customary international law;
  - Each Member has the right to grant compulsory licences as permitted by Article 31 of TRIPS;
  - Each Member has the freedom to determine the grounds upon which compulsory licences may be issued;
  - Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency in the context of Article 31. Public health crises such as those relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent such emergency or circumstances of extreme urgency but they are not the only ones;
  - Subject to the most-favoured nation and national treatment provisions of Articles 3 and 4 of TRIPS respectively, each Member is free to establish its own regime of exhaustion; that is, determine the extent to which parallel imports are allowed and such decision is not subject to challenge under the WTO dispute settlement system.
- WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector can face difficulties in making use of compulsory licensing and there is need to find a solution to these difficulties.
- High-income countries remain committed to providing incentives to their enterprises and institutions to promote and encourage transfer of technology to as required under Article 66.2, including in the pharmaceutical sector.
- LDCs will not be required to implement or apply the rules relating to patent protection and protection of confidential information in the area of pharmaceuticals at least until 2016. LDCs retain the right to seek further extensions after 2016 in line with Article 66.1 of TRIPS.

Since the Doha Declaration, Doha-inspired public health decisions have been taken by the TRIPS Council. These aimed to address the issues raised in paragraphs 6 and 7 of the Declaration – to help identify methods to enable countries with insufficient or no manufacturing capacity to effectively use compulsory licensing. They also intended to provide LDCs with a longer period during which they were not obliged to provide patents for pharmaceuticals, including antiretroviral medications. Box 2 below summarizes these decisions.[17]

Box 2: Doha-inspired public health decisions

TRIPS Council decision of 27 June 2002 on extension of transition period for LDCs in respect of pharmaceuticals (WTO doc. IP/C/25)

This decision was taken to formalize the agreement in paragraph 7 of the Doha Declaration. It provides that LDC members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016. It further provides that the decision is made without prejudice to the right of LDC members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

General Council Decision of 8 July 2002 waiving LDC obligations regarding exclusive marketing rights (WTO doc. WT/L/478)

This decision (in form of a waiver) was taken to complement the transition period extension of 27 June 2002 because the continued application of Article 70.9 to LDCs would negate the purpose of extending the transition period with respect to pharmaceuticals. The decision provides that the obligations of LDCs under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016.

Doha Declaration paragraph 6 decision of 30 August 2003 (WTO doc. WT/L/540)

Popularly known as the August 30th decision, this decision (in the form of a waiver) was adopted to address the problem faced by countries with insufficient or no manufacturing capacity when using compulsory licensing (Doha Declaration paragraph 6). It provides that the obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms of the decision. It also provides that where a compulsory licence is granted for the same products in the eligible importing Member as in the eligible exporting Member, the obligation of the importing Member under Article 31(h) shall be waived in respect of those products for which remuneration is paid in the exporting Member. Further, the decision provides that any measures taken pursuant to the waivers under it (that is to Article 31(f) and 31(h) of TRIPS) cannot be challenged on the basis of non-violation or situation complaints.

General Council Decision of 6 December 2005 adopting the TRIPS Amendment Protocol (WTO doc. WT/L/641)

This decision was adopted to address the problems countries with insufficient or no manufacturing capacity have with compulsory licensing (Doha Declaration paragraph 6). The decision adopts the Protocol amending the TRIPS Agreement to introduce a new Article *31bis, which* codifies the 30th August decision.

Any analysis of the impact of the Doha Declaration also needs to take into account the TRIPS Council decision of 20 February 2003. This decision established the mechanism for reporting on how high-income countries are meeting their obligations, under Article 66.2 of the TRIPS Agreement, to encourage their enterprises and institutions to transfer technology to LDCs. This decision provides a context for the linkage made between the transfer of technology and the LDC transition period in paragraph 7 of the Declaration.[18]

The Doha Declaration and the Doha-inspired public health decisions have had a marked impact. One of the Declaration's enduring legacies is its impact on the policy environment at the international and national level. There is also no doubt that the Declaration and related decisions have in the past 10 years led to a significant increase in the use of TRIPS flexibilities, including compulsory licensing, parallel importation, regulatory (bolar) exception and competition law, by low- and middle-income countries. It has also opened the door for large-scale generic production and supply of antiretroviral medications.

Generic competition has drastically reduced by almost 99% the annual price of first-line antiretroviral drugs. In 2000 such treatment cost more than US$10 000 per person per year. By 2010, the least expensive WHO-recommended first-line antiretroviral regimen cost less the US$120 per person per year.[19] This price reduction, along with increases in funding for drug purchases, health system and service delivery improvements and increased attention to overcoming related issues such as stigma, has made HIV management the first large-scale chronic-care programme in many low- and middle-income countries.[20] HIV treatment scale-up has profoundly changed perceptions and approaches to global health.[21] By the end of 2010, 6.6 million people in low- and middle-income countries were receiving antiretroviral treatment.[22]

Through the use of TRIPS flexibilities, governments, international organizations, civil society and other entities have been able to address the lack of access to medicines and, to some extent, the hindrances to innovation and research and development. In particular, low- and middle-income countries have:

- issued compulsory licences to allow third parties to make generic versions of patented medicines;
- permitted parallel imports by adopting an international exhaustion regime;
- taken remedial measures against pharmaceutical companies that engage in anti-competitive practices;
- limited the types of innovation for which pharmaceutical patents can be granted;
- accelerated the introduction of generics into the market by allowing third-party testing, manufacturing and/or export for purposes of meeting regulatory approval requirements; and
- permitted regulatory agencies to rely on test data provided by the originator of the product to register generics.

Beyond the use of flexibilities in countries, the Doha Declaration and the Doha-inspired public health decisions have also inspired broader global action on IP and public health matters. These broader global actions range from the decisions and actions of key procurement and funding agencies, such as the Global Fund, UNITAID and the World Bank, to policy decisions at the WHO, WIPO and the WTO.

3. Case studies on the Doha Declaration and the use of TRIPS flexibilities to promote access to antiretrovirals

In 2002, only 300 000 or 2.7% of the estimated 11 million adults who were eligible for antiretroviral therapy were receiving it.[23] In sub-Saharan Africa, which has the highest number of people living with HIV, only 1% of those eligible were receiving treatment. Since then, the situation has changed dramatically. Between 2004 and 2010, access to treatment has increased 13-fold to reach 6.6 million by the end of 2010 in low- and middle-income countries[24] representing 47% of the 14.2 million people eligible for treatment. This rapid scaling-up of access to antiretroviral therapy, coupled with wider availability of other types of HIV care and interventions, has led to a steady decrease in AIDS-related deaths from 2.4 million in 2004 to an estimated 1.8 million in 2009.[25] Higher rates of antiretroviral treatment, used in concert with a range of preventive measures, have probably contributed to a reduction in new HIV infections. While universal access to treatment has yet to be achieved, and the number of AIDS-related deaths remains high, the gap is closing.

There is no doubt that many factors have contributed to the scaling-up of access to antiretroviral therapy in low- and middle-income countries. The widespread availability of generic medicines and the consequent dramatic fall in originator product prices have been recognized as key factors. It was only when prices fell that funding and the political will to provide treatment were galvanized. The actions taken by countries, civil society, pharmaceutical companies and international organizations in the wake of the Doha Declaration increased the availability of generic medicines and stimulated competition. Examples from different regions illustrate how the use of flexibilities has made a difference.[26] The influence of the Doha Declaration on high-income countries and international organizations also reinforces this point.

3.1. The Doha Declaration and access to antiretroviral therapy in Africa

Access to antiretroviral therapy has improved significantly in sub-Saharan African countries. As of 2010, almost five million of the estimated 10.4 million people eligible for treatment in the region were receiving antiretroviral therapy.[27] This translates to an estimated antiretroviral coverage of 37%, compared with just 1% in 2004. The use of TRIPS flexibilities continues to play an important role in the sustained increase in antiretroviral therapy coverage in the region. A number of African countries have used one or more of the TRIPS flexibilities.[28]

Parallel importation

At least six African countries (Ghana, Kenya, Mauritius, Namibia, South Africa and Zimbabwe) have incorporated an international exhaustion regime in their laws, allowing parallel imports from anywhere in the world. The 16 countries forming the African Intellectual Property Organization (OAPI) also have a regional exhaustion regime. Since passing the Industrial Property Act in 2001, Kenya has actively and effectively used parallel importation to improve access to antiretroviral medications.
Box 3 below summarizes the use of parallel imports in Kenya.

Box 3: Parallel importation in Kenya

In June 2001, Kenya's parliament passed the Industrial Property Act 2001, which came into force by notice on 1 May 2002. During passage of the Industrial Property Bill, debate focused on the effects of patents on prices of essential medicines and the need to incorporate public-health safeguards aimed at promoting affordability and availability of essential medicines in Kenya.

Those public-health safeguards included parallel importation and compulsory licensing and government-use powers. The Act also makes specific provisions relating to the regulatory exception and gives the relevant minister the power to restrict the patenting of new uses of known pharmaceutical molecules. However, it was the parallel importation provision that had the biggest impact on antiretroviral medications.

The Industrial Property Act 2001 adopts the international exhaustion principle. Section 58(2) of the Act on limitation of patent rights provides that: *"The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya."* This provision has been elaborated in the Industrial Property Regulations of 2002. Regulation 37 clarifies that the limitation on the rights under a patent in section 58(2) extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market. Legitimacy of products in this context only implies compliance with the national laws applicable in those foreign markets.

Since May 2002, key procurement and treatment organizations, including MSF, the Mission for Essential Drugs and Supplies (commonly known as MEDS) and Action Aid have used the parallel importation provisions to import generic antiretroviral medications into Kenya.

Overall, at least 22 of the 54 countries in Africa have a regional or international exhaustion regime allowing parallel importation of medicines. It should be noted, however, that those countries applying regional exhaustion regimes have fewer opportunities to parallel import owing to the lack of capacity to produce low-cost generics in the region.

Compulsory licensing and government use

Many African countries have incorporated compulsory licensing provisions in their laws. In sub-Saharan Africa, at least 39 countries have compulsory licensing provisions in their patent laws, in part due to advocacy by key international partners. However, the grounds for issuing the licences vary widely. The most common grounds are failure to work, or insufficient working, of a patent and failure to sufficiently supply the domestic market.

With respect to the 30 August decision and the TRIPS Amendment on the import-export mechanism for countries with insufficient or no manufacturing capacity, only Rwanda has notified and used this system.[29] At the time of writing, five African countries have

ratified the amendment: Egypt, Mauritius, Senegal, Uganda and Zambia.[30]

Although many countries have incorporated compulsory licensing in their laws, use of this provision has been rare. Zimbabwe is one of the few countries to apply compulsory licensing for antiretroviral medications. (See Box 4).

Box 4: Compulsory licensing in Zimbabwe

In 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs issued a notice (General Notice No. 240 of 2002) declaring a period of emergency on HIV/AIDS for the purpose of enabling *"The State or a person authorised in writing by the Minister to make or use any patented drug, including any antiretroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions."*

The declaration was made pursuant to section 34, read with section 35 of the Patents Act. Section 34 empowers the minister to authorize the use of patented inventions by any government department or third party, for the service of the state, while section 35 clarifies that an authorization by the minister under section 34 during a period of emergency "shall include power to make, use, exercise and vend the invention for any purpose which appears to the minister necessary or expedient".

The declaration set an initial emergency period of six months but this was later extended to five years from January 2003 to December 2008. Following the emergency declaration, in April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwe-registered company, was granted authority to use relevant patents. Under the terms of this authorization, Varichem was to "produce antiretrovirals or HIV/AIDS-related drugs and supply three quarters of its produced drugs to state-owned health institutions".

At the start of production, Varichem reportedly agreed to supply the government with its generic version of Combivir at US$ 15 per patient per month and to meet 75% of the government needs for this drug. Two other companies later received authorization. Datlabs, a pharmaceutical manufacturer, was authorized to import antiretroviral medications from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, was authorized to import Cipla products.

Zambia also used this mechanism in 2004 when a compulsory licence was issued to Pharmco Ltd to manufacture a fixed-dose combination of lamivudine, stavudine and nevirapine. Interestingly, that licence prohibits export, which is not a TRIPS requirement. The royalty was set to not exceed 2.5% of the turnover of the product.

Measures to address anti-competitive practices

Most African countries have standard provisions on the control of anti-competitive licensing terms in contractual licences under their patent laws. However, there is limited enforcement or use of these provisions in the pharmaceutical sector. The one country that has both a robust law and enforcement capacity is South Africa, where the law has been used to address problems with access to antiretroviral therapy (Box 5).

Box 5: Competition law in South Africa

In 2002, treatment activists began to use competition law to push for an increase in the number of antiretroviral suppliers, resulting in increased competition and a lowering of essential medicine prices. The Competition Commission of South Africa found two pharmaceutical companies (GlaxoSmithKline and Boehringer Ingelheim) guilty of excessive pricing and referred the matter to the Competition Tribunal for ruling. Before the Competition Tribunal gave a decision, both companies entered into a number of agreements with the Commission and the complainants, permitting an increased supply of more affordable generic versions of antiretroviral medications still under patent in the country.

The companies agreed to issue three and four licences respectively to generic manufacturers. The effect of the agreements was that the Clinton Foundation deal, announced on 23 October 2003, could be implemented in South Africa and other sub-Saharan African countries. The four generic companies would sell triple-drug antiretroviral treatments to governments in sub-Saharan Africa at US$ 140 per patient per year. Royalties were set at no more than 5% of net sales of the medicines.

Various African countries have now updated their competition laws, which might provide an opportunity for more countries to use competition law to improve antiretroviral access in the future.[31]

2016 transition period

Most (24) of the LDC members of the WTO are African countries. The extension of the LDC transition period for pharmaceuticals to January 2016 is, therefore, of particular importance to the region. The African Group at the WTO was instrumental in pushing for the Doha Declaration, which mandated the 2016 extension. Broadly speaking, most of the African LDCs have not taken full advantage of the transition period, with their laws allowing patents to be granted on pharmaceuticals. There are only two clear cases where African LDCs have used the 2016 extension to facilitate access to antiretroviral medications. Rwanda invoked the extension to justify not issuing a compulsory licence when using the 30th August system to import antiretroviral medications from Canada [32], and Uganda has used it to promote local production. Other African LDCs, including non-WTO members, have cited the Doha Declaration to support importation of

generic antiretroviral medications by procurement agencies such as UNICEF.[33]

The use of the transition period in Uganda has permitted the establishment of a local manufacturing facility (Quality Chemicals) for antiretrovirals and other medicines (Box 6).

Box 6: Use of the transition period to promote local antiretroviral production in Uganda

In 2007 Quality Chemicals Limited, in cooperation with the Indian company Cipla, set up a US$ 38 million pharmaceutical plant in the capital Kampala to produce antiretroviral drugs for the domestic market. The aim was to eventually export to the East African region and beyond. In February 2009, the plant started producing the triple-therapy combination lamivudine, stavudine and nevirapine and the antimalarial therapy artemisinin and lumefantrin. The plant has been cleared to produce antiretroviral and antimalarial drugs for the International Committee of the Red Cross and by the WHO Pre-qualification of Medicines initiative.

Buoyed by the success of Quality Chemicals, the East African Community (EAC) is now promoting the use of the transition period to stimulate local production in the other three LDCs in the region (Burundi, Rwanda and the United Republic of Tanzania). Under a proposed protocol to the treaty establishing the EAC, the countries in the region are working towards a common approach on TRIPS flexibilities, which will ensure wider availability of generic medicines and support local production.[34]

3.2. The Doha Declaration and access to antiretroviral therapy in East, South and South-East Asia

At the end of 2009, of the 2.4 million people living with HIV eligible for antiretroviral therapy in East, South and South-East Asia, 739 000 (about 31%) were receiving treatment.[35] In 2002, only 4% (43 000 people of the one million eligible) received antiretroviral therapy. As in Africa, a number of countries have used one or more TRIPS flexibilities, which, in addition to other strategies, have led to a sustained increase in antiretroviral therapy coverage. Compulsory licensing is the main flexibility being used in this region to achieve access to antiretroviral therapy.

Compulsory licensing

Most countries in the region provide for compulsory licences and government-use in their patent laws, even though actual use has remained limited. However, Malaysia and Thailand have effectively used government-use orders and compulsory licensing to improve access to antiretroviral medications (Boxes 7 and 8). In Thailand, compulsory licensing has also been used for medications for cancer and heart disease.

Box 7: Government-use order in Malaysia

In 2003, the Government of Malaysia authorized a local company (Megah Pharmaceuticals Sdn Bhd) to import three antiretroviral medicines from India under section 84 of the Patents Act (1983) to supply public hospitals. In granting the authority, the minister laid down a number of conditions, including that: the authorization would be valid for two years; the prices of the medicines should not exceed the ceiling amount specified by the Ministry of Health; the imported medicines should be labelled with the words "Ministry of Health, Malaysia"; the shape or colour of the tablets or capsules should be differentiated from the patented product sold in Malaysia; and remuneration should be paid to the patent holder(s) within two months of the importation.

The government-use order was prompted by the lack of success in price negotiations between the Ministry of Health and the patent-holding companies in 2001. In August 2002, the Ministry of Health organized an inter-ministry workshop to discuss the implications of the Doha Declaration and the available legal options for accessing affordable antiretroviral medicines. The Ministry of Health made providing free antiretroviral therapy to patients with CD4 counts <400 a major policy objective and set a target of putting 10 000 patients on treatment. These developments, coupled with pressure from civil society organizations, added to the impetus for the government-use authorization.

The decisions to authorize the government-use order and permit the importation of generics also had an effect on the pricing set by originator companies. By 2004, GlaxoSmithKline reduced the prices of its antiretroviral medications by 53–80% compared with 2001 prices, and Bristol-Myers Squibb dropped the price of didanosine (100mg formulation) by 49% and the price of the 25mg formulation by 82%. In addition, there was a significant reduction in prices for generics. After the introduction of the generic version of Combivir, the cost of the generic zidovudine, lamivudine and patented efavirenz fell to US$ 115 per patient per month in 2004.

Box 8: Compulsory licensing in Thailand

In late 2006 and early 2007 Thailand issued compulsory licences for a number of pharmaceutical products – efavirenz, lopinavir/ritonavir and clopidogrel (a drug for managing cardiovascular disease) – at a royalty rate of 0.5%. By early 2008 the number of patients using lopinavir/ritonavir had tripled. Explaining the compulsory licensing decisions, the then health minister, Dr Mongkol na Songkla, made the following statement:

"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."

Just before compulsory licences were issued, some estimates (Revanga et al, 2006) indicated that the country could save as much as US$ 3.2 billion if it issued such licences for second-line treatments.

In 2004 Indonesia issued a presidential decree for the manufacture of lamivudine and nevirapine. In 2007 another decree was issued for the manufacture of efavirenz on behalf of the government. The royalty rate, as in Thailand, was set at 0.5% of the net sales price. The authorization is valid for seven years for nevirapine and eight years for lamivudine.

A number of countries and regions have also ratified the Doha paragraph 6 TRIPS amendment. These include Bangladesh, China (and its special administrative regions, Hong Kong and Macau), Mongolia, Pakistan, the Philippines and Singapore.

Other flexibilities

Although many countries in East, South and South-East Asia have used TRIPS flexibilities to facilitate access to medicines, no comprehensive study of laws or practices in the region has been undertaken. One example is the parallel importation regime in the Philippines. As in Kenya, (Box 3 above) the law in the Philippines allows for the importation of products into the country if they have been placed on the market anywhere in the world by the patent owner, or by any party authorized to use the invention.[36]

Cambodia has a specific legislative provision on the 2016 transition period. Under Article 136, the law provides that patent protection for pharmaceuticals would not come into effect until the expiration of the 2016 transition period as provided for under paragraph 7 of the Doha Declaration.[37]

India has taken advantage of the flexibilities to prohibit patenting of new uses of existing pharmaceuticals and other products. Under section 3.d of the Patent (Amendment) Act (2005), the law provides that "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" will not be considered an invention.[38]

3.3. The Doha Declaration and access to antiretrovirals in Latin America and the Caribbean

At the end of 2009, 478 000 (about 50%) of the 950 000 people living with HIV in Latin American and the Caribbean who were eligible for antiretroviral therapy were receiving it.[39] Though the absolute number of people receiving antiretroviral therapy has more than doubled, the coverage has not changed significantly since 2002 when it was 53% (196 000 of 370 000 eligible people). This coverage remains higher than that in other developing country regions and TRIPS flexibilities have played a positive role.

Available evidence suggests that TRIPS flexibilities have been important in sustaining the antiretroviral treatment coverage in the region, particularly in key countries such as Brazil, which has the largest number of people on treatment in the region. The main flexibility used effectively in this region is compulsory licensing.[40]

Compulsory licensing

Two countries, Brazil (Box 9) and Ecuador, have used compulsory licences to facilitate access to antiretroviral medications since the adoption of the Doha Declaration.

Box 9: Use of compulsory licensing in Brazil

The Government of Brazil has used compulsory licensing strategically in price negotiations, and it has also issued licences when price negotiations failed. Using the threat of compulsory licensing, the Brazilian Government negotiated significant price reductions for efavirenz and nelfinavir in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006. It has been estimated that the Brazilian Government's policies, including the use of TRIPS flexibilities, have saved the country about US$ 1.2 billion on antiretroviral purchasing costs between 2001 and 2005.

In 2007, however, the originator company could not meet the government's price expectations. A compulsory licence was issued for efavirenz, which is used by one third of Brazilians on antiretroviral therapy through the national programme. After the licence was issued, the price of efavirenz dropped from US$ 1.60 per dose to US$ 0.45 per dose for the imported generic version of the drug.

In 2009, Ecuador also issued a compulsory licence for lopinavir/ritonavir, valid until 2014. The Ecuadorian Intellectual Property Institute issued the licence to Eskegroup SA. According to the nongovernmental organization Public Citizen, the prices of the medicines fell immediately by more than 27%.[41]

The TRIPS Amendment relating to Doha paragraph 6 has been ratified by several countries: Brazil, Colombia, El Salvador, Mexico and Nicaragua.

Other flexibilities

Latin American and Caribbean countries have also taken proactive measures to use other TRIPS flexibilities to promote access to antiretroviral and other medicines.
A 2004 study on the use of TRIPS flexibilities for public health purposes found that, while countries had taken a range of measures, there were concerns about the low utilization of the flexibilities.[42] Examples include:

- Parallel importation: allowed in Argentina, Bolivia, Colombia, Dominican Republic, Ecuador, Panama, Peru and Venezuela.
- Regulatory (bolar) exception: permitted by Brazil and the Dominican Republic.
- Test data protection: Argentina has adopted an unfair competition approach to test data protection as opposed to data exclusivity.[43]

3.4 The Doha Declaration and access to antiretroviral therapy in Eastern Europe and Central Asia

The number of people living with HIV in Eastern Europe and Central Asia has been rising rapidly over the past decade. According to UNAIDS statistics, the number of people living with HIV had risen to an estimated 1.5 million by 2008, a 66% increase since 2001.[44] While a number of countries in the region have expanded access to antiretroviral therapy, overall treatment coverage remains quite low.
Only 114 000 (19%) of the 610 000 people living with HIV who were eligible for antiretroviral therapy were receiving it by the end of 2009.[45] In 2002, the coverage was only 9% (when 7000 people of 80 000 eligible received antiretroviral therapy).

The patent laws of countries in this region have been heavily influenced by WTO accession demands and partnership and cooperation agreements, as well as continuing negotiations on association agreements and free trade agreements (FTAs).
Nevertheless, various countries in the region have incorporated TRIPS flexibilities into their laws. These include[46]:

- International exhaustion (allowing parallel imports): Armenia and Georgia.
- Research exception: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine and Uzbekistan.
- Regulatory (bolar) exception: Kazakhstan, Kyrgyzstan, Moldova, Russian Federation and Tajikistan.
- Compulsory licensing: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russian Federation, Tajikistan, Ukraine and Uzbekistan.
- Government use: Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russian Federation, Tajikistan, Ukraine and Uzbekistan.
- Test data protection based on the unfair commercial use principle and not data exclusivity: Armenia, Belarus, Kyrgyzstan, Moldova, Tajikistan and Ukraine.

It is difficult to ascertain the use of TRIPS flexibilities in the region. There are no clear examples of proactive use of TRIPS flexibilities to promote access to antiretroviral therapy.

3.5. The Doha Declaration and high-income countries

The Doha Declaration also had an impact on the policies and approaches of high-income countries to IP and public health issues, both domestically and in their dealings with low- and middle-income countries, including FTAs. A number of countries have ratified the TRIPS amendment, which will establish a permanent change in TRIPS, and some have gone further. For example:

Canada:

- Has, by statute, established an export system under compulsory licences pursuant to the 30 August Decision.
- Has supplied antiretroviral medications to Rwanda under the 30 August decision.

European Union:

- Has adopted regulations to permit export of medicines under the 30 August 2003 Decision.
- In the context of FTAs and Economic Partnership Agreements (EPAs), the EU has in some instances, such as the EU-CARIFORUM EPA, specifically recognized the Doha Declaration and refrained from asking low- and middle-income country partners to take on further patent obligations that could affect public health.

United States:

- The 2002 Trade Act committed the United States to respecting the Doha Declaration. This has had some effect on its positioning in FTA negotiations with low- and middle-income countries, though many of its bilateral FTAs have been criticized for undermining the Declaration. For example, following widespread criticism of its approach to IP and public-health issues in FTAs, including that from members of the United States Congress, the United States Trade Representative responded by indicating in side letters that the obligations of the IP chapters of the FTA: *"[D]o not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency."*[47]

It should also be acknowledged that high-income countries, which have made significant investments in HIV treatment through various international and bilateral programmes, have, in part thanks to Doha and the associated campaigns, allowed these resources to be used on generic medicines. For example, in 2008 more than 76% of the US$ 202 million spent on procurement by the President's Emergency Plan for AIDS Relief (PEPFAR) was used to buy generic antiretroviral medications.[48]

3.6. The Doha Declaration and the policies, decisions and actions of international organizations, civil society and the pharmaceutical industry

Beyond low- and middle-income countries incorporating TRIPS flexibilities into their laws, and in a number of cases, proactively using these flexibilities to promote access to

antiretroviral therapy, the Doha Declaration and the Doha-inspired public health decisions have inspired the policies and actions of a broad range of other actors. These range from international organizations in the UN family and beyond, including international public-private partnerships and product-development partnerships, civil society organizations and pharmaceutical companies. The number of Doha Declaration-inspired policies, decisions and actions are numerous and cannot be comprehensively described and analysed in a study of this size and scope. The following are examples of such DOHA-inspired policies, decisions and actions.

UN agencies and other international organizations/initiatives

In the past decade, the Doha Declaration and the Doha-inspired public health decisions have inspired and/or influenced the policies, decisions and actions of UN agencies and other international organizations in many positive ways. For example:

- The Declaration inspired and/or influenced a number of WHA resolutions, including Resolution WHA61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property GSPOA.[49] The Declaration was also an inspiration for the proponents of establishing a development agenda at the World Intellectual Property Organization (WIPO).[50] Box 10 contains excerpts of some of the references to the Doha Declaration in WHO and WIPO documents.

Box 10: References to the Doha Declaration in WHO and WIPO documents

WHA61.21 – GSPOA (2008)

The Context

The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO members to protect public health and, in particular, to promote access to medicines for all.

The actions to be taken with respect to management of IP

[P]roviding as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments

related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products.

WHA60.30 – Public Health, Innovation and IP (2007)
The Sixtieth World Health Assembly
Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent members from taking measures to protect public health.

WHA59.24 – Public Health, Innovation, Essential Health Research and IP Rights (2006)
The Fifty-ninth World Health Assembly
Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent members from taking measures to protect public health;

Further noting that the Declaration, while reiterating commitment to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO members to protect public health and, in particular, to promote access to medicines for all;

Taking into account Article 7 of the TRIPS agreement that 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".

WHA57.14 – Scaling up Treatment and Care within a Coordinated and Comprehensive Response to HIV/AIDS (2005)
The Fifty-seventh World Health Assembly
Recalling the Declaration on the TRIPS Agreement and Public Health adopted at the WTO Ministerial Conference (Doha, 2001), and welcoming the decision taken by the General Council of WTO on 30 August 2003 on implementation of paragraph 6 of that Declaration.

WO/GA/31/11 – Proposal for the Establishment of a Development Agenda for WIPO (2004)
The development dimension of intellectual property protection
In this regard, the adoption of the Doha Declaration on the TRIPS Agreement and Public Health at the 4th Ministerial Conference of the WTO represented an important milestone. It recognized that the TRIPS Agreement, as an international instrument for the protection of intellectual property, should operate in a manner that is supportive of and does not run counter to the public-health objectives of all countries.

- The Declaration acted as a catalyst for a significant increase in both financial and technical resources directed towards scaling up antiretroviral therapy in low- and middle-income countries. For example, through Rounds 1–10, the Global Fund has invested more than US$ 12.3 billion (approved grant amount), of which about US$ 4.55 billion has been utilized and/or is earmarked for medicine and health product procurement for HIV, tuberculosis and malaria.[51] In 2002, the Global Fund board[52], specifically adopted an approach designed to encourage countries to use TRIPS flexibilities and set out a clear policy on IP-related matters (Box 11). UNICEF, a large procurer of antiretroviral medications, has also relied on the Doha Declaration and the 27 June 2002 decision to procure generics for a number of LDCs. Other key organizations, including UNAIDS, UNCTAD, UNDP, WHO and the World Bank, significantly increased TRIPS flexibilities technical assistance activities following the Doha Declaration.[53] For example, UNDP, in partnership with WHO and UNAIDS, has provided significant policy and technical support to countries reforming IP legislation to incorporate public health-related TRIPS flexibilities.

Box 11: Global Fund policy on IP and TRIPS flexibilities

Recipients must procure their products in accordance with national and international laws. The Global Fund encourages recipients to apply the flexibilities provided within national laws and in the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), as interpreted in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), to achieve the lowest possible price for products of assured quality.

In the event that a Principal Recipient does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may contract the necessary expertise using funds budgeted for this purpose in the Global Fund grant.

The Doha Declaration has also inspired and shaped the approaches of important international funding and research and development organizations, including UNITAID[54] and the Drugs for Neglected Diseases Initiative (DNDi)[55]. UNITAID, working with organizations such as the Clinton Health Access Initiative, has invested significant resources in treatment. So far, UNITAID and the Clinton Health Access Initiative have provided more than one million people with access to tenofovir by facilitating demand and reducing the price by more than 70%.[56] UNITAID provides in its constitution that, "*Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects on*

Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable."[57] In its early years, DNDi adopted a pro-access IP policy aimed at ensuring treatments are ultimately affordable to patients who need them and that access to these treatments is equitable.[58]

Civil society organizations

Civil society, particularly health groups and organizations of people living with HIV, were instrumental in bringing about the Doha Declaration. These organizations have also played a critical role in facilitating the positive outcomes attributed to the Declaration and the Doha-inspired public health decisions. The Doha Declaration has provided a powerful platform for civil society organizations and organizations of people living with HIV to push for greater use of TRIPS flexibilities within countries and beyond. Civil society has played a key advocacy role and helped provide antiretroviral therapy.

Advocacy: The Doha Declaration has been a launching pad for many civil society campaigns for policy changes in low- and middle-income countries and in high-income countries, as well as in international organizations. Advocacy campaigns inspired by the Doha Declaration have played an important role in changing treatment policies in key developing countries that have used the TRIPS flexibilities, including India, Kenya, South Africa and Thailand.[59] Civil society campaigns have also been important in high-income country policy changes referred to in section 3.5 above.

Provision of antiretroviral therapy: The second category of civil society action involves the actual provision of antiretroviral therapy and other treatment support services. In many low- and middle-income countries, international humanitarian organizations such as MSF were able to significantly scale up the delivery of antiretroviral therapy to thousands of people living with HIV. MSF is now providing antiretroviral therapy to more than 170 000 people in 29 countries in Africa and Asia.[60] Local organizations and hospitals in many countries have also relied on TRIPS flexibilities to run treatment programmes.

Pharmaceutical companies

The Doha Declaration and the Doha-inspired public health decisions have also affected policies and other decisions, including investment decisions, of both originator and generic companies.

For generic companies, the Declaration and related decisions have provided clarity and certainty, which has encouraged these companies to invest in and increase the production of generics. This has led to the development and production of fixed-dose combinations of antiretroviral medications. These have revolutionized HIV treatment, helping to make it possible to provide treatment in resource-poor settings.

The Doha Declaration also had an impact on the policies and decisions of originator pharmaceutical companies. Though originator companies continue to advocate for strong IP protection in the pharmaceutical sector, they have since Doha tempered their high-profile campaigns against the use of flexibilities, such as the one they carried out in South Africa from 1999–2001.[61] Recently, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has even supported calls for extending beyond 2016 the LDCs' transition period on pharmaceutical patents under TRIPS.[62]

4. Opportunities and challenges for the sustainable use of TRIPS flexibilities to promote access to antiretroviral therapy

Ten years on, the Doha Declaration still has a great impact. Both the Declaration and the Doha-inspired public health decisions are still playing an important role in efforts to scale up antiretroviral treatment. This will remain the case in coming years. There are new opportunities that the international community and national actors can utilize to further enhance the use of TRIPS flexibilities and promote the spirit of Doha. If strategically approached, these opportunities can play a major role in maintaining the momentum achieved in the first decade of the Doha Declaration.

However, important IP-related challenges still remain and must be addressed if the goal of treating 15 million people with antiretroviral therapy by 2015 is to be achieved. Several trends threaten to reverse the efforts to scale up treatment through the use of TRIPS flexibilities. These challenges, both national and international, are at the policy, legislative and practical level.

4.1. Opportunities for consolidating the achievements of the first decade of the Doha Declaration

There are a number of opportunities that national governments and stakeholders as well as the international health and trade communities can leverage to consolidate the achievements made in the first decade of the Doha Declaration. If capitalized upon, these opportunities could help address important research and development issues, including transfer of technology, as well as provide better information for decision-making on the use of TRIPS flexibilities. Four of these are examined below.

4.1.1. Patent pooling and other licensing approaches for promoting development and access to antiretroviral medications

The early discussions on IP and access to HIV medicines were characterized by an emotive and confrontational debate with entrenched positions. This polarization in the debate delayed and/or hampered any discussions on how to ensure both access and continuing innovation. Those who advocated for the use of TRIPS flexibilities were erroneously and at times deliberately painted as being opposed to the IP system, rather than being interested in making the system work for all.[63] Ensuring both access and innovation requires a comprehensive approach that goes beyond access to existing medicines or simply using TRIPS flexibilities.

The WHO Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPOA), which came out of a less polarized discussion, offers a platform for such a comprehensive approach.[64] The GSPOA was championed by the innovation plus access (i+a) movement, which emerged after the Doha Declaration, and was informed by the report of the Commission on Intellectual Property Rights Innovation and Public Health (CIPIH).[65] A key finding of the CIPIH was:

"Too few R&D resources are directed to the health needs of developing countries. In the private sector, companies do not have the incentive to devote adequate resources to develop products specifically adapted to the needs of developing countries, because profitability is mainly to be found in rich country markets. The great majority of health research funded by the public sector takes

place in developed countries, and its priorities principally reflect their own disease burden, resource position and social and economic circumstances." [66]

Products adapted to the needs of low- and middle-income countries are particularly critical for HIV treatment. Indeed, one of the earliest barriers to scaling up HIV treatment, other than the price of medicines, was the challenge of providing access to a complex treatment regimen in resource-limited settings. Adaptations in health systems and practices as well as the development of fixed-dose combinations (FDCs) have gone some way towards addressing the special needs of low- and middle-income countries. Important gaps, however, remain in developing better and more effective FDCs and in addressing neglected areas such as research and development on, and access to, paediatric antiretroviral medications. Addressing these challenges requires innovative approaches to the management and use of patents.

It is for the above reason that the GSPOA (under Element 4 – Transfer of Technology) explicitly recognized the need for developing new mechanisms to promote the transfer of and access to key health-related technologies. The GSPOA called on relevant actors to examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of, and access to, health products and medical devices. The creation, in 2010, of the Medicines Patent Pool Foundation (MPP) is one response to this call.[67] The MPP is an independent foundation initially created under the auspices of UNITAID in order to improve access to affordable and appropriate HIV medicines in developing countries through voluntary licensing of critical IP rights. The MPP has already obtained licences for a number of key antiretroviral medications and has started providing these to generic companies.[68]

The MPP provides an unprecedented opportunity for connecting the innovative capabilities of the originator pharmaceutical companies with the knowledge and pricing strategies of generic manufacturers to address the challenges around FDCs and paediatric antiretroviral medications. Increased availability of FDCs for first-, second- and third-line antiretroviral therapy and paediatric formulations, coupled with increased and better use of TRIPS flexibilities, is crucial to achieving the goal of reaching 15 million people with treatment by 2015. Successful application of the MPP should also reveal new opportunities for other collaborative and open licensing approaches for HIV research and development.

4.1.2. Efforts and processes to address sustainability of research and development financing

For diseases such as HIV, which disproportionately affect people in low- and middle-income countries, "*The market alone, and the incentives that propel it, such as patent protection, cannot by themselves address the health needs…*" [69] This explains why a key GSPOA goal was to secure and enhance sustainable financing mechanisms for research and development to deliver health products and medical devices needed by developing countries. Since the adoption of the GSPOA, continuing efforts have been made to explore mechanisms for delivering this. One opportunity that should not be underrated is the opportunity presented by the work of the Consultative Expert Working Group on R&D, Financing and

Coordination (CEWG) at WHO.[70] This work on sustainable R&D financing is important because the TRIPS flexibilities can only make a difference if the relevant products are being developed.

The work of the CEWG could lead to identification of new financing strategies for R&D and ensure lower prices and wider availability of new medicines. Like the MPP, such an outcome would significantly advance efforts to reach the 15 million target. Additionally, the work of the CEWG links directly with the goals of Treatment 2.0, the UNAIDS and WHO initiative to radically simplify HIV treatment.[71]

4.1.3. South-south cooperation

A key challenge faced by low- and middle-income countries to use TRIPS flexibilities to their fullest is access to technology. Even where patents are not applicable, such as in those LDCs that have taken advantage of the LDC 2016 transition, there has been insufficient technology transfer to enable local production. The efforts to implement Article 66.2 of TRIPS, which obliges high-income countries to provide incentives to enterprises and institutions within their territories to promote and encourage technology transfer to LDCs, has yielded few tangible results.[72]

However, since the late 1980s when the TRIPS Agreement was being negotiated, the technological map has changed significantly. A number of emerging economies, especially those of Brazil, China and India, now have considerable technological capabilities. Meaningful pharmaceutical technology transfer to LDCs may well come from south-south cooperation today. This is already happening, as illustrated by the case of Quality Chemicals in Uganda (Box 6 above). Brazil's provision of technology transfer to Mozambique is another example of effective south-south cooperation that enables LDCs to use TRIPS flexibilities in a meaningful way.[73]

4.1.4. Patent system transparency initiatives

The effective use of TRIPS flexibilities requires not only the technical expertise to interpret them but also accurate information on the patent status of antiretroviral medications being used in different countries. The lack of reliable patent data has been a major challenge during the past decade and will continue to be a challenge. Both R&D and access to treatment are hampered by this. R&D is hampered by difficulties understanding the patent landscape in a particular R&D area while access is blocked because procurement agencies cannot ascertain the patent status of a particular drug.

In recent years there have been major efforts to improve the methodologies for both patent landscaping and for generating information on patent status. WIPO has devoted significant resources to patent landscaping activities and has also provided technical support to WHO and the MPP.[74] The recently launched MPP database on the patent status of selected HIV medicines[75] is providing much greater information on the patent status of selected antiretroviral medications in low- and middle-income countries. It permits users to search by country/region and by medicine for information on key patents. With this type of information, national, regional and international actors can devise better responses to not only address patent barriers to access but also gaps in the R&D pipeline.

The availability of landscapes and patent-status information permits low- and middle-income countries and other actors, such as product-development partnerships and procurement agencies, to use TRIPS flexibilities to promote access to antiretroviral therapy and overcome bottlenecks and delays in weak procurement systems.

4.2. Challenges to the future use of TRIPS flexibilities

Continued effective use of TRIPS flexibilities enabling low- and middle-income countries and other stakeholders to exploit the opportunities discussed above, will depend on how a number of recent developments and trends in international patent law are handled. These pose important challenges for successful implementation of the Doha Declaration in the next decade and beyond, especially now that the global financial crisis that began in 2008 is having an impact on HIV financing. Three issues stand out as the most important challenges that will need to be tackled in the next decade of the Doha Declaration:

- The introduction of product patents in India (a major producer of generic antiretroviral therapy) since 2005;
- Patent-related (TRIPS-plus) provisions of free trade agreements;
- Trends in IP enforcement in the pharmaceutical sector.

4.2.1 Second- and third-line antiretroviral therapy in the wake of the expiry of the TRIPS Article 65.4 transition

At the time of the adoption of the TRIPS Agreement, a number of low- and middle-income countries did not grant patents for pharmaceutical products. This practice allowed generic companies to use a different process to develop generic versions of patented pharmaceutical products. Consequently, in order to achieve the stated aim of the TRIPS Agreement that, as a general rule, patents must be available "for any inventions, whether products or processes, in all fields of technology…" (Article 27.1), TRIPS provides (in Article 65.4) that:

"To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member… it may delay the application of the provisions on product patents… to such areas of technology for an additional period of five years." [76]

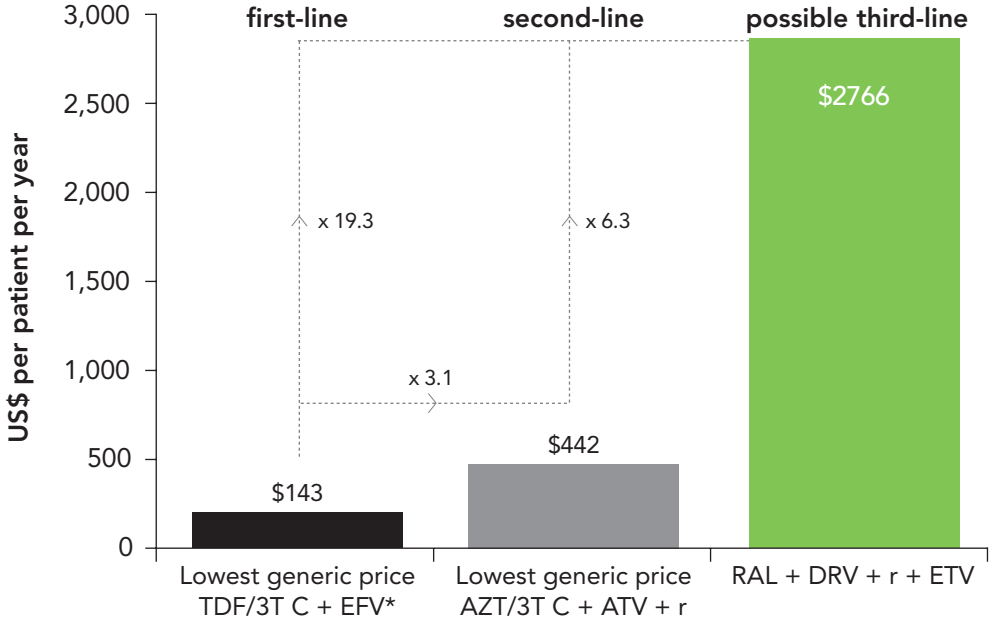
The most dramatic effect of the policy of not granting patents to pharmaceutical products and the use of the Article 65.4 transition period has been seen in India, which has become a leading generic producer. According to a 2010 study, Indian generic manufacturers accounted for more than 80% of annual global antiretroviral purchase by volume.[77] The same study found that between 2003 and 2008, the number of Indian generic manufactures supplying antiretroviral medications increased from four to 10, while the number of Indian-manufactured generic products increased from 14 to 53. The Global Fund, whose funding was, at the end of 2010, supporting antiretroviral treatment for three million people, reports that during 2009–2010, 93% of the antiretroviral volumes purchased for Global Fund-supported programmes were purchased from Indian generic manufacturers.[78] Likewise, the proportion of antiretroviral generics being supplied by the

President's Emergency Plan for AIDS Relief (PEPFAR) has steadily increased, with the majority now being sourced from India. PEPFAR estimates that the use of generic antiretroviral medications has achieved savings of more than US$ 323 million between 2005 and 2008.[79]

Full implementation of the TRIPS Agreement in India, therefore, raises important questions regarding the sustainability of generic antiretroviral supplies for low- and middle-income countries. While the older first-line antiretroviral therapies, most of which are unpatented in India, are likely to remain low-priced, the situation is going to differ for new first-line treatments and, most importantly, for second- and third-line treatments. According to Médecins Sans Frontières, the lowest price available in the global market for a second-line regimen recommended by the new WHO guidelines is US$ 442, more than three times the most affordable of the improved first-line regimens.[80] Third-line treatment could cost as much as 19 times more than improved first-line treatments. Figure 1 shows a comparison of first-, second- and possible third-line treatment prices.

Therefore, in addition to the need for India to continue using TRIPS flexibilities, other competitive generic suppliers will have to come into the market. This will, however, only be possible if other low- and middle-income countries step up the use of relevant flexibilities. A significant number of developing countries, including low-income

Figure 1: Price comparisons of first-, second- and possible third-line antiretroviral regimens



Source: MSF: Untangling the web of antiretroviral medicine prices, 2011

countries, have failed to either incorporate the TRIPS flexibilities in their laws or use them to proactively improve access to treatment. So far, where countries have used TRIPS flexibilities to facilitate access to medicines, it has usually been done for imports. The MPP initiative may be instrumental in changing this. Its role in facilitating licensing should enable the development of capacities for antiretroviral production in other low- and middle-income countries.

4.2.2. The use of TRIPS flexibilities and IP enforcement initiatives

Enforcement is a controversial topic on the international IP agenda that has received considerable global attention in recent years.[81] Rights holders and some governments point to what they see as record levels of trademark counterfeiting and copyright piracy as justification for paying greater attention to IP enforcement. Other governments, health groups and stakeholders, however, have concerns that these IP enforcement initiatives are being used as pretexts for preventing market entry by competitors. They fear IP enforcement will be used to erect barriers to legitimate trade, such as trade in generic medicines, and to compromise efforts to enhance transfer of technology, including in the pharmaceutical sector.

In the context of antiretroviral medications, there are two main issues. The first issue is the criminalization of patent infringement by extending the meaning of the term 'counterfeiting' to cover all IP rights infringements, including patent infringement.[82] The second is the application of IP enforcement procedures to goods-in-transit.

The problem with the definition of counterfeiting is that the debates, especially those focusing on medicines, "are often obscured by inappropriate use of the concept of 'counterfeiting' or piracy to describe situations in which legitimate generic versions of medicines are introduced without the consent of the originator of the drug".[83] The key issue, which has significant implications for access to generic medicines, is that trademarks do not protect goods *per se* but rather signs (marks). It is only patent protection that confers exclusivity to goods (products). In the context of TRIPS (Article 15 and 16), manufacturing, producing or making a good that is substantially identical to another good cannot constitute a trademark violation. It is only the imitation of signs or a combination of signs (marks) affixed on goods that can constitute a trademark violation. Consequently, a broad definition of counterfeiting could mean that a generic company that manufactures, produces or makes a generic medicine, which for safety and efficacy reasons must be an identical copy in its chemical composition as the originator medicine, may be found to have "counterfeited".

In the case of goods-in-transit, it has been argued that such an approach is inconsistent with general and IP-related WTO rules and that it is inconsistent with the purpose of the Doha Declaration.[84] In particular, it is contended that seizures of generics in transit, among others, contravenes Article V of GATT 1994, which requires WTO members to assure freedom of transit for goods passing through their territories; and are inconsistent with the principle of territoriality with respect to patents. In the context of the TRIPS Agreement it is also clear that such an approach runs counter to the desire of WTO members to ensure that IP protection and enforcement procedures do not distort or impede international trade,

including trade in pharmaceuticals, and to ensure that such measures do not become barriers to legitimate trade.

4.2.3. Free trade agreements and the implementation of the Doha Declaration

Intellectual property trends suggest that the existing flexibilities may be eroded, especially through bilateral and regional free trade agreements (FTAs) between high-income countries and low- and middle-income countries. New rules set by FTAs have affected the use of TRIPS flexibilities to facilitate access to medicines. FTAs, which seek TRIPS-plus provisions in the area of pharmaceutical patenting, raise a number of challenges for the effective use of TRIPS flexibilities. The problems that arise include the following[85]:

- Some of the agreements do not clearly spell out the object and purpose of the IP protection, nor do they emphasize the importance of technological innovation, transfer of technology and the protection of economic and social welfare. This means that, unlike TRIPS, which, following the Doha Declaration, should be interpreted in line with the object and purpose (Articles 7 and 8), FTAs lack an appropriate pro-access-to-treatment context for interpretation.
- Some FTAs require the application of a mandatory data exclusivity model, meaning that the registration of generics based on evidence of marketing approval or safety and efficacy in third countries, is prohibited for five or more years from the date of approval of the originator in the country. This applies even where the regulatory agencies in that country do not require the submission of test data.
- Under some FTAs, the concept of utilization of new chemical entities under Article 39.3 of TRIPS is reduced to meaning "one that does not contain a chemical entity that has previously been approved by the Party".
- Some of the FTAs require the developing countries party to them to introduce patent term extensions due to regulatory delays relating to both pharmaceutical registration and patent grant procedures. These provisions are based on arguments specifically rejected by the WTO dispute settlement panel in the *Canada generics case.*[86]
- In some cases, the freedom to determine the grounds for the issue of compulsory licences has been circumscribed contrary to the clarification in the Doha Declaration that each WTO member has the right to determine the grounds for issuing compulsory licences.
- In some cases, the freedom to determine the suitable regime for exhaustion of rights has been curtailed, also contrary to the clear statement in the Doha Declaration that this is an issue that should be left to each WTO member to determine.

The cumulative effect of these types of provisions is to reduce the policy space made available by the TRIPS Agreement for using legal tools and mechanisms to promote access to antiretroviral medications and other medicines.

5. Conclusion: the second decade of Doha and beyond

There have been significant successes in the use of TRIPS flexibilities to facilitate access to antiretroviral medications in the 10 years since the Doha Declaration. However, as the environment becomes more complex, bolder action will be required. India's full compliance with TRIPS pharmaceutical requirements, and the new standards arising from FTAs and IP enforcement initiatives, coupled with the need for better antiretroviral medications, including paediatric formulations, means more low- and middle-income countries will have to proactively use TRIPS flexibilities. The current squeeze on HIV-funding budgets also raises important issues of sustainability. Innovative approaches to R&D financing and IP management, as called for by the CIPIH and the GSPOA, will also need to be found.

Fortunately, a number of opportunities exist to consolidate the achievements of the first decade of the Doha Declaration. These include the creation of the MPP, the continuing efforts by WHO to address sustainable financing for R&D, the growing potential for south-south cooperation, and transparency initiatives in the patent system. The need for sustained use of TRIPS flexibilities while capitalizing on these new opportunities suggests that the Doha Declaration and the Doha-inspired public-health decisions will remain key to achieving universal access to antiretroviral medications and other medicines in the second decade of the Declaration and beyond.

Bibliography

Abbott F. Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: a threat to international trade, development and public welfare. *The WIPO Journal,* 2009, Issue 1:43–50

Abbott F, Reichman J. The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law*, 2007, 10(4)921–987.

Treatment timebomb. London, All Party Parliamentary Group on AIDS, 2009.

Avafia T, Berger J, Hartzenberg T. *The ability of select sub-Saharan African countries to utilize TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines*. TRALAC working paper No. 12. Stellenbosch, TRALAC, 2006.

Biadgleng E, Munoz V. *The changing structure and governance of intellectual property enforcement*. Research Papers 15. Geneva, South Centre, 2008.

Braithwaite J, Drahos P. *Global business regulation.* Cambridge, Cambridge University Press, 2000.

Chaudhuri S. *Indian generic companies, affordability of drugs and local production in Africa with special reference to Tanzania*. IKD working paper No. 37, 2008.

Chaudhuri S. *TRIPS and changes in the pharmaceutical patent regime in India*. Working paper No. 535/2005. Calcutta, Indian Institute of Management, 2005.

Integrating intellectual property rights and development policy. London, Commission on Intellectual Property Rights, 2002.

Commission on Intellectual Property Rights. *Public health, innovation and intellectual property rights.* Geneva, World Health Organization, 2006.

Correa C. *Implementing the WTO General Council decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. Geneva, World Health Organization, 2004.

Correa C. *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*. Health Economics and Drugs Series No. 012. Geneva, World Health Organization, 2002.

Correa C. *Integrating public health concerns into patent legislation in developing countries.* Geneva, South Centre, 2000.

Correa C, Yusuf A, eds. Intellectual property and international trade: the TRIPS Agreement (second edition). *Kluwer Law International*, 2008.

De Cock KM, El-Sadr WM, Ghebreyesus TA. Game changers: why did the scale-up of HIV treatment work despite weak health systems? *Journal of Acquired Immune Deficiency Syndromes,* 1 August 2011, 57(Suppl. 2):S61–S63.

Fink C, Correa C. *The global debate on the enforcement of intellectual property rights and developing countries*. Issue paper 22. Geneva, International Centre for Trade and Sustainable Development, 2008.

Fink C, Reichenmiller P. *Tightening TRIPS: the intellectual property provisions of recent US free trade Agreements.* World Bank Trade Note 20. Washington, DC, World Bank, 2005.

Guide to the Global Fund's policies on procurement and supply management. Geneva, Global Fund, 2009.

Heller M, Eisenberg R. Can patents deter innovation? The anticommons of biomedical research. *Science,* 1998, Vol. 280

Kerry VB, Lee K. TRIPS, the Doha Declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines? *Globalization and Health*, 2007, 3:3.

Lerner J, Jaffe A. *Innovation and its discontents: how our broken patent system is*

endangering innovation and progress and what to do about it. Princeton and Oxford, Princeton University Press, 2004.

Martin G, Sorenson C, Faunce T. Balancing intellectual monopoly privileges and the need for essential medicines. *Globalization and Health,* 2007, 3:4.

Maskus K, Reichmann J. The globalization of private knowledge goods and the privatization of global public goods. *Journal of International Economic Law,* 2004, 7(2)279–320

Moon S. *Does TRIPS article 66.2 encourage technology transfer to LDCs? – an analysis of country submissions to TRIPS Council (1999–2007).* Policy brief No. 2. Geneva, United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, 2008.

Surmounting challenges: procurement of antiretroviral medicines in low- and middle-income countries – the experience of Médecins Sans Frontières, MSF Access to Medicines Campaign. Geneva, World Health Organization and UNAIDS, 2003.

Musungu S. *The potential impact of WTO accession, FTAs and partnership agreements on access to medicines in the Commonwealth of Independent States (CIS).* Background paper commissioned by UNDP HIV Practice Group, 2009.

Musungu S. *Access to ART and other essential medicines in sub-Saharan Africa: intellectual property and relevant legislations. A UNDP commissioned study.* New York, United Nations Development Programme, 2007.

Musungu S, Oh C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Geneva, South Centre and World Health Organization, 2005.

Musungu S, Villanueva S, Blasetti R. *Utilizing TRIPS flexibilities through south-south regional frameworks.* Geneva, South Centre, 2004.

Nunn A et al. Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment. *Public Library of Science Medicine,* 2007, Vol. 4, issue 11.

Patents and innovation: trends and policy challenges. Paris, Organisation for Economic Cooperation and Development, 2004.

Oliveira MA et al. Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property that favours public health? *Bulletin of the World Health Organization,* 2004, 82(11).

Playing by the rules: using intellectual property and policy to improve access to essential medicines. New York, Open Society Institute, 2008.

Revanga A et al. *The economics of effective AIDS treatment – evaluating policy options for Thailand.* Washington, DC, World Bank, 2006.

Roffe P, Spennemann C. The impact of FTAs on public health policies and TRIPS flexibilities. *International Journal for Intellectual Property Management, 2006, Vol. 1, Nos. 1–2*

Sell S. *Global IP upward ratchet, anticounterfeiting and piracy enforcement efforts: the state of play.* IQsensato Occasional Paper 1. Geneva, IQsensato, 2008.

Seuba X. *Border measures concerning goods allegedly infringing intellectual property rights: the seizures of generic medicines in transit* (working paper). Geneva, International Centre for Trade and Sustainable Development, 2009.

't Hoen E. *The global politics of pharmaceutical monopoly power.* Diemen, AMB Publishers, 2009.

Chronic care of HIV and noncommunicable diseases. Geneva, UNAIDS, 2011a.

AIDS at 30: nations at the crossroads. Geneva, UNAIDS, 2011b.

UNAIDS Outlook Report 2011. Geneva, UNAIDS, 2011c.

Treatment 2.0: Is this the future of treatment? Geneva, UNAIDS, 2010a.

UNAIDS 2011–2015 strategy: getting to zero. Geneva, UNAIDS, 2010b.

The global economic crisis and HIV prevention and treatment programmes: vulnerabilities and impact. Geneva, UNAIDS, 2009,

Using TRIPS flexibilities to improve access to HIV treatment. Geneva policy brief. Geneva, UNAIDS, WHO and UNDP, 2011.

The TRIPS Agreement and developing countries. New York and Geneva, United Nations Conference on Trade and Development, 1996.

United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development. *Resource book on TRIPS and development.* New York, Cambridge University Press, 2005.

Good practice guide: improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement. New York, United Nations Development Programme, 2010.

Human development report 2001: making new technologies work for human development. New York, Oxford University Press, 2001.

Vandoren P, Van Eeckhaute J. The WTO decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health – making it work. *The Journal of World Intellectual Property,* 2003, *6:6,*779–793

Velasquez G, Boulet P. *Globalisation and access to drugs: perspectives on the WTO/TRIPS Agreement*. Health Economics and Drugs Series. Geneva, World Health Organization, 1999.

Waning B, Diedrichsen E, Moon S. A lifetime of treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS Society,* 2010, 13:35.

Waning B et al. Temporal trends in generic and brand prices of antiretroviral medicines procured with donor funds in developing countries. *Journal of Generic Medicines*, 2010, 7:159–175

Watal J. *Intellectual property rights in the WTO and developing countries.* The Hague, Kluwer Law International, 2001.

Towards universal access – scaling up priority HIV/AIDS interventions in the health sector (progress report). Geneva, WHO/UNAIDS/UNICEF, 2010

Patent-related flexibilities in multilateral legal framework and their legislative implementation at the national and regional levels. A document prepared by the secretariat for the CDIP. Geneva, World Intellectual Property Organization, 2010 (CDIP/5/4 REV).

Wong T, Dutfield G, eds. *Intellectual property and human development – current trends and future scenarios.* New York, Public Interest Intellectual Property Advisors and Cambridge University Press, 2011.

HIV/AIDS medicines and related supplies: contemporary context and procurement – technical guide. Washington, DC, World Bank, 2004.

World Trade Organization. *The legal texts: the results of the Uruguay round of multilateral trade negotiations.* Cambridge, Cambridge

Notes

[1] See UN General Assembly document A/RES/55/2 available at http://www.un.org/millennium/declaration/ares552e.htm.

[2] The MDGs consist of eight goals and 21 targets to be met by 2015. Their genesis is in the Millennium Declaration, which was adopted by UN Member States' Heads of State and Government in September 2000 at the end of the Millennium Summit.

[3] The Declaration of Commitment is accessible on the UNAIDS website at http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub03/aidsdeclaration_en.pdf.

[4] UNAIDS was established in 1994 by a resolution of the UN Economic and Social Council to provide an internationally coordinated response to the disease. The resolution is available at http://data.unaids.org/pub/ExternalDocument/1994/ecosoc_resolutions_establishing_unaids_en.pdf. Information on UNAIDS and its current work can be found on its website at http://www.unaids.org/en/.

[5] Following the award of the Nobel Peace Prize to MSF, it launched a campaign on access to medicines in 1999. The campaign became one of the major forces in the access-to-medicines movement. Information about the campaign and its work can be found at http://www.msfaccess.org/the-access-campaign.

[6] The Agreement Establishing the WTO (WTO Agreement) as well as the text of the TRIPS Agreement, which is Annex 1C to the WTO Agreement is contained in WTO (1999).

[7] For a detailed discussion of the South Africa dispute see e.g., 't Hoen (2009).

[8] For background on this debate see e.g., UNCTAD (1996), Correa (2000), Commission on Intellectual Property rights (2002), UNCTAD and ICTSD (2005) and 't Hoen (2009).

[9] The Declaration was adopted in November 2001 at the Fourth WTO Ministerial Conference held in Doha, Qatar. It is available on the WTO website at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[10] For general discussion of the negotiations on issues such as the patentability of all products and processes in all fields of technology, see UNCTAD and ICTSD (2005).

[11] After the adoption of TRIPS, at least 13 countries, including Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay, notified "mailbox" systems to the TRIPS Council, an indication that these countries did not grant patent protection to pharmaceutical products before TRIPS. See the WTO Technical Note on Pharmaceutical Patents and the TRIPS Agreement on the WTO website at http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm.

[12] For a discussion of compulsory licensing in the United States see e.g., Reichman and Hasenzahl (2003).

[13] See 't Hoen (2009), p. 41.

[14] *Supra* note 11.

[15] See the "Declaration on the TRIPS Agreement and Public Health", WTO document WT/MIN(01)/DEC/W/2 dated 20 November 2001.

[16] Some of the definitions in the box have been adapted from Musungu and Oh (2006) and WTO Factsheet on patents and pharmaceuticals (http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#eligibility).

[17] The texts of each of these decisions can be found on the WTO website by searching through the "documents online" system (http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[18] The decision is contained in WTO doc. IP/C/28.

[19] UNAIDS, WHO and UNDP Policy Brief (2011), p. 4.

[20] UNAIDS (2011a), p. 8.

[21] De Cock et al (2011) at S61.

[22] See UNAIDS (2011b).

[23] MSF (2003), p. 5.

[24] UNAIDS (2011a), p. 202.

[25] UNAIDS (2011a), *id.*

[26] The examples of how countries have used TRIPS flexibilities discussed in this study are primarily drawn from UNAIDS, WHO and UNDP (2011); UNDP (2010); Open Society Institute (2008); 't Hoen (2009); and Musungu and Oh (2006).

[27] Global response to HIV/AIDS: Epidemic update and progress towards universal access. WHO, UNAIDS and UNICEF, 2011 WHO, UNAIDS and UNICEF (2010), p.13.

[28] The data on incorporation of TRIPS flexibilities in national laws is based on Musungu (2007).

[29] For a discussion on this case see UNAIDS, WHO and UNDP (2011).

[30] See the dedicated ratification page at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[31] For basic information on status of competition laws in various countries see the Global Competition Forum website at http://www.globalcompetitionforum.org/africa.htm.

[32] See the notification of Rwanda to the WTO under the 30th August system at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm. In its notification, Rwanda stated that "Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product."

[33] For additional discussion of these cases see 't Hoen (2009).

[34] The Protocol has been developed with the support of German's GIZ project. Information on this project and the various inter-related activities is available at http://www.eacgermany.org/index.php/eac-giz-programme/trips-and-pharmaceutical-production.

[35] WHO, UNAIDS and UNICEF (2010), p. 13.

[36] For more discussion on the parallel importation regime in Philippines see UNDP (2010), pp. 39 - 40.

[37] The Cambodian law can be downloaded from WIPO Lex at http://www.wipo.int/wipolex/en/details.jsp?id=5781.

[38] Both the Indian Patent Act 1970 and the various amendment acts, including the 2005 one, can be found on WIPO Lex at http://www.wipo.int/wipolex/en/details.jsp?id=2393.

[39] WHO, UNAIDS and UNICEF (2010), p. 13.

[40] According to Oliveira *et al* (2004) Argentina, Brazil, Bolivia, Colombia, Dominican Republic, Ecuador, Honduras, Mexico, Peru and Venezuela all provide for compulsory licensing in their laws.

[41] See press release at http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3116.

[42] See Oliveira *et al* (2004).

[43] See UNDP (2010), p. 26 for a discussion of the provisions in the Argentinean law and the issues that have been raised by the United States.

[44] See UNAIDS "AIDS Epidemic Factsheets" at http://www.unaids.org/en/Dataanalysis/Epidemiology/2009AIDSEpidemicUpdate/.

[45] WHO, UNAIDS and UNICEF (2010), p. 13.

[46] This analysis is partly based on the review of laws in Musungu (2009).

[47] See e.g., the side letters to the US-Morocco and US-Bahrain FTAs. Both are available at http://www.ustr.gov/trade-agreements/free-trade-agreements.

[48] See PEPFAR press release at http://www.pepfar.gov/press/releases/2010/144808.htm.

[49] The Resolution is available on the WHO website at http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

[50] For information on the WIPO Development Agenda see the WIPO website at http://www.wipo.int/ip-development/en/agenda/.

[51] Perez Casas, C., "Global Fund Experience: Challenges in Procurement of antiretrovirals linked to IP Landscape" presentation at the Third UNITAID Consultative Forum, Geneva , 4 -5 October 2011 (http://www.unitaid.eu/en/component/content/article/330.html).

[52] See the Report of the Third Global Fund Board Meeting held in October 2002 available at http://www.theglobalfund.org/en/board/meetings/third/.

[53] In addition to providing advice and many technical assistance missions, these organizations have published guidance on the use of TRIPS flexibilities to promote access to antiretrovirals and other essential medicines, including UNAIDS, WHO & UNDP (2011); UNDP (2010); UNCTAD & ICTSD (2005); World Bank (2004) and Correa (2002).

[54] UNITAID's mission is to contribute to scaling up access to medicines for HIV/AIDS, tuberculosis and malaria in low-income countries by leveraging price reductions for quality diagnostics and medicines and accelerating the pace at which these are made available. Detailed information on the organization can be found on its website at http://unitaid.eu/.

[55] DNDI was established in 2003 as a collaborative, patients' needs-driven, non-profit drug R&D organization that is developing new treatments for malaria, visceral leishmaniasis, sleeping sickness (human African trypanosomiasis), and Chagas disease. Further information about the initiative can be found on its website at http://www.dndi.org/.

[56] See UNITAID Factsheet at http://unitaid.eu/images/Factsheets/md_factsheet_2011_en.pdf.

[57] See Article 1.2 of the UNITAD Constitution. http://unitaid.eu/images/governance/en_constitution_rev6july2011.pdf.

[58] DNDi's IP Policy is available at http://www.dndi.org/images/stories/pdf_aboutDNDi/ip%20policy.pdf.

[59] For a discussion on the role of civil society in these and other countries in promoting access to antiretrovirals and other treatments through the use of TRIPS flexibilities see OSI (2008).

[60] MSF began its treatment programme in 2000 in Cameroon, South Africa and Thailand. For more information on the programme and its current status see the 'MSF and HIV/AIDS' webpage at http://www.msfaccess.org/our-work/hiv-aids/article/1345.

[61] See 't Hoen (2009) for a discussion of the South Africa case and the hard-line approach of the companies then.

[62] See IFPMA press release at http://www.ifpma.org/fileadmin/content/Innovation/IP%20and%20Access/Release_TRIPS_%20extension_10Feb2011.pdf.

[63] For detailed discussions and the politics, including how language was used as a weapon in the debate, see e.g., 't Hoen (2009).

[64] The Strategy and Plan of Action were adopted under WHO Resolution WHA61.21, which is available at http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

[65] See CIPIH (2006).

[66] CIPIH (2006), p. 172.

[67] Information on the MPP Foundation can be found on its website at www.medicinespatentpool.org/.

[68] For information on the licences and the licensing terms see the MPP website at http://www.medicinespatentpool.org/LICENSING.

[69] CIPIH (2006), p. 17.

[70] The CEWG was established in May 2010 by Resolution WHA63.28 (http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R28-en.pdf) to continue the work of a previous expert group to, among other things, explore incentive schemes for R&D, including addressing, where appropriate, the de-linkage of the costs of R&D and the price of health products.

[71] Treatment 2.0 is a radically simplified HIV treatment platform that decreases AIDS-related deaths drastically and could also greatly benefit HIV prevention efforts. For details see UNAIDS (2010a).

[72] For a discussion on the limitations of Article 66.2 see e.g. Moon (2008).

[73] For information on the Brazilian initiative see e.g., the Reuters report of May 2007 at http://www.reuters.com/article/2007/05/29/health-aids-mozambique-brazil-dc-id UKL2957933720070529.

[74] Information on WIPO's work is available at http://www.wipo.int/patentscope/en/programs/patent_landscapes/pl_about.html.

[75] The database is available at http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-antiretrovirals.

[76] The general date of application for developing countries was 1 January 2000, hence five additional years meant 1 January 2005.

[77] See Waning, Diedrichsen & Moon (2010).

[78] See Perez Casas *supra* note 51.

[79] See PEPFAR press release at http://www.pepfar.gov/press/releases/2010/144808.htm.

[80] See MSF's Untangling the web of antiretroviral price reductions at http://utw.msfaccess.org/background/challenges.

[81] In addition to hundreds, if not thousands, of national initiatives there are now many international initiatives and processes that seeks to address IP enforcement. For a discussion of the issues at play see e.g., The OECD Report on "The Economic Impact of Counterfeiting and Piracy" available at http://www.oecd.org/dataoecd/11/38/38704571.pdf; The Report of the G8 Intellectual Property Experts Group (IPEG) to the 2009 G8 Summit available at http://www.g8italia2009.it/static/G8_Allegato/ITALY%20G8%20IPEG%20Final%20Report,0.pdf; Sell (2008); Fink and Correa (2008); and Biadgleng and Munoz (2008).

[82] Under the TRIPS Agreement (Footnote 14), counterfeiting means without authorization, using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which a trademark is validly registered, subject to any exceptions limiting the rights of the trademark owner. In other words, it is a term that is primarily related to trademark infringement.

[83] See Correa in Fink and Correa (2008).

[84] See Abbott (2009).

[85] For a discussion of these and other problems see e.g., Musungu and Oh (2006), Roffe and Spennemann (2006), 't Hoen (2009) and UNAIDS, WHO and UNDP (2011).

[86] See *Canada – Patent Protection of Pharmaceutical Products,* Report of Panel, WT/DS/114/R, 17 March 2000.

UNAIDS, THE JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, IS AN INNOVATIVE UNITED NATIONS PARTNERSHIP THAT LEADS AND INSPIRES THE WORLD IN ACHIEVING UNIVERSAL ACCESS TO HIV PREVENTION, TREATMENT, CARE AND SUPPORT.

20 Avenue Appia
CH-1211 Geneva 27
Switzerland

+41 22 791 36 66

publications@unaids.org
unaids.org

UNAIDS
Joint United Nations Programme on HIV/AIDS

UNHCR UNICEF WFP UNDP UNFPA
UNODC ILO UNESCO WHO WORLD BANK