



United Nations Development Programme

HIV/AIDS

**GOOD PRACTICE GUIDE:
IMPROVING ACCESS TO TREATMENT
BY UTILIZING PUBLIC HEALTH FLEXIBILITIES
IN THE WTO TRIPS AGREEMENT**

Good Practice Guide:
Improving Access to Treatment
by Utilizing Public Health Flexibilities
in the WTO TRIPS Agreement

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Foreword

Over the past ten years, there has been a remarkable and virtually unprecedented global scale-up of a life-saving medical technology: antiretroviral therapy for people with advanced HIV infection. This therapy not only prolongs life for most patients, it keeps people healthy enough to work, to continue their lives in families and as parents, and to contribute to their communities and countries. We now know that antiretroviral therapy also lowers the amount of HIV in the bloodstream, thus making people less infectious and contributing to HIV prevention goals as well.

This achievement is all the more remarkable given that only about 40,000 people in low and middle income countries were benefiting from such treatment in 2000. Now, ten years later, over 5 million people have access.

The successes of the past ten years are directly linked to the drastic fall in the price of these drugs. The cost of first generation antiretrovirals has decreased from over ten thousand US dollars to as low as 67 dollars per person per year. This amazing reduction has been achieved largely thanks to competition from generic manufacturers, which, for millions of people worldwide, has been the difference between life and death. Such competition has in large part been made possible by countries' utilization of the public health flexibilities in the World Trade Organization's TRIPS Agreement.

There is still a great deal of work to do. Despite the significant progress in access to HIV treatment worldwide, the global coverage remains low and only about a third of the people who need treatment have access to it. This coverage gap is combined with an increased demand for newer, better antiretroviral medicines, as people on treatment live longer. Resistance to first generation treatment regimens often requires patients to switch to more expensive second line therapy. Furthermore, the recently revised recommendations of the World Health Organization (WHO) will result in patients needing to commence antiretroviral therapy earlier, which will increase the number of people requiring treatment.

As patients develop drug resistance and require more expensive, patent-protected second- and third-line antiretroviral medicines, some projections see treatment costs escalating as much as twenty-fold. Cost of second generation first-line medicines is also higher, as is the cost of paediatric antiretroviral formulations. The situation is even more complex due to the high cost of patented pharmaceuticals for treatment of co-infections such as tuberculosis, or hepatitis C. These facts lead to warnings such as the report on long-term access to HIV medicines by the United Kingdom’s All-Party Parliamentary Group on AIDS that we are sitting on “a treatment time bomb”. To sustain and expand the coverage of life-saving treatment and its contributions to prevention, prices of drugs, diagnostics and delivery efforts must continue to fall.

In this context of impressive achievement and daunting goals, we are pleased to present this Good Practice Guide on improving access to treatment by utilizing WTO TRIPS flexibilities. The Guide is part of our work under UNDP’s mandate to provide capacity development support to governments to implement good practices in intellectual property law and policy with focus on public health and south-south cooperation. We consider this Guide to be an instrument that can be used to support national initiatives for protecting, upholding and fulfilling the universal right to the best attainable standards of health, as enshrined in international treaties and many national constitutions.

The Good Practice Guide analyses each of the public health flexibilities in the TRIPS Agreement and provides examples where and how have they been used by national governments. The Guide also provides some examples on the effect of adopting intellectual property protection measures, which exceed the minimum requirements of TRIPS and which are often introduced through bilateral trade instruments. An extensive bibliography allows further research on any of these matters.

This Good Practice Guide has been developed by the UNDP HIV/AIDS Practice at the Bureau for Development Policy with the support of numerous experts and field partners. We are grateful for their valuable contributions and welcome and appreciate your comments and feedback.



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I. Who Is this Guide for and How to Use It?

This Good Practice Guide has been prepared by the HIV/AIDS Practice at the Bureau for Development Policy of the United Nations Development Programme (UNDP). It aims to explain the impact of and connection between intellectual property rights (IPR) and access to treatment.¹ It also provides details about certain provisions under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) that governs intellectual property rights under the World Trade Organization (WTO) regime. These provisions allow governments and policy makers to shape their intellectual property protection systems while considering public health priorities. The Guide discusses ways in which these provisions and safeguards can be used in a flexible manner. It provides examples of how they have been applied by governments in various countries, and what effect such utilization has achieved thus far.

This Guide is designed for a broad audience of people concerned with the impact of IPR on public health. It can be used by legislators, policy makers and government officials in discussions on adopting or reforming relevant legislation, in the process of formulating national IPR and public health policies, as well as in negotiating WTO accession agreements, or bilateral trade agreements that contain reference to IPR obligations. The Guide can assist officials at UN agencies and other international organizations in their work on health, law and development. It can serve as a reference and advocacy tool to civil society actors in efforts to support access to essential medicines, access to knowledge and innovation, especially in low and middle income countries. As a teaching tool, this Good Practice Guide provides the basics. However, it includes an extensive bibliography that can be consulted for more extensive research.

For the purposes of simplicity and comprehensiveness, it is suggested that users first familiarize themselves with the system of public health flexibilities presented in Sections II–V of the Guide. Examples of various recommended national practices are also provided in highlighted boxes. Section V.6. of the Guide provides a set of recommendations about how to use the public health flexibilities and mitigate efforts to limit their effect.

¹ For the purposes of this Good Practice Guide treatment is understood to include medicines for HIV and opportunistic infections, as well as diagnostics.

This Guide is part of a broad scope of advisory services that UNDP provides in the field of IPR and public health. As a founding co-sponsor of the Joint United Nations Programme on HIV/AIDS (UNAIDS), guided by the health-related Millennium Development Goals and particularly MDG 6 “to halt and reverse the spread and HIV, Malaria and other epidemics by 2015”, UNDP offers policy and technical co-operation to reform national intellectual property legislation to incorporate public health flexibilities.

At the outset, this Guide acknowledges that the utilization of the TRIPS Agreement flexibilities solely in itself will not be sufficient to solve the issues surrounding public health and access to medicines. This utilization of flexibilities should be viewed as one of a number of national administrative, legislative and institutional ingredients which would collaborate to create a functioning and innovative system of checks and balances in this area. The role of these complementary agencies and policies including the judiciary, supporting bylaws and regulations, unfair competition laws and policies, civil society participation, proper pension schemes, adequate national medical health care insurance schemes, drug pricing and control regulations, national procurement mechanisms and access to information laws and policies are some of the other elements which will also impact such a regime.

II. Introduction

In 2010, there were around 33.3 million people in the world living with Human Immunodeficiency Virus (HIV).² Antiretroviral therapy (ART) saves lives, transforming a fatal disease into a chronic but treatable illness. By December 2009, approximately 5.2 million people worldwide were receiving ART, up from 4 million people in 2008.³ In the past six years there has been a twelve-fold global increase in people who have access to treatment. However, with the recent revision by the World Health Organization (WHO) of its HIV treatment guidelines, which now recommend starting ART at a higher white blood cell count, the number of people who require treatment has reached approximately 15 million.⁴ Notwithstanding the achievements in scaling up treatment, the need also persists in the prevention and treatment of tuberculosis and malaria, and, similarly to HIV, people who live in the Global South are of particular concern.

The lack of access to essential medicines represents not only a public health crisis, but a human rights challenge as well. The right of “everyone to the enjoyment of the highest attainable standard of physical and mental health” is enshrined in the International Covenant on Economic, Social and Cultural Rights (ICESCR)⁵ and this right also extends to the access to essential medicines.⁶ The right to health is included in various other public international law documents, as well as in about two-thirds of all national constitutions.⁷ International and domestic human

² UNAIDS. *Global Report: UNAIDS Report on the Global AIDS Epidemic 2010*. Geneva, UNAIDS, “UNAIDS/10.11E | JC1958E”, 2010.

³ WHO. *Antiretroviral Therapy for HIV Infection in Adults and Adolescents: Recommendations for a Public Health Approach—2000 rev.* Austria, WHO, (NLM classification: WC 503.2), 2010. Also see WHO. *New Progress and Guidance on HIV Treatment*. Geneva, WHO, 2010. Available at www.who.int/hiv/vienna2010/en/index.html.

⁴ WHO (*Antiretroviral Therapy for HIV Infection*), *Ibid.*

⁵ ICESCR, Article 12, www2.ohchr.org/english/law/cescr.htm.

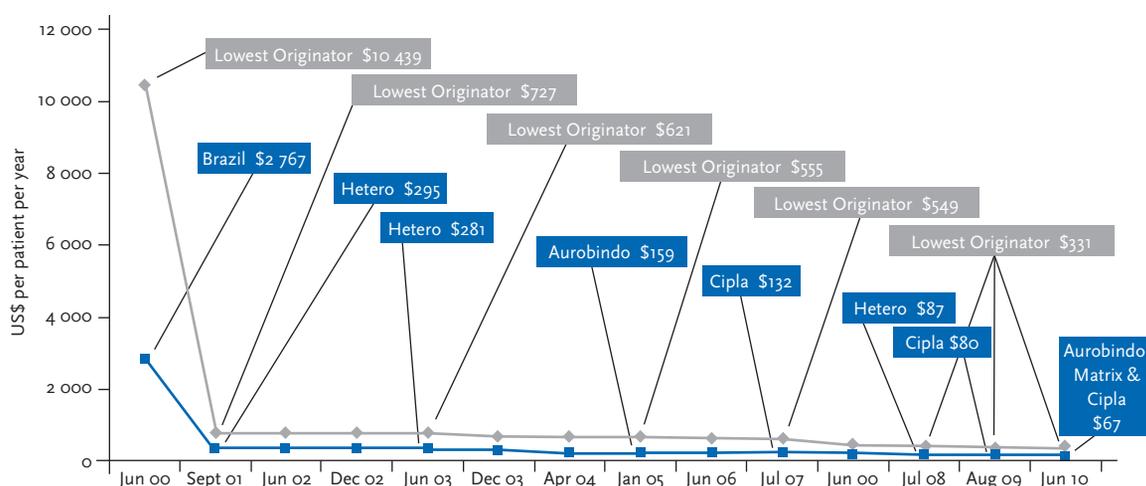
⁶ Committee on Economic, Social and Cultural Rights, *The Right to the Highest Attainable Standard of Health*, General Comment 14, 2000, www.unhcr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En.

⁷ Forman L. Trade Rules Intellectual Property and the Right to Health. *Ethics & International Affairs*, 2007, 21(3):337-357, at 346.

rights obligations to provide citizens with the highest attainable standard of health can be seen as an affirmative duty upon national policy makers to incorporate these flexibilities into their laws.

Over the past 10 years, the cost of first-line combination ART in low and middle income countries has decreased by more than 99% reaching as low as USD 67 per person per year in 2010 (see Figure 1). This drastic price reduction was achieved largely due to the competition from generic medicines manufacturers. In 2001, Indian generic medicine manufacturer Cipla offered the **antiretroviral** (ARV) combination Triomune (stavudine + lamivudine + nevirapine) at less than one dollar a day, precipitating a massive price reduction from the USD 10,000 to USD 15,000 per patient per year being charged by research based pharmaceutical companies.⁸ Today, the majority of the ARVs supplied by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) are generic. In 2009, some 90% of the ARVs delivered by the programs of the US President’s Emergency Plan for AIDS Relief (PEPFAR) were also generic.⁹

Figure 1
Prices of First Line Antiretroviral Medicines, 2000–2010



Source: MSF (2010), *Untangling the Web of Antiretroviral Price Reductions*, 13th ed.

There are many reasons which may inhibit the access to essential medicines. One very significant factor is their high prices. In low-income countries 50–90% of the money people spend

⁸ McNEIL D. Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa. *The New York Times*, February 7, 2001.

⁹ Holmes C. et al. Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs. *The Journal of the American Medical Association*, 2010, 304(3): 313-320.

on health goes toward buying medicines.¹⁰ While there are a range of factors that contribute to the prices of medicines, one of the more significant ones is intellectual property protection.¹¹ According to international IPR standards, patent holders usually have a 20-year monopoly over patented medicines.¹² As a result, competing producers of generic equivalents, which are traditionally cheaper, are often excluded from entering the markets where the medicines are patented during the protection term.

The WTO TRIPS Agreement is the most widely and controversially discussed instrument in the debate about IPR protection and access to treatment. The TRIPS Agreement was negotiated during the Uruguay Round and came into force on 1 January 1995.¹³ It established minimum protection standards for a set of IPR, which all WTO Member States are required to adhere to and implement through their national legislation. A key provision of the TRIPS Agreement obligates WTO Members to provide mandatory patent protection for inventions in all fields of technology for a minimum term of 20 years. In the beginning of the Uruguay Round in 1986, countries were free to determine the duration of patents and as many as 50 states did not grant patent protection for pharmaceutical products at all.¹⁴ Some countries also excluded pharmaceutical processes from patent protection.¹⁵ Commenting on the prevailing situation then, Abbott and Reichman state that it “otherwise left states free to devise and implement their own patent systems and, as many chose to do, even to deny any patent protection for pharmaceutical products at all”.¹⁶ The TRIPS Agreement reduced the discretionary powers of WTO Members to adapt their national IPR regimes to meet specific developmental needs through the imposition of a “one size fits all” IPR minimum standards protection regime.

¹⁰ WHO. *WHO Medicines Strategy: Countries at the Core 2004–2007*. WHO, Geneva, 2004. Available at http://whqlibdoc.who.int/hq/2004/who_edm_2004.2.pdf.

¹¹ Drahos P., Mayne R. (eds). *Global Intellectual Property Rights: Knowledge, Access and Development*. Basingstoke, Palgrave Macmillan, 2002, at 11.

¹² TRIPS, Art 33.

¹³ On the history of the Uruguay Round and the TRIPS Agreement see UNCTAD–ICTSD. *Resource Book on TRIPS and Development*. Cambridge, Cambridge University Press, 2005. Notably, countries that are signatory to the 1883 Paris Convention for the protection of intellectual property are more in number than WTO Member States (175 compared to 153). However, the TRIPS Agreement is more controversially quoted in the debate surrounding access to HIV treatment, primarily because it covers a broader scope of issues in particular extending patent protection to pharmaceutical products. The WTO also subjects Intellectual property conflicts to its Dispute Settlement Mechanism.

¹⁴ For more see Li X. The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement—A Comparative Study of China and India. *The World Economy*, 2008, 31(10): 1367–1382.

¹⁵ UNCTAD-ICTSD, *Supra* 13.

¹⁶ 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, at 927.

The TRIPS Agreement also contains minimum standards on “protection of undisclosed information” (not data exclusivity),¹⁷ as well as enforcement procedures, and remedies.¹⁸ Ratification of the Agreement is a compulsory requirement for WTO membership. The TRIPS Agreement’s provisions could be enforced through the Dispute Settlement Mechanism of the WTO.

The TRIPS Agreement specifies that IPR protection and enforcement are to contribute to the promotion of innovation, transfer and dissemination of technology, and use of technological knowledge “in a manner conducive to social and economic welfare” and should balance rights and obligations.¹⁹ **It contains a number of provisions that could be used by member states to promote public health, and, more specifically access to medicines. These provisions may be referred as “the public health-related TRIPS flexibilities” and are discussed in detail below.**

Despite the presence of such public health-related flexibilities, it has been argued that the TRIPS Agreement is clearly negotiated in favor of high income, knowledge based economies, which are the net-exporters of IPR-related revenues.²⁰ These countries are a minority in the WTO. About two thirds, or over 100 out of the 153 WTO Member States are low and middle income countries, and 30 are least developed countries (LDCs).²¹ However, if we compare the markets of these countries we will see that big markets, most notably the ones of the European Union (EU) and the United States (US), dominate the WTO system and its decision making process. Figure 2 illustrates this disparity.

UNDP has been monitoring the impact of the TRIPS Agreement on development in general and access to knowledge, food and health in particular. In 1999, the UNDP Human Development Report (HDR) warned that “the relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed—in every country—of the economic and social consequences of the TRIPS Agreement.”²²

¹⁷ TRIPS, Article 39.3. For more see Correa C. *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*. Geneva, South Centre, 2002.

¹⁸ See TRIPS, Part III.

¹⁹ TRIPS: Preamble and Articles 7 and 8.

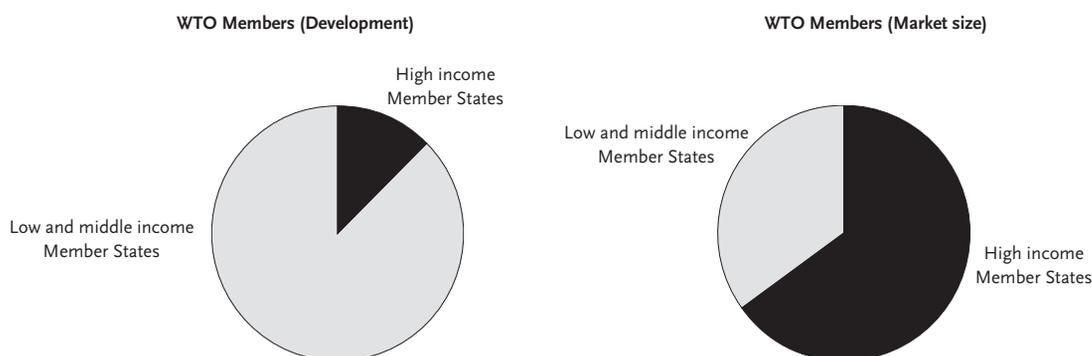
²⁰ See generally Correa C. *Intellectual Property Rights, the WTO and Developing Countries*. London, Zed Books, Third World Network, 2000.

²¹ See WTO website, *Understanding the WTO: Developing Countries; Overview*, www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm. (Last visited 7 September 2010). LDCs are those countries identified as such by the United Nations criterion, which generally relies on the country’s national income, human resource weakness and economic vulnerability. For more on this classification see www.un.org and www.wto.org. on the other hand, developing country status is determined by the WTO and is based on a self-selection criterion.

²² UNDP. *Human Development Report 1999*. New York, Oxford University Press, 1999, www.hdr.undp.org/en/media/HDR_1999_EN.pdf, at 73.

Figure 2

WTO Members According to Level of Development and Market Size



Source: Data from the WTO website on developing and least developed Member States (2010). Market size is represented based on GDP and PPP data of the World Bank (2009).

The early attempts of low income countries to utilize the TRIPS Agreement flexibilities to promote access to affordable medicines were fraught with challenges. When South Africa amended its Medicines and Related Substances Act in 1997, to enable parallel importation and compulsory licensing, 39 pharmaceutical companies and the South African Pharmaceutical Manufacturers' Association challenged the amendment before the South African Supreme Court of Appeal. In another case, the US Government initiated a complaint against Brazil within the WTO Dispute Settlement Mechanism, questioning the legality of the Brazilian law, which authorized the grant of compulsory licenses where patent holders have not worked their inventions locally (i.e., manufacturing the patented product in the country). The pharmaceutical companies in South Africa and the US Government eventually withdrew their claims, before any judgments or decisions were delivered on the validity of their causes of action.²³ Against this backdrop, low income WTO Member States pressed for the adoption of the **Doha Declaration on the TRIPS Agreement and Public Health** in 2001 (the Doha Declaration), to clarify ambiguities between the need for governments to implement the TRIPS Agreement and to protect the right to health.²⁴ The Doha Declaration affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive to protecting public health and promoting access to medicines for all.²⁵ The Doha Declaration reaffirmed some of the TRIPS Agreement flexibilities that could facilitate access to medicines.

²³ For more on both cases see T. Hoehn E. *The Global Politics of Pharmaceutical Monopoly Power*. Diemen, AMB Publishers, 2009.

²⁴ Two declarations were passed during this conference. The first one concerned the negotiations in agriculture and services and established the Doha Development Agenda. The Declaration on the TRIPS Agreement and Public Health was the second document adopted by the ministers.

²⁵ WTO, the Doha Declaration on the TRIPS Agreement and Public Health, 14 November 2001. <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/Min01/DEC2.doc>

The TRIPS Agreement does not directly apply to the national legal systems of WTO Member States. Countries have to adopt provisions that are consistent with the TRIPS Agreement in their domestic laws. This applies to the public health flexibilities as well. Despite the opportunities that the flexibilities provide, many countries have yet to amend their laws in order to incorporate them fully. Findings from a 2007 UNDP study showed that only six countries in sub-Saharan Africa, the region with the highest HIV prevalence in the world, have provisions on the international exhaustion of rights in their legislation.²⁶ A 2010 study of the World Intellectual Property Organization (WIPO), indicates that only 29 (26%) out of 112 countries who provided feedback have adopted international exhaustion of rights regime. The study also found that 36 countries (32%) have a regional exhaustion regime, thus allowing for parallel imports, while 42 (37.5%) have a national exhaustion regime, which does not allow the use of this flexibility. Out of 95 countries who submitted information, only 56% had integrated the early working (Bolar) exception into their patent legislation. The percentage of countries integrating this flexibility varied from 0% (0/20) for LDCs to 93% (25/27) for high-income countries.²⁷

WTO accession negotiations on IPR tend to be carried out at bilateral, rather than multilateral levels. Candidate countries are often pressed hard to adopt stricter IPR protection regimes (**TRIPS-plus**), in order to get the consent for their accession to the WTO from the other negotiating party.²⁸ In addition, TRIPS-plus provisions are introduced through bilateral agreements, such as free trade agreements (FTAs) and investment treaties.²⁹ In this regard, in 2006, the UN General Assembly adopted the Political Declaration on HIV/AIDS in which it expresses the commitment of UN Member States to find “appropriate solutions to overcome barriers in pricing, tariffs and trade agreements, and to making improvements to legislation, regulatory policy, procurement and supply chain management in order to accelerate and intensify access to affordable and quality HIV/AIDS prevention products, diagnostics, medicines and treatment commodities.”³⁰

²⁶ Musungu S. *Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislation*. Report submitted to UNDP Regional Services Centre for Eastern and Southern Africa, September 2007. www.soros.org/initiatives/health/focus/access/articles_publications/publications/artafrica_20090313/artafrica_20090313.pdf

²⁷ WIPO Secretariat. *Patent-related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels*. Geneva, CDIP/5/4, 1 March 2010. www.wipo.int/meetings/en/details.jsp?meeting_id=19686.

²⁸ Abbott F., Correa C. *World Trade Organization Accession Agreements: Intellectual Property Issues*. Geneva, Quaker United Nations Office Global Economic Issue Publication, May 2007, www.uno.org/geneva/pdf/economic/Issues/WTO-IP-English.pdf.

²⁹ See Drahos P. BITS and BIPS: Bilateralism in Intellectual Property. *Journal of World Intellectual Property*, 2001, 4(6): 791–808. Also El Said M. The Road from TRIPS-Minus to TRIPS to TRIPS-Plus: Implications of IPRs for the Arab World. *Journal of World Intellectual Property*, 2005, 8(1):53–66.

³⁰ Resolution adopted by the General Assembly, Political Declaration on HIV/AIDS, 2006, http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf

III. Stronger Patents, More Innovation?

One of the frequently attempted justifications for stronger global patent protection through TRIPS and TRIPS-plus provisions is that increased IPR protection would incentivize the development of new lifesaving drugs.³¹ However, since the signing of the TRIPS Agreement in 1995, consumers have not witnessed a significant increase in the output of new medicines, despite the substantially higher levels of IPR protection on a global scale. In 2006, the WHO Commission on Innovation, IPR and Public Health (CIPIH) concluded: “While developing countries (excluding least developed countries) with little technological and innovative capacity are bearing the cost of implementing the TRIPS Agreement, there are no documented cases of positive impact on innovation in the medical field as yet.”³²

Moreover, as many observe, the common belief that pharmaceutical patents are granted to protect “new medicines”, is inaccurate.³³ The number of patents obtained to protect genuinely new pharmaceuticals is small and declining. In the same time, thousands of patents are granted for pharmaceuticals, quite often for **minor modifications of already existing drugs**.³⁴ According to a report of the US National Institute for Health Care Management, in the period 1989–2000, only 15% of all new drug approvals were for medicines that provide a significant clinical improvement.³⁵

³¹ See Outterson K. Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets. *Yale Journal of Health Policy, Law and Ethics*, 2005, 5(1):193-291.

³² Commission on Intellectual Property, Innovation and Public Health (CIPIH). *Public Health, Innovation and Intellectual Property Rights*. WHO, Geneva, 2006, www.who.int/intellectualproperty/en/

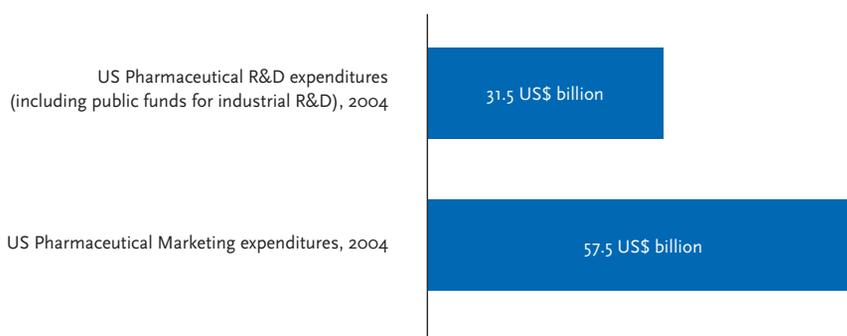
³³ Mercurio B. TRIPS, Patents and Access to Lifesaving Drugs in the Developing World. *Marquette Intellectual Property Law Review*, 2004, 8(2): 211-250, at 217.

³⁴ See Correa C. *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*. ICTSD, WHO, UNCTAD and UNDP, 2007, at 27. www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf

³⁵ National Institute for Health Care Management. *Changing Patterns of Pharmaceutical Innovation*. Washington D.C. NIHCM, 2008, at 3.

Today’s patent systems are primarily based on the market dynamics of industrialised countries.³⁶ They are designed to enable producers of patented drugs to recover costs and generate profit by charging prices, which will be covered by consumers or health insurance providers. In addition to their costs for research, development and production, the companies also have significant expenses for advertising and marketing. In 2008, Canadian scholars Gagnon and Lexchin analyzed pharmaceutical promotion versus research and development expenditures in the US by using data of global market research companies.³⁷ The summary of their findings, provided in the chart below (see Figure 3), indicates that marketing is predominant over R&D in the US pharmaceutical industry.

Figure 3
Comparison between R&D and Marketing Expenditures of US Pharmaceutical Companies



Source: Gagnon, Lexchin, 2008 (referring to adjusted data provided by IMS, CAM, as well as data of the International Science Foundation).

Pharmaceutical companies have, therefore, the incentives to produce medicines for markets that can pay for them, and focus on diseases and conditions that affect the developed world. Increasing efforts are put into developing non-essential “lifestyle” drugs, such as treatments for erectile dysfunction, or rejuvenation. For example, while there are at least three separate major

³⁶ Tvedt M. One Worldwide Patent System: What’s in It for Developing Countries? *Third World Quarterly*, 2010, 31(2): 277–293.

³⁷ Gagnon M.-A., Lexchin J. The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States. *PLoS Med*, 2008 5(1), e1, www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001.

branded medicines against erectile dysfunction on the market, there are still no effective treatments for the potentially fatal parasitic diseases kala azar and sleeping sickness.³⁸ The entire continent of Africa comprises just 1.1% of the global pharmaceutical market.³⁹ In 1996, the WHO found that health problems which affect 90% of the global population in fact receive only 10% of the USD 56 billion spent annually on health research ('the 10/90 Gap').⁴⁰

Creating incentives for research and development for new medicines is, without any doubt, necessary. The assumptions that patent protection alone would stimulate research and development for the particular needs of developing countries cannot be supported by any practical evidence. In fact, there is evidence that the incentives provided by the global patent regime do not necessarily address the needs of the developing world. It should be noted that India, a developing country, has managed to establish and build up its pharmaceutical industry in the absence of patent protection on pharmaceutical products (see Box 1).⁴¹

³⁸ According to Johns Hopkins Health Alerts, the lifestyle market amounted up to about USD 23 billion in 2009. While this is still a small fraction of the global medicine market that was predicted to top up to USD 750 billion in the same year according to IMS it is a rapidly growing share that is mainly paid out of the pocket. See Johns Hopkins Health Alerts, *What Is a Lifestyle Drug?*, (2009), Posted in Prescription Drugs on October 6, 2009 www.johnshopkinshealthalerts.com/alerts/prescription_drugs/JohnsHopkinsPrescriptionDrugsHealthAlert_3241-1.html See also IMS, *Health Lowers Global Pharmaceutical Market Forecast to 2.5–3.5 Percent Growth*, (2009), www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnnextoid=1e61fa8adbec0210VgnVCM100000ed152ca2RCRD

³⁹ CIPIH, *Supra* 32.

⁴⁰ Global Forum for Health Research. *10/90 Report on Health Research 1999*. GBFR, Geneva, 1999, at 7. www.globalforumhealth.org/Media-Publications/Publications/10-90-Report-on-Health-Research-1999.

⁴¹ For more see Dhar B., Rao C. *Transfer of Technology for Successful Integration into the Global Economy: a Case Study of the Pharmaceutical Industry in India*. New York and Geneva, UNCTAD, *UNCTAD/ITE/IPC/2003/6*, 2003.

Box 1

The Growth of India’s Pharmaceutical Industry in the Absence of Patent Protection on Pharmaceutical Products

In 1959, the Indian Government commissioned the jurist Rajagopala Ayyangar to draft recommendations to overhaul the country’s patent system. Ayyangar recommended that India should not recognise patent protection of food products and medicines. He justified his recommendation with the argument that “in none of the countries of Europe are patents granted for product claims for articles of food or medicine and in a few... even claims for processes for producing them are unpatentable.”

The recommendations of the Ayyangar report led to drafting India’s Patents Act of 1970, which abolished product patent protection for pharmaceuticals. The Patents Act provided the legislative framework that allowed Indian pharmaceutical companies to manufacture generic versions of patented medicines at a fraction of the price charged by originator companies. This policy choice helped India achieve self-sufficiency in medicines and its pharmaceutical industry has since become the largest supplier of affordable generic medicines in the developing world.

Sources: Musungu et al. (2004), Ayyangar (1959)

IV. Patents, Prices, and the Treatment Timebomb

As of 2005, all WTO Member States, except the LDCs, were expected to provide patent protection for pharmaceutical products.⁴² This includes developing countries like India, Thailand and Brazil who have traditionally been manufacturers and suppliers of generic medicines. In the absence of generic competition, significant and sustained price reductions would be more difficult to achieve. This situation applies particularly to second and third line antiretroviral medicines (ARVs). Today, the vast majority of adults (98%) and children (97%) receiving ART are on first line regimens.⁴³ However, as people on first line treatment develop resistance, they will have to be moved onto to second and third line regimes almost all of which are still under patent in many countries and therefore very expensive. Médecins sans Frontières reports the price of second-line treatment to be from 9 to 17 times higher in countries with patented medicines where there are no generic equivalents available.⁴⁴ The figure below illustrates the price discrepancies between the existing first and second line ARV regimes and the possible divergence between and a third line therapy in the future.

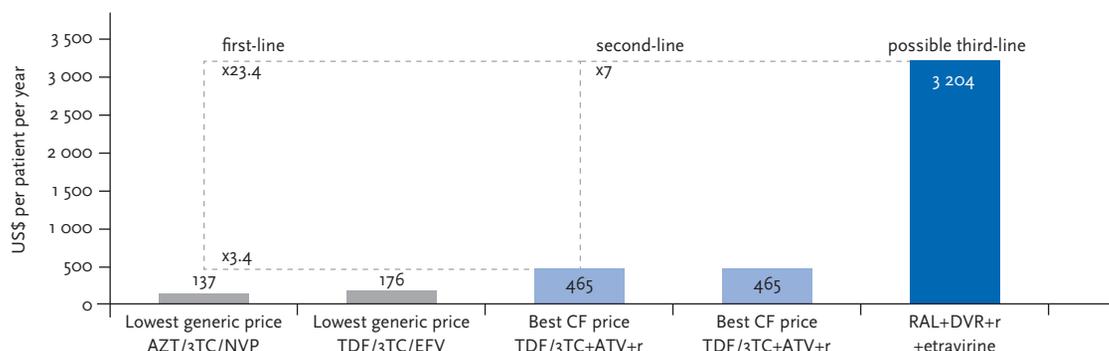
⁴² Following the 2001 WTO Ministerial Meeting in Doha, least developed countries were granted an extension until 1 January 2013 to apply the TRIPS Agreement provisions, with the possibility of extension, and until 1 January 2016 for the provision of pharmaceutical patents protection.

⁴³ UNAIDS. *Treatment 2.0: Is This the Future of Treatment*. 2010, http://data.unaids.org/pub/Outlook/2010/20100713_outlook_treatment2_0_en.pdf, at 5.

⁴⁴ Médecins Sans Frontières (MSF). *Untangling the Web of Antiretroviral Price Reductions*, 13th Edition, 2010, www.msfaccess.org/resources/key-publications/key-publication-detail/index.html%3ftx_ttnews%5Btt_news%5D=1631&cHash=1e60ab329f.

Figure 4

The Treatment Timebomb: the Impact of Switching to Second- and Third-line Regimens on the Price of ARV Treatment



Source: MSF (2010), *Untangling the Web of Antiretroviral Price Reductions*, 13th ed.

Even newer first line medicines which have fewer side effects, like tenofovir, remain under patent in several countries, thereby driving up the price of first line treatment as well.⁴⁵

The high cost of second line ARV medicines, in combination with the projected growth in people who need ART is the reason why treatment advocates warn about a “timebomb” effect in the near future. As pointed out by the All Party Parliamentary Union on AIDS, some national analyses already indicate that beyond 2015 the number of people in need of treatment is expected to grow drastically, with the global figure reaching up to 55 million persons in need by 2030.⁴⁶ **This volume would require unprecedented mobilization of resources and strategies in order to be adequately prepared to meet it. Utilizing the TRIPS Agreement flexibilities is indicated as one of the important avenues to secure access to more affordable generics.** The report stresses that countries need to carefully evaluate their IPR and public health policies and consider what advice is being provided to them in the field of intellectual property protection, as IPR regimes impact directly generic production and the public health systems.⁴⁷ However, as pointed out in the UNAIDS outlook document on the future of treatment ‘Treatment 2.0’, the cost of ARV medicines is only one of the components in the persisting need, and other important factors, such as testing, procurement, service delivery, and laboratory analyses should also be considered.⁴⁸

⁴⁵ WHO. *Global Price Reporting Mechanism Report*. 2010, www.who.int/hiv/amds/en/. See also MSF, *Ibid*.

⁴⁶ All Party Parliamentary Group on AIDS. *The Treatment Time bomb: Report of the Inquiry of The All Party Parliamentary Group on AIDS into Long-term Access to HIV Medicines in the Developing World*. 2009, www.aidsportal.org/repos/APPGTimebomb091.pdf,

⁴⁷ *Ibid*, at 5, 18-24.

⁴⁸ UNAIDS, *Supra* 43. Also see CIPIH, *Supra* 32.

V. The Health-Related TRIPS Flexibilities at a Glance

This Guide divides the health-related TRIPS flexibilities into three types: **preventative**, **remedial**, and **enforcement**-related. The table below provides a brief overview and more detail discussions follow.

Types of Flexibilities	Examples
<p>Preventative: <i>Policy options to ensure that patents do not hinder access to affordable medicines. Advantages: easier, faster, less politically sensitive compared to some remedial measures.</i></p>	<p>Exclusion from Patentability: Exclude new use of known substances, methods and processes (Articles 27.2 and 27.3) Patentability Criteria: Develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and “evergreening” opportunities. (Articles 1 and 27.1). Patent Opposition: Allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner. Waiver for LDCs: LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 1 January 2016 (and possibly longer, if extended).⁴⁹</p>
<p>Remedial: <i>Preventative flexibilities cannot always be used to meet existing and emerging needs to secure access to affordable medicines. Therefore, series of remedial flexibilities are included in the TRIPS Agreement.</i></p>	<p>Compulsory Licenses and Government Use Orders (Article 31 (a)—(j)) Compulsory Licenses for Export under the WTO 30 August, 2003 Decision. Exceptions: Bolar (early working) exception, research and experimental use exception, individual use (Article 30) Use of National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40) Parallel Importation (Article 6)</p>
<p>Enforcement: <i>Related to obligations under Part III of the TRIPS Agreement, which sets minimum standards for IPR enforcement.</i></p>	<p>No border measures for suspected patent infringement (Article 51) No criminalization of patent infringement (Part III, Section 5)</p>

⁴⁹ The Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 7. In 2002, the TRIPS Council (IP/C/25) affirmed this extension period until 2016, furthermore stressing that the deadline may further be extended according to Article 66, paragraph 1 if a duly motivated request by an LDC is made. www.wto.org/english/tratop_e/trips_e/art66_1_e.htm

1. Preventative TRIPS Flexibilities

Most developing countries did not have to implement the TRIPS Agreement in the field of providing patent protection for pharmaceutical products until 2000. Some countries that previously declined to patent pharmaceuticals enjoyed a transition period until 2005. These periods have expired, and traditional producers of generic medicines such as India, Brazil and Thailand now must provide patent protection for such products. Only LDCs remain exempt from having to implement the provisions of the TRIPS Agreement until July 2013, and for providing patent protection to pharmaceutical products until January 2016, and possibly later if the exception is extended.

While introducing patent protection for medicines in low and middle income countries is likely to create obstacles for increased access to affordable generic medicines, these countries still have a range of preventative and remedial flexibilities through which they could exercise in order to mitigate the negative impact of strengthened IPR protection on the availability of and access to medicines. It must be explained in this regard that having patents for medicines does not mean automatically granting protection for all medicines that are patented in developed countries, or elsewhere. Most preventative measures are applied **before** patents are granted, or during the process of patent examination. The statement “prevention is better than cure” is quite valid for these flexibilities, as they are faster to apply, and are likely to cause less political tensions, compared to some other remedial measures.

1.1 Exclusion from Patentability

WTO Member States (except LDCs) are now obliged to provide patent protection to pharmaceutical products. However, Articles 27.2 and 27.3 of the TRIPS Agreement contain subject matters that member states may exclude from patentability. Accordingly, Members may exclude from patentability diagnostic, therapeutic and surgical **methods**. Even though this flexibility is not directly related to pharmaceutical products, it is important that countries adopt and use it, as it prevents the granting of patents which ultimately would make treatments more expensive

in this area. In addition, the TRIPS Agreement also permits Member states to exclude plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes from the ambit of patent protection.⁵⁰

Member states may also exclude from patentability certain inventions, if their commercial exploitation would **harm the “ordre public” (public order), or morality, including life or health**. As pointed out by Correa and Yusuf, there is no generally accepted notion of what “ordre public” is. Addressing epidemics that endanger life and health could be construed as a matter of public order.⁵¹ However, the public order exception only applies if all commerce in the particular area violates the public order, not just patent-related monopolies. As yet, there are no practical examples of exclusion of pharmaceuticals from patentability for “ordre public”, or morality reasons.

1.2 Setting and Applying Strict Patentability Criteria

The TRIPS Agreement only sets minimum standards to which WTO members must adhere. According to Article 1 of the TRIPS Agreement provides freedom to member states “to determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice”.⁵² Article 27 of the TRIPS Agreement contains the three patentability criteria that an invention must meet in order to qualify for patent protection. These are ‘novelty’, ‘inventive step’ and ‘industrial applicability’.⁵³ **However, TRIPS does not define the meaning of these criteria and how should they be interpreted. This is left to the discretion of the WTO Member States.** In a footnote to Article 27, the TRIPS Agreement allows member states to interpret “inventive step”, which is the terminology used in most European countries, as “non-obvious”, which is the standard applied in the US. Similarly, countries could define ‘capable of industrial applicability’ (the common European standard) as a synonym to

⁵⁰ TRIPS, Article 27.3 states:

Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

⁵¹ Correa C. Yusuf A. *Intellectual Property and International Trade: the TRIPS Agreement*. The Netherlands Kluwer Law International, 2008, at 230.

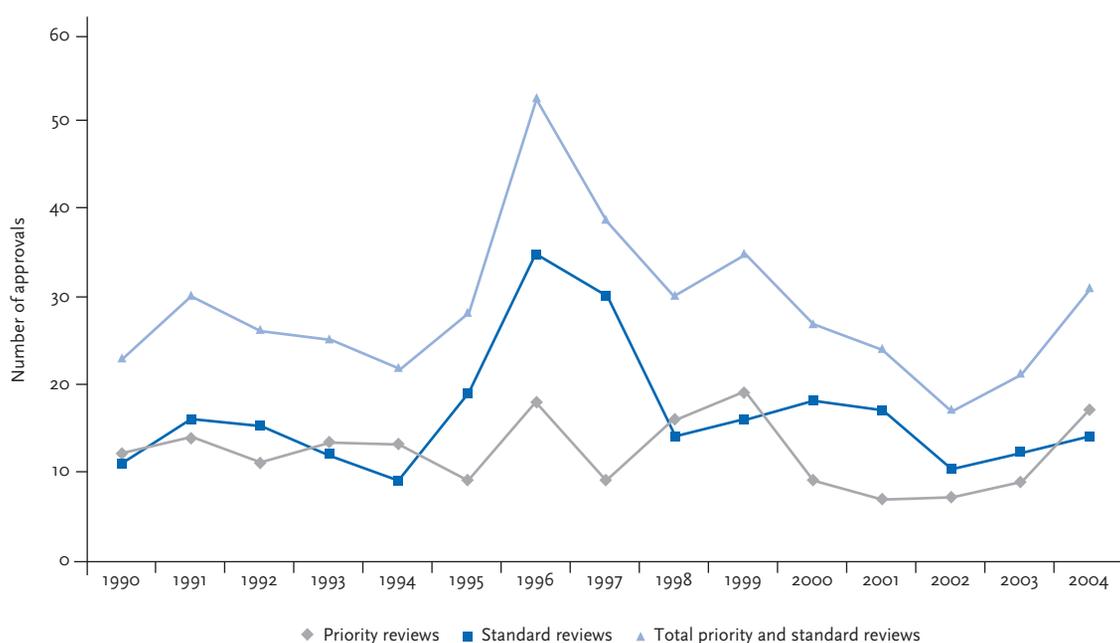
⁵² TRIPS, Art. 1.

⁵³ TRIPS, Art. 27.1.

‘useful’ (the US standard). The standards of “non-obviousness” and “usefulness” set a lower threshold and make many more inventions patentable than the standards of inventive step and industrial applicability.⁵⁴

As fewer new molecules are being discovered, originator pharmaceutical companies are increasingly trying to extend the patent terms of existing medicines by seeking patent protection on various new use and secondary features of medicines (see Figure 5). As stated earlier, the TRIPS Agreement does not require that Member states provide protection for new use and therefore member states may deny the patentability of new uses for lack of novelty, inventive step or industrial applicability.⁵⁵

Figure 5
New Drug Approvals by the US FDA, 1990–2004



Source: WHO (2006) *Public Health, Innovation and Intellectual Property Rights*, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)

⁵⁴ In a footnote to Article 27, the TRIPS Agreement allows member states to interpret “inventive step”. The footnote states that for the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

⁵⁵ See Correa C. *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. Geneva, South Centre, 2002, at 22.

A recent report of the European Commission explains this by noting a decline in the number of new medicines, while from 2000 to 2007 patent applications for pharmaceuticals have doubled. The vast majority (87%) of the applications are being filed for “secondary” patents—i.e., covering various ancillary features, such as formulations, salt forms, methods of treatment, etc.⁵⁶ Similar observations have been made in the US and France.⁵⁷

The proliferation of secondary patents on existing medicines has facilitated a practice known as “**evergreening**”. This occurs when patent holders try to extend the duration of a patent by introducing only small changes in the formulation of the products, or by claiming new uses of known active ingredients. If such application is accepted, this could lead to a *de facto* extension of a patent term for another 20 years, and to the prevention of generic competition, which would lower the price of the product.⁵⁸ By adopting strict criteria for what constitutes a patentable invention –which explicitly excludes new use of known substances-, developing countries can exclude secondary features from patentability and limit opportunities for “evergreening”.

Many developed countries allow the **patenting of new forms and/or new uses, of known substances**. Developing countries have been cautioned against applying this standard.⁵⁹ Some developing countries have taken active measures to prevent patenting of new forms and new uses. India, for example, has adopted such a provision (see Box 2).⁶⁰

⁵⁶ European Commission (EC). *Pharmaceutical Sector Inquiry Preliminary Report*. DG Competition Staff Working Paper, 2008, <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

⁵⁷ According to a 2005 survey published in France, it was found that 68% of the 3096 new products approved in France between 1981 and 2004 brought “nothing new” in comparison to previous preparations. For more see Prescrire. *A Review of New Drugs in 2004: Floundering Innovation and Increased Risk-taking*. *Prescrire International*, 2005, 14(76):68–73.

⁵⁸ United States Federal Trade Commission (USFTC). *Generic Drug Entry Prior to Patent Expiration: An FTC Study*. Federal Trade Commission, Washington, D.C, 2002, www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

⁵⁹ Commission on Intellectual Property Rights (CIPR). *Integrating Intellectual Property Rights and Development Policy*. DFID, London, 2002, www.iprcommission.org/papers/text/final_report/reportwebfinal.htm

⁶⁰ India, Patents Act, 1970, s. 3(d) excludes from patentability:

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.

Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Box 2

Preventative Measure—India’s Section 3(d) and the Novartis Case

When conforming its patent law with the TRIPS Agreement requirements that pharmaceutical products should be patentable, India adopted patentability criteria by introducing Section 3d to its Patent Act, according to which “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant” is not considered an invention and is thus not patentable under the Indian Patent Act.

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

Consequently, excluding new uses of known substances from patentability would bar a large number of “new-old” drugs from receiving another period of patent protection. For example, the first antiretroviral for treatment of HIV, AZT, was approved in 1987 but known since 1964 and initially researched as a cancer medicine. If countries where AZT was initially patented would have excluded new uses of known substances from patentability, AZT would have been ineligible for patent protection hence it would be available in the market at an earlier stage in its generic form.⁶¹

Moreover, adopting strict standards for the basic criteria for patentability—particularly the “inventive step” requirement—could prevent many secondary patents from being granted (see

⁶¹ MSF. *Drug Patents under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents*. Geneva, MSF, 2003, <http://apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf>, at 14.

Box 3). Such secondary patents (e.g., relating to a particular formulation, salt form, or crystalline form of a known drug) are in fact minor routine improvements that are carried out regularly in the pharmaceutical industry. Under a more rigorous application of the inventive step standard they will not be considered sufficient to justify patent protection.⁶²

Box 3

Developing Patent Examination Guidelines from a Public Health Perspective

Introducing the TRIPS Agreement flexibilities may, in some cases, require changes in national patent laws. However, adoption of stricter patentability criteria may also be achievable by simply developing guidelines for national patent offices, on the examination of pharmaceutical patent applications. WHO, UNCTAD and ICTSD, in partnership with UNDP, published a working paper authored by Correa, which discusses guidelines for the examination of pharmaceutical patents from a public health perspective.

An electronic copy of the publication can be found at:

http://ictsd.org/downloads/2008/04/correa_pharmaceutical-patents-guidelines.pdf

A version in Spanish is available at:

http://ictsd.org/downloads/2008/06/correa_guidelines2oespanol2ofinal.pdf.

1.3 Patent Oppositions (Pre-grant and Post-grant)

A study by the US Federal Trade Commission found that in 30% of the patent infringement cases between a generic manufacturer and an originator company that were fully litigated in the US, the patent at issue was ultimately found to be invalid.⁶³ Questionable patents, once issued, can be invalidated through litigation, but such court proceedings are usually extremely lengthy and can be prohibitively expensive.⁶⁴

One option to both improve patent quality and lessen transaction costs of patent challenges is to allow for civil society members, or other interested parties to oppose patents. This could happen either before the patent is granted when the patent application is published, shortly after the

⁶² Correa, *Supra* 34, at 1-4.

⁶³ United States Federal Trade Commission, *Supra* 58. In addition, the USFTC found that in another 30% of the cases, the courts ultimately found that the generic company did not infringe the patent at issue.

⁶⁴ Love J. *Compulsory Licensing: Models For State Practice In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord*. Consumer Project on Technology, Washington, D.C., 2001, www.cptech.org/ip/health/cl/recommendedstatepractice.html

patent is granted, or both. It is, of course, preferable that pre-grant opposition occur, as “prevention is better than cure”. It is important to enable a broad array of stakeholders—including civil society—to participate in such opposition proceedings (see Box 4).

Box 4

Civil Society Patent Opposition in Thailand

In 2001, civil society groups from Thailand were able to successfully challenge a patent granted by the Thai patent office on the important ARV didanosine. Despite the assertion by the patent holder (Bristol-Myers Squibb) position that the civil society groups lacked standing to bring a patent challenge, the Thai authorities allowed the challenge, citing the Doha Declaration: “Since the TRIPS Agreement must be interpreted and implemented so as to promote and support access to medicines for the people as a whole and since those suffering from HIV/AIDS can be injured by a patent blocking access to affordable medicines, [...] they had the right to challenge the patent.”

Source MSF (2003), p. 20

Following on the success of Thai civil society groups in challenging the didanosine patent, other civil society groups in countries such as Brazil, India and China have filed their own oppositions against patents on essential medicines, challenging their validity.⁶⁵ India in particular has seen a large number of patent oppositions filed—both by civil society groups and generic companies—making full use of the pre- and post grant opposition proceedings available under the current Indian law.⁶⁶ In this regard, it has been reported that since 2005 domestic Indian pharmaceutical companies have filed around 150 pre-grant oppositions to patent applications in India.⁶⁷

The Indian patent opposition proceedings provide for a pre-grant opposition to be filed at any time after the patent application is published and before the patent is granted. A post-grant provision allows for the filing of an opposition before the expiry of one year after the date of

⁶⁵ T. Hoen, *Supra* 23.

⁶⁶ For example, in 2006, a pre-grant opposition has been filed against the anti-HIV drug, Combivir, manufactured by GlaxoSmithKline, a leading pharmaceutical company. The Manipur Network of Positive People (MNP+) and the Indian Network of People Living with HIV/AIDS have lodged the complaint at the Kolkata patent office. See http://www.medindia.net/news/view_news_main.asp?x=8969&t=1, Published March 2008.

⁶⁷ Report in the Economic Times, quoted in Drahos P. *The Global Governance of Knowledge: Patent Offices and Their Clients*. Cambridge, Cambridge University Press, 2010, at 218.

⁶⁸ India Patent Act, section 25.

publication of the grant.⁶⁸ An alternative pre-grant opposition mechanism has been established in Brazil, where a requirement was introduced into the national Industrial Property Code to get a ‘prior consent’ by the National Sanitary Supervision Agency (ANVISA) before a pharmaceutical patent can be granted. Paraguay has also adopted a similar requirement.⁶⁹

1.4 Test Data Protection

Article 39.3 of the TRIPS Agreement provides for **test data protection** of pharmaceutical, or agricultural chemical products, but proponents of stronger IPR protection assert that Article 39.3 requires **data exclusivity**.⁷⁰ Data exclusivity is a legal regime, which prevents drug regulatory authorities from accepting applications for registration of generic medicines during the period of exclusivity, unless applicants provide their own test data.⁷¹ Applicants to register generic pharmaceuticals are prevented from relying on, or referring to the originator documentation on file with the regulatory authorities. Traditionally, regulatory authorities have evaluated generic applications against the originators’ documentation, instead of requiring the generic applicant to conduct unnecessary animal testing and clinical trials on humans, which have already been performed by the originators, and the results of which are already known. The repetition of clinical trials contradicts the ethical principles for medical research involving human subjects, adopted by the World Medical Association.⁷² In brief, **data exclusivity is an additional market protection form for originator pharmaceuticals**. Long after data exclusivity has expired, data of the originators could remain protected, for instance by copyright law, or other provisions.⁷³

⁶⁹ Correa, *Supra* 34, at 25.

⁷⁰ TRIPS, Article 39.3 states:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

⁷¹ Drug regulatory authorities operate independently from patent office and are concerned with ensuring that medicines and drugs are safe for use and compatible with quality standards before they are made available in the market.

⁷² World Medical Association. *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*. (as amended by the 59th WMA General Assembly), Seoul, 2008. www.wma.net/en/30publications/10policies/b3/index.html.

⁷³ European Generic Medicines Association Website. *Data Exclusivity and Market Protection*. www.egagenerics.com/gen-dataex.htm.

Article 39 of the TRIPS Agreement, entitled “protection of undisclosed information”, relates broadly to protection of trade secrets. This Article is a general clause, which protects trade secrets. Article 39.3 covers such obligations in the particular case where trade secret data is submitted to government agencies in order to obtain marketing approval. It imposes two obligations on governments: to protect data on new chemical entities collected with considerable effort, against **unfair commercial use (1)** and to protect such data **against disclosure (2)**, except where necessary to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use. The TRIPS Agreement does not define “unfair commercial use” hence giving member states considerable policy space in this area.

Some developed countries, notably the US and some EU countries, have argued that Article 39.3 of the TRIPS Agreement requires countries to create a regime of **data exclusivity**.⁷⁴ In these countries data exclusivity was adopted long before the TRIPS Agreement (1984 in the US and 1987 in the EEC). This viewpoint is shared by most representatives of the originator pharmaceutical industry. However, it cannot be supported by the TRIPS Agreement, especially considering its basic principles set forth in Article 8, read together with the Doha Declaration. Also the history of the negotiations of the TRIPS Agreement indicates that the US suggestion to introduce data exclusivity was rejected by developing countries.⁷⁵ Developing countries should refrain where possible from adopting data exclusivity regimes, since they are not required by the TRIPS Agreement. Alternatively, countries should aim towards restricting the impact of data exclusivity under national law.⁷⁶

Data exclusivity regimes are very likely to have a negative impact on access of affordable generic pharmaceuticals to national markets (see Box 5).⁷⁷ Growing evidence supports this claim. In addition, it is believed that data exclusivity will also deter generic manufacturers from seeking registration for their drugs given the costs of test data and low margins of generic production.

⁷⁴ For a discussion on this see Reichman J. *Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny: a Broader Perspective*. UNCTAD–ICTSD dialogue on moving the predevelopment IP agenda forward: preserving public goods in health, education and learning, Bellagio, Italy, 29 November–3 December 2004, at 11. Available at: http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

⁷⁵ Correa C. *Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*. UNCTAD–ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, 2004. www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf, at 5.

⁷⁶ The Chilean experience provides some useful insight in this regard. Under its national law, the Chilean government sought to restrict the effects of the data exclusivity provisions provided under the US–Chile FTA by explicitly excluding several issues from the scope of protection.

⁷⁷ WTO, *Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*. WTO, 2002, (wt/ds171). See also: WTO: *Argentina—Certain Measures on the Protection of Patents and Test Data* (wt/ds196) <http://docsonline.wto.org/DDFDocuments/t/WT/DS/196-3.DOC>

Such effects have been felt in the case of Jordan. According to a recent Oxfam report, data exclusivity provisions under the US–Jordan FTA have resulted in delaying the introduction of generic drugs into the market, while also increasing the costs of medicines as a result throughout the country.⁷⁸

Box 5

Refusal of Argentina to Introduce Data Exclusivity

On May 30, 2000, the US requested consultations with Argentina within the WTO Dispute Settlement mechanism, complaining about Argentina’s alleged failure to appropriately protect test data. After two years of discussions, the dispute was settled at the stage of consultations. Argentina did not accept the US claim that exclusive rights should be granted for test data and maintained its law unchanged. Even though the US has reserved its rights to refer the matter to the WTO Dispute Settlement Body (DSB) no further action has been taken by USA against Argentina, or any other country that does not recognize data exclusivity. However, the United States Trade Representative (USTR) has listed, under the Special Section 301 of the Trade Act, a large number of countries that, according to USTR, do not confer exclusive protection for test data, including Argentina.

Source: WTO, WT/DS171, WT/DS196

1.5 The Waiver for LDCs until 2016

The TRIPS Agreement recognizes that LDCs⁷⁹ have “special needs and requirements”⁸⁰ that must be considered. Many LDCs have high disease burdens and in the same time are lacking in institutional infrastructure and technological development. The costs to develop patent systems as called for in the TRIPS Agreement is likely to exceed whatever benefits could accrue from increased levels of IPR protection for LDC economies. This is particularly relevant with respect to access to essential medicines. According to the United Nations Conference on Trade and Development (UNCTAD), the cost estimates for establishing a functioning IPR authority are in the range of USD 1.5–2.0 million while the operating costs are estimated to be approximately USD 1 million per annum.⁸¹

⁷⁸ Oxfam. *All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines*. Oxford, Oxfam Briefing Note, March 2007.

⁷⁹ The list of LDCs is available on the website of the UN High Representative for Least Developed Countries, www.unohrrls.org/en/ldc/related/62/.

⁸⁰ TRIPS, Art. 66.

⁸¹ UNCTAD. *The TRIPS Agreement and the Developing Countries*. UNCTAD, Geneva, 1996.

Concerns raised by developing and least developed countries—in particular, the African Group—about the impact of increased levels of patent protection called for in the TRIPS Agreement on access to essential medicines resulted in the Doha Declaration.⁸² One of the key outcomes of the Doha Declaration was the extension of the transition period in which LDCs had to come into full compliance with the TRIPS Agreement. Under this decision, LDCs are not obligated to provide patent protection for pharmaceuticals, or to enforce patents and undisclosed information protection for pharmaceuticals, until at least 2016.⁸³ This flexibility has been used by Cambodia, which enacted its first patent law before acceding to the WTO (see Box 6).

Box 6

Cambodia's Use of the LDC Extension Period on Waiving Patents on Pharmaceuticals until 2016

Cambodia enacted patent legislation shortly before acceding to the WTO in 2004. As an LDC, Cambodia included a clause, specifying that the patent protection for pharmaceuticals would not come into effect until the expiration of the 2016 transition period. Under this provision, Cambodia was able to specify that the patent law would have no effect on all pharmaceutical products until the expiration of the 1 January 2016 transition period.

Source: Cambodian Law on Patents, Art. 136

www.ecap-project.org/fileadmin/ecap11/pdf/en/information/cambodia/patent_law_promulgated_220103.pdf

⁸² See T. Hoen, *Supra* 23.

⁸³ The Doha Declaration on the TRIPS Agreement and Public Health, Section 7.

2. Remedial TRIPS Flexibilities

Remedial flexibilities under the TRIPS Agreement allow WTO Member States to facilitate access to treatment after medicines have been protected under their national laws. The rationale for including remedial flexibilities in the TRIPS Agreement is to allow countries to balance between IPR protection and public health needs. Remedial flexibilities have been used effectively by some WTO Member States, but utilizing some of them, for instance compulsory licenses and government use, involves more procedures and, at times, has proven to be politically sensitive.⁸⁴

Other remedial flexibilities available under the TRIPS Agreement also include allowing member states to exempt certain activities from the ambit of protection in addition to allowing parallel importation. It is important in this regard that member states take positive steps to incorporate these flexibilities under their national IPR laws. These are explained in more detail in the following section.

2.1 Compulsory Licenses

A compulsory license (also known as a non-voluntary license) is issued to one or more parties, to “use” (e.g. manufacture, sell, or import) a product under patent protection without the authorization of the patent holder. This however should be subject to granting the patent holder a monetary remuneration.⁸⁵ Compulsory licenses have proven to be effective means to secure

⁸⁴ The TRIPS Agreement also requires WTO Member States to provide, in their legislation, an opportunity for independent review of authorizations to use patents without the consent of the patent holder, and decisions on remuneration (Article 31 (i) and (j)). The TRIPS Agreement only suggests judicial review. Countries are free to use other faster and less costly procedures, as long as reviews are independent. It is important to note that, according to the TRIPS Agreement, the opportunity for independent review is to guarantee due process in granting authorizations and providing remunerations and **is not a pre-condition** for utilizing the flexibilities.

⁸⁵ WHO and UNDP published a study authored by Love that aims to help countries to identify an appropriate royalty rate for non-voluntary licenses. See Love J. *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*. Health Economics and Drugs TCM Series No. 18, UNDP-WHO, Geneva, WHO/TCM/2005.1, 2005. www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf.

access to medicines through reducing medicines' prices due to generic competition.⁸⁶ In certain instance, the threat itself of using compulsory licensing also yielded positive price variations.⁸⁷

The TRIPS Agreement does not place any restrictions on the grounds upon which compulsory licenses may be granted, as long as the procedure for granting them follows the minimum requirements of Article 31. Consequently, countries could develop compulsory licensing regimes that, under certain conditions, or for certain policy objectives, allow the production, or import of generic equivalents of patented medicines.⁸⁸ Compulsory licenses have already been used for domestic production or import of ARVs and other essential medicines by many governments, most recently by Brazil, Ecuador and Thailand.

A legal framework in which the administrative burdens of issuing compulsory licenses would be minimized would ideally contain several features. Such a framework would require the inclusion of specific guidelines as to what constitutes reasonable terms for a license, what constitutes "adequate remuneration", strict timelines during which negotiations for voluntary licenses must be completed (when they are required), and a clear default policy in favour of the issuance of compulsory licenses.⁸⁹ Further, rather than have compulsory licenses reviewed by the courts in potentially lengthy and expensive proceedings, an expedited independent procedure could be adopted before a panel set up for such purposes. Finally, the possibility to delay the operation of

⁸⁶ For example, World Bank research indicates that if the United States and Thailand went ahead and signed the proposed FTA, compulsory licensing that could have reduced the cost of second-line ARVs by 90% in Thailand would have been severely restricted. The World Bank concludes that issuing compulsory licenses for second-line ARVs would represent a saving of US \$3.2 billion for the Thai national health budget over 20 years. See Revenga A et al. *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*. Washington DC, World Bank, 2006.

⁸⁷ For example, the Brazilian policy of providing free ARV treatment announced in 1996, was made possible by the production and import of generic first-line and second-line treatments. With Brazilian compliance to TRIPS in 2005, the latter was no longer permitted and the cost of second-line became an issue. Threatening to introduce compulsory licensing, the Brazilian government pressured and negotiated with Abbott, Merck and Roche (manufacturers of lopinavir, indinavir, nelfinavir and saquinavir respectively) to substantially reduce prices, thus enabling more than 100 000 people to receive free treatment. In this case, the threat of compulsory licensing itself was successful in obtaining concessions from the pharmaceutical companies. For more see Kerry VB, Lee K. TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines? *Global health*, 2007, 3:3.

⁸⁸ Love, *Supra* 64.

⁸⁹ India's Patents Act, section 83 provides that the provisions on compulsory licenses should be guided by several principles. These include: "that patents granted do not impede protection of public health" and "that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

the compulsory license could be eliminated by providing that any challenge to the validity of a compulsory license would not stay the operation of the license.⁹⁰

Contrary to the common misconception, compulsory licenses are **not limited to situations of national emergency**.⁹¹ The Doha Declaration clarified that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted,” and that “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁹²

As these provisions make clear, countries have complete freedom in determining the grounds upon which compulsory licenses can be granted. Moreover, countries have complete freedom in determining what constitutes a national emergency or a situation of extreme emergency, and can declare that such a situation exists in any number of public health crises, including, **but not limited to**, HIV and AIDS, tuberculosis, malaria and other epidemics. Some examples of the different kinds of compulsory licenses that countries may issue are discussed below.

⁹⁰ For further discussion see Third World Network (TWN). *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws*. Penang, 2003.

⁹¹ Indeed, many countries, including the US, issue compulsory licenses for any number of reasons, including for government use and to remedy anti-competitive practices. For a comprehensive list of examples of compulsory licenses granted in the US, see Love J. Palmedo M. *Examples of Compulsory Licenses of Intellectual Property in the United States*. CPTech Background Paper 1, 2001. <http://www.cptech.org/ip/health/cl/us-cl.html>.

⁹² Also, Article 31.b of TRIPS states:

such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the *case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use*. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. [emphasis added].

Box 7

Compulsory License for Lopinavir/Ritonavir in Ecuador

In October 2009, the President of Ecuador signed a decree allowing compulsory licenses in the country. The President justified his decision with provisions on the right to health in the Ecuadorean Constitution, as well as with Article 31 of the TRIPS Agreement and the Doha Declaration. On 14 April 2010, the Ecuadorean intellectual property office (IEPI) granted its first compulsory license for the ARV combination lopinavir/ritonavir, to Eskegroup, a local distributor for the Indian generic pharmaceutical Cipla. The compulsory license is valid until 30 November 2014. By the time the license ends the patent would expire. The owner of the patent for lopinavir/ritonavir, marketed as Kaletra®, is the US pharmaceutical company Abbott Laboratories. IEPI has instructed Eskegroup to pay remuneration to Abbott based on the tiered royalty method (TRM). This method is described in the “Remuneration Guidelines for Non-voluntary Use of a Patent on Medical Technologies”, authored by Love and co-published by UNDP and WHO (www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf)

After the compulsory license was issued the Ecuadorean Ministry of Health purchased lopinavir/ritonavir with a discount of USD 150,000 compared to the original offer.

Source: Third World Network Info services on Health Issues, 4 May, 2010

2.1.1 Government Use Authorizations

In many developing countries the majority of the population depends on health care services provided by the government.⁹³ Thus, considerable cost savings to the budget can be achieved by procuring lower-cost generic medicines for use in such services. However, often newer medicines are still under patent protection and their prices are higher, compared to older and generic versions. Public health services with limited budgets often have to choose between covering more patients and providing higher quality healthcare to a smaller group. Sometimes the purchase of expensive patented medicines could threaten the sustainability of government-provided health services. For example, although Brazil has a successful HIV treatment program that guarantees free access to ARVs nationwide, its purchase of “three patented AIDS medicines (out of a total of 17) accounted for 65% of the total national expenditure on ARV procurement.”⁹⁴

⁹³ For instance, in Thailand, 64% of total expenditure on health in 2005 was government funded. See: WHO. *Statistical Information System: Core Health Indicators*. 2008. www.who.int/whosis/database/core/core_select.cfm.

⁹⁴ See T. Hoen, *Supra* 23, citing data provided by the Brazilian Ministry of Health. See also Rosina et al., *Access to Medicines: Pharmaceutical Patents and the Right to Health*, in *Access to Knowledge in Brazil*, Shaver L., ed, Yale Law School, New Haven, 2008, detailing how high costs of medicines are threatening the sustainability of Brazil’s universal health care system.

In order to address this problem, some developing countries (including Brazil and Thailand—see Box 8) have successfully utilized the “government use” of patents flexibility available under the TRIPS Agreement to manufacture or import cheaper generic medicines.⁹⁵

According to the TRIPS Agreement, if they choose to, countries can implement simple procedures by which government officials authorize the use of a patented invention for government purposes, subject to the payment of adequate remuneration after the use to the patent owner.⁹⁶ For instance, in the US, the government retains broad powers to use any patented invention (or authorise any third party to do so), subject only to the payment of compensation, with no possibility of the patent holder obtaining an injunction to prevent such use.⁹⁷ Under this provision, the US Government can authorise virtually any third party to use the patented invention for government purposes, and the sole remedy provided to the patent holder is monetary remuneration. This also means a speedier manner in authorising the issuance of the license since the requirement of reasonable and prior negotiation with the patent owner is waived.

Box 8

Government Use Authorizations in Thailand and Brazil

Thailand and Brazil have public health services that are commonly considered to be among the best in the developing world. Thailand introduced a universal health care scheme in 2002, making health care services available to its citizens for a small co-payment.⁹⁸ In Brazil, the right to health is enshrined in the Constitution, and the implementing legislation has specifically incorporated universal access to medicines as part of that right.⁹⁹ However, due to the very success of these programmes, the costs to the government in maintaining them are considerable. 65% of Thailand’s total expenditure on health comes from the government, while Brazilian government’s burden is at 44%.¹⁰⁰ As such, both governments have taken strong and effective actions to lower the costs of the medicines they procure through government use authorisations.

⁹⁵ WHO, *Supra* 93. See also <http://www.cptech.org/ip/health/cl/> for a list of countries that have issued government use licenses and other forms of compulsory licenses.

⁹⁶ Love, *Supra* 64.

⁹⁷ 28 U.S.C. § 1498(a). See <http://www.cptech.org/ip/health/cl/us-1498.html> for information on how this provision has been applied in the US. See also Love, *Supra* 64 for further examples of state practice of government use authorisations in various countries.

⁹⁸ Coronini-Cronberg, S. Laohasiriwong, W., and Gericke, C. Health Care Utilisation Under the 30-Baht Scheme Among the Urban Poor in Mitrapap Slum, Khon Kaen, Thailand: a Cross-Sectional Study. *International Journal for Equity in Health*, 2007, 6 (11): 1–9. www.ncbi.nlm.nih.gov/pubmed/17883874.

⁹⁹ Rosina et al., *Supra* 94, citing Brazil Lei 8.080/90 Art. 6(I) (d).

¹⁰⁰ WHO, *Supra* 93.

Box 8 (continued)

Government Use Authorizations in Thailand and Brazil

From 2006–2008, Thailand issued a series of government use authorisations on a number of patented medicines. The cost savings to the Thai government were significant. For instance, the generic version of the heart medication clopidogrel that was sourced from India was 98% cheaper than the patented version.¹⁰¹ Although the Thai government came under fierce (and largely groundless) criticism for its actions by developed countries and industry groups, the Thai government maintained that its actions were perfectly compatible with both domestic law and TRIPS requirements.¹⁰²

Similarly, Brazil has long been successful in using the credible threat of issuing compulsory licenses as a negotiating tool to achieve significant price concessions on patented essential medicines.¹⁰³ Finally, in 2007, after lengthy negotiations had failed, Brazil issued a government use order for the patent on efavirenz, allowing Brazil to manufacture generic equivalents.¹⁰⁴ By doing so, Brazil was able to reduce the price of efavirenz from USD 1.56 to USD 0.45 per dose. According to estimates by the Brazilian government, projected cost savings of approximately USD 237 million are expected between 2007 and 2012, when the patent for efavirenz expires in Brazil.¹⁰⁵

The examples of Thailand and Brazil demonstrate the effectiveness of issuing compulsory licenses/ government use authorisations to significantly lower the costs of essential medicines.

2.1.2 Compulsory Licenses Solely or Largely for Export (August 30, 2003 Decision)

The Doha Declaration reiterated the right of WTO Member States to issue compulsory licenses. However, it did not address the needs of countries with insufficient capacity to domestically manufacture generic equivalents of the patented products. In such cases compulsory licensing

¹⁰¹ TWN. *Thailand Issues Compulsory License to Buy Plavix Generics from India*. TWN Info Service on Trade and WTO Issues, 2007, www.twinside.org.sg/title2/wto.info/twninfo080706.htm.

¹⁰² Thai Ministry of Public Health & National Health Security Office Thailand. *The 10 Burning Questions on the Government Use of Patents on the Four Anti-Cancer Drugs in Thailand*. MOH and NHSO, Bangkok, February 2008. http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5bEN%5d.pdf.

¹⁰³ WHO. *Countries Experiences in Using TRIPS Safeguards*. Briefing Note, Access to Medicines, WHO Regional Office for South East Asia, 2008, www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

¹⁰⁴ WHO, *Ibid.*

¹⁰⁵ Alcorn K. *Brazil Issues Compulsory License on Efavirenz*. AidsMap, 2007, www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp

would have had little if no effect. The reason for this is the requirement of Article 31(f) for compulsory licenses (except those that address anti-competitive practices) to be issued predominantly for the supply of the domestic market of the country in which they are issued. Countries with surplus manufacturing capacity were largely prevented from exporting medicines produced under a compulsory license. Recognising this fact, the Doha Declaration directed the Council for TRIPS to find an “expeditious solution” to this problem.

On August 30, 2003, the WTO General Council issued a Decision (**the 30 August Decision**) that aimed to remedy this situation.¹⁰⁶ The 30 August Decision introduced a waiver of the requirement of Article 31(f) for predominant domestic use and purported to provide a mechanism that allows WTO Member States to issue compulsory licenses for export of generic equivalents of patented medicines to countries with no pharmaceutical manufacturing capacity, or insufficient capacity. To utilize the mechanism, a number of conditions have to be satisfied.¹⁰⁷ Thus far, only a handful of WTO Member States that are potential exporting countries have introduced compulsory licenses for export into their national laws.¹⁰⁸ There has only been one case in which the 30 August Decision has been used to export medicines under a compulsory license to a country with insufficient manufacturing capacity (see Box 9).¹⁰⁹

The burdens that the 30 August Decision imposes upon both importing and exporting countries and the practical difficulties in meeting its requirements have led some to criticise the Decision for being “neither expeditious, nor a solution.”¹¹⁰ For example, the obligation under the TRIPS Agreement Article 31(b) to enter into prior negotiations with the patent holder is not waived,

¹⁰⁶ Decision of the General Council of 30 August 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The “temporary waiver” of the Decision was made into a permanent amendment to the TRIPS Agreement in December 2005, under a new Article 31bis. The amendment will become part of the TRIPS Agreement upon ratification by at least two-thirds of the WTO members.

¹⁰⁷ These conditions include notifying the WTO of the names and expected quantities of drugs needed, limiting the scope of the compulsory license for manufacture to only the amount necessary to meet the stated needs of the importing country; and clearly identifying the license products as having been produced for this purpose. See Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1 para 2. See www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

¹⁰⁸ This list includes so far Canada, China, India, the Netherlands, Korea, and Switzerland, as well as the European Commission.

¹⁰⁹ This was Rwanda in July 2007.

¹¹⁰ MSF. *Neither Expeditious, Nor a Solution: the WTO August 30th Decision is Unworkable*. Geneva, 2006, www.doctorswithoutborders.org/publications/article.cfm?id=3729&cat=special-report.

and is required for both the importing and exporting countries.¹¹¹ Moreover, a generic company interested in exporting to more than one country may need to apply for individual compulsory licenses for each separate country.¹¹²

Importantly, the 30 August Decision also provided a broader waiver of Article 31 (f) for countries that are parties to a regional trade agreement in which at least half of its membership consists of LDCs. In such situations, the Decision states that the export restriction “shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member State to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.” This represents a potential opportunity for a number of regional trade groups in Sub-Saharan Africa, a number of which contain a membership of which at least half are LDCs.¹¹³ It has been proposed that countries in such qualifying regional trade agreements could implement a system of “mutual recognition” of compulsory licenses, so that each member of the group could issue a compulsory license on the basis of one being issued in another member.¹¹⁴

Given the administrative complexities around implementing the 30 August Decision, it is imperative that the procedure for compulsory licensing for export is not made more cumbersome than it needs to be.¹¹⁵

¹¹¹ See T Hoen, *Supra* 23. Also see Paas K. Compulsory Licensing under the TRIPS Agreement- a Cruel Taunt for Developing Countries? *EIPR*, 2009, 12: 609–613.

¹¹² Elliott R. *Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export*. Canadian HIV/AIDS Legal Network, Ottawa, 2007. www.upr-info.org/IMG/pdf/CANHIVAIDS_LN_CAN_UPR_S4_2009_anx1_GettingtheRegimeRight.pdf.

See also Abbott and Reichman, *Supra* 16, These and other inherent difficulties in operationalising the 30 August Decision have led some to propose an alternate approach, based upon the “limited exception” provision in Article 30 of TRIPS, whereby a statutory compulsory license could be granted that would authorise the licensee to manufacture the product for any of the countries specified in the legislation that have insufficient manufacturing capacity. Such a proposal is certainly worth further consideration, and would greatly streamline the procedure for exporting medicines to many sub-Saharan countries.

¹¹³ The qualifying agreements that have been notified to the WTO as of 1 March 2007 are the following: ECOWAS [Economic Community of West African States]; COMESA [Common Market for Eastern and Southern Africa]; CEMAC [Economic and Monetary Community of Central Africa]; WAEMU/UEMOA [West African Economic and Monetary Union]; EAC [East African Community], and SADC [Southern African Development Community].

¹¹⁴ Musungu S. Villanueva S. and Blasetti R. *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks*. South Centre, Geneva, 2004, <http://apps.who.int/medicinedocs/en/d/Js4968e/>

¹¹⁵ For instance, the Canadian legislation implementing the 30 August Decision has been heavily criticised for imposing requirements that go above and beyond what the Decision requires. See Elliot, *Supra* 113 for full discussion.

Box 9**Rwanda's Use of the 30 August Mechanism**

Nearly four years after the adoption of the 30 August Decision, Rwanda became the first WTO Member to use it. On July 17, 2007, Rwanda notified the WTO (of its intent to import from Canada 260,000 packs of Apo-TriAvir, a generic version of a triple fixed dose ARV combination patented by GlaxoSmithKline, Shire and Boehringer Ingelheim. As an LDC, Rwanda did not have to demonstrate that it did not possess domestic manufacturing capacity, as specified by the Mechanism.

From the Canadian side, Rwanda's notification was matched by Canada's issuance of a compulsory license for export in September 2007 upon application from Canadian generic manufacturer Apotex. The license was issued under Canada's legislation to implement the 30 August Decision allowing domestic companies to produce generic products under patent protection for export. Canada notified the WTO on October 4, 2007, stating that its patent authorities had issued a compulsory license to national generic company Apotex, to legally make 15.6 million tablets of Apo-TriAvir for export to Rwanda over the next two years. The notification also provided the link to a new website of Apotex which described the product as required by the 30 August Decision.

It took almost another year before the products were finally shipped off to Rwanda in September 2008. While the case has been praised in terms of providing Rwanda with essential medicines, the time and effort to make it happen have been criticised, highlighting the complex nature of the mechanism and government procurement rules and practices. The head of Apotex stated: "While we are extremely pleased to be able to make this important and historic contribution, there is a reason no other company has tried to provide medicines under this regime. [...] It is too complex and has to be repeated for every request that comes in from a country. For Canada to truly be able to provide help, the regime must be changed."

Source: Canadian HIV/AIDS Legal Network, ICTSD, 2007b, 2008

2.2 Exceptions to Patent Rights

Article 30 of the TRIPS Agreement provides for "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." This provision allows countries some important flexibility which if properly applied, could improve access to medicines. Following are some examples of such exceptions.

2.2.1 Early Working (Bolar) Provision

Another important exception to patent rights is the “Bolar,” or early working exception which is adopted by a large number of countries worldwide.¹¹⁶ It allows a generic competitor to work the invention prior to the expiration of the patent in order to prepare the product for obtaining regulatory approval. By doing so the product is available in the market as soon as the patent expires. The compatibility of such a provision with the TRIPS Agreement has been confirmed by the WTO DSB in the EU-Canada case.¹¹⁷

Box 10

South Africa Adopts a Bolar Provision in 2002

South Africa amended its Patent Act in 2002 in order to introduce a Bolar type provision, as well as other amendments. Under South African law it is now possible to make, use, exercise, dispose or import a patented product on a non-commercial scale, solely for the purposes reasonably related to the obtaining, development and submission of information required under any law of South Africa that regulates the manufacture, production, distribution, use or sale of a product.

In a case between Monsanto v. Stauffer Chemicals in 1986 the lack of a national Bolar Provision led to Stauffer Chemicals infringing on a Monsanto patent for engaging in field trials of a product held under Monsanto’s patent protection in order to prepare for the marketing of the same product after the imminent patent expiration. Stauffer Chemicals argued that field trials did not constitute ‘use’ within the meaning of South Africa’s patent law, but ended up losing the case. A similar case would have a different set of outcomes following the 2002 amendment to the Patent Act.

Source: Spoor and Fisher, 2002; Monsanto v. Stauffer Chemicals (1986)

Without a Bolar provision, the *de facto* length of monopoly would be extended to the length of the patent (20 years) plus the time that would be needed to work the invention (at least 6 months, or more depending on the regulatory protection regime of each country) in order to develop the data needed for obtaining regulatory approval.

¹¹⁶ According to Musungu and Oh, the early working exception could speed up the approval of generic competition by as much as 3 years. The authors also point out that in 2000 the WTO Panel Decision has confirmed that the early working provision is TRIPS-consistent. Musungu S. Oh C. *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* Geneva, South Centre and WHO, 2006, at 31.

¹¹⁷ WTO. *Canada- Patent Protection of Pharmaceutical Products, Report of the Panel*. WTO WT/DS114/R, 2000, http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

2.3 Parallel Importation

Medicines often have different prices in various countries, even when made by the same manufacturer. The price differences may be due to local market conditions, based on factors such as differences in intellectual property rules, or prevailing income levels, as well as the degree of competition among producers.¹¹⁸ **Therefore, it is possible to realise significant savings by importing the same medicine from a country in which the medicine has a lower price.** This is commonly referred to as ‘**parallel importation**’. The TRIPS Agreement and Doha Declaration expressly recognises that countries are free to engage in parallel importation, based on the concept of international **exhaustion of IPR rights**.¹¹⁹ Under an international exhaustion regime, the patent holder is deemed to have “exhausted” the rights over the product once it is released into the channels of commerce anywhere in the world.¹²⁰ The opposite of an international exhaustion regime is referred to as a **national exhaustion of rights regime**, which essentially means that a patent holder only exhausts rights over his product once it has been released in the territory of the country. Under this regime, countries may not import the same product that was released by the same patent holder in another country. There also is a **regional exhaustion regime**, which recognizes that the right holder has exhausted the rights after the product has been released into commerce in a certain region.

Several countries have adopted the international exhaustion regime, which allows them to secure the supply of more affordably priced medicines from other countries in the world. Examples of good practices in this field are provided from the national regimes of the Philippines and Kenya (see Box 11).

¹¹⁸ TWN, *Supra* 90, Ch. 2, at 4.

¹¹⁹ TRIPS, Article 6, and The Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5(d).

¹²⁰ Abbott F. *Parallel Importation: Economic and Social Welfare Dimensions*. Winnipeg, International Institute for Sustainable Development, 2007. www.frederickabbott.com/uploads/parallel_importation.pdf.

Box 11**International Exhaustion Regimes in the Philippines and Kenya**

Both Kenya and the Philippines have amended their patent law to allow parallel importation of medicines from anywhere in the world, referred to as an international exhaustion regime. Unlike other international exhaustion regimes, however, both countries have included wording in their legislation that does not limit the possible source of import from a third country to products put on the domestic market by the original patent holder, but opened it up to equivalent products placed on the market by anybody who was authorised to do so. Whereas in most international exhaustion regimes the patent act limits the import of medicines from third countries to products that have been put on the market by the patent holder, the Philippines' wording of the provision allows for the importation 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." Similarly, in Clause 37 of Kenya's Intellectual Property Regulations (2002) the international exhaustion regime outlined in the country's IP Act specifically allows for the importation of "...articles that are imported from a country where the articles were legitimately put on the market".

Thus, in addition to products placed on the market by the patent holder or any of his authorised licensees, these wordings permit to import a medicine placed on the market by a generic company if no domestic patent protection existed. The provision also applies to products that were produced, for example, under a compulsory license, as the recipient of the compulsory license would have been authorized to use the invention. Since Kenya's change of legislation the provision has been used to import a range of generics that were still under patent protection in the country. Until now Kenya has not been challenged for its interpretation of international exhaustion, nor its use, at the WTO.

Source: TWN (2003), Munyi et al. (2004)

3. Remedies for Anticompetitive Practices

Another important flexibility available under the TRIPS Agreement lies in the possibility of using national IPR and competition laws and policies to prevent anti-competitive behaviour that could hamper access to affordable medicines, and/or providing remedies for anti-competitive practices. These flexibilities are broadly included under Articles 8.2, 31(k) and 40 of the TRIPS Agreement. Notably, the TRIPS Agreement does not define what behaviour is anti-competitive hence awards national authorities considerable policy space in determining the grounds of anti-competitive behaviours. As pointed out by Correa there are numerous forms of anti-competitive practices that patent holders may engage in.¹²¹

Article 8.2 of the TRIPS Agreement recognises the inherent tension between intellectual property protection and the promotion of free competition, and provides that countries may take “appropriate measures” to prevent practices which “unreasonably restrain trade or adversely affect the international transfer of technology.” As the TRIPS Agreement does not define what constitutes an anti-competitive conduct, countries have wide discretion in defining these parameters under national law.

Compulsory licenses adopted as a remedy for an anti-competitive practice under Article 31 (k) of the TRIPS Agreement require no prior negotiations with the patent holder, as opposed to compulsory licenses under Article 31 (b). There is not even a need to inform the holder, as required for government use authorizations. The only requirement is that the anti-competitive

¹²¹ Correa states in this regard “Competition law may be applied when particular intellectual property rights have not been obtained in the proper manner or are not deserved, for instance, when patents have been obtained by deceiving the patent office. In addition, low standards of patentability and shortcomings in patent examination may lead to the granting of “poor quality” patents that can hamper competition. Acquiring patent rights for frivolous developments or with overbroad claims can provide grounds for anti-competitive intervention even in jurisdictions where IP is essentially seen as compatible with competition law.” Correa C. *Intellectual Property and Competition Law: Exploring Some Issues of Relevance to Developing Countries*. ICTSD IPRs and Sustainable Development Programme Issue Paper No. 21, International Centre for Trade and Sustainable Development, Geneva, Switzerland, 2007, at 10, www.iprsonline.org/resources/docs/corea_Oct07.pdf.

practice is established by a procedure—administrative or judicial which exists nationally. If the practice is likely to recur, the competent authorities may refuse to terminate the anti-competitive measure (compulsory license) hence extending it further. This is a much broader flexibility compared to Article 31 (c), according to which the scope and duration of the compulsory license shall be limited to the purpose for which it was authorized.

According to the second sentence of Article 31 (k) the remuneration to the patent holder can be corrected with view to his anti-competitive practices. This means that, in especially grave cases of anti-competitive practices, remuneration may not be paid at all. Competition authorities also tend to impose fines on violators, which is an additional disincentive against anti-competitive behaviour.

Another advantage of the competition-based license is the authorization of exports. As explained, Article 31 (f) of the TRIPS Agreement stipulates that compulsory license should be used predominantly for the local market. Limiting the license to the local market prevents local producers from achieving economies of scale in order to be competitive. The 30 August Decision Mechanism attempts to address this constraint but its extensive procedural requirements have prevented its efficient use. Article 31(k) of the TRIPS Agreement waives the restrictions for predominant domestic use, which means that in a case of competition-based license, local production can be exported to any country where the product is not protected by a patent, or which has issued a compulsory license. In this way, local producers would be able to lower the cost, due to economies of scale.

Lastly, WTO members agreed that some IPR-related licensing practices or conditions, which restrain competition, may also impede transfer of technology (Article 40). Competition is an important part in the creation of a pro-competitive environment for access not only to pharmaceuticals, but to pharmaceutical technology in the developing world.

Despite the enabling provisions of the competition flexibilities in the TRIPS Agreement, so far there is only one case in which national competition laws have been successfully used to improve access to medicines. Carlos Correa points out that many developing countries do not have specific competition legislation to determine what constitutes anti-competitive conduct.¹²² South Africa is an exception and its competition law has already been used on more than one occasion to improve access to essential medicines (see Box 12). Nevertheless, developing countries do not necessarily need to enact new competition legislation in order to remedy anti-competitive conduct in connection with patent rights. Such anti-competitive remedies may also be included within their patent legislation, for example by allowing for compulsory licenses to

¹²² Correa, *Ibid.*

be granted upon encountering anticompetitive conduct by their patent offices. The Peruvian government, for example, houses both the national intellectual property office and the national competition authority into one institute to ensure appropriate cooperation.¹²³

Another example is the 2002 Egyptian IPRs law. Under the Egyptian law, anti-competitive conduct can be determined by the Egyptian Patent Office on any number of grounds, including exorbitant pricing. Furthermore, a compulsory license can be granted even where there was no prior negotiation and the products manufactured under such a license can be exported without restrictions.¹²⁴

It must be stated that the use of anti-competition law in the intellectual property sphere is a common feature in the developed world. In this regard, the IPRs Commission Report states that “In the US particularly, but also in other developed countries, pro-competitive regulation of intellectual property rights and control of related restrictive business practices are key features of anti-trust legislation and these are regularly put into effect by the courts, competition authorities and by other relevant government agencies”.¹²⁵

¹²³ Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual. See: <http://www.indecopi.gob.pe>

¹²⁴ Egypt, Law on the Protection of Intellectual Property Rights, Article 23(5).

¹²⁵ CIPR, *Supra* 59, at 148.

Box 12

Use of Competition Law in South Africa to Improve Access to Medicines

In 2002, a civil society coalition in South Africa filed a complaint against two multinational pharmaceutical companies (GlaxoSmithKline and Boehringer Ingelheim) before the South African Competition Commission. The coalition argued that these companies were engaging in anti-competitive practices through its excessive pricing of their patented ARVs (zidovudine, lamivudine, and nevirpaine). The complainants maintained that even taking into account costs of research and development, costs of production, reasonable profit, and other costs, the prices that the companies were charging were excessive and unjustifiable.

South Africa's Competition Commission agreed with the complainants, and found that the companies had engaged in excessive pricing, and in addition had denied generic competitors with an "essential facility" (in this case, licenses to manufacture these medicines), and recommended to South Africa's Competition Tribunal that a compulsory license be issued on the patents covering these ARVs, along with punitive measures.

Before the matter could be heard by the Competition Tribunal, considering the possible effect of the Competition Commission's findings, the companies agreed to grant voluntarily licenses for their patents to generic producers at a royalty not in excess of 5% of the sale price of the generic versions.¹²⁶

Again, in 2007, South Africa's Treatment Action Campaign (TAC) brought a complaint against the multinational Merck Sharp & Dohme (MSD) for refusing to license its patent on the ARV efavirenz on reasonable terms. Before the matter could be referred to the Competition Tribunal, MSD and TAC reached a settlement whereby MSD agreed to grant multiple licenses on its efavirenz patent to generic producers, for supply of both the public and private sectors. Further, MSD agreed to allow the generic producers to export their products to 10 other African countries, and waived any right to a royalty.¹²⁷

¹²⁶ Avafia T. Berger J. and Hartzenberg T. *The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries*. TRALAC Working Paper No. 12, Stellenbosch, 2006, www.iprsonline.org/unctadictsd/docs/Trade%20and%20Competition%2030%203%2006%20final%20Edit1%20_2_%20_2_.pdf.

¹²⁷ Treatment Action Campaign. *TAC Complaint Increases Access to Efavirenz: MSD Finally Agrees to Grant Licenses on Reasonable Terms*. 2008, www.tac.org.za/community/node/2329.

4. The Impact of IPR Enforcement Measures

Even where countries have adopted a robust set of preventative and remedial flexibilities as discussed above, the ability to exercise them in order to improve access to affordable medicines **may be compromised through unnecessarily strict standards for the enforcement of IPR rights**. It is important to define how, once IPRs are granted, they are enforced. For instance, while adopting IPR enforcement laws and policies, countries need to answer, among others, the following questions: Should the state enact criminal sanctions to punish patent infringement? Should customs officials be given authority to seize, confiscate, or destroy goods suspected of infringing IPR rights? Under what circumstances should a court grant injunctive relief to a patent holder in infringement proceedings? Should an *ex officio* actions be allowed without the need for a private complaint? The decisions a country makes on these policy issues regarding the enforcement of IPR rights can have a profound impact on the availability and access to affordable medicines.

WTO member states should be aware that the TRIPS Agreement only sets minimum requirements with respect to the enforcement of IPR rights. However, there have been increasing efforts in recent years to raise the levels of IPR enforcement far beyond what is required by the TRIPS Agreement.¹²⁸ For instance, some developing countries are coming under pressure to place criminal sanctions on a wide array of IPR violations, including patent infringement.¹²⁹ However, the TRIPS Agreement does not require the criminalisation of patent infringement, and limits criminalisation obligations to a limited class of wilful trademark counterfeiting and copyright

¹²⁸ Biadgleng E. Tellez V. *The Changing Structure and Governance of Intellectual Property Enforcement*. Research Papers 15, South Centre, Geneva, 2008. http://www.southcentre.org/index.php?option=com_content&task=view&id=614&Itemid=1. See also Sell S. *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*. Occasional Papers No. 1, IQsensato, Geneva, 2008, www.iqsensato.org/?p=69.

¹²⁹ Correa C. *The Push for Stronger Enforcement Rules: Implications for Developing Countries*, Programme on IPRs and Sustainable Development, Issue Paper No.22, International Centre for Trade and Sustainable Development, Geneva, Switzerland, 2007. <http://ictsd.org/i/publications/42762/>. See also Blakeney M. International Proposals for the Criminal Enforcement of Intellectual Property Rights: International Concern with Counterfeiting and Piracy. *Intellectual Property Quarterly*, 2009, 1: 1–26.

piracy at a commercial scale.¹³⁰ Placing criminal sanctions on patent infringement could have a chilling effect on generic manufacturers’ willingness to enter the market with affordably priced generic medicines. Other enforcement measures, such as overbroad powers granted to customs officials, have already been used to hinder the legitimate trade of affordable generic medicines (see Box 13).¹³¹

Box 13

Seizure of Generic Medicines in Transit by Customs Officials in Europe: an Illustration of Overbroad Enforcement Measures

Overbroad border measures regulations in some European countries grant customs officials the power to seize any goods suspected to infringe any IPR (including patents) regardless of whether the goods are intended for import, export, or are goods in transit. The broad scope of this regulation already appears to be having an impact on the trade of legitimate generic drugs. Between 2008 and 2010, customs officials in several countries in Europe made at least 17 seizures of legitimate, good quality generic medicines destined to developing countries, under the pretext that they were “counterfeit”.

In February 2009, Dutch customs officials seized 49kg of abacavir sulphate tablets, a second-line ARV medicine manufactured by the Indian pharmaceutical company Aurobindo, which has been pre-qualified by WHO, claiming that the medicines were “counterfeit” and violated patent rights. The Dutch authorities seized the shipment as it passed through the Schiphol Airport in Amsterdam on its way to Nigeria, where the medicines were to be distributed by the Clinton Foundation, an implementing partner of Nigeria’s HIV program. The shipment was funded by UNITAID, the international agency that purchases drugs and diagnostics for the treatment of HIV and AIDS, malaria and tuberculosis in developing countries. (Source: Humanitarian News and Analyses, UN Office for the Coordination of Humanitarian Affairs, March 13, 2009)

There is no obligation under TRIPS to allow for suspension or seizure of goods suspected of infringing a patent, nor is there any obligation to apply border measures to goods intended for export or in transit. In fact, Article 41 of the TRIPS Agreement requires that the enforcement measures set forth in the agreement, including the border measures outlined under Article 51, “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”

¹³⁰ TRIPS, Article 61 states:

Members shall provide for criminal procedures and penalties to be applied at least in cases of *wilful trademark counterfeiting or copyright piracy on a commercial scale*. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

Another illustration of the impact of IPR enforcement measures on the access to medicines is the spread of the so-called “anti-counterfeit” legislation. Substandard and spurious medicines seriously endanger the life and health of people worldwide and their production and placement is an organized criminal activity, condemned by the international community. Substandard and spurious medicines have at time been confusingly referred to as “counterfeits”, despite the lack of consensus among UN agencies, brand and generic pharmaceutical companies on the meaning of this term.¹³² Regional and national legislation that features definitions including generic medicines in the scope of “counterfeits” has emerged, which could seriously threaten access to affordable medicines. **Despite the fact that IPR enforcement cannot adequately address most of the serious problems of quality, safety and efficacy failures that threaten public health, “anti-counterfeit” laws covering medicines are being adopted** (See Box 14). In light of these ongoing developments, it is particularly important for developing countries and LDCs to be aware of the minimum requirements of the TRIPS Agreement with respect to their obligations on the enforcement of IPRs.

Box 14

Enforcement Measure—Kenya’s Anti-Counterfeit Act

In 2008, Kenya enacted its Anti-Counterfeit Act, purportedly designed to address the problem of counterfeit goods, including substandard and spurious medicines. It attached harsh criminal sanctions related to counterfeiting. However, according to the definition of the Act safe, effective and legitimate generic medicines were also considered “counterfeit”. By conflating the issues of safety, quality and efficacy, and the separate field of intellectual property, the Act potentially criminalized the manufacture, import, export, possession or sale of perfectly safe generic medicines, which are up to 90% of all medicines used in Kenya. Kenya’s Anti-Counterfeit Act was challenged before the High Court in July 2009 by three petitioners living with HIV on the basis that impinges on their constitutional right to health. The Court passed preliminary judgment in favour of petitioners on 23 April, 2010 and suspended powers of Anti-Counterfeit Agency to interfere with importation and distribution of generics pending ruling on the substance. In June 2010, unnamed officials from Kenya’s Health Ministry conceded that the Act was promoted by Kenya’s Industry Ministry without public health considerations.

Sources: MSF, HAI-Africa, Economic Times of India

¹³¹ See Ruse-Khan H. and Jaeger T. Policing Patents Worldwide?- EC Border Measures Against Transiting Generic Drugs Under EC and WTO Intellectual Property Regimes. *International Review of Industrial Property and Copyright Law*, 2009, 40(5): 502–538.

¹³² For a discussion on this see Gopakumar K. and Shashikant S. *Unpacking the Issue of Counterfeit Medicines*. TWN, Penang, 2010.

5. Preserving the Flexibilities of the TRIPS Agreement, Mitigating TRIPS-plus Obligations

The ability of developing countries to utilize the TRIPS Agreement flexibilities discussed so far is being slowly eroded away through various bilateral and regional negotiations with developed countries.¹³³ Whether through unilateral pressure, accession negotiations for countries entering the WTO,¹³⁴ or through bilateral or regional trade or investment agreements,¹³⁵ norms of IPR protection that go beyond the minimum requirements of the TRIPS Agreement have been implemented (or are being considered) by several developing and least-developed countries.

These measures often referred to as TRIPS-plus, are likely to have an adverse impact on medicine prices. According to one study that estimated the total economic impact of the TRIPS-plus provisions in the US-Colombia FTA, by 2020, Colombia would need to spend an additional USD 919 million dollars for medicines, or alternatively reduce medicine consumption by 40%.¹³⁶ There has been little indication of any beneficial effects of such TRIPS-plus measures in the form of increased foreign investment or increased innovation.¹³⁷ Countries should be aware of the various TRIPS-plus provisions that can have a negative impact the use of the TRIPS

¹³³ CIPR, *Supra* 59.

¹³⁴ Abbott and Correa, *Supra* 28.

¹³⁵ Reid-Smith S. *Intellectual Property in Free Trade Agreements*. Third World Network, Penang, 2008. See also Drahos, *Supra* 29, and El Said, *Supra* 29.

¹³⁶ Gamba M. *Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia*. Mission Salud-Fundacion Ifarma, Bogota, Columbia, 2006, at 8. http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf

¹³⁷ Oxfam, *Supra* 78. The Oxfam study examined the Jordanian pharmaceutical market since the US-Jordan FTA came into effect in 2001. It stated that there had been “nearly no foreign direct investment by drug companies into Jordan since 2001 to synthesise or manufacture medicines in partnership with local generics companies...”. Further the study found no evidence of increased R&D activity by domestic companies, while its citizens paid up to two to ten times more for the same medicines in Egypt.

Agreement flexibilities and subsequently on access to affordable medicines. Below are some of the most common TRIPS-plus provisions related to public health and access to medicines:

- *Waiving the LDC exception*—As mentioned, LDCs that are members of the WTO are entitled to a transition period until at least 2016 to fully implement patent protection for pharmaceuticals—and until 2013 to undertake the TRIPS Agreement other obligations-. However, LDCs that are negotiating accession to the WTO are generally pressured to shorten or forego entirely these transition periods.¹³⁸
- *Broadening patentability*—Although the TRIPS Agreement does not require that countries allow patenting new uses of known substances, some FTAs that the US has negotiated – and the EU are currently negotiating- expressly require that new uses, as well as methods of treatment be made patentable.¹³⁹
- *Extending patent terms*—TRIPS requires patent protection for 20 years, but some FTAs with the US in certain cases require an even longer period of protection.¹⁴⁰
- *Restricting patent oppositions*—As mentioned above, patent oppositions have proven to be successful in Thailand and India in preventing questionable patents on essential medicines from being granted. However, some FTAs restrict the ability of countries to provide for pre-grant patent oppositions.¹⁴¹

¹³⁸ See Abbott and Correa *Supra* 28. Cambodia, for example acceded to the WTO in 2004, and was given until 2007 to fully implement its TRIPS requirements. There were other developing countries who were also obliged to forgo such transition periods earlier. For example, Jordan forgo such periods as a result of the signing of the bilateral Association Agreement with the EU. See El Said M. *The Development of Intellectual Property Protection in the Arab World*. Lewiston NY, Edwin Mellen Press, 2008, at 191.

¹³⁹ Gaëlle P. Krikorian and D. Szymkowiak. Intellectual Property Rights in the Making: the Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicines. *Journal of World Intellectual Property*, 2007, 10(5): 388–418, at 394. For example, the US–Morocco FTA stipulates that:

The Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals.

Moreover, Article 15.9 (1) b of the US–Oman FTA provides that:

Each party confirms that it shall make patents available for any new uses for, or new methods of using, a known product, including new uses and new methods for the treatment of particular medical conditions.

¹⁴⁰ For example, the US–Bahrain FTA, Article 14.8 (7), provides:

When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other territory.

¹⁴¹ For example, the US–Bahrain FTA, Article 14.8 (4) states:

Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available *prior to the grant* of the patent. [emphasis added].

- *Joining the Patent Cooperation Treaty (PCT)*—In both FTAs and WTO accession negotiations, many developing countries are asked to join a number of international IPR treaties which they are not required to join under the TRIPS Agreement framework. Of particular concern in the medicines context is membership in the PCT, which greatly facilitates the ability of foreign entities to file a patent application in the national office.¹⁴²
- *Introducing data exclusivity*—Although Article 39.3 of the TRIPS Agreement, as mentioned, does not require data exclusivity, developed countries are pressuring developing countries to implement it through a variety of means, including bilateral pressure (e.g., India),¹⁴³ through WTO accession (e.g., China),¹⁴⁴ or through FTAs (e.g., US-Morocco FTA and CAFTA countries).¹⁴⁵ There is growing evidence highlighting the negative impact of this trend.¹⁴⁶
- *Linking patent systems to drug regulatory systems*—In addition to data exclusivity, some US FTAs require countries to link their patent systems with their drug regulatory systems, forbidding the drug regulatory authorities from approving a generic drug as long as there is a valid patent (or patents) for the drug.¹⁴⁷

¹⁴² Abbott and Correa, *Supra* 28, Reid-Smith, *Supra* 135.

¹⁴³ United States Trade Representative (USTR). *2008 Special 301 Report*. USTR, Washington, D.C, 2008, www.ustr.gov/about-us/press-office/reports-and-publications/archives/2008/2008-special-301-report

¹⁴⁴ Abbott and Correa, *Supra* 28.

¹⁴⁵ For example, Article 15.10.2 of the US–Morocco FTA states that:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical and agricultural chemical product, a) the submission of safety and efficacy data, or b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third parties not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party.

See also Annex V, Article 4 of the EU–Lebanon AA where data exclusivity must be provided for a period of at least six years from the date of approval.

¹⁴⁶ A recent study in Thailand projected that if a 10 year patent extension was granted as proposed under the Thai-US FTA, the following negative consequence will accrue over the next 20 years: a 32% increase in the price index for medicines; spending on medicines would increase from baseline to approximately USD 11,191 million; the domestic industry would lose USD 3,370 million. See Kessomboon N. Limpananont J. Kulsomboon V. Maleewong U. Eksaengsri A. and Paothong P. Impact on Access to Medicines From TRIPS-Plus: A Case Study of Thai-US FTA. *Southeast Asian Journal of Tropical Medicines and Public Health*, 2010, 41(3): 667–677, at 637–638.

¹⁴⁷ Reid-Smith, *Supra* 135.

- *Limiting compulsory licenses*—Although the Doha Declaration confirmed that countries have the right to determine the grounds upon which compulsory licenses can be granted, some FTAs place restrictions on this right—for example, limiting their use only to cases of national emergency or extreme urgency.¹⁴⁸
- *Limiting parallel import*—As mentioned, the Doha Declaration confirmed that countries are free to allow the parallel import of more affordably priced drugs that may be available in other countries. However, some US FTAs specifically restrict this freedom, expressly giving the patent holder the right to prevent parallel importation of the patented product.¹⁴⁹
- *Enforcement requirements* which go beyond those prescribed under the TRIPS Agreement imposing additional constraints on developing countries in the area of pharmaceutical products as discussed below.

The cumulative effect of these TRIPS-plus provisions is:

- Requiring countries to loosen the criteria for patentability, which in turn expands number of questionable patents granted, thereby increasing monopolies.
- Providing the possibility for extending the term of individual patents beyond the 20 years required by the TRIPS Agreement.
- Requiring test data protection which restricts the use of clinical test data of pharmaceutical products by drug regulatory authorities for the approval of generic medicines for a certain period of time. This hinders generic companies that rely on these data from proving the efficacy and safety of their products and delays the entry of generics into the market.

¹⁴⁸ Article 4.20 of the US-Jordan FTA states:

Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:

- (a) To remedy a practice determined after judicial or administrative process to be anticompetitive;
- (b) In cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
- (c) On the ground of failure to meet working requirements, provided that importation shall constitute working. Where the law of a Party allows for such use pursuant to subparagraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention.

¹⁴⁹ The United States has traditionally advocated a national exhaustion regime. Although no explicit reference has been inserted to that effect under some FTAs. For example, the US–Morocco FTA, Article 15.9 (4) states:

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.

However, the footnote to the same article stipulates that:

A Party may limit application of this paragraph to cases where the patent owner has placed

- Requiring drug regulatory authorities, most of which have limited expertise in patents, to consider the patent status of medicines before granting marketing authorization to generic manufacturers.
- Limiting the grounds and conditions under which compulsory licenses may be issued.
- Requiring countries to spend significant public financial, administrative and personnel resources on enforcing IPRs, which are private rights.

6. Recommendations

The right to the highest attainable standard of health, including the right to have access to essential medicines, is a fundamental human right which is included as a constitutional right in the majority of countries. As such, policy makers have an affirmative duty to craft all areas of national law and policy, including IPR policy, to ensure the fulfilment of this right. In implementing their obligations under the TRIPS Agreement, countries have a number of flexibilities they can and should utilize in order to ensure that patents and other barriers do not block the public's right to an affordable supply of essential medicines.

First, and perhaps most important, countries should adopt broad preventative flexibilities in order to ensure high quality of patents on medicines and mitigate patents on secondary features, new uses, therapeutic methods, as well as frivolous patents.

Second, countries should adopt a robust set of remedial flexibilities to ensure that if barriers to access to medicines arise, they can be overcome with a minimum of delay and administrative complexity, in order to adequately meet public health needs.

Third, in order to ensure the full efficacy of the TRIPS Agreement flexibilities, countries should adopt reasonable IPR enforcement policies that do not undermine the legitimate access of affordable medicines and balance IPR protection and public health objectives.

Finally, in order to ensure that all of the TRIPS Agreement flexibilities remain available, countries should be aware of try to mitigate “TRIPS-plus” obligations that can be demanded in a number of bilateral and multilateral situations.

More specifically, the various measures that countries should consider can be summarised as follows:

Preventative Measures:

- ✓ If possible, utilize the LDC extension to exclude patent protection for pharmaceuticals until at least 1 January 2016.
- ✓ Exclude “discoveries” from patentability; adopt robust definition of “discovery.”
- ✓ Adopt strict criteria for patentability.
- ✓ Implement patent examination guidelines that take public health considerations into account and reduce the risk of questionable patents from being granted.
- ✓ Provide for liberal pre- and post-grant opposition proceedings; allow for any person (including civil society) to challenge the grant of patents.
- ✓ Avoid/limit data exclusivity obligations.

Remedial Measures:

- ✓ Adopt a clear policy in favour of granting compulsory licenses to address public health needs.
- ✓ Formulate clear, reasonable and predictable remuneration guidelines for the issuance of compulsory licenses.
- ✓ Adopt streamlined administrative procedure for granting compulsory licenses; prevent granting of injunctions to stay operation of compulsory licenses.
- ✓ Provide for compulsory licensing as a remedy for a variety of anticompetitive practices, including refusal to license on reasonable terms; allow for export of goods produced under a compulsory license to remedy anticompetitive practices.
- ✓ Adopt broad powers to allow the government to use any patented invention for public non-commercial use, including uses necessary to address public health issues.
- ✓ Allow for expedited procedures to be used to grant compulsory licenses in situations of national emergency or extreme urgency.
- ✓ Implement streamlined procedures for grant of compulsory licenses for export; if available, take advantage of membership in qualifying regional trade agreements to develop a system of “mutual recognition” of compulsory licenses issued for import.
- ✓ Allow for the parallel import of a patented product 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.
- ✓ Adopt multiple exclusions from patent rights, including allowing for the experimental use and early working of a patent (Bolar Provision).

Enforcement Measures:

- ✓ Avoid criminalisation of patent infringement.
- ✓ Avoid overbroad border measures;
- ✓ Do not allow for suspension of goods suspected of patent infringement.
- ✓ Limit the grant of preliminary and permanent injunctions; provide that courts must take public health considerations in mind in determining whether to grant an injunction.

Preserving the TRIPS Agreement Flexibilities:

- ✓ If acceding to the WTO, be aware of and avoid “TRIP-plus” obligations in accession negotiations.
- ✓ Try resisting bilateral pressures to include “TRIPS-plus” obligations.
- ✓ Be aware of and try to mitigate “TRIPS-plus” obligations in various bilateral and regional free trade or investment agreements.
- ✓ Engage in and encourage national and regional cooperation to develop IPR policies that preserve the full complement of TRIPS flexibilities.
- ✓ Empower and enable national patents offices and competition authorities to take a leading role in protecting public health and access to medicines.

Given the highly technical nature of many areas of patent law and policy, policy makers in many countries may require assistance in formulating the appropriate legislative or regulatory changes to incorporate the TRIPS Agreement flexibilities. UNDP is mandated to provide support to governments in their implementation of policies and programmes that protect the human rights of people affected by HIV. In cooperation with other UN agencies, international organizations, and civil society actors, UNDP provides:

- Policy and technical co-operation to reform national intellectual property legislation and ensure that the TRIPS Agreement flexibilities are fully incorporated; to assist countries that are utilizing public health related flexibilities to do so while in compliance with their international obligations, and to assist during the procurement of essential medicines, with any intellectual property issues which may arise.;
- Capacity development assistance to national legislators, government offices and civil society actors in matters of intellectual property protection and public health. UNDP fosters and participates in discussing alternative models for stimulating innovation in low and middle income countries and mechanisms to promote affordability of medicines such as pooled procurement and explores opportunities to promote south-south co-operation dialogues and mechanisms to increase access to medicines.

- Knowledge development in the field of intellectual property rights and access to medicines by authoring, commissioning, publishing and disseminating analyses, reports, position and policy papers, scholarly materials, and other resources.
- Monitoring and analysis of the impact of intellectual property commitments which exceed those in the TRIPS Agreement on essential medicine prices.
- Advocacy in support of public health-sensitive reforms of intellectual property legislation, and adoption of measures that adequately address the need for affordable, accessible, safe and efficient medicines.

List of Acronyms and Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANVISA	National Sanitary Supervision Agency of Brazil (Agência Nacional de Vigilância Sanitária)
ART	Antiretroviral Therapy
ARV	Antiretroviral (Antiretroviral Medicine)
AZT	azidothymidine
CAFTA	United States-Dominican Republic-Central America Free Trade Agreement
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
DSB	Dispute Settlement Body of the World Trade Organization
EEC	European Economic Community
EU	European Union
FDA	United States Food and Drug Administration
FTA	Free Trade Agreement
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HAI	Health Action International
HDR	UNDP's Human Development Report
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTSD	International Centre for Trade and Sustainable Development
IEPI	Intellectual Property Office of Ecuador (Instituto Ecuatoriano de la Propiedad Intelectual)
IMS	Intercontinental Marketing Services
IPR	Intellectual Property Rights

LDCs	Least Developed Countries
MSF	Médecins sans Frontières (Doctors without Borders)
PCT	Patent Cooperation Treaty
PEPFAR	United States President's Emergency Plan for AIDS Relief
PPP	Purchasing Power Parity
TAC	Treatment Action Campaign
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRM	Tiered Royalty Method
TWN	Third World Network
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNGASS Declaration	United Nations General Assembly Political Declaration on HIV/AIDS
US	United States of America
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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This Good Practice Guide has been prepared by the HIV/AIDS Practice at the Bureau for Development Policy of the United Nations Development Programme (UNDP). It aims to explain the impact of and connection between intellectual property rights (IPR) and access to treatment. It also provides details about certain provisions under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) that governs intellectual property rights under the World Trade Organization (WTO) regime. These provisions allow governments and policy makers to shape their intellectual property protection systems while considering public health priorities. The Guide discusses ways in which these provisions and safeguards can be used in a flexible manner. It provides examples of how they have been applied by governments in various countries, and what effect such utilization has achieved thus far.



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