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Discussion Paper

The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health

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About the Authors

Carlos Correa is a lawyer and economist. He serves as Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics and of the Post-graduate Course on Intellectual Property at the Law Faculty, University of Buenos Aires. Professor Correa is also the Special Advisor on Trade and Intellectual Property at the South Centre in Geneva. He has been a visiting professor in post-graduate courses of several universities and consultant to numerous international organizations. He has advised several governments on intellectual property and innovation policy and is the author of numerous publications in that field.

Duncan Matthews is Professor of Intellectual Property Law at the Queen Mary School of Law, University of London and a member of the Centre for Commercial Law Studies. He holds masters' degrees from the University of Warwick and the University of Exeter, and a doctorate from the London School of Economics and Political Science (LSE). He has advised numerous national, regional and international organizations in intellectual property law, human rights, trade and development, and has published extensively in these fields, including two books: *Globalising Intellectual Property Rights* (published by Routledge in 2002) and *Intellectual Property, Human Rights and Development* (published by Edward Elgar in 2011).

Lead Authors: *Carlos Correa and Duncan Matthews.*

Tenu Avafia, Brook Baker, Mandeep Dhaliwal and Boyan Konstantinov contributed to this Discussion Paper.

Disclaimer: *This Discussion Paper aims to facilitate the dialogue about the role and impact of intellectual property rights on access to antiretroviral treatment and other essential medicines worldwide. The opinions and views expressed in this publication do not necessarily reflect the official position of UNDP, its board members or staff.*

Cover Photo: *Ethiopian Pharmaceuticals Manufacturing Factory (EPHARM), Addis Ababa, Ethiopia (WHO/P. Viro)*

Abbreviations and Acronyms

ACP	Africa, Caribbean and Pacific (countries)
AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral (medicines)
CARIFORUM	The Caribbean Forum (countries)
EFTA	European Free Trade Association
EPA	Economic Partnership Agreement
EU	European Union
FTA	Free Trade Agreement
HIV	Human Immunodeficiency Virus
IPR	Intellectual Property Right
LDC	Least Developed Country
MDGs	Millennium Development Goals
MSF	Médecins sans Frontières (Doctors without Borders)
MTCT	Mother-to-Child-Transmission
NCD	Non-Communicable Disease
NGO	Non-governmental Organization
PEPFAR	President's Emergency Plan for AIDS Relief (United States)
R&D	Research and Development
SUS	Sistema Único de Saúde (Brazilian National Public Health System)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USTR	United States Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

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Introduction

The human and social cost of the HIV pandemic – more than 60 million people have been infected with HIV and nearly 30 million people have died of HIV-related causes¹ – ought to make a strong enough case for access to treatment for all who need it. Furthermore, the **right** to health is present in several legally binding international human rights treaties,² in select regional treaties,³ and in numerous national constitutions.⁴ The right to health has been interpreted broadly to include a right to treatment and, more specifically, a right of access to medicines.

In the context of HIV, as specified in the International Guidelines on HIV/AIDS and Human Rights issued jointly by UNAIDS and the United Nations High Commissioner for Human Rights and promulgated specifically “to assist States in translating international human rights norms into practical observance in the context of HIV”, the right of access to essential medicines – among other things – means providing access to appropriate diagnostics including viral load and other point-of-care tests and to safe, easy-to-use and efficacious antiretrovirals (ARVs), medicines to treat opportunistic infections and co-morbidities (including tuberculosis, viral hepatitis), and analgesics for palliative care. In the emerging prevention context, it will mean providing access to improved ARVs to prevent vertical transmission and promising medicines for topical and oral pre- and post-exposure prophylaxis.⁵

The realization of access to medicines as a human right is heavily dependent on the legal framework applicable to the production and distribution of medicines, including intellectual property rights (IPRs). The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) in 1994 changed dramatically the international landscape with regard to IPRs, particularly in relation to access to medicines. Before the TRIPS Agreement came into force, countries had more freedom to design their national IPR regimes under the Paris Convention for the Protection of Industrial Property. They could exclude from protection entire fields of technology, determine the patent term and define many other aspects of such regimes.

As a result, in the pre-TRIPS era most developing and some developed countries excluded pharmaceutical products from patent protection. For instance, an amendment in 1969 to the Brazilian legislation declared pharmaceutical products and processes non-patentable. In 1970, India implemented a similar policy that eventually led to the development of a strong local pharmaceutical sector, which nowadays supplies more than 80 percent of antiretrovirals used in developing countries. Moreover, in the second half of the 1970s, developing countries attempted, in line with new perspectives on social and economic development,

1 UNAIDS (2010) *Report on the global AIDS epidemic*, UNAIDS, Geneva. Summary available at: http://www.unaids.org/documents/20101123_FS_Global_em_en.pdf.

2 These include the Universal Declaration of Human Rights, G.A. Res. 217 (III) A, and UN Doc. A/RES/217(III), art. 25 (Dec. 10, 1948), available at: <http://www.un.org/en/documents/udhr/>, the International Covenant on Economic, Social and Cultural Rights, G.A. res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316, art. 12 (1966), 993 U.N.T.S. 3, *entered into force* Jan. 3, 1976. For a fuller listing of relevant treaties and related instruments, see OHCHR & WHO (2008) *Right to Health: Fact Sheet 31*, WHO, Geneva. Available at: <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>.

3 For instance, the American Declaration of the Rights and Duties of Man (1948), O.A.S. Res. XXX, adopted by the Ninth International Conference of American States, O.A.S. Official Record OEA/ser. L/V1.4 Rev. (1965); American Convention on Human Rights (1969), O.A.S. Treaty Service No. 36, O.A.S. Official Record OEA/Ser. K/XVI/1.1 doc. 65 rev. 1 corr. 2 (1979); Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988), art. 10, 28 I.L.M. 156, 164; Organization of African Unity (1981), *Banjul Charter on Human and Peoples' Rights*, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982).

4 International Commission of Jurists, Courts and the Legal Enforcement of Economic, Social and Cultural Rights (2008), available at: <http://www.unhcr.org/refworld/category,POLICY,HANDBOOK,,4a7840562,0.html>.

5 A more detailed discussion on the right to health and access to HIV treatment is available in Tenu Avafia and Brook Baker, *Laws and Practices that facilitate or impede HIV-related treatment access*, Working Paper 13, prepared for the First Meeting of the Global Commission on HIV and the Law.

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to move forward a revision of the Paris Convention that would have provided more flexibility in patent legislation, particularly in the area of compulsory licences. This initiative, however, was defeated; a well-articulated counter-offensive by developed countries led to the negotiation of standards on IPRs as an item of the trade agenda.

With the incorporation of the TRIPS Agreement as one of the multilateral agreements of the World Trade Organization (WTO), Members of the WTO became bound to observe a set of minimum standards of IPRs protection. Failure to do so may lead to trade retaliations that may affect their main export products. One of these minimum standards is the obligation to grant patents in **all** fields of technology. Hence, being a Member of the WTO (which is critical for most countries to ensure access to foreign markets) became incompatible with the legal models based on the non-patentability of pharmaceuticals (as applied in a large majority of developing and some developed countries till then), short terms of patent protection⁶ and other measures aimed at promoting competition in the pharmaceutical market as a means to promote access to affordable medicines.

While the TRIPS Agreement was proposed to address IPRs as a 'trade-related issue', the rules it introduced have had far-reaching implications, well beyond the context in which they were negotiated and adopted. In particular, the right to exclusively exploit protected processes and products, thereby excluding any potential competition, may conflict with the fundamental right to health, one manifestation of which is the access to medicines needed by all. The paradigmatic change generated by the TRIPS Agreement has consequently led to calls for a reconsideration of the relationship between IPRs and the right to health (see further elaboration on this issue below), since a large part of the world population still lacks access to a sustainable supply of medicines needed to treat HIV and other diseases, and that IPRs may aggravate rather than improve this situation.⁷

Abundant literature and many authoritative reports⁸ have noted that the TRIPS Agreement allows for what have been termed 'TRIPS flexibilities'. Such flexibilities enable governments to mitigate, by enacting appropriate legislation and regulations, the negative impact that IPRs may have on the realization of the right to health. However, soon after the adoption of the Agreement important challenges to the use of such flexibilities raised concerns from developing countries about constraints on the effective room for manoeuvre available for countries seeking to protect public health.

This became abundantly clear when, despite the gravity of the HIV pandemic in sub-Saharan African countries, in 1998 multinational pharmaceutical companies legally challenged the implementation of TRIPS-compatible measures (parallel importation in particular) by the South African government, in a bitter court dispute that lasted approximately for three years and ended only after a massive domestic and international campaign mounted in support of the government by treatment activists and several organizations.⁹ This did not prevent the US government from placing South Africa on its 301 Special Watch List, suspending certain trade advantages and employing persistent diplomatic pressure to urge repeal of the Act. The matter was only

6 In India, for instance, patents for pharmaceutical products were not allowed, and process patents in that field could be granted for seven years only.

7 Although IPRs may create incentives for innovation in the pharmaceutical field, such innovation is irrelevant from a public health perspective if it is not accessible and affordable to patients in need of treatment.

8 Several documents, particularly by WHO, UNCTAD and UNDP, as well as extensive academic work and NGO statements highlighted the flexibility allowed by the TRIPS Agreement in areas such as exceptions to patent rights, parallel imports and compulsory licensing. See, for example, WHO, *Globalization and Access to Drugs - Health Economics and Drugs Series*, No. 007, available at <http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.7.1.html>; German Velásquez, Carlos Correa and Xavier Seuba (2011) *IPR, R&D, Human Rights and Access to Medicines. An Annotated and Selected Bibliography*, South Centre, Geneva.

9 See, for example, William W. Fisher III and Cyrill P. Rigamonti (2005) *The South Africa AIDS Controversy. A Case Study in Patent Law and Policy*, Harvard Law School, available at <http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf>.

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resolved when former President Clinton adopted an Executive Order preventing the United States Trade Representative (USTR) from interfering with attempts by sub-Saharan African countries to use TRIPS flexibilities to increase access to medicines.¹⁰ Meanwhile, a dispute arose between the United States and Brazil which resulted in the dispute settlement mechanism of the WTO being invoked on the allegation that the Brazilian regulations for the grant of compulsory licences were in violation of the TRIPS Agreement. The dispute was eventually resolved through a ‘settlement agreement’ between the parties, resulting in the US withdrawing its complaint.^{11,12}

Although one of the stated goals of the TRIPS Agreement was “to reduce tensions arising from intellectual property protection”,¹³ the possible conflict (as illustrated by the above-mentioned disputes) between such protection and essential public health objectives—particularly access to medicines—moved the African Group, supported by other developing countries and civil society, to request the Council for TRIPS to specifically consider the relationship between the TRIPS Agreement and public health in general, and access to medicines more specifically. Two special sessions on the matter were held by the TRIPS Council and, as a result of this process, developing countries sought the adoption of a WTO Declaration on the policy space available under the TRIPS Agreement to protect public health. Importantly, the Declaration was aimed not at the creation of such policy space, but instead **confirming** the right of WTO Member States to make effective use of existing TRIPS flexibilities.

The discussion of this proposed Declaration was one of the outstanding issues at the 4th WTO Ministerial Conference (Doha, 9–14 November 2001),¹⁴ which launched a new round of trade negotiations on a broad range of issues. After protracted negotiations, the Conference adopted the ‘Declaration on the TRIPS Agreement and Public Health’ (hereinafter ‘the Doha Declaration’).¹⁵

This paper examines the implications of the Doha Declaration on the right to health, and some of its repercussions on countries that have utilized some of the flexibilities confirmed by the Doha Declaration. The possible implications of using TRIPS flexibilities to increase access to products for HIV-related co-infections and for non-communicable diseases (NCDs) are also discussed, followed by some final reflections.

10 Executive Order 13155 (10 May 2000).

11 A Joint Communication issued by the USA and Brazil on 25 June 2001 in essence stated that Brazil would give the USA adequate notice and consult before issuing a compulsory licence based on Article 68.

12 See, for example, James Love (2011) What the 2001 Doha Declaration Changed, KEI, available at <http://keionline.org/node/1267>. See also, Brook Baker and Tenu Avafia (2011) The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access, Paper prepared for the Third Meeting of the Technical Advisory Group, Global Commission on HIV and the Law, UNDP, New York, USA.

13 See Preamble of the TRIPS Agreement.

14 On the opening day of the Conference, the Director General of WTO indicated that agreement on public health and TRIPS was the “deal breaker” of a new WTO round. Pascal Lamy, then the EU Commissioner for Trade, stated “... we must also find the right mix of trade and other policies — consider the passion surrounding our debate of TRIPS and Access to Medicines, which has risen so dramatically to become a clearly defining issue for us this week, and rightly so”

15 *Declaration on the TRIPS Agreement and Public Health*, Doha WTO Ministerial 2001, WT/MIN(01)/DEC/2, 20 November 2001, available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

Content of the Doha Declaration

The adoption of the Doha Declaration was a significant achievement for developing countries. It recognized the ‘gravity’ of the public health problems afflicting many developing and least-developed countries (LDCs), especially those resulting from HIV, tuberculosis, malaria and other epidemics. However, the Declaration is not limited to those diseases and epidemics, but applies to **any** disease, including NCDs.

While acknowledging the role of intellectual property protection “for the development of new medicines”, the Declaration specifically recognizes concerns about its effects on prices. A key element of the Declaration is contained in its Paragraph 4, according to which:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

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

This Paragraph made it clear that the main or sole objective of the TRIPS Agreement cannot be deemed to be the satisfaction of the private interests of right owners, but the realization of public interests that, in the case of health, include “access to medicines for all”.

More specifically, Paragraph 5 of the Doha Declaration confirmed some of the flexibilities available under the TRIPS Agreement, notably those relating to parallel imports and compulsory licences:

5. Accordingly and in the light of Paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - c. Each 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.
 - d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

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The wording of the *chapeau* of Paragraph 5 (“these flexibilities include”) makes it clear that it contains an illustrative rather than a comprehensive list of such flexibilities.

Under Article 31 of the TRIPS Agreement a compulsory licence can be granted by a government, *inter alia*, to allow a third party to produce a generic version of a patented pharmaceutical product without the authorization of the patent holder, in so doing allowing low-price generic pharmaceuticals to be produced locally or imported from abroad. The confirmation that each Member “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted” has particular significance. Not only had attempts by countries to use TRIPS flexibilities been obstructed as the cases against South Africa and Brazil indicate, but the United States also signed bilateral trade agreements with a number of developing countries (e.g. Jordan,¹⁶ Sri Lanka¹⁷) limiting such grounds to a narrow set of circumstances. In the case of Jordan, such circumstances were limited to “(a) remedy a practice determined after judicial or administrative process to be anti-competitive; (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” (Article 4.20).¹⁸

In addition to the policy space afforded by the existence of compulsory licensing provisions, the “exhaustion of intellectual property rights” can also assist countries seeking to ensure access to affordable medicines. Exhaustion of rights refers to instances where products produced under protection of a patent (or trade mark or copyright) in one market are subsequently exported to a second market and placed on that market without the authorization of the owner of the patent. This enhances market competition between sources of the same products, which tends to drive down prices. Under Article 6 of the TRIPS Agreement, countries are free to adopt an international, regional or national exhaustion of rights regime. International exhaustion allows countries to parallel import from any other country, while regional exhaustion of rights restricts parallel importation to products originating in other members of a regional trade or economic agreement. National exhaustion of rights excludes parallel importation.¹⁹

A number of other flexibilities, not explicitly mentioned in Paragraph 5 above are relevant to the protection of public health.

As mentioned previously, the TRIPS Agreement changed the international patent regime by obliging WTO Members to make patents available for any inventions, including both product and processes, regardless of the field of technology, provided that they meet the patentability criteria of being new, involving an inventive step and being capable of industrial application. However, one crucial flexibility is the ability of a WTO Member to determine for itself what an ‘invention’ is and how the patentability requirements (novelty, inventive step, industrial applicability) are to be applied to decisions on whether to grant or not grant a patent. In the area of pharmaceuticals, in particular, it is of great significance to distinguish between what has been invented

16 See http://www.ustr.gov/webfm_send/1041.

17 See <http://lists.essential.org/pharm-policy/msg00262.html>.

18 In the case of the bilateral US–Sri Lanka agreement, the only permitted grounds for the grant of a compulsory licence would be (1) to remedy an adjudicated violation of competition laws, (2) to address, only during its existence, a declared national emergency, and (3) to enable compliance with national air pollutant standards, where compulsory licences are essential to such compliance.

19 Duncan Matthews and Viviana Munoz-Tellez (2007) ‘Parallel Trade: A User’s Guide’, in Anatole Krattiger, Richard Nelsen Mahoney et al. (eds.) *Intellectual Property Management in Health and Agriculture Innovation: A Handbook of Best Practices*, MIHR, Oxford, UK and PIPRA, Davis, USA, p. 1429.

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or discovered, and to rigorously apply such requirements to avoid the proliferation of patents on minor developments that may be used to block legitimate competition.²⁰ Other flexibilities are provisions for pre- and post-grant opposition and strict disclosure standards.

Articles 27.3(a) and 30 of the TRIPS Agreement provide further public health-related flexibilities. They allow WTO Members to exclude from patentability therapeutic, surgical and diagnostic methods, and to provide for exceptions to rights conferred by a patent including for research and experimentation, prior use and early working (often known as 'the Bolar exception').²¹

Another important flexibility relates to the extent of protection conferred to "test data" under Article 39.3 of the TRIPS Agreement. Interpreted in accordance with the Vienna Convention on the Law of the Treaties (Articles 31 and 32), this provision only requires protection under the discipline of unfair competition.²² It does not oblige WTO Members to provide for a period of exclusivity, as advocated for and implemented by some developed countries and required by the United States, the European Union (EU) and the European Free Trade Association (EFTA) in free trade agreements (FTAs) signed with a number of developing countries.²³

Further, the Doha Declaration clarified that "public health crises" can represent "a national emergency or other circumstances of extreme urgency". An 'emergency' may be either a short-term problem, or a long-lasting situation. Importantly, the Doha Declaration makes it clear that the determination of when such circumstances exist is a matter of decision by the WTO Member affected.

The Doha Declaration also recognized, in its Paragraph 6, the limitations that countries with no or insufficient manufacturing capacity in pharmaceuticals would face to use compulsory licences to address public health needs. Although the provisions on compulsory licensing permit generic drug companies to manufacture a patented product without the authorization of the right holder, Article 31(f) of the TRIPS Agreement also requires that medicines produced under compulsory licence conditions should be predominantly for the supply of the domestic market of the WTO Member authorizing such use. This constitutes a major problem for WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector, since these countries would be unable to make effective use of compulsory licensing because an exporting producer might be limited in the quantity of medicines it could export pursuant to a compulsory licence.²⁴ Paragraph 6 of the Declaration on TRIPS and Public Health recognized this problem and instructed the Council for TRIPS to find "an expeditious solution" to it.

After protracted and often acrimonious negotiations, on 30 August 2003, WTO Members agreed on a temporary waiver to Article 31(f) and (h) to allow for the export of medicines under compulsory licences. However, the 30 August Decision involved only a temporary waiver. On 6 December 2005 an amendment to the TRIPS Agreement was agreed, to make perma-

20 See, for example, Sudip Chaudhuri, Chan Park and K. M. Gopakumar (2010) Five Years into the Product Patent Regime: India's Response, UNDP, New York. Available at: <http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf>; Carlos Correa (2011) Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, Research Paper No. 41, South Centre, Geneva. Available at: http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en.

21 This exception allows a company to initiate procedures for the marketing approval of a generic product before the expiry of the relevant patent.

22 See, for example, Carlos Correa (2011) 'Test data protection: rights conferred under the TRIPS Agreement and some effects of TRIPS-plus standards, in the law and theory of trade secrecy', in Rochelle C. Dreyfuss and Katherine J. Strandburg (eds.) *A Handbook of Contemporary Research*, Edward Elgar Publishing, Cheltenham.

23 See below.

24 Article 31(k) authorizes export of unlimited quantities where a licence is granted on competition grounds.

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ment the waiver of article 31(f) and (h). The amendment is, however, subject to the approval by two thirds of the WTO Members.²⁵ The 6 December 2005 agreement was criticized by a number of civil society groups and non-governmental actors—in particular, the international humanitarian aid organization Médecins sans Frontières (MSF), which expressed alarm that the decision to amend the TRIPS Agreement was based on a mechanism that had failed to prove that it could improve access to medicines.²⁶ Concerns about the effectiveness of this mechanism have also been raised by several developing countries recently at the Council for TRIPS.²⁷

Finally, the Doha Declaration reaffirmed “the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country [LDC] members pursuant to Article 66.2” of the TRIPS Agreement.²⁸ It also declared the need to extend the transitional period granted to LDCs under Article 66.1 for the implementation of Sections 5 (patents) and 7 (test data) of Part II of the TRIPS Agreement and for the enforcement of rights provided for under these Sections until 1 January 2016, without prejudice to the right to seek further extensions.²⁹

25 As of October 2011, only 36 Members and the EU had notified their approval to the amendment.

26 *WTO Members Should Reject Bad Deal on Medicines*, Joint Statement by NGOs on TRIPS and Public Health, 3 December 2005. Available at: www.cptech.org/ip/wto/p6/ngos12032005.html.

27 Kaitlin Mara (2010) *TRIPS Council Discusses Efficacy Of ACTA, Public Health Amendment*, 29 October. Available at: <http://www.ip-watch.org/weblog/2010/10/29/trips-council-discusses-efficacy-of-acta-public-health-amendment/>.

28 On the very limited compliance with the obligation established by Article 66.1, see Carlos Correa (2007) *Intellectual Property in LDCs: strategies for enhancing technology transfer and dissemination*, study prepared for UNCTAD. Available at: www.unctad.org/Templates/Page.asp?intItemID=4316&lang=1.

29 See: *Decision on the Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, adopted by the TRIPS Council on 27 June 2002, IP/C/25, 1 July 2002. There are currently 48 LDCs on the UN list, 32 of which to date have become WTO Members. A list of WTO Members that are LDCs is available at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

The Doha Declaration and the right to health

The Doha Declaration does not explicitly refer to the right to health. However, the recognition that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” is crucial for the realization of that right.

Article 25 of the Universal Declaration of Human Rights (1948) recognises that a standard of living adequate for the health and well-being of the individual and that person’s family, including medical care, is a right to which all human beings are inherently entitled to.³⁰ Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) requires that States take steps necessary for the full realization of this right, including those steps necessary for: the reduction of infant mortality and for the healthy development of the child; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and the creation of conditions which would assure to all medical service and medical attention to all in the event of sickness.³¹

The presence of a right to health in several national constitutions has helped to focus attention on the problem of access to medicines. In South Africa, the right to health care services, including reproductive health care, is enshrined in Section 27.1(a) of the Constitution and can be read in conjunction with the obligation on the state to take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights (section 27.2) and the right of every child to basic health care services (section 28.1). These human rights became the basis of a complaint related to access to patented pharmaceutical products that was brought before the South African Constitutional Court in July 2002. The applicants, the Treatment Action Campaign (TAC), were concerned that the refusal of the South African government to make the ARV nevirapine available in the public health sector and not setting out a timeframe for a national programme to prevent mother-to-child transmission (MTCT) of HIV breached these terms. Finding in favour of the applicants, the South African Constitutional Court held that sections 27.1 and 27.2 of the Constitution require the government to devise and implement within its available resources a comprehensive and coordinated programme to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat MTCT of HIV. The Court also confirmed that the State is obliged to ensure that children are accorded the protection contemplated by section 28.1(c) of the Constitution. The South African government was ordered to remove the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of MTCT of HIV without delay.³²

Similarly, the right to health is enshrined in Article 196 of the 1988 *Constituição da República Federativa do Brasil* (Constitution of the Federal Republic of Brazil) and quickly became the focus of attention for NGOs acting on behalf of people living with HIV and seeking to articulate the universal right of access to ARVs. The three principles of universality, equality and integrated health care define the Brazilian State’s promotion of health as a fundamental social right and, although the Brazilian Constitution does not mention specifically access to medicines as part of the right to health, it is generally acknowledged that the right to access to medicines is derived from its implementing legislation.³³ Specifically, Article 6(I)(d) of Law 8.080/90, which estab-

30 Article 25(1) of the Universal Declaration of Human Rights of 1948.

31 Article 12(2) of the International Covenant on Economic, Social and Cultural Rights of 1966.

32 Constitutional Court of South Africa, *Minister of Health & Others v. Treatment Action Campaign & Others*, Case CCT 8/02, 5 July 2002, 10 BCLR 1033 CC: <http://www.saflii.org/za/cases/ZACC/2002/15.html>.

33 See Monica Rosina, Steffen Guise, Daniel Wang and Thana Christina de Campos (2008) ‘Access to Medicines: Pharmaceutical Patents and the Right to Health’, in Lea Shaver (ed.) *Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development*, Information Society Project, Yale Law School, New Haven, CT, p. 170.

lished the founding principles of the Brazilian national health system, the *Sistema Único de Saúde* (SUS), provides that the SUS “must be responsible for promoting full medical assistance, which includes pharmaceutical assistance”.

In line with this obligation, in 1990 the Federal Government began free delivery of ARVs, to people living with HIV in Brazil and, subsequently, this universal right to health, including access to medicines, has acted as a catalyst for the mobilization of compulsory licensing provisions contained in Articles 69 and 71 of Industrial Property Law 9.279/96 to secure price reductions for patented pharmaceutical products in Brazil. By 2001, this strategy had enabled the Brazilian Federal Government to negotiate substantial price reductions for ARVs with several pharmaceutical manufacturers, including a 64.8 percent price reduction for indinavir, 59 percent for efavirenz, 40 percent for nelfinavir and 46 percent for lopinavir.³⁴ The right to health has thus contributed to a greater emphasis on the importance of using in-built flexibilities in the TRIPS Agreement to ensure access to medicines.

It is sometimes argued that IPRs also have a human rights dimension because intellectual property is essentially the same as ‘property’ in tangible assets and must therefore be secured by the same legal guarantees. It is also pointed out that Article 27 of the Universal Declaration of Human Rights states that everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. Article 15 of the International Covenant on Economic Social and Cultural Rights contains a similarly worded provision.

However, the UN Committee on Economic, Social and Cultural Rights drew the distinction in its influential General Comment 17 (2005) between IPRs and human rights, including the right to health, which are fundamental, inalienable and universal entitlements belonging to individuals and, in certain circumstances, groups of individuals and communities.³⁵ General Comment 17 noted that human rights are fundamental because they are inherent in the human person as such, whereas IPRs are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole. Furthermore, in contrast with human rights, IPRs are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, IPRs, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.

In addition, while IPRs can provide, in certain contexts, incentives to stimulate innovation, they can conflict with, and have adverse implications for, the international human right to health. The 2001 report of the United Nations High Commissioner on Human Rights (UNHCHR) on the impact of the TRIPS Agreement acknowledged this fact, noting that IPRs could have adverse implications on the right to health and stressing the need to balance the protection of both public and private interests.³⁶

34 Duncan Matthews (2011) *Intellectual Property, Human Rights and Development*, Edward Elgar Publishing, Cheltenham, p. 132

35 United Nations Economic and Social Committee (2005) *General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15(1)(c) of the Covenant)*, Committee on Economic, Social and Cultural Rights, 35th session, 7–25 November, E/C.12/2005/GC/17.

36 United Nations Commission on Human Rights (2001) *Economic, Social and Cultural Rights: The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human Rights: report of the High Commissioner*, 27 June, E/CN.4/Sub.2/2001/13/, p. 5.

THE DOHA DECLARATION AND THE RIGHT TO HEALTH

The adoption of the Doha Declaration triggered a number of actions at the international level aimed at addressing the tension between IPRs and the right to health. For instance, the 59th World Health Assembly (2006) expressed concerns about the implications that IPRs could have on prices for pharmaceutical products and on access to medicines.³⁷ In 2008, the 61st World Health Assembly adopted the World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which called for more efforts to implement States' obligations arising under applicable international human rights instruments with provisions relevant to health.³⁸ In particular, the WHO global strategy acknowledged Article 7 of the TRIPS Agreement, and required actions to be taken to: promote transfer of technology and the production of health products in developing countries; support improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development; and develop possible new mechanisms to promote transfer of, and access to, key health-related technologies.

Significantly, the WHO Global Strategy alluded in several sections to the flexibilities recognized by the Doha Declaration. Thus, Paragraph 38 stated:

[I]nternational agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, including those contained in the TRIPS Agreement and recognized by the Doha Declaration on the TRIPS Agreement and Public Health that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries.

The Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health has stressed the relevance of various aspects of the Doha Declaration for the realization of the right to health, particularly as it "recognized concerns over the effect of IP on medicine prices and reaffirmed the right of member States to use TRIPS flexibilities to achieve public health needs and promote access to medicines for all".³⁹ The Special Rapporteur also noted that several countries have not taken advantage of the policy space guaranteed by the Doha Declaration and are yet to revise their laws to incorporate TRIPS flexibilities, and that the early implementation of intellectual property legislation in LDCs, coupled with the unwillingness or inability of countries to insert TRIPS flexibilities into national legislation, leaves the sustainability of treatment scale-up in some jeopardy.⁴⁰

The limited progress made in attaining Goal 6 of the Millennium Development Goals (MDGs),⁴¹ makes it imperative to use such flexibilities to the fullest extent possible. In 2003, the WHO published *The Public Health Approach to Antiretroviral Therapy: Overlapping Constraints*, in which it laid out a strategic rationale for the rapid scale-up of antiretroviral therapy (ART) in low and

37 World Health Assembly Resolution on Public Health, Innovation and Essential Health Research and Intellectual Property Rights, 27 May 2006.

38 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 24 May 2008.

39 *Promotion And Protection of All Human Rights, Civil, Political, Economic, Social And Cultural Rights, Including The Right To Development*, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/11/12, 31 March 2009, p. 11.

40 Ibid.

41 Goal 6: Combating HIV/AIDS, Malaria and Other Diseases, with the following targets: (1) Halt and begin to reverse, by 2015, the spread of HIV/AIDS; (2) achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it; (3) halt and begin to reverse, by 2015, the incidence of malaria and other major diseases.

middle-income countries.⁴² Preliminary data indicate that, by the end of 2010, more than 6 million adults and children were receiving ART, compared with only 30,000 in 2003.⁴³ This achievement is impressive, but much work remains. In view of the expanded use of ARVs mentioned above, 10 million people who are eligible do not have access to ART.⁴⁴ Dedicated financing for ART rose from US\$1.6 billion in 2001 to US\$15.9 billion in 2009, with substantial increases in funding through the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR) and other bilateral programmes and charitable contributions.

Yet there is a very real risk that the global economic downturn may have a negative impact on the sustainability of these types of programmes, with the world facing a shortfall in financing AIDS in the context of the current global economic constraints.⁴⁵ Another important reason for retaining policy space is that the new 2010 WHO HIV treatment guidelines for adults and adolescents have recommended earlier treatment, thereby increasing the number of people estimated to need ART to nearly 15 million.⁴⁶ Furthermore, it is becoming clear that the cost of treatment for Hepatitis C and NCDs associated with HIV, such as certain types of cancers, is also extremely high.

Patented medicines almost always cost much more than the equivalent, unpatented, 'generic' versions.⁴⁷ The need to shift to newer therapies involving patented products (namely to overcome resistance to current treatments) will increase dramatically the need for funding. For instance, raltegravir, a new ARV, is sold in Brazil for \$5,870 per patient per year (ppy) and for \$675 ppy in LDCs (which are not bound to recognize patent protection until 2016). Even the price for LDCs is already four times that of the recommended triple first-generation combination (TDF/3TC/EFV).⁴⁸ A report on PEPFAR's activities in Vietnam noted that "[E]xpectations that the cost of lopinavir/ritonavir would fall by 50% in 2009 due to the introduction of generic versions were dashed when it was discovered that Abbott has patents pending in Vietnam and that Abbott intended to use the patents to prevent the procurement of generic alternatives."⁴⁹ Figure 1 comparatively shows prices of different ARVs and their dramatic increase for new treatments.

42 Ian Grubb, Jos Perriens and Bernhard Schwartländer (2003) *The Public Health Approach to Antiretroviral Therapy: Overlapping Constraints*, WHO, Geneva. Available at: http://www.who.int/hiv/pub/prev_care/en/PublicHealthApproach_E.pdf.

43 WHO (2010) *Antiretroviral Therapy for HIV Infection in Adults and Adolescents: Recommendations for a public health approach*. 2010 revision. Available at: http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf.

44 Gottfried Hirnshall and Bernhard Schwartländer (2011) 'Treatment 2.0: Catalysing the next phase of scale-up', *The Lancet*, 25 February.

45 Ibid. See also Jennifer Kates, Adam Wexler, Eric Lief, Carlos Avila, Benjamin Gobet (2011) *Financing the Response to AIDS in Low- and Middle-Income Countries: International Assistance from the G8, European Commission and other donor governments in 2010*. Available at: <http://www.kff.org/hivaids/upload/7347-07.pdf>.

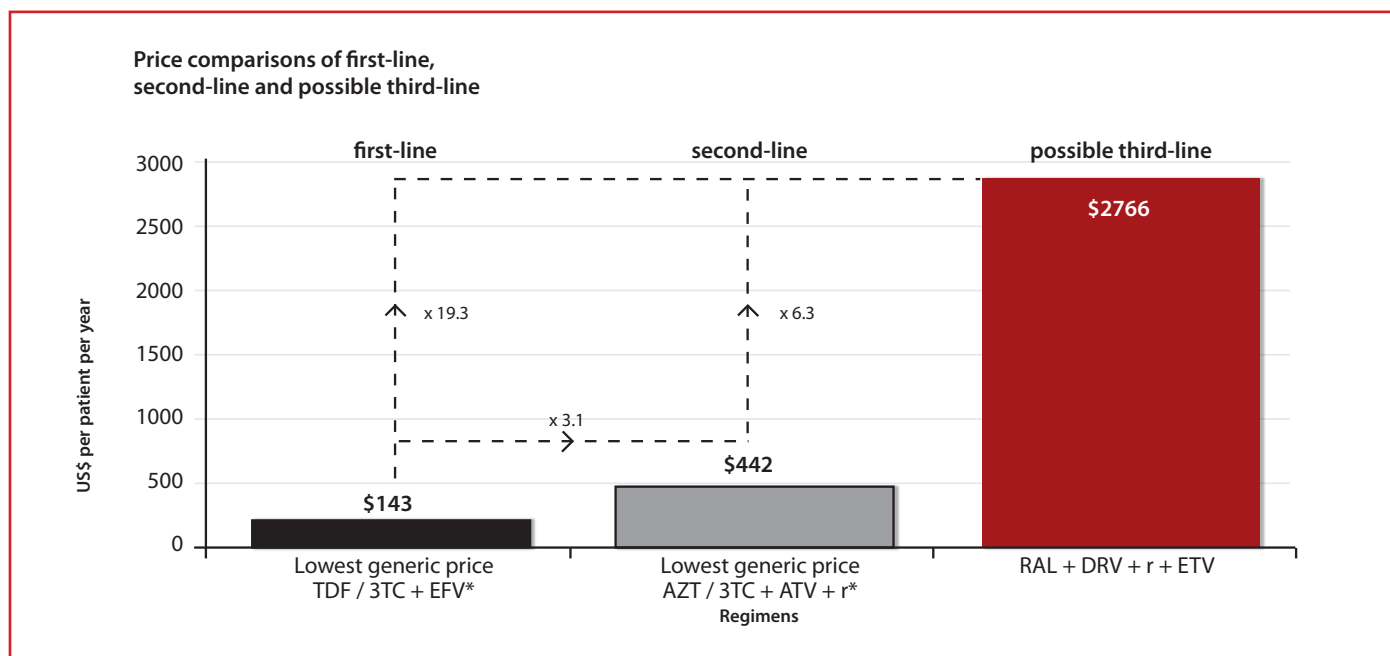
46 The situation is even more urgent among children living with HIV. See UNAIDS, UNDP, WHO (2011) *Using TRIPS flexibilities to improve access to HIV treatment*, Policy Brief. Available at: <http://content.undp.org/go/newsroom/publications/hiv-aids/using-trips-flexibilities-to-improve-access-to-hiv-treatment.en>.

47 A recent report notes that, in general, "[O]riginator brand medicines generally cost substantially more than their generic equivalents. Patients purchasing medicines in the private sector in developing countries pay, on average, 2.6 times more for originator brands than for their lowest-priced generic equivalent", United Nations, The Global Partnership for Development (2011) *Time to Deliver, MDG Gap Task Force Report 2011*, UN, New York, p. 54.

48 See MSF (2011) *Untangling the Web of antiretroviral price reductions*, Press Release. Available at: <http://msf-utw.tumblr.com/post/7755591372/14th-edition-of-untangling-the-web-launches-at>.

49 PEPFAR (2010) *Vietnam COP Report FY 2010*. Available at: <http://www.pepfar.gov/documents/organization/145740.pdf>.

Figure 1: Evolution of prices for selected antiretrovirals



Source: MSF (2011) *Untangling the web, 14th edition*

However, while the prices of new medicines require additional resources from governments and other donors, as a result of the global financial crisis there are indications already that donor funding is being frozen or even reduced.⁵⁰ The TRIPS Agreement, in addition, has limited the extent to which developing countries can produce, import and export cheaper generic versions of medicines. Because Article 27.1 of the TRIPS Agreement prohibits discrimination relating to the field of technology, the previously available possibility of deciding whether or not to grant patent protection for pharmaceutical products has been eliminated. All WTO Members were required, at the end of the appropriate transitional periods, to provide patent protection for pharmaceutical products.

In this context, the use of TRIPS flexibilities, notably compulsory licences, will be increasingly necessary in many countries to drive prices of needed medicines down. As noted by the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard to Physical and Mental Health, the TRIPS Agreement and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect and fulfil the right to health. The report, therefore, recommends that developing countries and LDCs review their laws and policies and consider whether they have made full use of flexibilities contained in the TRIPS Agreement or included TRIPS-plus measures and, if necessary, consider amending their laws and policies to make full use of the flexibilities available to them.⁵¹ In light of the Special Rapporteur's report, the link between the right to health and the use of flexibilities contained in the TRIPS Agreement, and the review of national implementing legislation, look set to remain central to attempts to promote access to medicines in developing and least-developed countries in the future.⁵²

⁵⁰ See, for example, Jennifer Kates, Kim Boortz, Eric Lief, Carlos Avila and Benjamin Gobet (2010) *Financing the Response to AIDS in Low-and Middle-Income Countries: International Assistance from the G8, European Commission and Other Donor Governments in 2009*, The Henry J. Kaiser Foundation/UNAIDS. Available at: <http://kff.org/hivaids/upload/7347-06.pdf>.

⁵¹ See recommendations contained in UNAIDS, UNDP, WHO Policy brief, op. cit.

⁵² United Nations (2009) *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (Anand Grover)*, United Nations General Assembly, 11th Session, 31 March 2009, Agenda Item 3, A/HRC/11/12, United Nations, New York.

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In sum, adherence to the Doha Declaration by ensuring that the TRIPS flexibilities are effectively applied, may promote the realization of the right to health by enhancing access to affordable medicines and other pharmaceutical products. While the TRIPS Agreement has been adopted and is enforced in the context of a trade organization, governments should bear in mind that its implementation may have far-reaching implications in the area of public health. Paragraph 4 of the Doha Declaration indicates, in fact, that governments not only **may** but also **have the duty** to use the TRIPS flexibilities necessary to protect public health. Therefore, actions should be taken to provide for such flexibilities in domestic legislation and preserve the room to apply them in trade and other bilateral, regional or international agreements.

Promoting the use of flexibilities confirmed by the Doha Declaration

The main objective of the Doha Declaration was to confirm the right of any WTO Member, particularly developing countries, to use the TRIPS flexibilities as described above, to offset the adverse effects of higher prices resulting from the patenting of pharmaceutical products and to facilitate access to them. To what extent has it actually contributed to achieving this objective?

The Doha Declaration has had a number of significant repercussions. It helped to attract public attention to a problem that not only has socio-economic but ethical implications: while medicines may be available, people in need may be deprived of treatment as a result of the enforcement of IPRs. International and non-governmental organizations have relied heavily on the Doha Declaration in analyses and advocacy regarding access to medicines. The Declaration has also been invoked as a basis for policy action at both national and regional level in the field of access to medicines. For instance, the European Parliament, in its Resolution on the TRIPS Agreement and access to medicines (12 July 2007), cited the Doha Declaration and asked the European Council:

to support the developing countries which use the so-called flexibilities built into the TRIPS Agreement and recognized by the Doha Declaration in order to be able to provide essential medicines at affordable prices under their domestic public health programmes (para. 8).⁵³

The Resolution further called on the European Council:

to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries (para. 11).⁵⁴

The Doha Declaration was also expressly referenced in the US Trade Promotion Authority prior to its lapse in 2007.⁵⁵ From a legal point of view, and although the Doha Declaration is not formally an authoritative interpretation of the TRIPS Agreement (in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO),⁵⁶ in affirming that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health”, the Declaration gives guidance to panels and the Appellate Body for the interpretation of the Agreement’s provisions in cases involving public health issues.⁵⁷ Therefore, panels and the Appellate Body should opt for interpretations on the meaning of particular

⁵³ See <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN>. The Resolution also “[E]ncourages the developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licences and the mechanism provided by Article 30 thereof” (para. 9).

⁵⁴ Ibid.

⁵⁵ 19 U.S.C.A. §3802(b)(4)(C). See CIEL (2007) *Putting Health on the Fast Track*. Available at: http://www.ciel.org/Publications/Lee_DohaUSTR_25July07.pdf.

⁵⁶ A ‘declaration’ has no specific legal status in the framework of WTO law.

⁵⁷ The European Commission, for instance, stated that “in the case of disputes (e.g. in the context of WTO dispute settlement procedures) Members can avail themselves of the comfort provided by this Declaration. Panelists are likely to take account of the provisions of the TRIPS Agreement themselves as well as of this complementary Declaration, which, although it was not meant to affect Members’ rights and obligations, expresses the Members’ views and intentions. Hence, the Declaration is part of the context of the TRIPS Agreement, which, according to the rules of treaty interpretation, has to be taken into account when interpreting the Agreement” (European Commission (2001). *WTO Ministerial Declaration on the TRIPS Agreement and Public Health*. European Commission, Brussels, 19 November 2001, p. 2).

provisions that are “supportive of WTO Members’ right to protect public health in disputes”. Significantly, no complaint against a WTO Member has been filed under the Dispute Settlement Understanding on matters relating to IPRs and public health since the adoption of the Declaration, despite arguments about inadequate IPRs protection in some countries. For instance, countries issuing compulsory licences aimed at enhancing access to ARVs and related treatment continue to be placed on the United States Special 301 Watch List.⁵⁸ However, no complaint has been submitted under WTO rules against those countries. It is not possible to determine whether this is a concrete **effect** of the Declaration, but potential complainants would have had the burden of overcoming public health-related interpretations submitted by complained Members.

The implementation of Paragraph 6 of the Doha Declaration has been mentioned in a WTO dispute, not as a defensive argument, but to establish non-compliance with WTO obligations by the EU. India initiated dispute settlement consultations on 11 May 2010 with the EU in relation to the EC Custom Regulation 1383/2003 as a result of the repeated detention of generic medicines produced in India while in transit through EU territory. In its complaint, India argued that detentions were inconsistent with the EU’s obligations under Article 31 of the TRIPS Agreement read together with the provisions of the WTO Decision of 30 August 2003.⁵⁹

The impact of the Doha Declaration as an interpretative tool of the obligations under the TRIPS Agreement can also be observed in some court decisions at the national level. For instance, in a case where Novartis argued that Article 39.3 required data exclusivity in relation to its product Gleevec[®] in Argentina, the appeal court argued, *inter alia*, that the Doha Declaration allowed for a “flexible interpretation” of that provision and confirmed that the TRIPS-consistency of the Argentine regime was consistent with TRIPS, which does not grant exclusive rights in relation to test data.⁶⁰

Despite these multiple repercussions of the Doha Declaration, an evaluation after five years of the adoption of the Declaration noted that developed countries had taken little or no action towards their obligations and were in some cases actually undermining the Declaration.⁶¹ Ten years after its adoption, this situation has not improved. The Doha Declaration has promoted only to a limited extent the incorporation of the TRIPS flexibilities in national laws and regulations and their effective use.⁶²

A study on the implementation of said flexibilities has shown that 29 developing countries, including many low-income countries,⁶³ provide for national or regional exhaustion of rights. Article 6 of the TRIPS Agreement, as noted, allows instead

58 See United Nations (2009) *Promotion And Protection of All Human Rights, Civil, Political, Economic, Social And Cultural Rights, Including The Right To Development, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, A/HRC/11/12, 31 March 2009, United Nations, New York, p. 20.

59 On 28 July 2011, the Government of India announced an “Understanding” with the European Union to settle the dispute. See Brook K. Baker (2011) *Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn’t Good Enough*. Available at: http://www.google.fr/search?client=safari&rls=en&q=india+eu+border+measures+wto+case&ie=UTF-8&oe=UTF-8&redir_esc=&ei=Kb6UTuKiDITJ4QtcwLScCA.

60 Novartis Pharma AG c/Monteverde SA s/ varios propiedad industrial e intelectual, Sala III, Camara Nacional de Apelaciones en lo Civil y Comercial Federal, 1 February, 2011.

61 Oxfam (2006) *Patents vs. Patients: Five Years After the Doha Declaration*, Oxfam, Oxford. Available at: www.oxfam.org/en/policy/bp95_patentsvspatients_061114.

62 See, for example, United Nations Development Programme (2008) *Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislation*; World Intellectual Property Organization (2010) *Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels*, CDIP/5/4, WIPO, Geneva. Available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=19686.

63 China, Philippines, Sri Lanka, Thailand, Barbados, Belize, Trinidad and Tobago, Brazil, Botswana, Morocco, Nigeria, Tanzania, Zimbabwe, Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo, based on Carloyn Deere (2010) ‘The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries’, presentation at The TRIPS@10 Conference, 16–18 November 2010, at Columbia University’s Faculty House. Available at http://www.earth.columbia.edu/tripsat10/?id=related_materials. See also World Intellectual Property Organization (2010) *Patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels*, CDIP/5/4, WIPO, Geneva. Available at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=19686.

for an **international** exhaustion, which may be critical for ensuring access to low-price medicines available in foreign markets. Similarly, only a relatively small number of developing countries specifically provide for the 'Bolar exception'.⁶⁴ In at least 45 developing countries⁶⁵ patents on the second indication of pharmaceutical products are allowed, although this is not required by the TRIPS Agreement and is based on a legal fiction on novelty and industrial applicability. Although Article 39.3 of the TRIPS Agreement does not require the grant of exclusive rights in respect of test data, at least 41 developing countries do grant such rights.⁶⁶

Most national laws incorporated provisions on different modalities of compulsory licences and government use for non-commercial purposes before the adoption of the TRIPS Agreement. Although such provisions have been retained or modified to meet the Agreement's standards on the matter, only few developing countries⁶⁷ have granted such licences to address public health needs, particularly to ensure the supply of low-cost treatments for HIV in the last 10 years.⁶⁸

Therefore, the Doha Declaration did not seem to have triggered a widespread incorporation and use of TRIPS flexibilities to increase access to medicines. This is possibly the result of many factors.⁶⁹

First, many countries prematurely changed their IPRs regimes, including patent laws, before the end of the transitional period for the general application of the TRIPS Agreement in developing countries (1 January 2000) and before recognizing the full impact of IPRs on access to medicines. Given the sensitivity of IPRs issues, governments have been reluctant to review the adopted legislation to incorporate flexibilities not present in the existing legislation. One exception has been India, as noted above. The Philippines also changed its legislation through the Universally Accessible Quality and Cheaper Medicines Act of 2008 (Republic Act 9502) to introduce a number of TRIPS flexibilities (patentability requirements similar to those of Section 3(d) of the Indian Patents Act, Bolar exception, international exhaustion of IPRs, amendment to the conditions for the use of a patented invention by the government without agreement of the patent owner).⁷⁰ China amended its patent law in 2010. The amendment introduced the standard of absolute novelty (Article 22),⁷¹ the 'Bolar exception' (Article 69) and modified provisions on compulsory licences. Article 50 of the revised patent law states that for the purpose of public health the Patent Administration Department under the State Council may grant a compulsory licence to make a patented pharmaceutical product and to export it to the relevant country or region that satisfies the provisions of relevant international

64 Jordan, Thailand, China, India, Malaysia, Costa Rica, Dominican Republic, Paraguay, Argentina, Brazil, Nigeria, Egypt, Kenya, Tunisia, and Zimbabwe (Deere, op. cit).

65 Deere, op. cit. Only in 12 developing countries are second-indication patents are specifically excluded.

66 Ibid.

67 Zimbabwe, Malaysia, Zambia, Ghana, Indonesia, Thailand, Brazil and Ecuador.

68 See below additional information on some of these cases.

69 See, for example, Sisule F. Musungu, Susan Villanueva and Roxana Blasetti (2004) *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks*, South Centre, Geneva, p. 30.

70 See, for example, Ronil Emmavi J. Remoquillo (2009) 'Implications of the Patentability Requirements and Other Policy Considerations to the Pharmaceutical Industry - The Japanese and Philippine Experience', *Intellectual Property Philippines*. Available at: http://www.training-jpo.go.jp/en/uploads/text_vtr/ws_pdf/ws-145.pdf.

71 The principle of 'absolute novelty' means that the novelty of an invention is judged against all information available at the priority date of the invention, irrespective of where the information was released or the form in which it was released. This means that all material made available to the public anywhere in the world forms part of the state of the art and can be distinguished from relative novelty, whereby a publication available in any country will destroy novelty, but use of the invention outside the country in which protection is sought does not.

treaties entered into by China. Other developing countries have moved, however, in the opposite direction. For instance, the broadly defined concept of ‘counterfeit’ contained in the Kenyan ‘Anti-counterfeit Bill 2008’ may be used to block the commercialization of legitimate generic medicines.⁷²

Second, and most importantly, a significant number of developing countries have entered into FTAs and other bilateral agreements that incorporate, in exchange for trade concessions, measures – commonly referred to as ‘TRIPS-plus’ provisions – that exceed the obligations under the TRIPS Agreement and limit the capacity of developing countries to effectively issue compulsory licences, allow parallel importation or use other TRIPS flexibilities.⁷³ TRIPS-plus obligations that may affect access to medicines include:⁷⁴

- extension of patent terms to compensate for delays in the examination of a patent application or in obtaining marketing approval for a drug;
- patent linkage requirements that prevent the marketing approval of generic versions of a medicine when patents relating to it exist (required in US FTAs);
- requirements to grant patents for second indications of known pharmaceuticals;
- periods of exclusivity for test data; and
- enhanced enforcement provisions—for instance, in relation to border measures (allowing customs authorities to seize goods on suspicion of infringement of a patent in cases of importation, exportation or transit).

Third, some developing countries (not involved in FTAs) do not seem to have received appropriate technical assistance and capacity-building to fully understand and incorporate the TRIPS flexibilities.⁷⁵ Often, governments have been subject to demands and pressures from developed countries and industry lobbies to apply levels of IPRs protection beyond what is required by the TRIPS Agreement (e.g. data exclusivity, linkage between drug registration and patent protection).⁷⁶ In particular, the use of compulsory licensing provisions has sometimes been problematic not only because governments are subject to such pressures, but the procedural requirements are complex and burdensome to apply, particularly for developing and least-developed countries that lack the necessary technical and legal expertise and administrative capacity.

Fourth, the system established by the WTO Decision of 30 August 2003 is subject to a number of conditions and limitations (for instance, export of specified quantities of a medicine to a particular country). The Decision does not provide sufficient incen-

72 “Counterfeiting” is a term with a very specific meaning in intellectual property law. It is a term defined in Article 51, footnote 14 of the TRIPS Agreement and describes the theft of brand owners’ intellectual property, namely a trademark violation. See also Charles Clift (2010), “Counterfeit Medicines: Health and Harm”, *The World Today*, Volume 66, Number 12: <http://www.chathamhouse.org.uk/publications/twt/archive/view/-/id/2102/>.

73 Sisule F. Musungu, Susan Villanueva and Roxana Blasetti (2004) “Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks”, Geneva: South Centre, page 30.

74 See, for example, Bryan Mercurio (2006) “TRIPS-Plus Provisions in FTAs: Recent Trends”, in Lorand Bartels, and Federico Ortino (eds.) I, Oxford University Press, 215-237, page 224.

75 See Duncan Matthews (2005) ‘TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements’, *European Intellectual Property Review*, 28, 11: 420–427, p. 425.

76 El Said, M. and Amy Kapczynski (2011) ‘Access to medicines: The role of intellectual property law and policy’, Paper prepared for the Third Meeting of the Technical Advisory Group, Global Commission on HIV and the Law, UNDP, New York, USA.

tives for generic companies to supply low-cost medicines, inter alia, because such companies are bound to obtain a compulsory licence in the exporting (and, in some cases, also the importing) country, cannot exploit economies of scale and, at any time, the patent owner may reduce the prices of (or even donate) the required medicines and thereby undermine the efforts made to supply a generic version of the products. A major hurdle is also the need for potential suppliers to undertake prior negotiations with patent owners. So far, only a few countries have enacted legislation to implement the WTO Decision as potential exporters (namely Canada, China, Norway, India, the Netherlands, Iceland and the EU through Regulation (EC) No. 816/2006), and the system has only been used in one case (supply of an ARV from Canada to Rwanda). This case has demonstrated the hurdles that the Decision creates for potential exporters and importers, and the extent to which generic firms may be reluctant to take the risk and make the investment necessary to provide a particular medicine under the system.⁷⁷

In some limited cases, the Doha Declaration may have dissuaded countries from introducing TRIPS-plus demands. In the case of the US–Jordan FTA, as noted above, limitations on the grounds for granting compulsory licences have been included. This agreement was negotiated before the Doha Declaration; the absence of such limitations in other US FTAs with developing countries may suggest that the clear confirmation in Paragraph 5(b) of the Declaration of the freedom to determine such grounds has discouraged US demands in that respect. Similarly, in line with the clear confirmation of the principle of the right to define the scope of the exhaustion of rights in Paragraph 5(d) of the Declaration, most FTAs do not restrict parallel trade (the US–Morocco FTA is an exception).

The Bipartisan Agreement on Trade Policy reached in May 2007⁷⁸ also reflected, to some extent, the concerns that led to the adoption of the Doha Declaration. On the basis of this agreement, this New Trade Policy mitigated some public-health TRIPS-plus provisions (relating to data exclusivity, patent term extensions and patent-registration linkage) demanded by the US government in FTAs with Peru, Colombia, Panama and South Korea. According to some commentators, however, the US government seems to have backtracked from the New Trade Policy in the proposals for a Trans-Pacific Partnership Agreement, which, despite claims to the contrary in the Office of the USTR White Paper on trade goals to enhance access to medicines,⁷⁹ have raised concerns among civil society groups that they contain many new TRIPS-plus terms that are collectively more onerous than have ever previously been presented.⁸⁰

The Doha Declaration may have also played a role in limiting EU demands for TRIPS-plus protection in the European Partnership Agreement (EPA) signed with CARIFORUM countries. In accordance with Article 139:2, “[N]othing in this Agreement shall be construed as to impair the capacity of the Parties and the Signatory CARIFORUM States to promote access to medicines.” However, although this EPA does not contain substantive standards directly affecting the level of IPRs protection for pharmaceuticals, it does contain TRIPS-plus provisions on enforcement that may affect the commercialization of generic medicines.⁸¹

77 See Richard Elliott (2008) ‘Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada’s Law on Compulsory Licensing for Export’, *McGill International Journal of Sustainable Development Law & Policy*, Volume 3, Issue 1.

78 Available at http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf.

79 USTR (2011) *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*. Available at: <http://www.ustr.gov/about-us/press-office/press-releases/2011/september/trade-enhancing-access-medicines>.

80 Sean Flynn (2011) *Statement on USTR Release of White Paper on ‘Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines’*, 12 September 2011. Available at: <http://infojustice.org/archives/5453>.

81 For instance, Article 163 of the CARIFORUM EPA is TRIPS-plus in requiring signatories to adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or

Interestingly, while IPRs chapters in FTAs contain, as a result of developed countries' demands, TRIPS-plus provisions that may affect access to medicines, specific references to the Doha Declaration may be found in many such chapters.⁸² Such references in some cases are of general nature, such as recognizing the "principles"⁸³ or the "importance"⁸⁴ of the Doha Declaration. These provisions may have a role in interpreting other provisions of the agreements when they are ambiguous, but would not help to mitigate clearly worded TRIPS-plus obligations. In the case of the EU–Colombia–Peru FTA, a reference to the importance of the Doha Declaration is complemented by a provision stating that "in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration" (Article 197:2). This rule may be useful to interpret some exceptions in the agreement, such as the one relating to data exclusivity (Article 231.4).⁸⁵

In sum, the Doha Declaration has had a clear impact on the international discourse relating to IPRs and access to medicines and some impact on the implementation of national laws and the use of TRIPS flexibilities, but has not been sufficient to prevent TRIPS-plus demands, concessions and commitments in FTAs and other bilateral agreements that may negatively affect access to medicines.

placement under a customs-free zone or a customs-free warehouse of goods infringing an IPR may take place, to lodge an application in writing with competent authorities, administrative or judicial, the suspension by the customs authorities of the release into free circulation or the retention of such goods. This provision in the CARIFORUM EPA exceeds the enforcement obligations of Article 51 of the TRIPS Agreement, which requires only that WTO Members adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods (i.e. not suspected patent-infringing goods) may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Under Article 51 of TRIPS, however, WTO Members retain the flexibility to determine for themselves whether these enforcement measures apply to goods destined for exportation from their territories.

82 The Preamble of the Anti-Counterfeiting Trade Agreement (ACTA), which somehow epitomizes the TRIPS-plus paradigm, also contains a preambular reference to the Doha Declaration.

83 See US–Chile FTA, preamble.

84 See EU–CARIFORUM EPA, Article 147(b).

85 For a general analysis, see Henning Grosse Ruse-Khan (2011) 'The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?', *Journal of Intellectual Property Law*, Vol. 18, No. 2, p. 1. Available at SSRN: <http://ssrn.com/abstract=1849204>. This article notes that, in some cases, language similar or identical to parts of the Doha Declaration is included in some FTAs (e.g. US–Colombia TPA, Article 16.13.2).

Using TRIPS flexibilities to attain the right to health: successes and challenges

A number of experiences in developing countries show how the use of TRIPS flexibilities may be instrumental in pursuing public health objectives. After failed attempts to negotiate a price reduction for the ARV drug Kaletra[®] with Abbott, in June 2005 Brazil's Minister of Health signed a decree declaring Kaletra[®] to be in the public interest, paving the way for compulsory licence and the manufacture of a generic version of Kaletra[®] to be produced by the Farmanguinhos laboratory of the Oswaldo Cruz Foundation. However, at the same time that it declared Kaletra[®] to be in the public interest, the Brazilian government gave Abbott a timeframe in which to offer a lower price for the drug and so avert the compulsory licence from being issued. Subsequently, in October 2005, an agreement was reached between the Brazilian Federal Government and Abbott to supply the drug at a lower price than had previously been available. In return for a lower price, the Brazilian Federal Government undertook to increase the number of patients prescribed Kaletra[®], and to refrain from issuing a compulsory licence or engage in other technology transfer or foreign direct investment activities to manufacture Kaletra[®] locally, and fixing the stipulated price until the end of 2011, when the patent for Kaletra[®] would be close to expiry.

Later, in May 2007, the Brazilian government took the decision to grant a compulsory licence on a patent relating to efavirenz, an ARV of growing importance in the successful national programme to treat HIV. A remuneration of 1.5 percent of the price of the generic medicine was offered to the originator. The compulsory licence allowed the government to obtain the drug at 28 percent of the price of the original product.⁸⁶

In India, the use of TRIPS flexibilities has focused on Article 27.1 of the TRIPS Agreement. When India became a founding Member of the WTO, it was obliged to introduce a series of amendments to the Patents Act of 1970 that were designed to ensure compatibility with obligations set out in the TRIPS Agreement. These amendments included measures designed to meet the obligation contained in Article 27.1 of the TRIPS Agreement to extend patent protection to all fields of technology, including food, pharmaceutical and chemical products. In drafting legislative amendments to comply with its obligations under the TRIPS Agreement, India was also keen to address concerns about the adverse impact of compliance, particularly the likely implications of the TRIPS Agreement for the human right to life as enshrined in the Indian Constitution.⁸⁷

To ensure that the constitutional right to life is respected, Section 3(d) of the Indian Patents (Third Amendment) Act of 2005 set out that the mere discovery of a new form of a known substance is not to be considered an invention but that this could be regarded as such if it enhances the efficiency of a known invention. An explanation to that Section clarified that salts, polymers and other new versions are to be treated as the same substance and not as new, patentable forms unless they differ in their properties significantly with regard to efficacy. Although raising concerns for patentees that Section 3(d) excludes

86 Amy S. Nunn et al. (2007) 'Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment', *PLoS Med* 4(11). Available at: <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040305&ct=1>.

87 "No person shall be deprived of his life or personal liberty except according to procedure established by law." Article 21 of the Constitution of India of 1950.

some applications that, on the usual criteria of patentability, would qualify as inventions,⁸⁸ the provision has been described as an essential tool for keeping open the door for generic manufacture of medicines.⁸⁹

As a result of Section 3(d), a patent claim relating to a pharmaceutical product may relate to an active ingredient as such independently of or jointly with formulations, salts, prodrugs, isomers and so on, or cover any of these subject matters separately, but subject to a higher standard of inventive activity.⁹⁰ This provided India with considerable flexibility to determine what constitutes an invention for the purposes of granting a patent⁹¹ and allows it to draw a distinction between genuinely patentable inventions and the practice of 'evergreening' spurious inventions.⁹²

Furthermore, the Indian Patents Act of 2005 retained pre-grant opposition, which allows third parties to oppose patent applications prior to grant.⁹³ Since "any person" may have legal standing to bring pre-grant opposition proceedings, generic producers and patient groups have been able to initiate numerous successful pre-grant oppositions under Section 3(d) of the Act.⁹⁴ In addition, the 2005 amendment introduced post-grant opposition, thereby offering the possibility of re-examining a patent application afresh.

The utilization of compulsory licences in Thailand also provides a telling example of the use of TRIPS flexibilities. The Thai Patent Act 1999 contains provisions for compulsory licensing in Section 51, which provides that, to carry out any service for public consumption, any government ministry, bureau or department may exercise the rights in any patent without the requirement of prior negotiation with the patentee.⁹⁵ Its objective relates specifically to non-commercial purposes and public interests – for example, the public health service. In 2006 the Thai government issued compulsory licences for a number of medicines used to treat HIV, cancer and heart disease.⁹⁶

88 Thus, Novartis has challenged a decision that prevented it from patenting imatinib mesylate. It argued that Section 3(d) of the Patents Act is inconsistent with the TRIPS Agreement and that the definition of 'efficacy' should be broad enough to include increases in bioavailability and not an enhanced "therapeutic effect in healing a disease", as defined by the Madras High Court that rejected its patent application. See, for example, Lawyers Collective (2011) *Novartis case: background and update – Supreme Court of India to recommence hearing*. Available at: <http://www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html>.

89 MSF (2009) *HIV/AIDS Treatment in Developing Countries: The battle for long-term survival has just begun*, Campaign for Access to Essential Medicines, p. 5.

90 Carlos Correa (2000) *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, Geneva, p. 25.

91 This policy space, however, has not always been used, and patents of questionable inventive step have been granted. See Sudip Chaudhuri, Chan Park and K.M. Gopakumar (2010) *Five Years into the Product Patent Regime: India's Response*. New York: UNDP, New York. Available at: <http://apps.who.int/medicine-docs/documents/s17761en/s17761en.pdf>.

92 'Evergreening' is the term used to describe the process whereby pharmaceutical companies seek to reformulate, recombine and repackage the active ingredients and change the methods of administration, such as the dosages and the administration routes in order to obtain a new patent for pharmaceutical products soon to reach or which have reached patent expiry.

93 Section 25 of the Indian Patents Act of 1970 (as amended by the Patents (Amendment) Act, 2005): Opposition to grant of patent.

94 Janice M. Mueller (2007) 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation', *University of Pittsburgh Law Review*, 68(3), p. 570..

95 Jakkrit Kuanpoth (2006) "Patents and Access to Medicines in Thailand – the ddi case and beyond", *Intellectual Property Quarterly*, 12: 149-158.

96 See UNAIDS, UNDP, WHO (2011) *Using TRIPS flexibilities to improve access to HIV treatment, Policy Brief*. Available at: <http://content.undp.org/go/newsroom/publications/hiv-aids/using-trips-flexibilities-to-improve-access-to-hiv-treatment.en>

Finally, competition law is another tool that may be used to increase access to treatment if hampered by anti-competitive practices, including – in some countries – excessive pricing. Actions under competition law may be initiated by the governments themselves, competitors and, depending on local legislation, by patients and civil society. Article 31(k) of the TRIPS Agreement enables compulsory licences to be granted on grounds of remedying anti-competitive abuses, such as excessive pricing, refusals to licence or the denial of an essential facility.⁹⁷ A rare, but telling, example of the use of competition law in a developing country as a tool to increase access to medicines was a decision by the South African Competition Commission in 2003.⁹⁸ It found that two pharmaceutical firms had abused their dominant position in the ARV market by denying “a competitor access to an essential facility”.⁹⁹

97 Brook K. Baker (2004) *Processes and Issues for Improving Access to Utilise TRIPS Flexibilities in Non-Producing Countries*, DFID Health Systems Resource Centre, London, p. 26.

98 The complaint to South Africa's Competition Commission in *Hazel Tau and Others v. GlaxoSmithKline and Boehringer Ingelheim* arose when 11 complainants (joined in February 2003 by a further two new complainants) brought an action against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI). Bringing their action under section 49B(2)(b) of the South African Competition Act, which permits “any person” to “submit a complaint against an alleged prohibited practice”, the complainants alleged that, to the detriment of consumers, as prohibited by section 8(a) of the Competition Act, the two companies were acting in violation of competition law by charging excessive prices for their ARV medicines and were directly responsible for the premature, predictable and avoidable loss of life, including of people living with HIV, including both children and adults. Five of the 11 complainants were people living with HIV. On 16 October 2003 the Competition Commission announced that it had decided to refer the complaint to the Competition Tribunal for adjudication. The Commission's investigation had revealed that GSK and BI had contravened the Competition Act of 1988 by refusing to licence their patents on ARVs to generic manufacturers in return for a reasonable royalty. More specifically, GSK and BI were found to have abused their dominant positions in their respective ARV markets by engaging in restrictive practices consisting of: first, denying a competitor access to an essential facility; second, excessive pricing; and, third, engaging in an exclusionary act. According to the Commission, GSK and BI were using their exclusive patent rights to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high. On 10 December 2003, the Competition Commission announced that it had concluded a settlement agreement with GSK, resulting in the grant of non-exclusive, royalty-free voluntary licences, and that it was in discussions with BI, also regarding a settlement agreement. See CPTech (2003) *Competition Commission concludes an agreement with pharmaceutical firms*, 10 December 2003: <http://www.cptech.org/ip/health/sa/cc12102003.html>. See also, Tenu Avafia, Jonathan Berger and Trudi Hartzenberg (2006) *The ability of select sub-Saharan African countries to utilize 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, tralac, Stellenbosch.

99 See www.wcl.american.edu/pijip/documents/MediaRelease.doc. Although the Commission decided to refer the matter to the Competition Tribunal for determination, the case was later settled as the firms accepted the grant of voluntary licences..

NCDs and the Doha Declaration

As already mentioned, the Doha Declaration confirmed the right of WTO Members to grant compulsory licences and the freedom to determine the grounds upon which such licences may be granted. In particular, the Declaration identifies public health crises related to HIV, tuberculosis, malaria and other epidemics as situations of national emergency or other circumstances of extreme urgency.

Importantly, the Doha Declaration does not provide a closed list of diseases. On the contrary, it is intended to be used as guidance to address any public health need. In addition, WTO Members may themselves determine what constitutes “a national emergency or other circumstances of extreme urgency.” Therefore, heart disease, diabetes, cancer or other NCDs may be subject to compulsory licences.

According to the MDG Gap Taskforce Report, NCDs are responsible for no less than 40 percent of deaths in low-income countries.¹⁰⁰ Thailand, for instance, took steps to address access to medicines for chronic diseases such as heart disease and cancer as discussed above. According to a White Paper issued by the Thailand Ministry of Public Health in February 2008, cancer causes 30,000 deaths in the country annually.¹⁰¹

The Thai Constitution mandates the task of providing universal health care for the public, which includes the obligation to facilitate access to essential medicines. According to the Ministry of Public Health’s White Paper, most of the new anti-cancer medicines are patented, expensive and inaccessible to middle-income and poor people in Thailand.¹⁰²

From the point of view of the Thai government, cancer and cardiovascular diseases are no less serious than HIV or other infectious diseases. Although the international and Thai legal frameworks do not require prior negotiations with the patent owners, the Thai Ministry of Public Health tried to reduce the gap between the public and the private postures before resorting to compulsory licences to make the patented products available at prices that most people can afford.

Pursuant to its public health analysis of the need for medicines to treat NCDs, on 25 January 2007 the Thai Ministry of Public Health granted compulsory licences on Plavix (marketed by Bristol-Meyers Squibb), a drug used as a medication for cardiovascular disease. Subsequently, in January 2008, the Thai government announced its decision to issue compulsory licences for three cancer medicines: docetaxel, used for the treatment of breast and lung cancer (sold as Taxotere® by Sanofi Aventis); erlotinib, used to treat lung cancer (sold as Tarceva® by Roche); and letrozole, used to treat breast cancer (sold as Femara® by Novartis).

100 United Nations (2010) *MDG Gap Task Force Report 2010: The Global Partnership for Development at a Critical Juncture*, United Nations publication, Sales No. E.10.I.12, UN, New York.

101 See Ministries of Public Health and National Health Security Office of Thailand (2007) *The ten burning issues related to the government use of patents on three patented essential drugs in Thailand*. Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>.

102 An official study in Thailand showed that, by using compulsory licences, the country could save almost 4 billion baht (US\$125 million) in 2008–2012 through the use of cheaper generic medicines which are between four and 30 times cheaper than patented products. See SUNS No. 6442 (2008) *Recent Thai Compulsory Licenses and the Aftermath*, SUNS No. 6442, 27 March 2008. Available at: <http://www.twinside.org.sg/title2/wto.info/twninfo20080401.htm>.

NCDS AND THE DOHA DECLARATION

The grant of compulsory licences for NCDs in Thailand provoked criticism by the EU and the United States. In particular, the US government made use of the Special Section 301 procedure to move Thailand from the status of 'Watch List' to 'Priority Watch List'. On the other hand, Thai and international NGOs and other forums representing patients groups have applauded the new government's decision and urged Thailand and other countries to issue similar compulsory licences in the future.¹⁰³

Thailand's decision to issue compulsory licences for chronic NCDs hits at the heart of the global pharmaceutical industry's profit model. Cardiovascular ailments, cancer and diabetes are prevalent in developed countries, and the global pharmaceutical industry spends much of its research money to develop medicines to treat such diseases. The global pharmaceutical industry argues that the inclusion of NCDs in compulsory licensing could restrain research and development (R&D) for chronic diseases, which would bring fewer medicines to market. However, a massive use of such licences is unlikely, and, although the share of emerging economies will grow over time,¹⁰⁴ developed countries currently account for an overwhelming proportion of the global pharmaceutical market. In any case, new R&D models should be considered to ensure that the price of new medicines is delinked from the cost of R&D and, therefore, they are made available at affordable prices.

103 See, for instance, Knowledge Ecology International Statement on Thailand Compulsory Licenses on 25 January 2007: "Knowledge Ecology International (KEI) applauds the decision by the Thailand Ministry of Health to issue new compulsory licenses on patents for the AIDS drug Kaletra (LPV+RTV) and the heart disease drug Plavix (clopidogrel bisulfate). We expect that Thailand will issue other compulsory licences on medicines in the future." Available at: <http://www.cptech.org/ip/health/c/thailand/kei-thaicl-statement.html>.

104 See IMS Institute for Healthcare Informatics (2011) *The Global Use of Medicines: Outlook Through 2015* (May 2011). Available at: http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global_Use_of_Medicines_Report.pdf.

Sustaining and scaling up treatment for the future: The Doha Declaration and Beyond

As mentioned above, there has been an impressive scale-up in HIV treatment since 2003. Despite the rapid scale-up of treatment in the past decade or so, the sustainability of treatment is under threat – as patients move to newer and more expensive regimens, and funding the AIDS response flat-lines. It remains imperative that countries preserve policy space needed to regulate medicine prices including the use of the TRIPS flexibilities, so as to promote competition and thereby reduce the price of the needed medicines, if patented.

As already noted, a key flexibility is the implementation of rigorous standards to assess patent applications. This is a key flexibility that has not been sufficiently used to date and could be important for the future. Lax standards lead to the proliferation of patents on minor, often trivial, developments that may be used by title-holders to discourage or exclude generic competition. A rigorous assessment¹⁰⁵ and the timely rejection of a patent application that does not meet the patentability requirements may avoid the need to resort to compulsory licences or government use. The quality of patent examination may be significantly increased by an effective pre-grant and/or post-grant opposition system, whereby third parties provide examiners with evidence that may contribute to a thorough evaluation of applications.¹⁰⁶ The effectiveness of such a system, in turn, may be enhanced by full transparency regarding the subject matter of the protected inventions. A recent study, for instance, has shown that patent applicants rarely indicate in the patent application the known generic name of a drug; this makes opposition and searches more difficult and costly.¹⁰⁷

Developments in India, which supplies the majority of developing countries' essential medicines, will impact on the sustainability of treatment for second- and third-generation medicines. A matter of concern is the acquisition of local generic companies by foreign companies that are likely to operate under different business models and interrupt or limit the supply of low-cost medicines for the Indian and other developing countries' markets.

EU demands of TRIPS-plus obligations in the FTA under negotiation with India, particularly in relation to data exclusivity and patent term extensions, have also raised concerns among patients' civil society groups and some UN organizations.¹⁰⁸

Patent incentives only work when rich markets exist; there is a chronic under-funding of R&D for diseases that prevail in developing countries, such as malaria and tuberculosis. In addition, patent strategies increasingly aim at blocking competition rather than seeking a reward for genuine innovations.¹⁰⁹ Policies aimed at enhancing access to medicines in developing countries should include an increased use of competition laws to remedy patent-based anti-competitive practices.

105 See, for example, Carlos Correa (2006) *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, Working Paper, WHO, ICTSD, UNCTAD and UNDP, Geneva. Available at: http://www.emro.who.int/emp/media/pdf/patentability_guidelines.pdf.

106 Discussions on mechanisms to enhance the quality of patents have been proposed at the WIPO Standing Committee on Patents (SCP). The Africa Group and the Development Agenda Group also submitted to its 15th session (May 2011) a proposal for a work programme on the topic 'patents and health'. Among other actions, it requests a study on the cost-benefit of the admissibility of 'Markush claims' (broad patent claims that may apply to a broad range of compounds). The SCP may, thus, offer developing countries a forum to air concerns about the proliferation of patents of low or in-existent inventive activity.

107 Carlos Correa (2011) *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, Research Paper No. 41, South Centre, Geneva.

108 See, for example, *Head of UNAIDS Warns Against Overly TRIPS-Plus IP Provisions in the India-EU Free Trade Agreement*. Available at: <http://infojustice.org/archives/4153>.

109 See, for example, European Commission (2009) *Pharmaceutical Sector Inquiry Report. DG Competition Staff Working Paper*, European Commission, Brussels. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf.

Without prejudice to the use of TRIPS flexibilities and other policy tools, longer-term responses are needed to increase treatment of HIV and other diseases (including NCDs). Such responses should be built on an IPRs system that exploits TRIPS flexibilities to facilitate local production of medicines, technology transfer, pooled procurement and other mechanisms aimed at increasing supply and reducing prices. In promoting local production, tensions between industrial policy and public policy objectives (promoting investment, job creation and local value added, as opposed to pursuing the most affordable treatment available) need to be reconciled.

Another fundamental problem is the drying up of the R&D pipeline for ARVs and other essential medicines. Despite advances in R&D tools and substantial funding, innovation in the pharmaceutical sector is declining. Alternative models for increasing R&D focused on the needs of developing countries are necessary. They may include prizes, advanced purchase contracts and new institutional mechanisms, such as an international instrument for financing and coordination of pharmaceutical R&D. The WHO has already started to consider these issues in the framework of its Global Strategy and Plan of Action.¹¹⁰

In sum, the Doha Declaration has contributed significantly to providing legal clarity on the flexibilities contained in the TRIPS Agreement, and to provide some certainty on the space available to pursue public health policies while observing the Agreement's substantive and enforcement provisions. However, much remains to be done to give full force to the Declaration and to develop other policies that ensure that access to medicines by all becomes a reality. Policy makers and legislators in developing and least-developed countries face important decisions and administrative challenges in terms of how best to meet their international intellectual property obligations. These decisions include how to enforce IPRs while balancing adherence to obligations with use of the full range of flexibilities afforded under the TRIPS Agreement. Demand-driven and appropriate intellectual property-related technical assistance will facilitate greater use of these mechanisms. Efforts to develop the capacity of low- and middle-income countries' governments to comply with international IPR obligations while using the TRIPS flexibilities to protect and fulfil the right to health, including as measures to redress anti-competitive practices, must continue and grow.

As noted by former Special Rapporteur Paul Hunt,¹¹¹ the private business sector has human rights responsibilities. In particular, pharmaceutical companies, including originator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines.¹¹² His guidelines note that companies should respect the rights of countries to use TRIPS flexibilities to the fullest extent possible to increase access to treatment, and should also negotiate and conclude non-exclusive voluntary licences with a view to increase access to medicines in developing countries and LDCs.¹¹³

110 An Expert Working Group (EWG) on R&D financing and coordination was established in November 2008, but its report was not approved by the WHO. A new expert group (the Consultative Expert Group on R&D financing and coordination – CEWG) is currently examining proposals on the subject. It has made a preliminary recommendation for starting negotiations on a binding instrument on R&D in the framework of the WHO. Available at: http://www.who.int/phi/news/cewg_2011/en/.

111 See United Nations (2008) *Human Rights Guidelines for Pharmaceutical companies in Relation to Access to Medicines by Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, United Nations General Assembly, A/63/263, 11 August 2008. Available at: http://www.essex.ac.uk/human_rights_centre/research/rth/docs/GA2008.pdf.

112 Ibid. Paragraphs (h) and (j) of the preamble.

113 Ibid. Paragraphs 26–29 in particular.

Concluding reflections

While the Doha Declaration was essential in clarifying the right of WTO Member States to use public health-related TRIPS flexibilities to increase access to medicines, recent developments, in particular the proliferation of FTAs, most of which contain intellectual property provisions that impact negatively on access to medicines, could impede the sustainability of treatment for HIV and related diseases. Furthermore, as the eligibility of treatment programmes for multilateral funding assistance from the Global Fund and other organizations decreases because of the global economic downturn, it will become increasingly important for countries to use TRIPS flexibilities to keep the cost of treatment sustainable. In addition, as more patients move onto improved, more efficacious and less toxic first-generation ARVs as well as more expensive second- and third-generation ARVs, it is anticipated that countries will need all policy options available to reduce cost and to sustain and scale up treatment.

With these considerations in mind, developing countries that have not fully incorporated the TRIPS flexibilities specifically geared to promote access to medicines should consider doing so without further delay. In particular, governments should ensure that procedures for pre- and post-grant patent opposition are available, and review the policies relating to the examination of pharmaceutical patents to avoid the proliferation of patents with low or in-existent novelty, inventive step and/or industrial applicability. LDCs should refrain from granting pharmaceutical patents during the transitional period allowed under Doha Declaration and should seek to make the exception permanent after 2016. They should also remove any TRIPS-plus language where it exists, and, where TRIPS-plus commitments have been undertaken, should give a public health interpretation to these commitments to the fullest extent possible.

Both developed and developing countries with significant manufacturing capacity should encourage and facilitate where possible the transfer of technology between the global North and the global South for the production of ARV medicines and other essential health products, and invest in regional and national production capacity in the pharmaceutical sector and in the development of local expertise.¹¹⁴ Developing countries and LDCs in particular should encourage regional cooperation to develop intellectual property and trade policies that promote innovation and that allow for the full use of the TRIPS flexibilities to promote access to affordable HIV medicines and other medicines essential for HIV care and the treatment of opportunistic infections for all who need them.

Developing countries and LDCs negotiating trade agreements, as well as those involved in WTO accession negotiations, should not accept TRIPS-plus provisions that could prove to impede access to treatment.

114 See UNAIDS, UNDP WHO, *supra*.

Abstract

Access to medicines is a human right, enshrined in legally binding international human rights treaties, select regional agreements and numerous national constitutions. The realization of access to medicines, including antiretroviral treatment, as part of the human right to health depends heavily on the legal framework for the production and distribution of medicines, including intellectual property rights. The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) within the framework of the World Trade Organization (WTO) changed dramatically the international landscape with regard to intellectual property, particularly in relation to access to medicines.

Although one of the stated goals of the TRIPS Agreement was “to reduce tensions arising from intellectual property protection”, the possible conflict between such protection and essential public health objectives, particularly access to medicines, moved developing-country WTO Member States to request the Council for TRIPS to specifically consider the relationship between the TRIPS Agreement and public health in general, and access to medicines more specifically. After negotiations, in 2001 the 4th WTO Ministerial Conference adopted the Declaration on the TRIPS Agreement and Public Health.

This Discussion Paper briefly describes the content of the Doha Declaration and examines its implications for the realization of the right to health. The Paper discusses a number of repercussions of the Doha Declaration with regard to the international discourse on the right to health and access to medicines, and its implications within the WTO system and for national legislation. It presents some examples of use of the flexibilities confirmed by the Doha Declaration, and discusses the issue of compulsory licences with regard to patents relating to products for non-communicable diseases. Finally, a number of conclusions and recommendations are presented.