Discussion Paper

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

20 December 2011

United Nations Development Programme

Bureau for Development Policy

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. Virot)*

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

Table of Contents

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 causes[1] – 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.

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 protection[6] 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 reports[8] 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.

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