

The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation

I. Introduction

The Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health was adopted on 14 November 2001 by the 4th World Trade Organization (WTO) Ministerial Meeting at Doha, Qatar. The declaration was made by the highest decision-making body of the WTO, with the aim of promoting a balanced interpretation and implementation of the provisions of the TRIPS Agreement in a manner that is supportive of a WTO Member's right to protect public health and promote access to medicines for all.

The Doha Declaration reaffirmed that WTO members can make use of the public health related flexibilities of the TRIPS Agreement. However, there is considerable difficulty faced by developing and least developed countries in implementing these flexibilities in practice.

This policy brief seeks to examine the implementation of the Doha Declaration in the ten years since its adoption and the challenges of implementing the TRIPS flexibilities for ensuring access to affordable medicines. This brief also analyses the impact of the WTO General Council decision

of 30th August 2003 implementing paragraph 6 of the Doha Declaration for facilitating access to medicines for countries with none or insufficient pharmaceutical manufacturing capacity.

II. Background to the Doha Declaration

The TRIPS Agreement brought about significant changes to the standards of IP protection by requiring all countries to provide patent protection in all fields of technology for a minimum period of 20 years. Thus, developing countries that did not recognize product patents in certain areas of technology, such as pharmaceutical inventions, had to amend their laws to become TRIPS compliant and grant product patents on medicines.

However, the TRIPS Agreement also allows countries to take measures such as compulsory licenses, parallel imports, exceptions to patent rights, and to apply a rigorous definition of patentability criteria. These flexibilities can be implemented as a means to balance patent rights with public health needs. They may be used to stimulate competition, protect consumers and promote the production of generics, in order to encourage

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access to medicines at prices affordable to governments and patients.

In 1996, the World Health Assembly (WHA), passed resolution WHA 49.14 on the Revised Drug Strategy (RDS) requesting the World Health Organization (WHO) “to report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate”. This resolution provided WHO with the mandate to examine the new architecture of the multilateral trading system brought about by the establishment of the WTO in relation to public health.

Following the mandate of the RDS, in 1998 the WHO’s Action Programme on Essential Drugs published a monograph entitled, “Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement”.² This guide was written with the objective of informing health policy professionals with limited or no legal background on the potential impact of the TRIPS Agreement on public health and pharmaceutical policy. Although the authors noted that TRIPS imposed standards historically derived from industrialized countries, they maintained that the Agreement still provided considerable discretion to safeguard public health. The monograph examined TRIPS from a public health perspective, identifying the safeguard provisions in the Agreement that enabled countries to protect health and promote access to medicines.

After two years of debate, in 1999 the 52nd World Health Assembly approved a new Revised Drug Strategy resolution WHA 52.38 that urged Member States to “ensure that public health interests are paramount in pharmaceutical and health policies” and requested the WHO

“to cooperate with Member States, at their request, and with international organizations in monitoring and analyzing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subse-

quently develop pharmaceutical and health policies and regulatory measures that... maximize the positive and mitigate the negative impact of those agreements.”

In practice, however, the right to make use of these flexibilities by developing countries was being challenged, legally and politically, by multinational pharmaceutical companies and governments of developed countries.

In 2000, when 39 drug companies took the South African government to court to challenge the legislation that sought to use the TRIPS flexibilities³ based on WHO recommendations, there were mass public protests. After an intense international campaign backing the South African government - especially the work of the Treatment Action Campaign (TAC) - the issue finally arrived before the WTO on 20 June 2001, as a result of an initiative by a group of African countries. This was the genesis of discussions in the WTO that culminated in the Doha Declaration.

The South African court case and other similar actions including the WTO dispute settlement case brought by the USA against Brazil on its local working provision on compulsory licensing, resonated with the international community because of their inextricable association with the HIV/AIDS pandemic.

In this context, developing countries sought to clarify the relationship between the TRIPS Agreement and public health. In April 2001, following a proposal by the African Group, the TRIPS Council agreed to hold a Special Session to discuss “..the interpretation and application of the relevant provisions of the TRIPS Agreement, to clarify the flexibilities to which Members are entitled to and, in particular, to establish the relationship between intellectual property rights (IPRs) and access to medicines.”⁴

The process initiated by the African Group at the special Session of the TRIPS Council had the ultimate objective to clarify and confirm the right of WTO members to use the TRIPS Agreement’s public health safeguards, as described and recommended in the WHO mentioned publication in

1998 and in other studies and reports.⁵

Developing countries sought action in the WTO to ensure that the TRIPS Agreement does not undermine the "... right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health."⁶ The developing countries affirmed that "... nothing in the TRIPS Agreement

reduces the range of options available to Governments to promote and protect public health ..."⁷ and they sought a confirmation of this understanding by all WTO members. It was with this objective that the developing countries sought a declaration on TRIPS and Public Health.⁸

Box 1 - Proposals by Developing Countries

Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.

Members have the right to establish their own policies and rules regarding the exhaustion of IPRs.

Use of the patented subject-matter without the authorization of the right holder can be allowed other than on grounds allowed under Article 30 (research exemption).

Right to grant compulsory licenses without prior attempts to obtain a voluntary license from the patent holder in cases of national emergency, extreme urgency or for non-commercial use.

The right to authorize suppliers within its territory to make and export the product covered by a CL issued by another country, predominantly for the supply of the domestic market of that country.

Waiver of Article 31 (b) and (f) of TRIPS to allow the use of a patented subject matter to remedy a practice that has been determined to be anti-competitive.

Right to establish or maintain marketing approval procedures for generic medicines, or applying summary or abbreviated marketing approval procedures based on marketing approvals granted earlier for equivalent products.

Right to disclose or use, in the public interest, information held by the national authorities or the patent holder, including disclosure necessary to effectively implement a CL or other measure.

Extension of the scope of Article 30 of TRIPS to allow governments to authorize the production and export of medicines by persons other than the patent holder to address public health needs in importing Members.

Each Member must restrain from imposing or threatening the imposition of sanctions or granting incentives or other benefits in a manner which could curtail the ability of developing and least developed countries from availing every possible policy option to protect and promote public health

Members must exercise utmost restraint in initiating or pursuing dispute settlement proceedings relating to measures adopted or implemented to protect and promote public health.

Non-violation and situation complaints shall not be applicable to any measure adopted and implemented by Members to protect and promote public health.

Extension of the transition period for developing and least-developed countries.

The TRIPS Council shall monitor and evaluate on an ongoing basis the impact of the TRIPS Agreement on public health, particularly on access to medicines and research and development on medicines for prevention and treatment of diseases predominantly affecting people in developing and least developed countries.

In the TRIPS Special Session of September 2001, the African Group and other developing countries presented a draft text for a Ministerial Declaration on the TRIPS Agreement and Public Health.⁹ On the other hand, developed countries stressed that IPRs contributed to public health objectives by incentivizing research and development.¹⁰ As a result of protracted negotiations, the Doha Declaration was eventually adopted through last minute compromises. Developing countries were compelled to abandon some of their proposals; developed countries, notably the USA, was forced to admit the applicability of the Declaration to all diseases and not only to malaria, tuberculosis and HIV/AIDS.

III. Reaffirmation of TRIPS Flexibilities for Public Health

The Doha Declaration has significant positive attributes, despite the compromises made by developing countries for its adoption.

The Declaration reaffirms the right of WTO Members to use the TRIPS flexibilities to the fullest extent possible for the purpose of protecting public health and promoting access to medicines. The scope of the Declaration is not limited to the impact of patents on public health, but applies to all IPRs that are within the scope of the TRIPS Agreement, such as test data protection. Moreover, the declaration is valid for any public health problem and epidemic.

Importantly, the Declaration recognizes the concerns on the impact of IPRs on prices of medicines (paragraph 3). This consensus was one of the major political achievements for developing countries.¹¹

The Declaration also provides for a clear rule of interpretation in Paragraph 4 such that any measure that is necessary to protect public health cannot be held to violate the provisions of TRIPS. This applies even when the measure derogates from certain obligations under the TRIPS Agreement. The Declaration states that the TRIPS Agreement “does not and should not prevent members from taking measures to

protect public health” and it “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” (emphasis added).

Therefore, WTO members are obliged to implement the TRIPS Agreement in a manner supportive of public health and measures to improve access to medicines. Not only does the Declaration reaffirm the right of developing countries and LDCs to take any appropriate measure to protect public health, it also requires developed countries to restrain from any action that may hinder the exercise of such measures by developing countries and LDCs. Contravening actions include obligations advanced by developed countries in bilateral trade agreements that may limit the use of TRIPS flexibilities for public health.

The Doha Declaration has given a public health related understanding to the purpose of the TRIPS Agreement, which should inform the interpretation of its provisions. The Declaration specifies in a non-exhaustive manner some of the aspects of the Agreement that provide flexibility for promoting public health and access to medicines.

In Paragraph 5, it reaffirms that the provisions of the TRIPS Agreement shall be interpreted in the light of its object and purpose, as expressed, in particular in its objectives and principles (article 7 and 8 of the TRIPS Agreement).

The Declaration also identifies in Paragraph 5 some of the TRIPS flexibilities for public health. It includes mention of the right of Members to grant compulsory licenses (CLs) and determine the grounds for issuing them. Members have full freedom to determine the grounds for granting a compulsory license such as non-working, public health or public interest.

The right to determine what constitutes a national emergency or other circumstances of extreme urgency, with the understanding that public health crises, including HIV/AIDS and Tuberculosis (TB), was also recognized by the Declaration. Malaria and other epidemics can represent such a situation.

The freedom to determine what constitutes a national emergency or a situation of extreme urgency with a presumption that public health crises can represent such a situation is crucial. In such a situation developing countries can grant a compulsory license without the obligation of prior negotiations with the patent owner (article 31.b of TRIPS). Such measures can be maintained as long as the situation of national emergency or other extreme urgency persists. Moreover, if a dispute is brought before the WTO panel about the declaration of a situation of national emergency or extreme urgency, the burden of proof is on the complainant rather than on the Member taking such a measure.

Moreover, it is confirmed that Members are free to apply an international principle of exhaustion of rights that will allow parallel importation of an IPR protected product that has been legitimately marketed in another country.

IV. The Paragraph 6 System

An essential requirement for utilizing the public health related TRIPS flexibilities, particularly compulsory licenses, is the capacity to locally produce the required drugs. A major limitation for many developing countries and LDCs is the lack of sufficient domestic pharmaceutical manufacturing capacity. In this context, paragraph 6 of the Doha Declaration recognized that countries with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement and instructed the TRIPS Council to find an 'expeditious solution' to this problem and report to the General Council by the end of 2002.

Various proposals for resolving this problem were considered by the TRIPS Council in 2002. The European Community (EC) proposed two options: 1) carving out an exception to TRIPS article 31 (f) to enable compulsory licensing for export of products needed to combat public health problems under certain conditions and safeguards; and 2) interpretation of the limited exceptions clause under article 30 to allow production for exporting to certain countries to

combat serious public health problems. The United States (US) proposed a moratorium on WTO complaints against countries that export medicines to countries in need, but sought to limit the scope of this to HIV/AIDS, TB and malaria only.

The African Group and other developing countries proposed an amendment to article 31 (f) or an authoritative interpretation of article 30 for allowing production of medicines without the consent of the patent holder.¹² It is worth noting that the statement of the representative of the WHO made at the TRIPS Council on 16 September 2002 also clearly stated that the limited exception under article 30 is the most consistent solution with the public health principle that

“... countries which does not have the capacity for domestic production of a needed product should be no less protected by compulsory license provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.”¹³

The US, however, sought to impose very stringent conditions on any solution under paragraph 6 of the Doha Declaration. These conditions aimed to restrict export licenses to “grave” or “urgent” public health crises like HIV/AIDS, TB and malaria, to limit the sectors that could be supplied under the mechanism to public and non-commercial sectors and the importing countries that might benefit from the system¹⁴, and limiting the countries that might export to only developing countries. The USA also expressed its position in favour of a solution based on a temporary waiver of article 31 (f), with multiple administrative and procedural requirements, and strict anti-diversion guarantees and limitations on re-export.¹⁵ Developing countries were strongly opposed to accepting any disease and other restrictions under the Paragraph 6 solution.

The WTO General Council finally adopted a Decision on 30 August 2003. The decision

established a system¹⁶ under which a country can issue a compulsory license for the purpose of exporting generic medicines to countries with insufficient or no manufacturing capacity, under certain conditions. This is known as 'the paragraph 6 system'.¹⁷

V. Transfer of Technology and Pharmaceutical Waiver for LDCs

Paragraph 7 of the Doha Declaration reaffirmed the commitment of developed countries under article 66.2 of TRIPS to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs in order to enable them to create a sound and viable technological base. The TRIPS Council was also instructed to take necessary action to extend the TRIPS transition period available for LDCs under article 66.1 till 2016, specifically for pharmaceutical products.

Accordingly, the transition period for LDCs in respect of pharmaceutical products was extended till 1 January 2016. Thus, LDCs do not have to implement the TRIPS provisions on patents and test data protection till then. Further, LDCs were also waived from the exclusive marketing rights (EMR) requirements under TRIPS article 70.9 for pharmaceutical products.

VI. The Doha Declaration: Implementation Challenges

After ten years since the adoption of the Doha Declaration, the main constraints for its effective implementation are evaluated below.

VI.1 *Low Use of TRIPS Flexibilities and Lack of Enabling National Laws*

The Doha Declaration is not self-executing and requires amendments to national legislations, as is the case in order to make full use of the TRIPS flexibilities. Lack of appropriate national legislation for fully implementing the TRIPS flexibilities remains a key challenge for developing countries.

National IPR legislations should at minimum include rigorous standards for the examination of pharmaceutical patents and thereby avoid the proliferation of patents (often called 'evergreening' patents) on minor or trivial developments; provisions for compulsory licensing on all admissible grounds for issuing a CL with simplified the procedures; provisions for parallel importation based on an international exhaustion principle; early working ('Bolar') exceptions and full use of the transition period for developing countries and LDCs.¹⁸

Important -but still insufficient- efforts have been made by developing countries to incorporate TRIPS flexibilities to the fullest extent in order to further public health objectives. For example, the East African Community (EAC) has been discussing a Regional Intellectual Property Policy and a Protocol on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.¹⁹ According to a 2006 survey by the South Centre and WHO, 33 developing countries and LDCs have opted for an international exhaustion regime for enabling parallel importation.²⁰ The survey also revealed that a number of developing countries such as Zimbabwe, Zambia, Mozambique and Malaysia have granted compulsory licenses related to public health and access to medicines in the post-Doha years.²¹ In India, the grant of patents for new uses of known substances and for other pharmaceutical products that do not entail a significant increase in therapeutic efficacy has been excluded under section 3 (d) of the Patents Act.

At the international level, it is necessary to improve the legal and technical assistance that is provided to developing countries in relation to intellectual property (IP) and public health. Evidence suggests that in the ten years since the Doha Declaration technical assistance has been insufficient or inappropriate, particularly that which is provided bilaterally by developed countries or by intergovernmental organizations such as WTO and WIPO²². Legal and technical assistance to developing countries and LDCs in this area should fully take into account the public health priorities and context of the country concerned in drawing up national IP law and policy.

VI.2 *Deterrents to the Use of Compulsory Licenses*

The Doha Declaration clarified that compulsory licenses can be issued for public health purposes on any ground, and not limited to situations of HIV/AIDS, TB or malaria. Until recently compulsory licenses/government use had been mainly utilized in developed countries (notably in the USA). Remarkably, in the past decade several developing countries have issued compulsory licenses/government use authorizations in order to increase access to medicines.²³ It is also noteworthy, that compulsory licenses have been issued for diseases other than HIV/AIDS, TB or

tion, multinational pharmaceutical companies and developed countries continue to exert commercial and political pressure on developing countries not to make use of TRIPS flexibilities for public health. For example, in 2006, when Thailand authorized the Government Pharmaceutical Organization (GPO) to manufacture generic versions of Efavirenz until 2011 and import the medicine from India until domestic production capacity was achieved, the US pressurized Thailand to revoke the compulsory license and negotiate with Merck. Again, in 2007 when Thailand issued a CL for the drug Kaletra (lopinavir/ritonavir), the patent holder

Box 2 - Compulsory License/Government Use Authorizations by Developing Countries

Zimbabwe, May 2002, compulsory license to produce seven generic versions of ARVs

Malaysia, November 2003, compulsory license to import ARVs from India for 2 years from 1 November 2003

Mozambique, April 2004, compulsory license to locally manufacture ARVs

Zambia, September 2004, compulsory license to locally manufacture ARVs

Indonesia, October 2004, compulsory license for ARVs

Eritrea, June 2005, compulsory license for import of generic ARVs

Ghana, October 2005, compulsory license to import generic ARVs

Thailand, November 2006, government use authorization to locally produce generic efavirenz and import the same from India

Thailand, November 2006, government use authorization for cardiovascular drug Plavix (clopidogrel)

Thailand, January 2007, government use authorization for ARV drug Kaletra (lopinavir+ritonavir)

Brazil, May 2007, government use authorization to import generic efavirenz from India

Ecuador, April 2010, compulsory license to import generic lopinavir+ritonavir from India

malaria. In 2008, Thailand issued a compulsory license for government use of four anti-cancer drugs.²⁴ Thailand had also issued a compulsory license for a heart disease drug - clopidogrel - in 2007. These are telling examples –albeit scarce–with regards to the use of the TRIPS flexibilities.

Nevertheless, the decision on the use of compulsory licenses by developing countries continues to be plagued by political considerations. It is appalling that ten years since the Doha Declara-

tion, multinational pharmaceutical companies and developed countries continue to exert commercial and political pressure on developing countries not to make use of TRIPS flexibilities for public health. For example, in 2006, when Thailand authorized the Government Pharmaceutical Organization (GPO) to manufacture generic versions of Efavirenz until 2011 and import the medicine from India until domestic production capacity was achieved, the US pressurized Thailand to revoke the compulsory license and negotiate with Merck. Again, in 2007 when Thailand issued a CL for the drug Kaletra (lopinavir/ritonavir), the patent holder

VI.3 *Push for TRIPS plus Standards*

The continued push by developed countries for standards of patent protection and enforcement that go beyond those of the TRIPS Agreement is another significant challenge to the effective implementation of the Doha Declaration. The

imposition of TRIPS plus standards on developing countries and LDCs through bilateral and regional trade and investment agreements as well as WTO accession agreements, can significantly undermine the existing TRIPS flexibilities. For example, some US FTAs extend the scope and length of data protection, introduce a 'linkage' between drug registration and patent protection, and require patent term extensions for offsetting the time taken for patent examination or securing marketing approval.²⁶ While US FTAs generally specify Bolar exceptions, they may have possible restrictions on foreign markets. On the other hand, some of the Economic Partnership Agreements (EPAs) between the EU and developing countries make reference to the "importance of the Doha Declaration". However, there is variance in the treatment of the declaration in different EPAs²⁷, and some of them (e.g. Peru-Colombia) include a set of substantive TRIPS-plus obligations that may limit access to medicines. Most EPAs also include TRIPS-plus enforcement provisions that may also act as deterrents to the use of public health flexibilities.

VI.4 Constraints of the August 30 Decision

To date, only a limited number of countries have adopted legislation to implement the August 30th Decision as an exporting country. These are: Norway, Canada, India, the European Union (EU), Hong Kong, Switzerland, Philippines, Singapore, Albania, Croatia, China, Republic of Korea, and Japan.²⁸

There has also been very limited use of the system. Only one importing country (Rwanda) used the mechanism to import cheaper life-saving medicines from the Canadian generic company Apotex for 21000 HIV/AIDS patients.²⁹

Therefore, while the Paragraph 6 system has been celebrated as a 'solution' to the problems faced by developing countries and LDCs in accessing affordable medicines, in actual practice it has not contributed to address such problems.

This is largely due to the fact that the system is

unnecessarily burdensome and complicated. The Paragraph 6 system places obligations on importing countries making use of the system that are more onerous than those for countries that can issue a CL to supply the domestic market.

The experience in making use of the system also suggests that there are hurdles within the Decision that make it difficult for countries to import a generic drug under a CL, and also makes it difficult for generic manufacturers to export a drug under CL. In the Canada-Rwanda case, the only instance in which the Paragraph 6 system has been used, it took almost 27 months to meet all of the requirements.³⁰ Thus, the system is less effective than it should be. Therefore, it is important that WTO members carefully examine the reasons behind the limited use of the system and address systemic deficiencies before making it permanent as article 31bis of the TRIPS Agreement (currently in the process of approval by WTO members).

Some of the key problems in using the Paragraph 6 system are:

- 1) Generic companies need to undertake negotiations for voluntary licenses with the patent holder before applying for a CL. Such negotiations may be protracted and complex, and a source of considerable delay and discourage generic manufacturers to participate in the process.
- 2) The Decision comprises a succession of complex procedural steps. First, a potential purchaser has to forecast the need for a medicine and identify a generic producer willing to participate in the process and fill the drug order. Second, the manufacturer has to try to negotiate a voluntary license with the patent holder. Third, if the negotiations are unsuccessful, a CL application must be filed in the home country of the generic producer. Fourth, if a patent exists in the country of export the generic producer has to apply for and obtain a CL in that country too. Each of these steps is time-consuming, involves substantial financial expense and holds no guarantee of success.

A potential importing country must also send a notification in writing to the WTO TRIPS Council, declaring its intention to import phar-

maceutical products. The notification must include the specific names and expected quantities of the product needed. Unless the importing country is classified as an LDC, it must also specify whether the product is under patent, and provide information that establishes that it lacks sufficient manufacturing capacity in the pharmaceutical sector to develop the drug being ordered.

The system also imposes conditions for commercialization of the products made under the CL. They must be clearly identified as being produced under the system through specific labelling; they should be specially packaged to be distinguishable from the branded product and in respect of its shape or colour. The generic manufacturer must post specific information about the quantity of the product, its destination and distinguishing features. These 'anti-diversion' measures are to ensure that the product will only be exported to the destination stated in the CL.

- 3) The Paragraph 6 system requires a drug-by-drug, country-by-country and case-by-case decision-making process. Indeed, the CL application must stipulate the destination and the quantity of drugs that are to be purchased and exported under the licence. Drug needs must therefore be determined with precision beforehand. If more patients are included, the only way to purchase more drugs is to begin the process again. A stock-out due to the procedural hurdles may lead to the treatment being interrupted and as a consequence patients may develop increased drug resistance (as in case of HIV/AIDS), creating the need for more expensive treatment. Conversely, if the needs have been overestimated, re-exportation of medicines imported under the system to another developing or least developed country in a similar situation is not permitted, unless there is a regional trade agreement between the two and the majority of its members are LDCs.
- 4) There is substantial scope for the patent holder to undermine the system. For example, the patent holder may decide at any time to offer the medicines at lower cost or for free, thus frustrating any efforts made to use the system

in that particular case. This creates a huge uncertainty and additional risk and disincentives for potential suppliers.

In the TRIPS Council session of June 2010, Member States shared their experiences regarding the use of the Paragraph 6 system. India, for instance, pointed out that in 2007 three applications for CL for manufacture and export of a patented drug to Nepal under Section 92 A of the Patents Act had to be withdrawn by the applicant because of non-issuance of the required CL in Nepal, as well as of the notification and anti-diversion requirements under the August 30 decision. In view of the limited impact of the system, developing countries called for a review of the August 30 decision and proposed holding an open-ended workshop to discuss these issues. However, developed countries opposed this proposal. This issue is currently on the agenda of the TRIPS Council.

VI.5 Insufficient Progress during the Transition Period

While the extension of the transition period for LDCs has been a significant gain for these countries, there has been no substantial progress towards realizing the fundamental objective behind the extension of the transition period: to provide LDCs with sufficient policy space to create a 'viable technological base' (article 66.1 of the TRIPS Agreement). With regard to pharmaceuticals, this would imply development of local pharmaceutical manufacturing capacity. A corresponding obligation under article 66.2 of TRIPS is for developed countries to encourage transfer of technology to LDCs for this purpose, as reaffirmed by the Doha Declaration. However, in practice developed countries have not effectively complied with Article 66.2 obligations. In 2003, the TRIPS Council adopted a decision on implementation of article 66.2 and established a reporting mechanism on actions taken or planned by developed countries under their article 66.2 commitments. Most of the reports submitted by developed countries under this mechanism have failed to meet the reporting criteria and many have actually reported about technical and financial assis-

tance provided under article 67 to enable developing countries and LDCs to implement the TRIPS Agreement by reforming their legal and administrative systems.

VII. Conclusions

Ten years since the adoption of the Doha Declaration on TRIPS and Public Health, the Doha Declaration remains a landmark achievement for clarifying the relationship between IP and public health.

The declaration remains a useful tool for policy makers to take TRIPS-compatible public health measures. However, there is substantial scope for better implementation of the TRIPS flexibilities in order to secure public health objectives, particularly access to medicines.

The Doha Declaration continues to be useful as a tool for the interpretation of the provisions of TRIPS Agreement to support the use of measures to promote public health. The Doha Declaration has also evolved as a tool for guiding the interpretation of the IPR provisions in some trade agreements and in national legislation and jurisprudence. In particular, the express reference to the Doha Declaration in treaty provisions has given some normative weight to the principles of the Declaration.

It is worth noting that since the adoption of the Doha Declaration, the use of TRIPS flexibilities for public health has never been challenged by developed countries before the WTO dispute settlement body. This is despite the commercial and political pressure that developing countries are subjected to as deterrent to their use. This singularly testifies to the importance of the Doha Declaration for developing countries.

Some developing countries are increasingly making use of TRIPS flexibilities for public health purposes, but many still need to adopt the appropriate laws and regulations and to ensure that patent offices act as stewards of the public interest. They also need to more effectively resist demands of TRIPS-plus obligations in exchange for trade or other concessions.

Dissemination of information and sharing of experiences among developing countries relating to the grant of CLs, the application of rigorous standards to avoid 'evergreening' patents and the use of other flexibilities can further contribute to empower countries to make more regular use of the available measures.

There is, hence, scope for substantial improvement in implementation of the Doha Declaration.

Developing countries need to review and amend as necessary their national laws to make full use of the TRIPS flexibilities. There is also a need to ensure that technical assistance and capacity building work of relevant intergovernmental organizations such as WTO and WIPO contribute and do not hinder this objective.

Moreover, there is a need to assess the August 30 Decision to find an effective solution to the problem identified in paragraph 6 of the Doha Declaration. WTO members should not shy away from considering alternative solutions to address the limitations of the system, including a solution based on article 30 of TRIPS.

It will be pertinent to consider a permanent waiver for LDCs after 2016 for pharmaceutical products, and how to ensure that adequate transfer of technology takes place from developed countries to the LDCs.

It will also be useful for developing countries to exchange views about ways to overcome or mitigate the additional obligations imposed by way of bilateral or regional trade or investment agreements with developed countries.

End Notes

1. Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN (01)/DEC/2.
2. See German Velásquez and Pascale Boulet, *Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement*, Health Economics and Drugs, DAP Series No.7, WHO/DAP/98.9, November 1997, Action Programme on Essential Drugs, World Health Organization, Geneva.
3. In 1997, South Africa proposed several amendments to its Medicines and Related Substances Control Act to allow parallel importation of pharmaceutical products for reducing the cost of essential medicines.
4. See Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, *TRIPS and Public Health*, WTO Document IP/C/W/296, 29 June 2001, p.2.
5. See South Centre, *The TRIPS Agreement: A Guide for the South. The Uruguay Round Agreement on Trade-Related Intellectual Property Rights*, November 1997, South Centre, Geneva; United Nations Conference on Trade and Development, *The TRIPS Agreement and Developing Countries*, United Nations, New York and Geneva, 1996, available at http://www.unctad.org/en/docs/ite1_en.pdf.
6. *Ibid*, p.1.
7. *Ibid*, p.3.
8. Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, June 2002, p.2, available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf.
9. Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Document IP/C/W/312, WT/GC/W/450, 4 October 2001, available at http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm
10. Carlos M. Correa, *supra* note 8, p.3.
11. *Ibid*, p.7.
12. Carlos M. Correa, *supra* note 8, p.26.
13. Statement by the representative of the World Health Organization made at the WTO Council for TRIPS, 16 September 2002, on file with the authors.
14. These conditions included excluding countries with technical manufacturing capacity but insufficient market size, strict application of "insufficient manufacturing capacity" standard, and income limits that would exclude many middle-tier developing countries.
15. Brook K. Baker, "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health", 14 *Indiana International & Comparative Law Review*, May 2004, 613-715 at 630.
16. The text of this Decision has been incorporated as article 31bis of the TRIPS Agreement, subject however to its approval in accordance with WTO rules. So far only 37 members have notified their approval of the amendment.
17. See below an analysis of the implementation of this Decision.
18. See, e.g. Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, Oxford University Press, December 2008; *Using TRIPS Flexibilities to Improve Access to HIV Treatment*, UNAIDS, WHO, UNDP Policy Brief, 2011, available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf. A study of the patent laws of 11 Latin American and Caribbean countries concluded that these countries have not included all the TRIPS flexibilities in their national laws. For example, Panama has no legislative provision for issuing a CL. Honduras does not have a provision in the law for issuing a CL to remedy anti-competitive practices or on grounds of unfair competition. See Maria Auxiliadora Oliveira, Jorge Antonio Zepeda Bermudez, Gabriela Costa Chavez and Germán Velasquez, "Has implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?", *Bulletin of the World Health Organization*, November 2004, 82 (11), pp.1-7. The situation has not substantially changed after publication of this study.
19. The Protocol seeks to provide guidance to the EAC Partner States on how their IP legislation should be adjusted to enable them to fully use the public health related TRIPS flexibilities, to restrict patentability of pharmaceutical products and medical devices in order to keep them in the public domain, promote a local pharmaceutical industry and ensure access to affordable medicines. See the *EAC Regional Intellectual Property Policy, the Protocol on the Public Health Related WTO-TRIPS Flexibilities and the EAC Regional Pharmaceutical Manufacturing Plan of Action*, available at http://www.eacgermany.org/index.php/documents-and-studies/cat_view/41-wto-trips.

20. Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, South Perspectives, South Centre and World Health Organization, 2006, Geneva, pp.47-33, available at http://www.southcentre.org/index.php?option=com_content&task=view&id=70&Itemid=67&lang=en.
21. Ibid, p.33.
22. See Duncan Matthews and Viviana Munoz-Tellez, "Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective", *The Journal of World Intellectual Property*, vol.9, issue 6, November 2006, pp. 629-53. At WIPO, developing countries from the African Group and the Development Agenda Group have submitted a proposal at the sixteenth session of the Standing Committee on the Law of Patents (SCP) on patents and health to draw up a work programme that will assist countries in adapting their patent regimes and make full use of the patent flexibilities; see World Intellectual Property Organization, *Proposal Submitted by the Delegation of South Africa on behalf of the African Group and the Development Agenda Group*, document SCP/16/7, May 18, 2011, Standing Committee on the Law of Patents, Sixteenth Session, Geneva, available at http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_ref_scp_16_7.pdf.
23. For a detailed discussion on this point, see Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, Research Paper 41, September 2011, South Centre, Geneva, pp. 17 - 21, available at http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&lang=en.
24. The Ministry of Public Health and the National Health Security Office, Thailand, *The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand*, February 2008, available at http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5bEN%5d.pdf.
25. Vanessa Bradford Kerry and Kelley Lee, "TRIPS, the Doha Declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?", *Globalization and Health*, 2007, 3:3, available at <http://www.globalizationandhealth.com/content/pdf/1744-8603-3-3.pdf>.
26. Such provisions can be found in various US FTAs, for example, with Jordan, Morocco, Singapore.
27. For example, while the draft EU-India FTA states that in interpreting and implementing the provisions in the chapter on IPRs, consistency with the Doha Declaration shall be ensured, such a provision is absent from the EU-CARIFORUM EPA. Moreover, in spite of the recognition of the Doha Declaration, TRIPS plus standards have been proposed by the EU in the FTA negotiations with India and other countries. On the case of India, see Carlos M. Correa, *Negotiation of a Free Trade Agreement European Union-India: Will India Accept TRIPS Plus Protection?*, Oxfam Deutschland and EED, June, 2009, p.10, available at http://www.eed.de//fix/files/doc/eed_oxfam_Correa_EU-India_FTA_2009_eng.pdf.
28. World Trade Organization, *Members' laws implementing the 'Paragraph 6' system*, available at http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.
29. However, this product was already available from Indian generic companies.
30. After the generic medicine Triavir from Apotex was approved in June 2006, Rwanda notified the WTO of its intent to import the medicine from the Canadian company Apotex in July 2007 and the first batch was delivered to Rwanda in September 2008.
31. For example, article 6.3 (b) and article 9 of the EC Regulation No. 816/2006 implementing the decision states that an applicant for a compulsory license has to produce evidence of efforts to have prior negotiations with the right-holder. See *Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF>.
32. In order to avoid delays, the Canadian law provides for a thirty day period of negotiations for a voluntary license with the patent holder, before filing an application for compulsory license. See Section 21.04 (3) (c) (i) of the Patent Act of Canada, available at <http://laws-lois.justice.gc.ca/eng/acts/P-4/page-10.html>.



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