World Health Organization

WHO/EDM/PAR/2002.3
Original: English

Implications of the Doha Declaration on the TRIPS Agreement and Public Health

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June 2002

Health Economics and Drugs
EDM Series No. 12

Essential Drugs and Medicines Policy

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Foreword

The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001, which affirms that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all, marked a watershed in international trade demonstrating that a rules-based trading system should be compatible with public health interests. The Declaration enshrines the principle WHO has publicly advocated and advanced over the last four years, namely the reaffirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement to protect public health and enhance access to medicines.

Article 31 (f) of the TRIPS Agreement stipulates that a compulsory licence must be issued predominantly for the supply of the domestic market of the Member granting the licence. Consequently, many countries without a significant pharmaceutical sector have not been able to take advantage of the compulsory licensing provisions of TRIPS. Although Members may issue compulsory licences for importation, they are restricted to importing goods from countries where pharmaceuticals are not patented, or where their term of protection has expired. As the sources for generic production of newer life saving drugs will increasingly run out after 2005, resolving this problem is of extreme importance to Members' efforts to secure access to affordable medicines to address public health needs.

Consequently, Paragraph 6 of the Doha Declaration instructs the Council for TRIPS to find an expeditious solution to the problem faced by countries with insufficient or no adequate pharmaceutical production capacity in making effective use of the compulsory licensing provisions of the TRIPS Agreement. To this end, WHO has publicly stated its commitment (WTO Council for TRIPS, 5-7 March 2002) to support WTO Members and the TRIPS Council in whatever way they wish to find an expeditious solution to this problem.

Shortly after the Doha Ministerial, WHO/EDM commissioned Professor Carlos Correa (University of Buenos Aires) to write a paper examining the public health implications of the Doha Declaration. This paper: (1) provides an overview of the Declaration's antecedents, (2) offers a general treatment of the Declaration's provisions, (3) provides guidance to WTO Members in finding an expeditious solution by presenting possible options WTO Members may consider in resolving the problem posed in Paragraph 6 of the Declaration, and (4) discusses related issues not covered in the Declaration.

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Acknowledgements

This paper has been produced with the support of the Department of Essential Drugs and Medicines Policy (EDM) of the World Health Organization (WHO). An expert consultation organized by the Rockefeller Foundation and WHO/EDM was held on 10 June 2002 in New York. The author wishes to acknowledge the valuable comments and input made by the participants at the expert consultation which included: Nick Drager, WHO/Strategy Unit, Office of the Director-General; Desmond Johns, Joint United Nations Programme on HIV/AIDS; Jim Keon, The Canadian Drug Manufacturers Association; Heinz Klug, University of Wisconsin; Sisule Fredrick Musungu, South Centre; Jonathan D. Quick WHO/EDM; Pedro Roffe, United Nations Conference on Trade and Development; Jorgen Smith, Norwegian Patent Office; Germán Velásquez, WHO/EDM; and Robert Weissman, Essential Information; as well as for the comments made by Robert Howse (University of Michigan) and Adrian Otten (World Trade Organization).

Although participants in the review process brought different perspectives to the table, all reviewers, by consensus, agreed that this paper advanced ideas consistent with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health.

Any views expressed are the views of the author and do not necessarily reflect the views of the World Health Organization or the Rockefeller Foundation. The author, is solely responsible for the opinions expressed herein.

This document has been edited by Robert Weissman.

Abbreviations and acronyms

ARIPO	African Regional Industrial Property Organization
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Commission
EMR	Exclusive Marketing Rights
EU	European Union
GATT	General Agreement on Tariffs and Trade
IIPI	International Intellectual Property Institute
IPRs	Intellectual property rights
LDCs	Least developed countries
MFN	Most-favoured-nation
OAPI	Organisation Africaine de la Propriété Intellectuelle
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

1. The adoption of the Doha Ministerial Declaration on TRIPS and Public Health was the outcome of carefully elaborated strategy by developing countries and a significant achievement for those nations.

2. The Doha Declaration recognizes the "gravity" of the public health problems afflicting many developing and LDCs, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. But the Declaration reflects the concerns of developing countries and LDCs about the implications of the TRIPS Agreement with regard to public health in general, without limitation to certain diseases.

3. While acknowledging the role of intellectual property protection "for the development of new medicines", the Declaration specifically recognizes concerns about its effects on prices.

4. The Declaration affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health", and that it should be interpreted accordingly.

5. In establishing that Public Health is a clearly stated purpose of the Agreement, the Doha Declaration establishes a specific rule of interpretation that gives content to the general interpretive provisions of the Vienna Convention on the Law of the Treaties on which GATT/WTO jurisprudence has been built up. Therefore, in cases of ambiguity, panels and the Appellate Body should opt for interpretations that are effectively "supportive of WTO Members' right to protect Public Health".

6. The confirmation that the TRIPS Agreement has left room for flexibility at the national level has important political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement. In legal terms, it means that panels and the Appellate Body must interpret the Agreement and the laws and regulations adopted to implement it in light of the public health needs of individual Members.

7. The Declaration clarifies that "public health crises" can represent "a national emergency or other circumstances of extreme urgency", and that an "emergency" may be either a short-term problem, or a long-lasting situation. The Declaration also places the burden on a complaining Member to prove that an emergency or urgency does *not* exist.

8. The Doha Declaration clarifies Members' right to adopt an international principle of exhaustion of rights (determining the rules by which parallel imports may be accepted). The Declaration states that "the effect of the provisions in the TRIPS Agreement … is to leave each Member free to establish its own regime for such exhaustion without challenge".

9. The Declaration recognizes an unresolved problem relating to TRIPS and Public Health – the use of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand – and commits the governing body of the TRIPS, the TRIPS Council, to reach a solution in 2002.

10. In considering various approaches to the problem of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand, Members must be mindful of choosing an approach that provides adequate incentives for the production and export of the medicines in need.

11. Desirable features of any possible solution to the problem of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand would include: a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines.

12. The Doha Declaration permits LDCs to opt for an extension of the transitional period provided for under Article 66.1 of the TRIPS Agreement in relation to pharmaceutical patents. However, because all but a few LDCs already grant patent protection to pharmaceuticals, this apparent concession to LDCs may have little practical effect.

13. It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals, as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents may be treated differently from other patents.

14. The Doha Declaration is a strong political statement that can make it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle. The Declaration is also a Ministerial decision with legal effects on the Members and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS.

Introduction

At the Doha World Trade Organization (WTO) Ministerial Conference (9-14 November 2001), the WTO Members took the unprecedented step of adopting a special declaration[1] on issues related to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health[2]. Discussion on this declaration was one of the outstanding issues at the Conference[3], which launched a new round of trade negotiations on a broad range of issues[4]. This was the first outcome of a process that started in early 2001 when, upon the request of the African Group, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and Public Health.

The African Group's request, supported by other developing countries, reflected growing concerns about the implications of the TRIPS Agreement (particularly the Agreement's provisions on patents) with regard to access to drugs. The HIV crisis in sub-Saharan African countries, the attempts by the pharmaceutical industry, backed by some governments[5], to block the implementation of TRIPS-compatible measures

[1] Paragraph 17 of the general Ministerial Declaration states: "We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration".

[2] "Doha Ministerial Declaration on the TRIPS Agreement and Public Health" (hereinafter "the Doha Declaration"), WT/MIN(01)/DEC/W/2, 14 November 2001 (see the full text in Annex 1) .

[3] The Director General of WTO emphasized the importance of this issue on the opening day of the Conference, indicating that agreement on public health and TRIPS was the "deal breaker" of the new round. Pascal Lamy, the EU Commissioner for Trade, stated at the Conference that "… 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".

[4] Including implementation, agriculture, services, industrial tariffs, subsidies, anti-dumping, regional trade agreements and environment.

[5] US Public Law 105-277 (105th Congress, 1999) established that "..None of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15 (c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997". After the adoption of the TRIPS Agreement, the US Government continued to list countries according to the Special 301 section of the US Trade Act, in many cases challenging provisions in national laws relevant to public health.

by the South African Government, and the complaint brought by the USA against Brazil in relation to compulsory licences[6], were perceived as manifestations of a conflict between the recognition of intellectual property rights (IPRs) and essential public health objectives. Although one of the stated goals of the TRIPS Agreement was to reduce tensions arising from intellectual property protection[7], intellectual property protection for pharmaceuticals and its effects on public health, and access to drugs in particular, remained a highly controversial issue[8].

The developing countries' move to specifically address public health issues at the Council for TRIPS was grounded on the conviction that the TRIPS Agreement should not prevent Members from adopting measures necessary to ensure access to medicines and to satisfy other public health needs. Several documents, particularly by WHO[9] and UNCTAD[10], as well as extensive academic work[11] and NGO statements[12], had highlighted the flexibility allowed by the TRIPS Agreement, especially in relation to exceptions to patent rights, parallel imports and compulsory licensing. The developing countries sought a declaration, not because of the lack of clarity in the Agreement, but as a result of the obstacles that the authorities in those countries had experienced when trying to make effective use of such flexibility at the national level.

The relationship between public health and the TRIPS Agreement had been examined in 1996 by the World Health Assembly, which addressed the subject in a resolution on the Revised Drug Strategy[13]. Subsequent resolutions adopted by the World Health Assembly in 2001[14], addressed the need to evaluate the impact of the TRIPS Agreement on access to drugs, local manufacturing capacity and the development of new drugs[15].

The Council for TRIPS systematically considered the relationship between public health and TRIPS for the first time in a special session in June 2001. A number of

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[6] The declared intention of the Brazilian Government was to procure anti-retrovirals at prices lower than those charged by patent owners, in the framework of its government-supported program against AIDS. The USA withdrew its complaint upon an agreement with the Brazilian government in March 2001

[7] See the Preamble of the Agreement, paragraph 7: "*Emphasizing* the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures".

[8] See e.g., Abbott, 2002a.

[9] See, e.g., Velasquez and Boulet (1999).

[10] UNCTAD (1996).

[11] See an annotated bibliography in WHO (2001).

[12] See, e.g., Oxfam (2002), Médecins Sans Frontières (2001); VSO (2001).

[13] WHO was mandated "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" (Resolution WHA49.14, 25 May 1996).

[14] Resolutions WHA54.10 and WHA54.11.

[15] The UN Sub-Commission for the Promotion and Protection of Human Rights also pointed out the "apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other", including human rights to food, health and self-determination (Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second session, Agenda item 4, The Realization of Economic, Social and Cultural Rights, Intellectual Property Rights and Human Rights).

developing countries[16] and the European Commission and its Member States[17] each submitted documents to the Council. In August and September 2001, the TRIPS Council held additional sessions for discussions on this issue. At the June meeting, the African Group and other developing countries[18] presented a draft text for a ministerial declaration on the TRIPS Agreement and Public Health. This proposal was a comprehensive text addressing political principles to ensure that the TRIPS Agreement does not undermine the legitimate right of WTO Members to formulate their own public health policies, as well as practical clarifications for provisions related to compulsory licensing, parallel importation, production for export to a country with insufficient production capacity, and data protection (Article 39.3 of the TRIPS Agreement). The text also included a proposal for evaluation of the effects of the TRIPS Agreement, with particular emphasis on access to medicines and research and development for the prevention and treatment of diseases predominantly affecting people in developing and least developed countries (LDCs). The USA, Japan, Switzerland, Australia and Canada circulated a non-paper with alternative text stressing the importance of intellectual property protection for research and development, arguing that intellectual property contributes to public health objectives globally. An EC non-paper was also circulated that proposed possible solutions to the problem of production for exports to fulfil a compulsory licence in a country with no or insufficient production capacity. Negotiations on these texts took place at the General Council.

The eventual adoption of a declaration on Public Health and TRIPS was the outcome of a carefully elaborated strategy by developing countries[19]. Despite the initial resistance by some developed countries[20], the Doha Declaration was adopted by consensus, on the basis of last minute compromises and a delicate balance in wording[21] .

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[16] See the 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 (IP/C/W/296).

[17] See IP/C/W/280, 12 June 2001.

[18] Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.

[19] "Doha is a concrete success to which developing countries and NGOs can point. Whether Doha represents a significant shift in the power of developing countries to influence the standard-setting process in intellectual property within WTO remains a matter of conjecture" (Drahos, 2002, p. 26).

[20] For some observers, the "anthrax crisis" shifted the balance to the public interest side in the Doha debate on public health and TRIPS (see, e.g., South Centre, 2001, p. 11). "The US was suddenly faced with a situation where there was a perceived need for immediate and widespread access to a product still on-patent, where the exclusive owner of that patent, Bayer in this case, appeared unable or unwilling to offer enough supplies to meet immediate demand. The US Government's first instinct was to consider the compulsory licence option and seek out alternative manufacturers." (Kettler, 2002, p. 9) The Canadian government also took actions to ensure supply of the anti-anthrax drug despite the patent held by Bayer (see, e.g., Harmon, 2001).

[21] Developing countries, in particular, abandoned for study their original position asking for the declaration to state that "*Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health*" (IP/C/W/312, WT/GC/W/450, 4 October 2001), which had been one of the main points of contention during the preparatory work.

Scope

The Doha Declaration includes preambular provisions (paragraphs 1 to 4), a provision aimed at confirming the interpretation of certain rules of the TRIPS Agreement (paragraph 5), and two operative provisions requiring action by the Council for TRIPS in relation to countries with no or insufficient manufacturing capacity in pharmaceuticals (paragraph 6), and for the extension of the transitional period for LDCs in relation to the protection of pharmaceutical products (paragraph 7).

The problems addressed by the Doha Declaration are defined in paragraph 1 in broad terms. Members recognize the "gravity" of the public health problems afflicting many developing and LDCs, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Doha Declaration on TRIPS and Public Health: Paragraph 1

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

While some developed countries attempted to limit the scope of the Declaration[22] to the HIV/AIDS crisis, the adopted text reflects the concerns of developing countries and LDCs about the implications of the TRIPS Agreement with regard to public health in general, without limitation to certain diseases. The reference to some specific "epidemics"[23] does not imply that the Declaration is limited to them. It covers any "public health problem", including those that may be derived from diseases that affect the population in developing as well as developed countries, such as asthma or cancer.

Further, though access to medicines was the main preoccupation that led to the Doha Declaration, the Declaration covers not only medicines, but any product, method or technology for health care. Thus, the Declaration applies to pharmaceutical products, processes and uses, surgical, therapeutic and diagnostic methods[24], diagnostic kits as well as medical equipment.

[22] The disagreement on the scope of the declaration was reflected in the partly bracketed title of the draft declaration ("access to medicines") ("public health"). Throughout the negotiations, the USA, supported by Switzerland, proposed a text that referred to "health crisis", "pandemics" and "infectious disease" only. See 't Hoen, 2001, p.13.

[23] "Epidemic" is a disease prevalent among a community at a special time; one of the draft texts of the Declaration alluded instead to "pandemics", that is, a disease prevalent over the whole of the country or over the whole world (*The Concise Oxford Dictionary*, p. 324 and 738).

[24] It should be noted that WTO Members can exclude these methods from patentability (see Article 27.3 (a) of the TRIPS Agreement).

Finally, while patents have been the focus of the debate on this issue, the Declaration applies to all areas of intellectual property covered by the TRIPS Agreement, including protection of test data submitted for the marketing approval of pharmaceuticals[25].

[25] See para. 7 of the Declaration.

The role of TRIPS and IPRs

Doha Declaration on TRIPS and Public Health: Paragraphs 2 and 3

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

Paragraphs 2 and 3 of the Doha Declaration express the Members´ view with regard to the role of TRIPS and IPRs in the context of public health.

Paragraph 2 stresses "the need for" the TRIPS Agreement "to be part of the wider national and international action to address these problems". This statement, read in conjunction with paragraph 4, seems to indicate that the extent to which the Agreement is part of the problem or of the solution to public health needs, crucially depends on the way in which the Agreement is implemented and interpreted. This paragraph suggests that intellectual property rights are one but not the only factor that affects public health and, in particular, access to drugs[26].

The first sentence of paragraph 3 alludes to the "important" role of intellectual property protection "for the development of new medicines". Unlike other preambular paragraphs, this one specifically refers to "medicines"[27]. This statement – welcomed by the pharmaceutical industry – is balanced by the second sentence, which recognizes one of the troubling effects of patent protection: its impact on prices.

The patent system is designed to enable patent holders to set prices higher than those that would be obtained in a competitive market. The Doha Declaration recognizes that the high prices of medicines caused by patent protection are part of the grave problems that afflict developing countries and LDCs and is a "concern" that needs to be addressed. The consensus achieved on patent protection's impact on drug prices may be considered one of the major political achievements of the developing countries in the Doha Ministerial Declaration.

[26] Some analyses, particularly by the pharmaceutical industry, have stressed that access to drugs is fundamentally determined by non-IPR factors, such as health infrastructure and medical services. See, e.g., IIPI. See also the US submission to the Council of TRIPS (IP/C/W/340, 14 March 2002).

[27] The crucial role of patents in inciting research in drug development has been the subject of extensive academic work, See, e.g. Kettler, 2002.

Public health measures

Doha Declaration on TRIPS and Public Health: Paragraph 4

4. 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.

Paragraph 4 of the Doha Declaration was one of the most controversial provisions of the document and the subject of intense negotiations during the preparations for and at the Ministerial Conference in Doha. Developing countries' negotiating target was, as mentioned above, to obtain recognition that nothing in the TRIPS Agreement shall be interpreted as preventing Members from adopting measures necessary to protect public health.

Developing countries were essentially seeking a declaration recognizing their right to implement certain pro-competitive measures, notably compulsory licences and parallel imports, as needed to enhance access to health care. They were frustrated by the opposition and pressure exerted on some countries by the pharmaceutical industry and governments[28]. Moreover, some felt that the final proviso in Article 8.1 establishing that any measures adopted, *inter alia*, to protect public health should be consistent with the provisions of the TRIPS Agreement,[29] provided less protection for public health than under the corresponding exceptions of Article XX (b) of GATT[30] and the Sanitary and Phytosanitary Measures and Technical Barriers to Trade agreements.

[28] See, e.g., Drahos, 2002.

[29] TRIPS Article 8.1: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

[30] GATT Article XX: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

...

(b)necessary to protect human, animal or plant life or health;"

Developed countries did not view the TRIPS Agreement as representing a barrier to the achievement of public health objectives, and they were not prepared to undermine any of the obligations under the Agreement[31]. According to the EU, "the TRIPS Agreement cannot be held responsible for the health crisis in developing countries, while it must not stand in the way for action to combat the crisis". The EU was, consequently, "ready to contribute constructively to any debate concerning the interpretation of its provisions"[32]

The text, drafted by the chair of the WTO General Council, which provided the basis for the negotiations in Doha, offered two options for paragraph 4:

Option 1

[Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement shall be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to ensure 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.]

Option 2

[We affirm a Member's ability to use, to the full, the provisions in the TRIPS Agreement which provide flexibility to address public health crises such as HIV/AIDS and other pandemics, and to that end, that a Member is able to take measures necessary to address these public health crises, in particular to secure affordable access to medicines. Further, we agree that this Declaration does not add to or diminish the rights and obligations of Members provided in the TRIPS Agreement. With a view to facilitating the use of this flexibility by providing greater certainty, we agree on the following clarifications.][33]

The wording of the first part of paragraph 4, reflects the delicate compromise reached in Doha. It reaffirms Members' rights to take measures "to protect public health", in a much less elaborated way than article XX (b) of GATT and the respective provisions in the SPS and TBT agreements[34].

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[31] See. e.g., the statement by the US delegation at the special session of the Council for TRIPS of 21 June 2001, IP/C/M/31.

[32] IP/C/W/280.

[33] During the negotiating process, the European Commission proposed the following compromise text for paragraph 4:"*Nothing in the TRIPS Agreement prevents Members from pursuing and achieving public health objectives. Accordingly, the TRIPS Agreement shall be interpreted and implemented in a manner supportive of WTO Members' ability to enhance access to affordable medicines for all in the context of public health objectives*".

[34] The "necessity" test, central to those provisions, is not mentioned in the Doha Declaration. On the application of such test in GATT/WTO jurisprudence, see e.g., Correa (2000b).

A possible interpretation for paragraph 4 is that the TRIPS Agreement does not raise conflicts with public health. Paragraph 4 would constitute a statement of fact ("the TRIPS Agreement does not … prevent …") rather than a rebalancing of the Agreement in the sense that public health overrides commercial interests. Thus, for the European Commission, "the issue is not whether or not intellectual property overrides public health or vice versa. Intellectual property and public health can and should be mutually supportive because without effective medicines, public health policies would be hampered"[35]. In the view of the European Commission, the statement contained in paragraph 4 "is important in order to give meaning to the obvious principle that a Member's right (or indeed duty) to pursue public health objectives and policies is unaffected by the TRIPS Agreement"[36] .

In order to give meaning to paragraph 4, however, it is possible to interpret that the intention of the Members was to indicate that in cases where there is conflict between IPRs and public health, the former should not be an obstacle to the realization of the latter[37]. A possible reading of this paragraph is that such a conflict may arise, and this is precisely why "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".

As mentioned, a basic issue underlying the discussions leading to the Doha Declaration was the extent to which the final proviso of article 8.1 would mean that intellectual property can override public health. One possible interpretation of this proviso is that, unlike Article XX (b) of the GATT, under the TRIPS Agreement Public Health and other reasons enumerated in Article 8.1 permit Members to adopt measures (e.g. commercialization and price controls), but not to derogate obligations relating to the availability or enforcement of IPRs. However, in the light of paragraph 4 of the Doha Declaration, it may be argued that Article 8.1 would not prevent derogation from certain obligations under the TRIPS Agreement if necessary to address public health needs.

The realization of public health becomes, with the Doha Declaration, a clearly stated *purpose* of the Agreement. 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 and, in particular, to promote access to medicines for all", paragraph 4 gives guidance to panels and the Appellate Body for the interpretation of the Agreement's provisions in cases involving public health issues. In doing so, Members have developed a specific *rule of interpretation* that gives content to the

[35] European Commission, 2001, p. 2.

[36] Ibid.

[37] The Brazilian delegation pointed out at the Doha Ministerial Conference that "in the area of intellectual property, different readings of the TRIPS Agreement have given rise to tensions. To a certain extent, it is natural that conflicts of interests should reflect themselves in divergent interpretations of common rules. But the commercial exploitation of knowledge must not be valued more highly than human life. There are circumstances in which the conflict of interests will require that the State exercise its supreme political responsibility… Brazil promotes and upholds intellectual property rights…However, if circumstances so require it, Brazil, like many other countries, will not hesitate to make full use of the flexibility afforded by the TRIPS Agreement to legitimately safeguard the health of its citizens." See also, e.g. 't Hoen (2001), p. 11; Raja, p. 2002, 14, and the Joint Statement of 14 November 2001, by MSF, Oxfam, TWN, CPT, Consumers International, HAI and The Third World Network Third World Economics, No. 268, 1-15 November 2001.

general interpretive provisions of the Vienna Convention on the Law of the Treaties (hereinafter "the Vienna Convention") on which GATT/WTO jurisprudence has been built up[38]. Therefore, in cases of ambiguity, or where more than one interpretation were possible, panels and the Appellate Body should opt for the interpretation that is effectively "supportive of WTO Members' right to protect public health".

It also should be noted that paragraph 4 makes a specific reference to the issue of "access to medicines for all", indicating that in the interpretation of the Agreement's obligations, special attention should be given to the achievement of this goal.

Finally, paragraph 4 alludes to the *implementation* of the Agreement, and not only to its interpretation. Implementation takes place at the national level, but is influenced by actions taken by other governments, either in the context of bilateral dealings or in the multilateral framework. The important message of the Declaration in this regard is that the Agreement can be implemented[39] in a manner supportive of WTO Members' right to protect public health. As a result, other Members should restrain from any action that hinders the exercise of such rights by Members, especially developing countries and LDCs.

According to this paragraph, however, Members not only *can* implement the TRIPS Agreement "in a manner supportive of WTO Members' right to protect public health", but they *should* also implement it in that way. This means that all Member countries, including developed countries, are bound to contribute to the solution of the public health problems addressed by the Doha Declaration[40]. One possible way of doing so would be, for instance, by adopting measures to allow the export of medicines needed in a country with no or insufficient manufacturing capacity, an issue which paragraph 6 of the Declaration requires Members to address (see below).

[38] As stated by a panel, the TRIPS Agreement has a "relatively self-contained, *sui generis* status within the WTO", but it is "an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947". See *USA- India – Patent Protection for Agricultural and Chemical Products*, WT/DS50/R, adopted on 16 January 1998, para. 7.19.

[39] Since implementation is in the last instance an obligation imposed on Member States , the logical reading of the second sentence of paragraph 4 is that the Agreement should be interpreted and can be implemented in a manner supportive of WTO Members' right to protect public health.

[40] See also Paragraph 17 of the general Doha Ministerial Declaration, as quoted in footnote 1 above.

Flexibility in TRIPS

The second part of paragraph 4 of the Doha Declaration reflects one of the main concerns of developing countries in the process leading to the Doha Ministerial.

The concept of "flexibility"[41] as applied to the obligations imposed by the TRIPS Agreement, has been central to several analyses of the TRIPS Agreement[42] and to the position of developing countries at the Council for TRIPS in the special sessions on TRIPS and health[43]. Spelling out some of the available flexibility was the main objective of the Declaration.

The Declaration stresses the flexibility "for this purpose", that is, for the purpose of adopting measures to protect public health. As indicated by the coverage of paragraph 5, Members, only specified, in a non-exhaustive manner, some of the aspects of the Agreement that provide for such a flexibility ("…we recognize that these flexibilities *include*…)[44].

The confirmation that the TRIPS Agreement has left room for flexibility at the national level has important political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement, especially in the light of the recognized "gravity of the problems" faced in the area of public health by developing countries and LDCs. In legal terms, such confirmation means that panels and the Appellate Body must interpret the Agreement and the laws and regulations adopted to implement it in light of the public health needs of individual Members States.

[41] "Flexible" means "easily led, manageable, adaptable, versatile, supple, complacent" (*Concise Oxford Dictionary*, p. 373).
[42] See, e.g., Correa (2000a); Reichman (1997).
[43] The European Commission also held, in its submission of 12 June 2001, that "In the view of the EC and their Member States, the Agreement's objectives, principles and purpose (set out in Articles 7 and 8), special transitional arrangements and other provisions give these countries a sufficiently wide margin of discretion in implementing it. This margin enables them to set up an intellectual property regime that meets their policy needs and is capable of responding to public health concerns" (IP/C/W/280).
[44] Note that both the developing countries' and the EC submissions to the special session of 20 June 2001, mentioned other aspects where members enjoy flexibility, such as the "Bolar provision" and the protection of data submitted for the marketing approval of pharmaceuticals (Article 39.3 of the Agreement). See IP/C/W/296 and IP/C/W/280.

Interpretation

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (a)

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.

The objective of developing countries in proposing sub-paragraph 5(a) of the Doha Declaration was to stress the importance of TRIPS Articles 7 and 8 in the interpretation of the Agreement, particularly in the light of Article 31 of the Vienna Convention[45]. They attained their objective without ignoring, however, that other provisions of the Agreement also contribute to the determination of its object and purpose.

That TRIPS purposes are elaborated in its Articles 7 and 8, but also in other provisions of the Agreement has, in fact, already been recognized in TRIPS/WTO jurisprudence. In the *Canada-Patent protection of pharmaceutical products case*[46], the WTO dispute settlement panel argued, in connection with Article 30 of the TRIPS Agreement, that "the goals and the limitations stated in Articles 7 and 8 " as well as those of "other provisions of the TRIPS Agreement which indicate its object and purposes …must obviously be borne in mind" when examining the conditions set forth by said Article. The panel thus determined that Articles 7 and 8 express the "object and purpose" of the TRIPS Agreement, but that these are not the only provisions establishing the Agreement's objectives.

It is also relevant to note that the EC and their Member States emphasized the key role of Articles 7 and 8 in the interpretation of the TRIPS Agreement, in its submission to the Council for TRIPS of 12 June 2001[47] . It stated that

> "Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives".

In fact, the Doha Declaration goes beyond merely confirming the relevance of Articles 7 and 8 for the interpretation of the TRIPS Agreement. It provides an *understanding* about the purpose of the TRIPS Agreement in relation to public health

[45] It is unclear why this interpretive rule has been considered as one of the "flexibilities" in paragraph 5. In fact, such rule, properly applied, should ensure that due deference to national law is given in appropriate cases; that is, that the flexibility left to Member States is respected by the DSB.
[46] WT/DS114/R, 17 March 2000 (hereinafter the "EC-Canada case").
[47] See IP/C/W/280.

issues, which should guide any future rulings by panels and the Appellate Body dealing with such issues.

Compulsory licences

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (b)

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
…

b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Developing countries have identified compulsory licensing as one of the key instruments that may limit the exclusive rights of the patent owner when needed to fulfill certain objectives of public policy, particularly in order to ensure the availability of alternative sources for the supply of medicines at lower prices[48].

Sub-paragraph 5 (b) of the Doha Declaration deals with an issue central to the interests of developing countries. It simply states what is apparent: Article 31 sets forth a number of *conditions* for the granting of compulsory licences (case-by-case determination; prior negotiation, in certain cases, with the patent owner; remuneration, etc.), but it does not limit the *grounds* on which such licences can be granted. Though Article 31 refers to some of the possible grounds (such as emergency and anti-competitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as non-working, public health or public interest.

Though sub-paragraph 5 (b) does not add anything substantively to the understanding of TRIPS, the Doha Declaration specifically employs the expression "compulsory licence", which is not found in the TRIPS Agreement itself[49]. The use of this terminology may help to create awareness, particularly among health ministries in developing countries and LDCs, about the possible utilization of compulsory licences to meet public health and other objectives[50].

[48] See, e.g., Velasquez and Boulet, 1999; Correa (2000a).
[49] TRIPS Article 31 is entitled "[O]ther use without authorization of the right holder".
[50] Despite the fact that the governmental use for a non-commercial purpose of a patent is not mentioned in the commented paragraph, such mechanism can also be important to attain public health objectives.

Emergency

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (c)

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
…
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.

Paragraph 5 (c) of the Doha Declaration states what is an unquestionable right of Members States: the right to determine "what constitutes a national emergency or other circumstances of extreme urgency". Such determination may be relevant for the granting of compulsory licences, the establishment of exceptions under Article 30, or the adoption of other measures permitted under Article 8.1 of the Agreement[51].

> Paragraph 5 (c) also includes a presumption:
>
> "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".

This provision is important for three reasons. First, it clarifies that "public health crises" can represent "a national emergency or other circumstances of extreme urgency", thereby allowing for the granting of compulsory licences when provided for under national law[52] and, pursuant to TRIPS Article 31 (b), without the obligation for prior negotiation with the patent owner.

[51] In May 2002, the Minister of Justice, Legal and Parliamentary Affairs of Zimbabwe issued a Declaration of Period of Emergency (HIV/AIDS) (Notice, 2002). In view of the rapid spread of HIV/AIDS among the population of Zimbabwe, the Minister declared "an emergency for a period of six months, with effect from the date of promulgation of this notice, for the purpose of enabling the State or a person authorised by the Minister under section 34 of the Act (a) to make or use any patented drug, including any anti-retroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; (b) to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions". A Declaration of Sanitary Emergency until 31 December 2002 was also issued by the Executive Power of Argentina (Decree 486, 12 March, 2002), but it does not make explicit reference to patent law provisions.

[52] A survey covering the patent laws of 70 developing countries indicates that only 13 have provided for national emergency or health emergency as specific grounds for the granting of compulsory licences. See Thorpe (forthcoming 2002).

Second, the reference to "HIV/AIDS, tuberculosis, malaria and other epidemics" indicates that an "emergency" may be not only a short-term problem, but a long-lasting situation, as is the case with the epidemics specifically mentioned for illustrative purposes. This recognition may be deemed an important achievement for developing countries in the Doha Declaration, since it implies that specific measures to deal with an emergency may be adopted and maintained as long as the underlying situation persists, without temporal constraints.

Third, if a Member complains about the qualification of a specific situation by another Member as a "national emergency or other circumstances of extreme urgency", the language of paragraph 5 (c) places the burden on the complaining Member to prove that such emergency or urgency does not exist. This represents an important difference with respect to earlier GATT/WTO jurisprudence outside of the TRIPS context that, under the "necessity test", put the burden of proof on the Member invoking an exception to its obligations[53].

Exhaustion

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (d)

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
…

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.

The authorization of parallel imports under an international principle of exhaustion has also been regarded by developing countries as a key component of a patent system sensitive to public health needs. This was one of the key issues raised by pharmaceutical companies against South Africa in the already mentioned case[54].

Developing countries were keen to clarify in the Doha Declaration the Members' right to adopt an *international* principle of exhaustion of rights[55], in accordance with article 6 of the Agreement. Paragraph 5 (d) provides the sought-after clarification. It specifically states that "the effect of the provisions in the TRIPS Agreement… is to leave each Member free to establish its own regime for such exhaustion *without* challenge" (emphasis added).

[53] See, Correa, 2000b.
[54] See, e.g. Bond, 1999.
[55] This principle permits the import of a patented product into a country without the authorization of the title holder or his licencees, to the extent that the product has been put on the market elsewhere in a legitimate manner. See, e.g., Velásquez and Boulet, 1999.

Though this paragraph does not add substantively to the TRIPS Agreement, it certainly reassures Members wishing to apply an international exhaustion principle that it would be legitimate and fully consistent with the Agreement to do so.

It is necessary to stress that in order to take advantage of this and other flexibilities allowed by the TRIPS Agreement – and confirmed by the Doha Declaration – national laws must incorporate the appropriate rules in the form of compulsory licences, exceptions and other relevant provisions. Such flexibilities do not automatically translate themselves into national regimes, and do not protect governments (or private parties) from legal actions based on national laws and regulations that fail to make use of the TRIPS Agreement's flexibilities. For example, specific legal provisions allowing for parallel imports would be normally necessary in order to benefit from the principle of international exhaustion of rights[56].

A survey of patent laws in developing countries shows that many of such countries have not or only partially used the flexibilities allowed by the TRIPS Agreement[57]. The effective implementation of the Doha Declaration in those countries, therefore, would call for an amendment to national laws so as to incorporate the exceptions and safeguards necessary to protect public health[58] .

[56] Though in some countries this principle may result from jurisprudential elaboration, it may take a long time to test what the legal solution is. The ensuing uncertainty is likely to discourage or effectively prevent the use of such a mechanism as a means to obtain medicines at lower prices than those domestically available.
[57] See Thorpe, 2002.
[58] For possible options for such a reform, see, e.g. Correa, 2000c.

Members with insufficient or no manufacturing capacities

Doha Declaration on TRIPS and Public Health: Paragraph 6

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

In paragraph 6 the Doha Declaration instructs the Council for TRIPS to address a delicate issue: how can Members lacking or with insufficient manufacturing capacities make effective use of compulsory licensing. The Declaration requests the Council for TRIPS "to find an expeditious solution to this problem and to report to the General Council before the end of 2002". As discussed below, in order to be effective such a solution should be economically viable, and not only legally acceptable.

A major limitation in compulsory licensing rules under Article 31 (f) of the TRIPS Agreement is the requirement that a product made under a compulsory licence be supplied predominantly to the licensee's domestic market[59], unless the licence were issued to remedy anti-competitive practices (Article 31 (k) of the Agreement). This means, in practical terms, that Members with large markets, like India, the UK or the USA, typically could easily grant compulsory licences for the supply of patented medicines to meet public health needs (for instance, those arising from the threat of bioterrorism). However, for Member countries with small markets, like the African countries where the AIDS crisis is most severe, it might be extremely difficult to establish economically viable production if the manufactured product has to be "predominantly" sold in the local market.

The basic problem underlying paragraph 6 is that many developing countries lack or have an insufficient capacity to manufacture medicines on their own. As indicated in Annex 2[60], manufacturing capacities in pharmaceuticals are distributed very unevenly in the world. Not many countries have the capacity to produce both active

[59] TRIPS Article 31: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
…
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use".

[60] See also WHO, 2000, p. 32.

ingredients and formulations, and very few countries maintain significant research and development capabilities.

Given that only a few developing countries have substantial manufacturing capacity in pharmaceuticals, once the TRIPS Agreement becomes fully operative (after 2005), many countries may face difficulties in acquiring medicines at affordable prices. Today, for example, some countries, such as India, do not provide patent protections for pharmaceutical products, and produce generic versions at a fraction of the price of the patented product. A Member country where the price of patented products is high has the option of issuing a compulsory licence to permit import from such countries. The problem is that, as countries fully comply with the TRIPS Agreement by 2005 at the latest, they will no longer be able to produce and export cheap generic copies of patented medicines. Consequently, the sources of affordable new medicines will dry up and countries without sufficient manufacturing capacity and market demand will not be able to grant a compulsory licence either for the local production or for the importation of such medicines: they will become entirely dependent on the expensive patented versions[61].

This problem had been raised by developing countries during the special sessions on TRIPS and health at the Council for TRIPS, and by the EC and their Member States in its submission of 12 June 2001. Developing countries argued that "nothing in the TRIPS Agreement prevents Members from granting compulsory licences for foreign suppliers to provide medicines in the domestic market… In this respect, the reading of Article 31 (f) should confirm that nothing in the TRIPS Agreement will prevent Members from granting compulsory licences to supply foreign markets"[62].

The EC and their Member States noted the problems posed by the limitation imposed by Article 31 (f). A Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired. However, when a patent exists in the potential supplier country, the patent owner may block exports to the country in need of the medicines[63]. Moreover, since Article 31 (f) requires that a compulsory licencee predominantly supply the domestic market, that provision would prevent the granting of a compulsory licence exclusively or mainly to export to a country in need of certain medicines.

Addressed problem

To determine the problem addressed under paragraph 6, it must be read in the context of paragraphs 1 to 4 of the Doha Declaration. As mentioned above, though the Declaration specially refers to the problems resulting "from HIV/AIDS, tuberculosis, malaria and other epidemics", it is intended to provide solutions to "health problems" in general. There is nothing in paragraph 6 limiting its application to cases of crises or public emergency.

[61] See, e.g., Oxfam, 2002.
[62] See IP/C/W/296.
[63] See IP/C/W/280.

Paragraph 6 refers to "manufacturing" capacities in the pharmaceutical sector. "Manufacturing" is the "making of articles by physical labor or machinery, *especially on large scale*"[64]. This suggests — based on the ordinary meaning of the words used, as mandated by the Vienna Convention — that the Declaration is intended to address the problems that arise when production on a large scale, that is, in an economically viable manner, cannot be conducted.

The pharmaceutical sector includes — as indicated in Annex 2 — both the manufacturing of *active ingredients* (that is, the compounds that possess therapeutic activity) as well as of finished products or *pharmaceutical formulations* (active ingredients and the excipients added, as necessary, for the administration of a medicine to a patient). Paragraph 6 does not distinguish between these two categories of activities. It should be interpreted, therefore, that paragraph 6 addresses the lack of or insufficient capacity either to produce active ingredients or pharmaceutical formulations or both.

A country may have the technical capacity to produce active ingredients or formulations, but such production may not be economically viable. One of the main objectives of the Doha Declaration is to "promote access to medicines for all" (paragraph 4). This objective would not be achieved if low-priced medicines (and other health-care products) could not be produced because meaningful economies of scale were out of reach. A "solution" under paragraph 6 may be illusory if it does not benefit countries where manufacturing may be technically feasible but not economically viable.

The determination of the coverage of paragraph 6 raises other interpretive issues, namely:

(a) Does paragraph 6 refer to medicines only, or does it encompass any health care product? To the extent that a product is expended through pharmacies (such as diagnostic kits), it will fall under the ordinary meaning of a "pharmaceutical" product[65].

(b) Does the notion of "capacity"[66] refers to the general capacity to manufacture or to the capacity to manufacture a particular product? A country may have manufacturing capacity *in general* to produce active ingredients or formulations, but lack the equipment, technology or access to the intermediate chemicals necessary to produce a *particular* product. For instance, some countries may be able to manufacture relatively simple drugs, but not anti-retrovirals, where production and quality control standards are extraordinarily important because of the risk of drug resistance and/or toxicity. A reasonable reading of paragraph 6 suggests that it is intended to address both the cases of general and particular lack or insufficient

[64] *The Concise Oxford Dictionary*, p. 617 (emphasis added).
[65] "Pharmaceutical" is "of or engaged in pharmacy; of the use or sale of medicinal drugs" (The Concise Oxford Dictionary, p. 768). It is also opens the possibility, given the broad scope of the Doha Declaration, as mentioned above, for Members to discuss the inclusion of other products, such as testing equipment.
[66] "Capacity" is the "power of containing, receiving, experiencing or producing" (*The Concise Oxford Dictionary*, p. 136).

capacity, since otherwise it would not be possible for the concerned country to address its "health problems" (paragraph 1) and to "protect public health" (paragraph 4).

Under this interpretation, the solution to be worked out in line with paragraph 6 should not be based on the determination of categories of Member countries with or without manufacturing capacity, or with or without a sufficient manufacturing capacity. Rather a solution should apply to any Member, or at least to *any* developing country or LDC where the effective use of compulsory licensing is not possible because of capacity limitations and insufficient market demand.

(c) Who can receive compulsory licences in the exporting or the importing country? Pursuant to paragraph 6, recipients clearly may include State as well as *commercial* entities. There is no limitation under Article 31 in this respect, and it would be contrary to the objective of the Doha Declaration to exclude the possibility of granting the required compulsory licence to a for-profit entity.

(d) Where should potential suppliers of medicines be located? Potential suppliers of the required medicines may be located in developed and developing countries alike[67]. The purpose of the Doha Declaration is to alleviate grave public health problems, independent of the location of the source of supply. Hence, in order to effectively implement the Declaration, both developed and developing countries should introduce legislative changes, as necessary, to allow exports to countries in need.

(e) Can countries where no patent protection exists benefit from a solution under paragraph 6? Since a compulsory licence can only be granted when a patent exists, paragraph 6 seems to relate only to cases where a pharmaceutical patent is in force in the importing country. This would include cases where product or process patents have been granted[68], but would exclude and seriously disadvantage[69] countries where no patent protection for pharmaceuticals is granted[70], or even countries where such protection exists but where the needed product or process is, for any reason[71], off-patent. Finding a solution to the problems of these latter countries will be an essential component in the implementation of the Doha Declaration, if not specifically under paragraph 6, as a part of the "action" necessary to address the public health problems that afflict developing countries and LDCs (see paragraphs 1 and 2 of the Declaration)[72].

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[67] Thus, in July 2000, a Canadian generic pharmaceutical manufacturer announced that it could supply, at cost, alternatives to the major AIDS treatments for developing countries within months, if the Canadian Federal Government granted the needed compulsory licences under the Patent Act.

[68] It would also cover cases where patents on new uses have been conferred, if admissible under the relevant national law.

[69] See the joint letter sent on January 28, 2002 to the TRIPS Council members by Consumer Project on Technology, Médecins Sans Frontières, Third World Network, Oxfam, Health Gap Coalition and Essential Action.

[70] As discussed below, LDCs have been authorized by the Doha Declaration to delay such protection until 2016.

[71] Because a patent has not been applied for, has been rejected or cancelled.

[72] It should be noted that nothing would prevent the Council for TRIPS from considering a situation not expressly mentioned in paragraph 6 of the Declaration.

(f) Does paragraph 6 cover cases where an authorization for governmental use has been accorded? Though it is possible to distinguish between "compulsory licences" and authorizations for governmental use[73], their effect is similar and they are jointly treated in Article 31 of the TRIPS Agreement. There is no reason to exclude government use authorizations from the coverage of paragraph 6.

Box 1
Designing a Solution to the Paragraph 6 Problem

In considering approaches to implement paragraph 6, it is vital to consider the efficiency and workability of alternative approaches. This will not only depend on the decisions adopted in the framework of WTO but, crucially, on the steps taken at the national level to introduce legislative changes necessary to implement the adopted solution.

Some of the desired features of any possible solution would include:

- stability of the international legal framework, in order to ensure a long-term solution;
- transparency and predictability of the applicable rules in the exporting and importing countries, so as to provide the required incentives to the private sector to act within the established framework;
- simple and speedy legal procedures in the exporting and importing countries, to allow for the fast supply of needed medicines, with the required quantity and quality;
- equality of opportunities for countries in need of medicines, even for products not patented in the importing country and for countries which are not WTO Members[74];
- facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries;
- broad coverage in terms of health problems and the range of medicines (not limited to certain diseases or products).

In addition, the legal solution should not be encumbered with limitative conditions that could deprive it of practical value, nor should it limit the grounds for granting compulsory licences.

[73] While in the case of compulsory licence a private party may be authorized to use and commercialize the invention for a profit, under governmental use the exploitation of the invention should be made to satisfy a governmental need, for non-profit purposes. This includes the case — for example — in which a private company produces a patented drug, as a subcontractor, to supply the government, who distributes the drug through public hospitals.

[74] There are a significant number of countries which are not members of the WTO (while many are negotiating accession) that may face the problems addressed in paragraph 6.

Possible approaches

Different approaches may be followed in order to address the problem posed by lack of or insufficient manufacturing capacity in pharmaceuticals. The main options include:

(a) To amend[75] Article 31 (f), in order to allow for the granting of a compulsory licence which is not "predominantly" for the domestic market.
(b) To provide for a specific exception for exports under Article 30 of the TRIPS Agreement[76], possibly by means of an authoritative interpretation[77];
(c) To agree on a moratorium with regard to complaints against countries that export some medicines to countries in need, under certain conditions[78].
(d) To declare exports to a country eligible under paragraph 6 as non-judicable under the WTO rules[79];
(e) To allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognized the licence (which it would not be obliged to do under the Agreement)[80], and provided that all the goods manufactured under the licence were exported to the country granting the licence[81].

Other options include the transfer of technology in order to create manufacturing capacity in the country in need[82], the creation of a "regional pharmaceutical supply center"[83], and the establishment of "pharmaceutical production export zones"[84].

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[75] In the absence of consensus, an amendment to a WTO Multilateral Trade Agreement must be approved by a two-thirds majority, but it only becomes binding on Members that accepted it. An amendment may also be adopted by a three-fourths majority as binding on all Members, but any Member which has not accepted it shall be free to withdraw from the WTO or to remain as a Member with the consent of the Ministerial Conference (Article X.1 and 2 of the Agreement Establishing the WTO).
[76] See the letter of 28 January 2002 sent to the Members of the Council for TRIPS by Consumer Project on Technology, Médecins Sans Frontières, Third World Network, Oxfam, Health Gap Coalition and Essential Action.
[77] An authoritative interpretation needs to be adopted by a three-fourths majority of Members, and should not be used "in a manner that would undermine the amendments provision of article X" (article IX.2 of the WTO Agreement).
[78] Proposed by the USA delegation at the March 2002 session of the Council for TRIPS.
[79] Unlike the moratorium, this solution would be permanent. See, e.g. Attaran, 2002.
[80] The effective application of this option faces jurisdictional barriers. An authority in a given country can only grant a compulsory licence valid in that country. There is no obligation on other countries to admit extraterritorial effects of such a grant. This could be done, however, under the concept of "Comity See", e.g., Abbott, 2002b, p. 29.
[81] See IP/C/W/280.
[82] According to the statement by Kenya on behalf of developing countries at the March 2002 session of the Council for TRIPS, "any expeditious solution to address the problem acknowledged in Paragraph 6 should not detract the TRIPS Council from the need to consider measures that support the acquisition of all necessary technology and the building of a sound technological base including in respect of medical technology; this is the proven sustainable way to address the public health and public policy concerns of developing countries and least developed countries". This would be, however, a long-term solution and not an "expeditious" solution as envisaged under paragraph 6.
[83] See Reichman, 2002.

Some of the options mentioned above have been examined at the session of the Council for TRIPS held in March 2002 (see Box 2).

Box 2
Proposals relating to implementation of Paragraph 6 discussed at the Council for TRIPS (March 2002)

The EC and their Member States submitted two possible options to address the paragraph 6 problem[85]:

1) an amendment to Article 31 of the TRIPS Agreement in order to carve out an exception to Article 31 (f) for exports under compulsory licences, under certain conditions, of products needed to combat serious public health problems; or

2) an interpretation of the limited exceptions clause of Article 30 of the TRIPS Agreement in a way to allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems;

Option (1) would be subject to three conditions: criteria ensuring that importing countries actually face serious public health problems, safeguards against re-exportation of the cut-price generics, particularly to rich countries, and reporting requirements that would inform trading partners of such action.

Option (2) would be subject to two minimum conditions: the entirety of the product must be exported to the country with the public health problem, and re-export from the importing country would be prohibited[86].

3) The USA proposed a moratorium whereby WTO Members would agree not to bring a WTO complaint against countries that export some medicines to countries in need, so long as certain other conditions are met[87].

On behalf of the African Group, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand, Kenya made a statement suggesting, as possible options, an amendment to Article 31 in order to eliminate paragraph "f", or to develop an authoritative interpretation that would recognize the right of Members to allow the production without the consent of the patent holder to address public health needs in another country, under Article 30 of the TRIPS Agreement.

[84] See, e.g., Abbott, 2002b.
[85] See IP/C/W/339, 4 March 2002.
[86] In addition, the EC and their Member States indicated that the Article 30 exception should conform with other TRIPS provisions, in particular Article 27.1.
[87] According to the USA submission, any solution should only apply to epidemics referred to in the Doha Declaration – HIV/AIDS, tuberculosis and malaria -- and only to countries with insufficient or no pharmaceutical manufacturing capability. The USA also questioned whether commercial entities should be allowed to produce under such licences. See IP/C/W/340, 14 March 2002.

It is beyond the remit of this study to examine thoroughly the merits of the different options mentioned above. In the light of the previous analysis, however, some of the advantages and disadvantages of the proposals described in Box 1 are considered in more detail.

(a) Article 31 (f)

Article 31 (f) prevents the granting of a compulsory licence exclusively or mainly to export to a country in need of certain medicines[88].

The option based on the amendment of Article 31 (f) of the TRIPS Agreement would require three steps: (a) a political decision to open the Agreement to renegotiation and an approval of the agreed modification; (b) a change in the national law of the potential exporting country in order to delete the "predominantly" requirement already incorporated in many laws, and to specify as a ground for a compulsory licence the need to address a paragraph 6 situation, and (c) the granting in the exporting country of a compulsory licence upon request of an interested party.

The first step may encounter political resistance by those countries that are reluctant to amend any part of the Agreement, because of the risk of stimulating the renegotiation of other provisions. The second step is likely to require action by national parliaments. Legislative processes are generally complex and lengthy. In addition, though domestic producers may benefit from new export opportunities, an amendment to the national compulsory licence system may be perceived as benefiting mainly the population in a foreign country, and may fail to gain sufficient political support. Finally, if the law were amended, the government would still need to exercise its power to grant a particular compulsory licence, provided that requests were made for that purpose.

Where there was a request for a compulsory licence, it would be necessary to undertake a prior negotiation on commercially reasonable terms with the patent holder, and to determine the level of royalty compensation to be paid upon issuance of a compulsory licence. Moreover, the granting authority may have to make a determination of the level of "capacity" of the importing country and of the public health need, if these conditions were required under the Article 31 (f) amendment and/or under the national law. Compulsory licence procedures, in addition, may be costly and burdensome, and may be subject to industry's opposition and give rise to political pressures at the bilateral level.

[88] It is interesting to note, however, that some developed countries provide for compulsory licences or governmental use for export without the limitation imposed by Article 31 (f). Such is the case of Article 168 of the Australian Patent Act and Article 55 (2) of the Patent Act of New Zealand, which permit exports under an agreement with a foreign country to supply products required for the defence of that country. Article 48B(d)(i) of the UK Patent Act provides for a compulsory licence in respect of a patent whose proprietor is not a WTO proprietor when the owner's failure to licence the patent on reasonable grounds means that a market for the export a patented product made in the UK is not being supplied.

A possible solution based on an amendment to Article 31 (f) may also provide for double compensation to be paid to the patent holder (in both the importing and exporting countries), thus increasing the cost and possibly reducing access to the products in need.

The three-step process required for the compulsory licence option may mean that a practical solution may be years away, and does not constitute an "expeditious" solution.

(b) Article 30

Article 30 allows Members to provide for limited exceptions to the exclusive rights conferred by a patent, that is, to define acts that would not be deemed as infringing when made without the authorization of the patent owner. Such exceptions may include, for instance, acts of experimentation and the request for marketing approval of a pharmaceutical product before the expiration of the patent (known as the "Bolar exception")[89] .

An Article 30 solution may be more streamlined and easier to implement than an Article 31 (f) solution, since no amendment and parliamentary approval is involved, and the exporting country would not be bound to grant case-by-case compulsory licences.

The solution based on an interpretation of Article 30 avoids two of the three steps mentioned above and the double compensation issue. There is no need to amend the Agreement; the TRIPS Council could simply provide an authoritative interpretation. An amendment to national law in exporting countries would be required (a step that may encounter the same type of difficulties as mentioned above), but once provided, the exception could be invoked without the need to obtain, case-by-case, a compulsory licence from the government of the exporting country. The exception could be invoked at any time, and without time limit, by any third party. Finally, compensation would only be payable under the compulsory licence in the importing country.

[89] See, e.g., Velasquez and Boulet, 1999.

An Article 30 solution must overcome possible objections about the consistency of an exports exception with the conditions of Article 30[90], which have been narrowly interpreted by a panel in the EC-Canada case[91].

It must be noted, however, that the interpretation given by a panel (or the Appellate Body) to a particular provision does not bind Members, who may depart from such interpretation in exercising their "exclusive authority to adopt interpretations" (Article IX.2 of the WTO Agreement). In fact, in adopting the Doha Declaration, Members have established a precedent for reading the exception in Article 30 in a broader way than the panel in the EC-Canada case, whenever public health issues are at stake. In effect, since the TRIPS Agreement is "a part of the wider national and international action" to address public health problems (paragraph 2 of the Doha Declaration), the panels and the Appellate Body should consider the public-health implications of exceptions to the patent owner's exclusive rights.

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[90] A possible difficulty is that any interpretation may be read across to other Articles of TRIPS. See IP/C/W/340.

[91] WT/DS114/R, 17 March 2000.

The panel provided an interpretation of what "limited" means in Article 30:

> *"The word "exception" by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question (para. 7.30)*
>
> *In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged The term "limited exceptions" is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with" (para. 7.31).*
>
> *The panel also considered what "normal exploitation" means. It argued that:*
>
> *"The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws" (para. 7.55).*

Finally, the panel indicated that "*legitimate interests*" must be "*construed as a concept broader than legal interests*" (para 7.71), but did not address what "unreasonably" means, since the panel's analysis led to the conclusion that there was not in the case "conflict" with the normal exploitation of a patent, and therefore it was not necessary to elucidate whether the Canadian exception was reasonable or not. If a conflict of such kind were found, however, the way in which "unreasonably" were to be interpreted would acquire crucial importance and become a delicate issue.

For an interpretation of Article 30 in the context of paragraph 6, see Abbott, 2002b.

An export exception, if circumscribed to situations defined in accordance with paragraph 6, may be reasonably deemed to fall under the three conditions stipulated by Article 30. The exception

- would be "limited" to specified circumstances;
- would "not unreasonably conflict with a normal exploitation of the invention" since, though exportation is a normal mode of exploiting an invention, supplying of a market at low prices by a third party may not conflict with such exploitation (which is normally made in order to obtain the monopolistic rent generated by patent protection);
- would not "unreasonably prejudice the legitimate interests of the patent owner", to the extent that safeguards are adopted in order to avoid diversion to other markets;
- would positively "take account of the legitimate interests of third parties" (consumers in the importing country)[92].

(c) Moratorium

A moratorium[93] does not imply any change of the substantive treaty obligations; it only temporarily suspends their operation[94]. The moratorium approach offers an "expeditious" response to the problem posed by paragraph 6, but not a "solution", since it would not be straightforward enough either to induce potential exporting countries to change their legislation to permit production for export, or to induce generic manufacturers to invest in creating or increasing export capacity. In addition, it is unclear what procedures would be applied in order to adopt a moratorium, and whether formal changes to the TRIPS Agreement would be necessary[95].

Though most waivers apply to just one named contracting party, in GATT history at least two waivers were framed in general terms to apply to any contracting party who fulfilled the *criteria*. At their eleventh session, the Contracting Parties formulated a series of guidelines for the issuance of waivers, partly as a response to the perception that a waiver could produce an effect substantially the same as an amendment (Jackson, 2000, p. 29).[96] In exceptional circumstances, the Ministerial Conference can, by a three-fourth majority, waive an obligation imposed on a Member, for a determined period. A waiver is bureaucratic to administer, since it

[92] Questions may also arise as to whether – given the territoriality of patent grants – the interests of the consumers in a foreign country may be deemed a "legitimate interest" for the purposes of Article 30. Canada held, in this regard, in the EC-Canada case that "[a]s the TRIPS system was designed to be international and so to extend across borders there was no reason why the legitimate interests of the third parties in other countries could not be taken into account when applying a limited exception under Article 30" (para.4.38(d)).

[93] A "moratorium" is "a period during which an obligor has a legal right to delay meeting an obligation" (*Blacks' Law Dictionary*, Abridged Sixth Edition, St. Paul, Minnesota, West Publishing, 1991, p. 698).

[94] See Article 57 of the Vienna Convention of the Law of Treaties.

[95] See, e.g. Article 64.2 of the TRIPS Agreement, which established a five years moratorium for "non-violation" complaints.

[96] Procedures adopted November 1, 1956, *Basic Instruments and Selected Documents*, 5th Supplement, 25.

requires regular renewal by the Ministerial Conference if granted for a period of more than one year[97].

The main characteristics and some implications of the three above-examined proposed solutions are presented in Table 1.

Table 1
The main proposed solutions in comparison

Option	Steps to achieve	Conditions[98]	Considerations	Considerations
(a) To amend Article 31 (f) to carve out an exception for exports under CL, or to remove limitations on export entirely.	a. Agreement to reopen TRIPS and approval of amendment b. Changes in national laws c. Grant of CL	a. Criteria to ensure importing countries face serious public health problems b. Safeguards against re-exportation of CL product c. Reporting of action to trading partners	* Requires granting of two CLs * Requires compensation in exporting and importing countries * Changes in CL legislation in importing countries may be required	*Would require exporting country to asses "capacity" of importing country *Subject to pressures both in importing and exporting * Granting of licence case-by-case
(b) To interpret limited exceptions clause of Article 30 to allow production for export to countries with no or inefficient manufacturing capacity	a. Authoritative interpretation (¾ vote) b. Change in national laws of exporting countries c. Change in CL legislation in importing countries may be required	a. Entirety of the product must be exported to countries with the public health problem b. Prohibition of re-export.	*Export country not required to do a case-by-case decision *No amendment of TRIPS needed *Compensation payable only in importing country	*Any party can invoke the exception, at any time, in exporting country
(c) Moratorium on WTO complaints/ disputes	Ministerial Conference/ Amendment	Criteria to be established	*Not a solution, as such, since it is only temporary *The criteria could be disputable even if mechanism is not	

CL= compulsory licence.

[97] See Article IX. 3 and 4 of the Agreement
[98] According to proposals by the USA and the EC and their Member States.

As indicated in the precedent Table, an Article 30-based solution would be more straightforward than one based on Article 31 (f). Some Members may fear that an authoritative interpretation of Article 30 might spill over into unforeseen categories of intellectual property, particularly copyright, because of the existence of a similar exceptions provision. However, appropriate wording may be adopted in order to avoid an unintended reading of such an interpretation.

Safeguards

If developed countries agreed to any of these solutions, they are likely to demand the establishment of certain "safeguards", as indicated in the submissions by the USA and the EC and their Member States to the Council for TRIPS of March 2002. Such safeguards would aim at ensuring that any agreed solution is not utilized to attain objectives other than those related to the protection of public health in the countries with no or insufficient manufacturing capacity for the economically viable production of pharmaceuticals.

A basic safeguard would be the provision of mechanisms to prevent the diversion of products exported to a country qualifying under paragraph 6 to other countries[99], and that the entire output of the relevant pharmaceuticals manufactured be exported to the Member in need. The notification to other Members of actions taken has also been mentioned[100].

Compulsory licence in the importing country

In order to import a patented product, the country in need may apply the international exhaustion principle and allow parallel imports or grant a compulsory licence either to *import* or to *manufacture* the protected product. The understanding given by the Members to paragraph 6 in some of the proposals mentioned above, clearly implies that a compulsory licence can be satisfied by imports, and not only by local production[101].

[99] However, it may be excessive (due to complexity and costs) to impose the burden of monitoring and preventing such a diversion on the importing country in need of pharmaceuticals. The European Commission has noted that "the industry acknowledges that to date there is no reimportation of medicines from the poorest developing countries into the EU, i.e. the problem of reimportation is still largely theoretical" (European Commission, 2002, p. 10). In addition, restrictions on the export of products may violate Article XI of GATT (prohibitions or restrictions on the importation or exportation of products).

[100] See IP/C/W/340. One additional question might be if, in order to be validated under a paragraph 6 exception, certain pricing conditions would be attached to the exported products.

[101] Some national laws require, however, the compulsory licencee to locally produce the invention. Unless amended, such legislation can make illusory a solution under paragraph 6 based on either Article 31 (f) or Article 30, since in both cases the assumption is that the compulsory licencee is able to import in order to execute his licence.

A review of the patent laws of seventy developing countries and LDCs (Table 2) indicates that the majority provide for compulsory licences in case of failure to exploit or to do it on reasonable terms – in line with Article 5A of the Paris Convention – while only 13 provide for grounds relating to public interest and/or national emergency or health emergency.

Table 2
Grounds for compulsory licences in developing countries and LDCs

Grounds for granting compulsory licences	Countries providing such grounds	Total
Failure to exploit or exploit on reasonable terms	16 + OAPI	32
Public interest	8 + Andean	13
National emergency or health emergency	8 + Andean	13
Remedy anti-competitive practices, unfair competition	6 + Andean	11
Failure to obtain licence under reasonable terms	4	4
Failure to work domestically	2	2
No apparent provisions	2	2

Source: Thorpe, 2002.

Though more detailed research on national laws is required, this information suggests that in order to make operative any solution under paragraph 6, many developing countries and LDCs would need to amend their national patent laws.

Economic feasibility

For any possible solution under paragraph 6 to work, it is crucial that the designed legal framework provide the adequate incentives for the production and export of the medicines in need. Overcoming the normative obstacles to exports would not mean much if no firms were interested in supplying the required pharmaceuticals at a low cost.

Generic companies operate today as suppliers of off-patent medicines, and have not generally used the compulsory licence system to get access to patented products. Their main interest lies in the rapid introduction of products after patent expiry, relying – where available – on "Bolar" type exceptions. In case a need emerges in a country under paragraph 6, a generic company would need to develop and implement a method for the production, on viable economic terms, of the active ingredient. In addition, a suitable formulation would need to be developed and

approval obtained in the importing country. Offering the required drug would require considerable investment and time. A premise of paragraph 6 is that the drugs would have to be supplied at *low cost*, making the realization of economies of scale an essential condition for the implementation of any acceptable solution.
In the already mentioned EC-Canada case, Canada argued that

> *"Both the brand name and generic pharmaceutical industries were global in nature. Very few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generic (as well as brand name) products from other countries. Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products"* (para. 4.38 (a).

If individual countries with small markets look for supplies under a solution (whatever it is) under paragraph 6, generic companies may lack sufficient incentives to incur the necessary costs of development and marketing of a low cost version of the patented drug. A good diplomatic solution to the problem posed by paragraph 6, therefore, may not necessarily provide effective relief to the countries in need. An option to address this problem would be for several countries to pool their buying power of certain drugs, in order to allow potential suppliers to realize economies of scale (Engelberg, 2002). The time at which a request under paragraph 6 is made may also make a difference. Generic companies may be more inclined to satisfy requests when the relevant patent is about to expire (and therefore investments made may be soon recovered in other markets) than in cases where the patent will still be valid for a long period.

The economic feasibility of supply may be also depend on the importing country's regime for protection of data submitted for marketing approval. If the local regulation strictly follows Article 39.3[102] of the TRIPS Agreement and provides protection against unfair commercial use of such data, but not an exclusivity period, the registration of the generic product may be relatively simple and straightforward[103]. However, if a TRIPS-plus approach is adopted, and the registration of subsequent products is banned until a period of exclusivity expires – as is the case in the USA and Europe – the entry of the generic product may be delayed or frustrated. Generic companies may not be willing to make the substantial investment needed to duplicate the tests necessary to prove efficacy and safety.

Legal implementation

Changes in the TRIPS Agreement, or new interpretations, do not translate automatically into changes in national laws. Therefore, any solution found at the

[102] See on this issue, Correa, 2002.
[103] Depending also on the kind of studies required to prove the "similarity" of the product with the original one, such as bioequivalence and bioavailability tests.

Council for TRIPS is likely to call for amendments to national laws in potential exporting countries in order to become operative. All potentially exporting countries, including developed countries, should appropriately amend national law to facilitate effective implementation of the Council for TRIPS solution to the paragraph 6 problem.

The implementation of an effective solution under paragraph 6 may also depend on the conditions under which compulsory licences are granted in the importing country. The remuneration to be paid to the patent holder should be such that it does not nullify the aim of the licence, to ensure the supply of *low cost* pharmaceuticals. In addition, national governments should carefully implement Article 31 (g)[104] of the TRIPS Agreement, in a manner that does not undermine the incentives to apply for and execute a compulsory licence[105].

[104] TRIPS Article 31 (g): "[The] authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances".

[105] This also applies, of course, to a possible solution under Article 31 (f).

Transfer of technology to LDCs

Doha Declaration on TRIPS and Public Health: Paragraph 7

We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Paragraph 7 of 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 Members pursuant to Article 66.2."

LDCs have repeatedly raised concerns at the Council for TRIPS about the lack of effective action by developed countries to comply with Article 66.2 of the TRIPS Agreement[106].

Though some developed countries provide different forms of technical assistance on IPR-related issues, LDCs have repeatedly noted that no or little action has been taken by developed countries to specifically implement their obligations under Article 66.2. It remains to be seen whether the reaffirmation in the Doha Declaration of such obligations has a practical impact on developed countries' actions in this area.

[106] Also note that paragraph 11.2 of the Implementation Decision adopted on 14 November 2001 states the following: "Reaffirming that the provisions of Article 66.2 of the TRIPS Agreement are mandatory, it is agreed that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed-country members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and information shall be updated by Members annually". For information on home country measures encouraging transfer of technology, see IP/C/W/132, Add. 1-7.

Though the wording in paragraph 7 is broad, its inclusion in the Doha Declaration indicates that effective incentives should be granted in developed countries in order to specifically foster the transfer to LDCs of health-related technologies, including pharmaceutical technologies.

Extension of transitional period for LDCs

The Doha Declaration permits LDCs to opt for an extension of the transitional period provided for under Article 66.1 of the TRIPS Agreement. Paragraph 7 establishes the grounds for an extension of the transitional period for LDCs[107] in relation to pharmaceutical patents only. It contains a "duly motivated request" – in the terms of Article 66.1 of the TRIPS Agreement[108] – on the basis of which the Council for TRIPS must give effect to that extension. LDCs do not need to individually follow the procedure provided for under Article 66.1 to enjoy this period. The Declaration, however, explicitly preserves the right of LDCs to request extensions for other matters (not related to pharmaceutical patents) in accordance with Article 66.1's procedure[109], without diminishing their right to request further extensions for pharmaceutical patents after 2016.

This extension applies to "pharmaceutical products". However, the protection conferred to a patented process encompasses, according to Article 28.1 (b) of the TRIPS Agreement, the protection of the products directly obtained with such process. Hence, the extension of the transitional period should also be deemed to apply to process patents[110]. Likewise, extension would apply to cases involving a *second indication* of a pharmaceutical product, since claims are generally drafted in these cases as product claims on the basis of the "Swiss-claims" formulation[111] .

The extension of the transitional period applies in relation to Sections 5 (patents) and 7 (undisclosed information) of Part II of the TRIPS Agreement, and to the enforcement of such rights.

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[107] Though this paragraph does not amend Article 66.1 of the Agreement, it does innovate with regard to the procedure applicable for the extension of the transitional period for LDCs.

[108] TRIPS Article 66.1. "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period".

[109] In fact, it would have seem more logical to extend the transitional period for all fields of technology since, unless individual extensions are accorded, LDCs would be required anyway to bear the costs of granting patents in other sectors.

[110] This is also the interpretation of the European Commission, who held that "all least developed Members benefit from the extension of the transition period from 1.1. 2006 to 1.1.2016 (and probably beyond) with regard to product and process patent protection and its enforcement" (European Commission, 2001, p. 4). Also note that the USA delegation, while submitting their proposal for paragraph 7 at the Doha Ministerial Conference did not refer to product patent protection only: "We recommend granting the least-developed countries a 10-year extension to 2016, to come into full compliance with *pharmaceutical-related patent* obligations under TRIPS" (emphasis added). See also Vandoren, 2002, p. 10.

[111] See Correa (2000c).

An important practical aspect is to determine which are the LDCs that can effectively benefit from paragraph 7 of the Doha Declaration. Out of thirty African LDCs, only two[112] do not currently grant patents for pharmaceuticals[113]. These would be, in principle, the only African LDCs that can benefit from this paragraph, unless they amend their legislation.

Twelve out of the 34 African LDCs are members of the Organisation Africaine de la Propriété Intellectuelle (OAPI) and 10 of the African Regional Industrial Property Organization (ARIPO).

Table 3 indicates that 12 out of the 16 members of OAPI are LDCs. Figure 1 illustrates the patents granted by OAPI over a year period from 1984 to 1996. Also indicated is the proportion of these patents relating to pharmaceuticals[114]. Figure 1 shows the increase of the number of patents granted in such fields since 1991.

Table 3
Current membership of OAPI

Benin	***Burkina Faso***	Cameroon	***Central African Republic***
Chad	Congo	Côte d'Ivoire	***Equatorial Guinea***
Gabon	***Guinea***	***Guinea Bissau***	***Mali***
Mauritania	***Niger***	***Senegal***	***Togo***

[Countries in ***italics*** are United Nations designated Least Developed Countries (LDCs)]

There are 10 LDCs among ARIPO's members (see Table 4). Figure 2 illustrates the patents granted by ARIPO from 1985 to 1999[115].

Table 4
Current Membership of ARIPO

Botswana	***Gambia***	Ghana	Kenya
Lesotho	***Malawi***	***Mozambique***	***Sierra Leone***
Somalia	***Sudan***	Swaziland	***United Republic of Tanzania***
Uganda	***Zambia***	Zimbabwe	

[Countries in italics are United Nations designated Least Developed Countries (LDCs)]

[112] Angola and Eritrea. See Thorpe, 2002 forthcoming.
[113] The majority of non-African LDCs also seem to confer patent protection for pharmaceutical products, due to the application of their ex-metropolis' legislation (personal communication from WIPO).
[114] The data include patents classified under IPC classification mark A61K (preparations for medical, dental, or toilet purposes) or having a corresponding patent filed elsewhere classified under mark A61K. Since medicinal-related inventions can also be classified under other marks, the figures shown should only be taken to represent the bottom end of possible medicinal-related patents.
[115] Also indicated is the proportion of these patents classified under IPC classification mark A61K (preparations for medical, dental, or toilet purposes) or having a corresponding patent filed elsewhere classified under mark A61K.

Figure 1 Patents Granted by OAPI

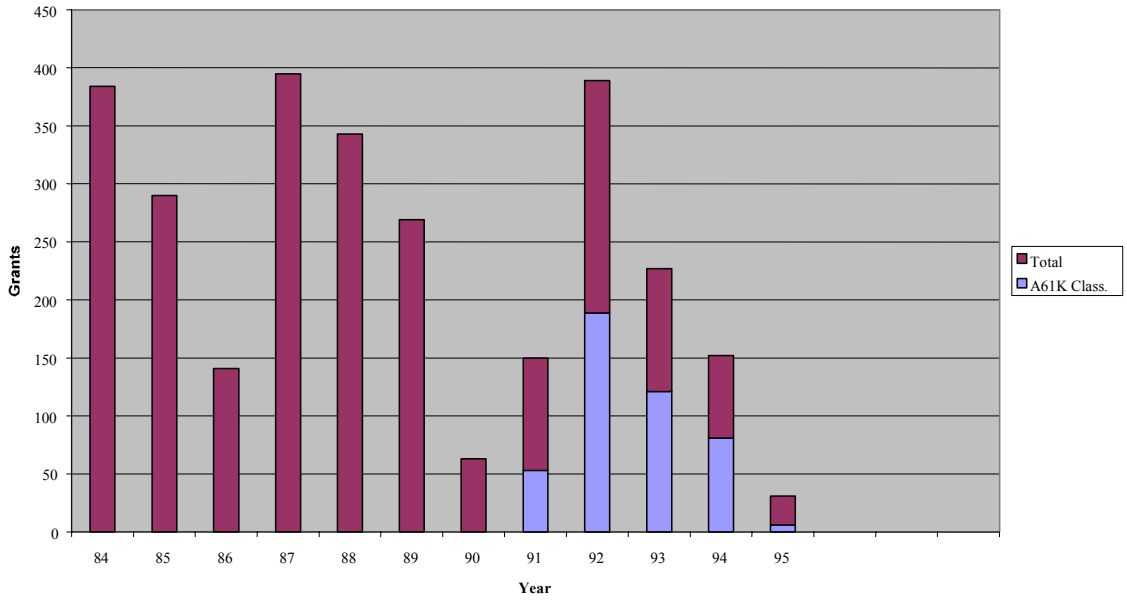
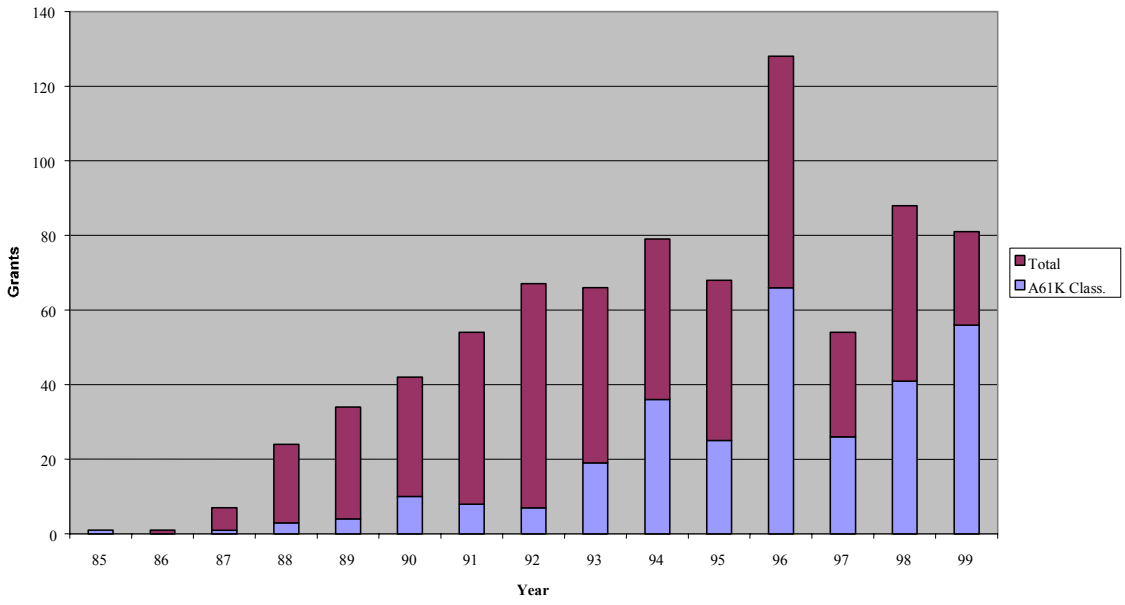


Figure 2 Patents Granted by ARIPO



LDCs that already grant pharmaceutical patents could, however, amend their legislation and not grant product patents until 2016[116], since they are not constrained by the "freezing clause" of Article 65.5 of the TRIPS Agreement.

Another crucial point is whether LDCs will be obliged to grant exclusive marketing rights (EMRs) under Article 70.9 of the TRIPS Agreement during the extended transitional period[117]. Paragraph 7 does not explicitly exclude the application of that provision. If LDCs were bound to grant EMRs[118], the value of the concession made by the Doha Declaration to LDCs would be very limited, since access to medicines and other products could be effectively blocked for at least five years.

An alternative interpretation for paragraph 7 is possible. Since EMRs do not constitute a category of intellectual property rights (as enumerated in Article 1.2 of the TRIPS Agreement), the granting of such rights only provides one way of *enforcing* foreign patent rights. As mentioned, paragraph 7 exempts LDCs from the enforcement of rights provided for in accordance with the patents section of the TRIPS Agreement. Under this interpretation, LDCs would be exempted from compliance with Article 70.9.

In addition, in relation to those LDCs that *did grant* patent protection for pharmaceutical products as of the entry into force of the WTO Agreement [119], the chapeau of Article 70.8 of the TRIPS Agreement makes it clear that the mailbox obligation applies to members that did "not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products." Article 70.8, literally interpreted, means that those LDCs who granted such a protection would not be subject to the obligation to grant exclusive marketing rights.

[116] Such a change, where possible, is likely to raise some complex legal issues under the relevant national laws, including of a constitutional nature. In the case of the LDCs members of OAPI, the use of the additional traditional period would require the amendment of the Libreville Agreement of 1962 (amended in 1977 and 1999). The OAPI establishes a uniform law and a centralized system of examination and registration. In contrast, the African Industrial Property Organization (ARIPO), provides for a centralized system of examination and registration, but it does not establish a common regional law and all designated States are given a chance to refuse an application before granting by the Regional Office. See, e.g., Chirambo, 2002.

[117] TRIPS Article 70.9. "Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member".

[118] Article 70.8 makes it clear that its application (and that of Article 70.9 which provides for EMRs) proceeds "notwithstanding the provisions of Part IV" which includes Article 66.1.

[119] January 1, 1995.

Special treatment under TRIPS

The non-discrimination clause contained in Article 27.1 of the TRIPS Agreement[120] has often been mentioned as preventing any differentiation under patent law in the treatment of various products or sectors. This interpretation would suggest that any solution under paragraph 6 would likely violate Article 27.1's non-discrimination clause.

However, as stated by the panel in the EC-Canada case[121] Article 27.1 prohibits "discrimination," as opposed to "differentiation". The panel held that:

> "Article 27 prohibits only discrimination as the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit *bona fide* exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose" (para 7.92)[122].

It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (paragraphs 6 and 7), as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents.

The French patent law provides an interesting example of a patent law that differentiates the treatment of pharmaceutical products on public health grounds. It provides that:

> *"Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex officio licences in accordance with Article L. 613-16 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the Minister responsible for health.*[123]

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[120] TRIPS Article 27.1 "Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

[121] WT/DS114/R, 17 March 2000.

[122] The USA also held in the same case, based on the panel report on Section 337, that "differential treatment was not necessarily treatment that was inconsistent with TRIPS requirements" (para. 5.36 (b)(3)(ii), WT/DS114/R).

*[123] Article L. 613-16.

Moreover, public health is not a "field of technology", but a problem area that may be addressed with products originating in different technological fields, such as equipment, software, diagnostic kits, medicines, and a large variety of devices used for medical treatment.

Legal status of the Doha Declaration

The Doha Declaration is a strong political statement that can make it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle[124]. The Declaration is also a Ministerial decision[125] with legal effects on the Member States and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS[126]. It states the *purpose* of the TRIPS Agreement in the area of public health, *interprets* the TRIPS Agreement with regard to some important aspects, *instructs* the Council for TRIPS to take action, and *decides* on the implementation of the transitional provisions for LDCs.

A "declaration" has no specific legal status in the framework of WTO law[127]; it is not strictly an authoritative interpretation in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO. However, given the content and mode of approval of the Doha Declaration, it can be argued that it has the same *effects* as an authoritative interpretation. In particular, in providing an agreed understanding on certain aspects of the TRIPS Agreement in paragraph 5, Members have created a binding precedent for future panels and Appellate Body reports. According to the European Commission,

> "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

[124] See e.g. Weisbrot, 2002, p. 16; Raja, 2001, p. 14.
[125] See article IX.1 of the WTO Agreement.
[126] It should be noted that the Ministerial Conference rejected proposed language ("*Desiring to clarify the provisions of the TRIPS Agreement, while preserving the rights and obligations of Members under the Agreement*") that would have suggested that the Declaration would only *clarify* provisions of the TRIPS Agreement.
[127] The WTO adopted several "declarations" prior to the document examined here: "Declaration on the Contribution of The World Trade Organization to Achieving Greater Coherence In Global Economic Policymaking"; "Declaration on the Relationship of the World Trade Organization with the International Monetary Fund"; "Declaration on the Dispute Settlement Pursuant to the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 or Part V of the Agreement on Subsidies and Countervailing Measures".

> 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"[128].

Moreover, the Declaration can be regarded as a "subsequent agreement" between the parties regarding the interpretation of a treaty or the application of its provisions, under Article 31.3 (a) of the Vienna Convention on the Law of the Treaties.

Any WTO Member could bring a complaint under the DSU on issues covered by the Doha Declaration[129], and it would be theoretically possible for a panel or the Appellate Body to find an inconsistency between the Doha Declaration and the TRIPS Agreement itself. This is unlikely, however, since in adopting the Declaration, Members have exercised their exclusive competence to interpret a WTO agreement[130], and it would be extremely difficult to challenge the adopted interpretation.

It should be stressed, however, as mentioned above, that the Doha Declaration is not self-executing and both developed and developing countries should adopt the legal amendments necessary to implement it. Developing countries, in particular, should ensure that they are using to the full extent possible the flexibilities allowed by the TRIPS Agreement to protect public health and facilitate access to health care by all.

[128] European Commission, 2001, p. 2. Se also Vandoren (2002), who notes that "the Declaration provides comfort to Members in the case of disputes…A Member whose legislation is being challenged by another Member because of alleged incompatibility with the TRIPS Agreement can refer to the contents of this Declaration in support of the measures under dispute, where relevant…and panelists are likely to take account of this complementary Declaration as well as the provisions of the TRIPS Agreement in their decisions" (p. 8).

[129] See Gillespie-White, 2001.

[130] Panels and the Appellate Body can only "clarify" the provisions of the WTO agreements; they "cannot add or diminish the rights and obligations provided in the covered agreements" (article 3.2 of the Dispute Settlement Understanding).

Issues not covered in the Declaration

The Doha Declaration does not cover all the areas where flexibility of the TRIPS Agreement exists, such as the exceptions to patent rights (Article 30) and the protection of data submitted for the registration of pharmaceutical (and agrochemical) products (Article 39.3). Nor does it refer to the room left to Members to determine the patentability standards in ways that prevent patenting strategies aiming at expanding or temporally extending the protection conferred in the pharmaceutical field[131].

Proposals made in the pre-Doha negotiation phase by different Members included, *inter alia*, language on the need to prevent diversion of drugs sold at discounted prices in developing countries to high-income markets[132], and to ensure that data protection requirements of Article 39.3 do not become a barrier to the registration and introduction of generic drugs and the use of compulsory licensing[133]. The USA proposed a five year moratorium on dispute settlement action in relation to "non-violation" complaints, which was limited to sub-Saharan African countries[134].

[131] See, e.g., Correa, 2001.

[132] The EC regretted that this issue was not dealt with by the Conference (European Commission, 2001, p. 6).

[133] See IP/C/W/296.

[134] Acceptance of this proposal would have implied that Article 64 of the TRIPS Agreement on "non-violation" complaints could be immediately applied to any other Member, something that most Members rejected since the scope and modalities of such complaints have not been determined yet by the Ministerial Conference.

Conclusions

The Doha Declaration addresses real and urgent problems faced by many developing countries in the area of public health. It is not intended to amend the TRIPS Agreement in any substantial manner. Rather, it aims to clarify the relationship between the TRIPS Agreement and Public Health policies of Member countries, and confirm the rights that Members have retained under the Agreement, particularly by defining the flexibility allowed in certain key areas.

The Declaration addresses most of the concerns of developing countries on the issue of public health. The ambiguous wording used in some paragraphs – particularly in paragraph 4 – was the obvious price paid to build a consensus for the adoption of the Declaration. Despite such wording, the Declaration makes it clear that a conflict may exist between TRIPS standards and public health, and has reaffirmed the right of Members, particularly developing countries, to take measures necessary to protect public health. The Declaration has set the ground for a differentiation of intellectual property policies when necessary to protect health.

Though an important political document, the Doha Declaration also has legal effects, equivalent to those of an authoritative interpretation under WTO rules.

As the mandate given in paragraphs 6 and 7 illustrates, the Doha Declaration represents, rather than the end of a process, the initial step for rethinking the TRIPS Agreement in light of the public interest.

Paragraph 6 aims at addressing a problem created by the extension of patent protection for pharmaceutical products to all WTO Members, irrespective of their level of development and of their pharmaceutical manufacturing capacity. While many different legal approaches may be developed, an effective solution must create the right economic conditions for countries with no or insufficient manufacturing capacity to obtain pharmaceutical products at low cost. Likewise, the TRIPS Agreement will continue to create tensions in the public health area, if the case of countries where no patent protection exists is not also a part of viable legal and economic solution.

All WTO Members should, in due time, take the steps, as necessary, to implement the Doha Declaration. Amendments to national laws should be introduced in order to facilitate exports of needed pharmaceuticals under paragraph 6 of the Declaration. Developing countries should be encouraged (and the relevant technical assistance provided) to review their legislation in order to ensure that the flexibilities, as clarified in the Declaration, as well as other flexibilities allowed by the TRIPS Agreement, are incorporated in national laws and effectively used to address public health concerns.

The situation of LDCs received special attention at the Doha Conference, but the paragraph 7 action item did not represent any significant improvement for the great majority of them. Hence, the problems faced by LDCs to gain access to needed pharmaceuticals are likely to require further consideration by the WTO Members, in order to accomplish the objectives sought by the Doha Declaration.

Annex 1
Doha Declaration on the TRIPS Agreement and Public Health

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/W/2
14 November 2001

(01-5770)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. 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.

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.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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Annex 2
Levels of development of pharmaceutical industry, by country

Sophisticated Pharmaceutical Industry and Research Base	Innovative Capabilities	Reproductive Capabilities – Active Ingredients and Finished Products	Reproductive Capabilities - Finished Products from Imported Ingredients only	No Pharmaceutical Industry
Belgium	Argentina	Bahamas	Afghanistan	Andorra
France	Australia	Bolivia	Albania	Antigua and Barbuda
Germany	Austria	Brazil	Algeria	Aruba
Italy	Canada	Bulgaria	Angola	Bahrain
Japan	China	Cuba	Bangladesh	Bermuda
Netherlands	Denmark	Czechoslovakia	Barbados	Bhutan
Sweden	Finland	Egypt	Belize	Botswana
Switzerland	Hungary	Indonesia	Benin	British Virgin Islands
United Kingdom	India	Macau, China	Brunei	Burkina Faso
United States	Ireland	Norway	Cambodia	Burundi
	Israel	Poland	Cameroon	Central African Republic
	Mexico	Puerto Rico	Cape Verde	Chad
	Portugal	Romania	Chile	Comoros
	Republic of Korea	Turkey	Colombia	Congo
	Spain		Costa Rica	Cook Islands
	USSR		Côte d'Ivoire	Djibouti
	Yugoslavia		Cyprus	Dominica
			Democratic People's Republic of Korea	Equatorial Guinea
			Dominican Republic	Faeroe Islands
			Ecuador	French Guyana
			El Salvador	French Polynesia
			Ethiopia	Gabon
			Fiji	Greenland
			Gambia	Grenada
			Ghana	Guadeloupe
			Greece	Guam
			Guatemala	Guinea
			Guyana	Guinea-Bissau
			Haiti	Iceland
			Honduras	Laos
			Hong Kong, China	Libyan Arab Jamah.
			Iran (Islamic Republic of)	Liechtenstein
			Iraq	Luxembourg
			Jamaica	Maldives
			Jordan	Martinique
			Kenya	Mauritania
			Kiribati	Mayotte
			Kuwait	Micronesia
			Lebanon	Nauru
			Lesotho	

Sophisticated Pharmaceutical Industry and Research Base	Innovative Capabilities	Reproductive Capabilities – Active Ingredients and Finished Products	Reproductive Capabilities - Finished Products from Imported Ingredients only	No Pharmaceutical Industry
			Liberia Madagascar Malawi Malaysia Mali Malta Mauritius Mongolia Morocco Mozambique Myanmar Namibia Nepal New Zealand Nicaragua Niger Nigeria Pakistan Panama Papua New Guinea Paraguay Peru Philippines Saudi Arabia Seychelles Sierra Leone Singapore Solomon Islands Somalia South Africa Sri Lanka Sudan Syrian Arab Republic Chinese Taipei Thailand Tonga Trinidad and Tobago Tunisia Uganda United Arab Emirates United Republic of Tanzania Uruguay Venezuela Viet Nam Yemen Zaire Zambia Zanzibar Zimbabwe	Netherland Antilles New Caledonia Niue Oman Qatar Reunion Rwanda St. Kitts and Nevis St. Lucia St. Vincent-Grenadines Samoa San Marino Sao Tome and Principe Senegal Suriname Swaziland Togo Tuvalu US Virgin Island Vanuatu Western Samoa

Source: Ballance et al, 1992.

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