A WIDER ACCESS TO PATENTED DRUGS UNDER THE TRIPS AGREEMENT

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I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement)[1] is the most controversial component of the World Trade Organization's (WTO) "package deal" struck in 1994,[2] and has been the subject of many different commentaries expressing either praise or blame.[3] In effect, the TRIPs Agreement has exerted negative influence on the implementation of domestic public health policies in many developing country Members of the WTO by adversely affecting their access to medicines. Africa is suffering the anguish and plight of an HIV/AIDS epidemic, loud protests rise high into the sky above Seattle squares, and heated debates occur among the attendees of many international conferences; these are all examples of the heavy pressure aimed at the TRIPs Agreement. Appeals that the WTO undertake to reform the Agreement with respect to public health issues have never been so loud and clear.

The Declaration on the TRIPs Agreement and Public Health, adopted on 14 November 2001 by consensus at the Doha Ministerial Conference

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, art. 28.1 (1994) [hereinafter TRIPs Agreement].

[2] *See* J.H. Reichman, *Taking the Medicine, with Angst: An Economist's View of the TRIPS Agreement*, 4 J. INT'L ECON. L. 795 (2001) (reviewing KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (Institute of International Economics 2000).

[3] *See, e.g.*, UNCTAD, *The TRIPS and Developing Countries*, Commercial Dipolmacy Programme, Geneva and New York 1996; UNCTAD, *Training Tools on the TRIPS Agreement: The Developing Countries Perspective*, Commercial Diplomacy Program, Geneva, January 2002; KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (Institute for International Economics 2000); CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS (2000); JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES (2001); W. Lesser, The Effects of TRIPS-Mandated Intellectual Property Rights on Economic Activities in Developing Countries (2001) (World Intellectual Property Organization Research Paper 2001) (on file with author).

(Doha Declaration)[4] enables people to see globally the aura of reform in the intellectual property regimes regarding public health. The Declaration clarifies the flexibility in the TRIPs agreement by giving developing country Members the autonomy to make and implement domestic public health policies with respect to intellectual property protection. Nevertheless, the Declaration does not fully dismantle obstacles created by the TRIPs Agreement that significantly constrain the autonomy of national legislatures to shape intellectual property laws in the public health perspective. Instead, there are still significant legal and economic barriers to the implementation of policies that will result in the availability of reasonably priced medicines. While there is consensus that meeting the immediate public health needs of developing countries requires substantial subsidization, there is currently little evidence that such subsidization will be forthcoming.[5]

If a WTO Member has insufficient or no manufacturing capabilities in the pharmaceutical sector, it will face difficulties in making effective use of compulsory licensing under the TRIPs Agreement to manufacture pharmaceuticals domestically. If a predominant part of compulsory-licensed production must supply the local market, the quantity of available exports will be limited. How to solve this problem is of great significance to the effectiveness of the Declaration. According to the Declaration, the TRIPs Council in the WTO should have found an expeditious solution to this problem and reported it to the General Council before the end of 2002.[6] Unfortunately, Members failed to meet the year-end deadlines for negotiations related to the problem. Now that the Doha meeting has been concluded, it is the Members' duty to implement the entire Doha Declaration in good faith, ensuring that the flexibility embodied in the TRIPs Agreement works for both rich and poor Members; for Members with large or small domestic markets; and for Members with different levels of technological development.

This article seeks to shed some light on this issue, which is vitally important to discussions on the TRIPs Agreement and public health. Section II provides a general introduction to the context of the discussion on the TRIPs Agreement and public health, and the result of the Doha Declaration and its subsequent development. Section III makes a detailed analysis of the emerging problem under Article 31(f) of the TRIPs Agreement. Section IV sets forth a number of legal options then,

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[4] WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, (Nov. 14, 2001), *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter Doha Declaration].

[5] Frederick M. Abbott, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries 3 (2000) (U.K. Commission on Intellectual Property Rights (CIRP) Study Paper 2a), *available at* http://www.iprcommission.org/text/documents/study_papers.htm (last visited May 8, 2003).

[6] Doha Declaration, *supra* note 4, at para. 6.

having compared the possible solutions under the TRIPs Agreement, Section V brings forward an Article 30-based solution to the problem set forth in the Paragraph 6 of the Doha Declaration.

II. THE IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Recognizing the gravity of the public health problems afflicting many developing countries, WTO members at the Doha Ministerial Conference attempted to integrate the TRIPs Agreement into part of the international action to address public health problems. Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPs Agreement could be used, the Doha Declaration helped to prevent situations where developing country Members could not avail themselves fully to the flexibility provided in the TRIPs Agreement due to pressure from interested groups. The Doha Declaration marked a turning point for political and legal relations at the WTO.[7]

As the Doha Declaration states, protection of intellectual property is important for the development of new medicines,[8] however, the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, the Agreement can and should be interpreted and implemented in a manner supportive of a WTO Member's right to protect public health and, in particular, to promote access to medicines for everyone.[9] Applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement should be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.[10] The Declaration clearly outlines all the key flexibilities available in the TRIPs Agreement, including: the right of Members to use compulsory licensing and to determine the grounds upon which such licenses are granted;[11] the right of Members to determine what constitutes a national emergency or other circumstances of extreme urgency, which can ease the granting of compulsory licenses;[12] the right of Members to determine their own parallel import regimes, "subject to the MFN and national treatment provisions of Articles 3 and 4;"[13]and the right of least devel-

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[7] For the negotiating history of the Doha Declaration, see Frederick M. Abbott, *The Doha Declaration on The TRIPS Agreement and Public Health: Lightening a Dark Corner in WTO*, 5 J. INT'L ECON. L. 480-89 (2002); James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. TECH. 296-98 (2002).

[8] *See* Doha Declaration, *supra* note 4, at para.3.

[9] *See id.* para. 4.

[10] *Id.* para. 5(a).

[11] *Id.* para. 5(b).

[12] *Id.* para. 5(c).

[13] *Id.* para. 5(d).

oped country Members to postpone providing pharmaceutical patents until *at least* 2016, and possibly longer.[14]

In addition, the Declaration reaffirms 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.[15] In particular, considering many developing 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, the Declaration instructs the TRIPs Council to find an expeditious way to facilitate effective use of compulsory licensing to address public health needs and to report to the General Council before the end of 2002.[16]

Furthermore, since granting exclusive marketing rights (EMRs) will materially impair the additional extension accorded by the Doha Declaration to the least-developed country Members by delaying the application of providing patent protection to pharmaceutical products for ten years, paragraph 7 of the Declaration instructs the TRIPs Council to take the necessary action to give effect to this extension.[17] Considering that obligations of granting exclusive marketing rights, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration, the General Council adopted a waiver decision in July 2002. Pursuant to this decision, the obligations of least-developed country

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[14] *Id.* para. 7. The TRIPs Council has decided that 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. *See* Decision of the TRIPs Council, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with respect to Pharmaceutical Products*, IP/C/25, para. 1 (June 27, 2002), *available at* http://ww.wto.org.

[15] Doha Declaration, *supra* note 4, at para. 7. Pursuant to Decision on Implementation-Related Issues and Concerns, the provisions of Article 66.2 of the TRIPs Agreement are mandatory.

> 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.

See WTO Ministerial Conference, *Implementation-Related Issues and Concerns*, WT/MIN(01)/17, para. 11.2 (Nov. 14, 2001), *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm.

[16] Doha Declaration, *supra* note 4, at para. 6.

[17] Exclusive marketing rights under Article 70(9) of the TRIPs Agreement appear to be very similar to patent rights under the obligation of the TRIPs Agreement and are possibly even stronger than patent rights. *See* WATAL, *supra* note 3, at 118-19.

Members under paragraph 9 of Article 70 of the TRIPs Agreement are waived with respect to pharmaceutical products until 1 January 2016. The decision is part of the WTO Members' ongoing efforts to ensure that intellectual property protection supports, and does not obstruct, a poorer country's need to tackle serious public health problems. Therefore, the former WTO Director-General Mike Moore commented as follows:

> I am pleased that WTO members have acted promptly to implement this important part of the Doha Declaration on TRIPS and public health, and have seen fit to go beyond the strict reading of that declaration by also approving a draft waiver on exclusive marketing rights.[18]

This waiver indicates that the reform in the TRIPs Agreement concerning public health will take the developing country Members' essential needs into account, and the remaining unsolved issue of how to assist some developing Members to make effective use of compulsory licensing under the TRIPs Agreement will have more optimistic prospects.

III. COMPULSORY LICENSING AND PUBLIC HEALTH: THE EMERGING PROBLEM UNDER THE TRIPS AGREEMENT

A. *Compulsory Licensing: An Important Tool to Promote Public Health*

The purpose of patents is to provide a temporary monopoly to rights holders to stimulate inventions and their commercialization in turn for disclosing information about the invention. According to Article 28 of the TRIPs Agreement, exclusive rights shall be conferred to patent holders, which prevents others from making, using, offering for sale, selling, or importing a patented product or process without the patent holder's permission.[19] Additionally, patent holders are given the exclusive power to assign or transfer patent rights, or to enter into voluntary licensing arrangements, subject only to domestic laws governing abuse and other anticompetitive practices.[20] It should be noted, however, that the monopoly right provided by a patent normally only excludes others from making, using or selling that particular invention, it does not prevent competition from other drugs, patented or not, that address the same medical conditions. Nevertheless, all things being equal, there is a presumption that the producer of a patented product, through the ability to exclude copies, will attempt to earn a monopoly profit and charge higher prices than would otherwise be the case. Therefore, patent protection may limit or impede public access to drugs.

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[18] *See* Press Release, WTO, Council Approves LDC Decision with Additional Waiver, Press/301 at 1 (June 28, 2002), *at* http://www.wto.org/english/news_e/pres02_e/pr301_e.htm.

[19] TRIPs Agreement, *supra* note 1, art. 28.1

[20] *Id.* art. 28.2.

In order to restrict the powers of the patentee, even in the absence of abuse, countries grant compulsory licensing for a variety of reasons that are generally supposed to promote the "public interest."[21] Not surprisingly, compulsory licensing was of particular interest to countries seeking to regulate patents covering medicinal products and food products.[22] Compulsory licensing has long been recognized as the most important tool for addressing the adverse effects of the patent grant on public welfare.[23] Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder, thus reducing the adverse effects of patents on price and availability. Such licensing mitigates the restrictive effect of exclusive rights and strikes a balance between the title-holders' interests and those of the public in the diffusion of knowledge, innovation and creativity, and affordability of the product. Moreover, granting compulsory licenses for specific classes of technologies, such as pharmaceuticals, is an important tool to promote competition and low prices.[24] Therefore, compulsory licensing functions as a significant instrument to protect public interests and promote innovation, disseminate newly-developed technologies, and reduce the adverse effects of patents on price and availability. Compulsory licensing also reflects the objectives and principles contained in Articles 7 and 8 of the TRIPs Agreement, namely the balance of rights and obligations; the promotion of technological innovation and transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the protection of public health and nutrition.[25]

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[21] *See* STEPHEN P. LADAS, 1 PATENTS, TRADEMARKS, AND RELATED RIGHTS - NATIONAL AND INTERNATIONAL PROTECTION 532-37 (1975).

[22] *See id.* at 533.

[23] *See* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 223-34 (1951).

[24] *See* CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS AND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES 24 (South Centre, Trade-Related Agenda, Development and Equity, Working Paper 5, October 1999). Professor Correa also emphasizes that countries should examine the potential negative impact of compulsory licensing, as with other measures limiting patentees' rights. The consequences include the possibility of discouraging foreign investment, transfer of technology, and research, including research into local diseases. *See also* Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* 91-100 (South Centre, Report, 2000), *available at* http://www.southcentre.org/publications/publichealth/publichealth.pdf (last visited Apr. 15, 2003).

[25] TRIPs Agreement, *supra* note 1, arts. 7, 8.

B. *The Nature of the Problem Set Forth by Paragraph 6 of the Doha Declaration*

Compulsory licensing is essential to many developing country Members so that sources of generic or low-cost drugs can be made available.[26] Developing countries can limit the costs of the patent system for their population by facilitating generic entry and generic competition. In most cases, however, their options are severely limited by the small size of their markets and lack of indigenous technological, productive and regulatory capacity. It is this lack of capacity to create a competitive environment for both patented and generic products that makes the existence of patents more contentious than in developed markets with greater capacity to enforce a strongly pro-competitive regulatory environment.[27] In the Canada-Generic Pharmaceuticals 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.[28]

However, developing country 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 in order to improve their access to low price drugs. The following Table indicates that manufacturing capacities in pharmaceuticals are dis-

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[26] *See* Frederick M. Abbott , *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health* 17 (Quaker United Nations Office (QUNO), Occasional Paper 9, 2002), *available at* http://www.geneva.quno.info/pdf/OP9%20Abbott.pdf.

[27] There is extensive evidence from developed countries that prices fall quite steeply as soon as drugs go off patent, assuming there are generic competitors. The price fall seems to be greater the more generic competitors enter the market. Governments can encourage price reductions by facilitating the early entry of generic producers into the market. *See* U.K. Commission on Intellectual Property Rights (CIPR), Final Report, *Integrating Intellectual Property Rights and Development Policy* 42 (2002) [hereinafter CIPR Final Report].

[28] Report of the Panel, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, para. 4.38(a) (March 17, 2000), *at* http://www.wto.org/english/tratop_e/7428d.pdf.

tributed very unevenly in the world. There are many developing countries that still lack fundamental manufacturing capacities in the pharmaceutical sector and very few countries maintain significant research and development capabilities in this sector.

LEVEL OF MANUFACTURING CAPACITIES IN THE PHARMACEUTICAL SECTOR (BY THE NUMBER OF COUNTRIES)[29]

Sophistication	Innovation	Reproductive I	Reproductive II	No Capacities
10	16	13	89	60

Sophistication: Sophisticated Pharmaceutical Industry and Research Base
Innovation: Innovative Capabilities
Reproductive I: Reproductive Capabilities - Active Ingredients and Finished Products
Reproductive II: Reproductive Capabilities - Finished Products from Imported Ingredients only
No Capacities: No Pharmaceutical Industry

It is simply economically inefficient to require domestic production for every medicine a county may need. Other barriers to local production also exist such as scarce know-how, trade secrets and regulatory barriers. Because intellectual property laws are territorial, the right to import does not amount to the right to export unless the law in the country where manufacture for export takes place authorizes such production.[30] Some commentators have observed that the only way to dismantle the barrier is

[29] Essential Drugs and Medicines (EDM), World Health Organization (WHO), Document Series No. 12, *Implication of Doha Declaration on the TRIPS Agreement and Public Health*, WHO/EDM/PAR/2002.3 (June 2002), *at* http://www.who.int/medicines/library/par/who-edm-par-200203/doha-implications.doc. The pharmaceutical sector includes both the manufacturing of *active ingredients* (the compounds that possess therapeutic activity) as well as 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. 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.

[30] TRIPs Agreement, *supra* note 1, arts. 3, 4, 6. According to Article 6 of the TRIPs Agreement, for the purposes of dispute settlement under the Agreement, and subject to the MFN and national treatment provisions, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights. And pursuant to paragraph 4(d) of the Doha Declaration, the provisions in the TRIPs Agreement relevant to the exhaustion of intellectual property rights effectively 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. Therefore, under the TRIPs Agreement, Members have the right to determine their own parallel import regimes, subject to the MFN and national treatment provisions of Articles 3 and 4.

through importation of low-price drugs under compulsory licenses.[31] Nevertheless, Article 31(f) of the TRIPs Agreement provides that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[32]

With this restriction, the manufacture of patented pharmaceuticals according to the authorized compulsory license shall be used for the predominant supply of the domestic market of the Member that issues the compulsory license. The term "predominantly" requires that virtually all the pharmaceuticals manufactured will be distributed or sold by the Member who authorized the compulsory license.[33] Hence, it would be inconsistent with Article 31(f) for that WTO Member to grant a compulsory license to its manufacturer to produce the drug solely for export to a country afflicted by a grave public health crisis that has insufficient or no manufacturing capabilities in the pharmaceutical sector. Difficulties could arise, therefore, when a country with insufficient domestic manufacturing capacity experiences grave health problems and seeks to import a needed pharmaceutical from a manufacturer in a WTO Member nation where a patent exists on that pharmaceutical. The restriction imposed by Article 31(f) of the TRIPs Agreement raises two inter-linked problems:

> 1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;
> 2. By requiring compulsory licensees to supply a predominant part of their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.[34]

This makes it impossible for those Members with production capabilities to grant a compulsory license to their manufacturers for the production of drugs solely for export to other Members experiencing grave public health problems that do not have adequate manufacturing capaci-

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[31] *See* CORREA, *supra* note 3, at 93; Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement—Two Proposals*, 4 J. WORLD INTELL. PROP. 23-36 (2001); Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 J. WORLD INTELL. PROP. 23-29 (2002).

[32] TRIPs Agreement, *supra* note 1, art. 31(f).

[33] Professor Abbot pointed out that the word "predominantly" suggests that more than 50% of the production by a compulsory license would be intended for the supply of the domestic market of the Member authorizing such use. *See* Abbott, *supra* note 7, at 499.

[34] Utenriksdepartementet, Norwegian Ministry of Foreign Affairs, *The TRIPS Agreement*, *at* http://odin.dep.no/ud/norsk/handelspolitikk/032061-090003/index-hov 007-b-f-a.html (last visited Mar. 7, 2003)

ties in the pharmaceutical sector. Therefore, Members with insufficient or no manufacturing capabilities cannot obtain a compulsory license for a domestic manufacturer to make the needed medicines domestically available, nor can they turn to one Member for the needed medicines which will be exported to their territory. Furthermore, Article 31(f) of the TRIPs Agreement creates difficulties for the demand and supply side of the generic drug pipeline.[35] The demand side problem is self-evident. If a developing country Member lacks manufacturing capacity for a particular drug, and there are no Members that are able to supply it by exporting under the authorized compulsory license and there is no affordable supply of drugs large enough to combat public health crises, then demand for the drug will not be met. The supply side problem looms large because competent WTO Members are prohibited from exporting compulsory-licensed drugs to a Member afflicted with grave public health problems.

The consequences of this restriction as analyzed above are not theoretical but probable. Take the recent case of the Indian generic company, Cipla, which offered to sell HIV/AIDS-related drugs to Kenya at US$650 per dose. This offer was legal in India because the drugs in question were not covered by the TRIPs Agreement because they were inventions made prior to 1994, which is the cut-off date for world-wide protection. But in a year or two, when new HIV/AIDS-related drugs are covered by the TRIPs Agreement, the Indian company will not be able to make such an offer. Against this background, Cipla have to obtain a compulsory license from India, so as to export some of their total production to Africa.[36]

Based on the preceding analysis, the TRIPs council needs to address the problem of dismantling the hindrance created by the restrictions contained in Article 31(f) because some developing country Members are fighting against public health crises. In addition, the expeditious solutions envisaged by the TRIPs Council should also address situations where no patents exist in the countries in need of access to public health-related products, or cases where economies of scale make domestic production for a particular product impractical or too costly.[37] It is clear that the expeditious solution set forth in paragraph 6 of the Declaration is intended to benefit those developing and least-developed country Mem-

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[35] *See* Abbot, *supra* note 5, at 499-500.

[36] *See* Background Paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, *More Equitable Pricing for Essential Drugs: What Do We Mean and What Are the Issues?*, Høsbjør, Norway (April 8-11 2001), *at* http://www.wto.org/english/tratop_e/tn_hosbjor_e.htm?.

[37] This is advocated by some developing country Members (Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela). *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Paragraph 6 of the Ministerial Declaration of the TRIPS Agreement and Public Health*, IP/C/W/355 at 1 (June 24, 2002).

bers that have insufficient or no manufacturing capacities in the pharmaceutical sector so that they have affordable access to medicines. In sum, the nature of this problem is to expand access to affordable medicines for those developing and least-developed country Members that have insufficient or no manufacturing capacities in the pharmaceutical sector, yet are susceptible to grave public health crisis.

IV. LEGAL OPTIONS UNDER THE TRIPS AGREEMENT

A. *Criteria to Evaluate the Solution*

Pursuant to paragraph 6 of the Doha Declaration, the TRIPs Council should find an expeditious solution to this problem and report it to the General Council.[38] Discussions on the fundamental problems concerning the TRIPs Agreement and public health commenced at the TRIPs Council in June 2001.[39] Based on the Doha Declaration, the TRIPs Council held several meetings over the course of 2002 to discuss how to find an expeditious solution to the current issue set forth by paragraph 6 of the Doha Declaration. No compromise was reached, thus, Members' opinions diverge on a proposal for an expeditious solution. Given the significance of the solution and the fact that the deadline was approaching, the Mini-Ministerial meeting of WTO Trade Ministers was held in Sydney on 14-15 November 2002 to discuss the problem. Unfortunately, WTO Members failed to reach consensus on the final solution to this problem by the end of 2002.[40]

The Doha Declaration mandates reading the TRIPs Agreement in light of its objectives and principles, thereby giving developing country Members a legal basis in the Agreement itself to argue in favor of public policies.[41] In considering approaches to implement paragraph 6, therefore, it is vitally important to ensure that the possible solution will be conducive to developing country Members' domestic implementations of public health policies. The final solution should contain the following features.

1. Accessibility

The gradual realization of the universal right to health requires that health-related pharmaceuticals be accessible to everyone, without dis-

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[38] Doha Declaration, *supra* note 4, para. 6.

[39] See WTO News, Governments Share Interpretations on TRIPS and Public Health, 2001 News Items, June 20, 2001, *at* http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm.

[40] *See* Press Release, WTO News 2002 Press Releases, Supachai Disappointed Over Governments' Failure to Agree on Health and Development Issues, Press/329 (December 20, 2002), *at* http://www.wto.org/english/news_e/pres02_e/pr329_e.htm.

[41] Doha Declaration, *supra* note 4, at para. 5(a)

crimination, within the jurisdiction of the State.[42] With regard to public health, accessibility has three overlapping dimensions:[43]

(a) Non-Discrimination: Health-related pharmaceuticals must be accessible to all, in law and in fact, without discrimination on any of the prohibited grounds;

(b) Physical Accessibility: Health-related pharmaceuticals must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS;

(c) Affordability: Health-related pharmaceuticals must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, must be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all.

2. Sustainability

The word "expeditious," found in paragraph 6 of the Doha Declaration, is exclusively intended to place a time limitation on the TRIPs Council to find a proper solution. It urges the TRIPs Council, after 14 November 2001 (the day on which the Doha Declaration was adopted),

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[42] The human right to health is recognized in numerous international instruments. Article 25(1) of the Universal Declaration of Human Rights (UDHR) affirms that "everyone has a right to a standard of living adequate for the health of himself and his family, including food, clothing, housing, and medical care and necessary social service." Universal Declaration of Human Rights, G.A. Res. 217A(111), at art. 25(1) (1948), *available at* http://www.un.org/Overview/rights.html. The International Covenant on Economic, Social and Cultural Rights (ICESCR),G.A. Res. 2200(XXI), U.N. Doc (1996), *available at* http://www.unhchr.ch/html/menu3/b/a_cescr.htm, provides the most comprehensive article on the right to health in international human rights law. According to Article 12 (1) the Covenant, State Parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," while Article 12(2) enumerates, by way of illustration, a number of "steps to be taken by the States Parties to achieve the full realization of this right." *Id.* art. 12. Additionally, the right to health is recognized, *inter alia*, in the United Nations Convention on the Elimination of All Forms of Racial Discrimination (CERD), Mar. 12, 1963, 660 U.N.T.S. 13; the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), Sept. 13, 1981, 1249 U.N.T.S. 13; and in the Convention on the Rights of the Child (CRC), Sept. 2, 1990, 1577 U.N.T.S. 3. Similarly, the right to health has been proclaimed by the Commission on Human Rights and further elaborated in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

[43] *See* Committee on Economic, Social and Cultural Rights, General Comment No 14: The Rights to the Highest Attainable Standard of Health (Article 12 of the Covenant), twenty-second session, 25 April – 12 May, E/C. 12/2000/4, para. 12.

to expeditiously find a solution before the end of 2002.[44] An expeditious solution does not necessarily mean that the solution reported to the General Council should be a temporary solution or provide transitional arrangements.

Moreover, since the Declaration also allows least developed countries not to apply pharmaceutical patents until 2016, countries that take advantage of this provision, as well as any country where a patent has not been issued, will not be able to issue compulsory licenses. At present, such Members may be able to import cheaper supplies from other Members without patents on the relevant products, but this situation will change after 2005.[45] Once developing country Members that have significant drug manufacturing capability, like India and Brazil, fully implement pharmaceutical patent enforcement, the ability to develop and export generic versions of patented drugs in those Members may completely disappear. Thus paragraph 6, while referring specifically to compulsory licensing, is clearly intended to address this wider context of action regarding the affordability and accessibility of medicines, particularly in developing and least developed country Members. Obviously, the ultimate goal of including paragraph 6 in the Doha Declaration was to create a pro-competitive solution for the market in patented drugs in developing country Members, after the TRIPs Agreement is fully in force, which will allow expeditious procurement of drugs in a sustainable manner at the lowest possible cost.

Therefore, the solution should be long-term, rather than an "expeditious" solution as envisaged under paragraph 6 of the Declaration. The solution should set up a stable international legal framework that will help the least developed country Members to gradually build a sound technological base to address their public health and public policy concerns. Additionally, the solution should provide a sufficient economic incentive to spur the development of low-cost generic drugs by companies located in developing country Members.

3. Economic Feasibility

To improve affordable access to medicines of appropriate quality and quantity, the proposed solution should allow production in the most economically viable manner, whether domestically or overseas. If individual Members with small markets seek supplies under a solution (whatever it is), generic companies may lack sufficient incentives to incur the necessary costs of development and marketing of a low cost version of the patented drug. Therefore, the proposed solution should bring disease-fighting remedies to the market in the shortest time and at the lowest cost possible. For any possible solution under paragraph 6 to work, it is crucial that the designed legal framework provide adequate incentives for

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[44] Doha Declaration, *supra* note 4, at para. 6.

[45] *See* TRIPs Agreement, *supra* note 1, art. 65.4.

the production and export of the medicines in demand. Overcoming the normative obstacles to exports would not mean much if no firms were interested in supplying the required pharmaceuticals at a low cost. In addition, the solution should be quick, simple and easy to operate. A solution under paragraph 6 may be illusory if it does not benefit countries where manufacturing is technically feasible but not economically viable.

4. Transparency

Rules are expected to result in significantly greater transparency of national public health policies. The solution should contain applicable rules of a transparent nature in both the exporting and importing Members, so as to provide the required incentives to the private sector to act within the established framework. This is a central element in providing security and predictability to the international patent protection system. In devising the solution, participants should seek to ensure that it gives Members the opportunity to promptly respond to the grave health problems facing developing and least-developed Members with insufficient or no capacity in the pharmaceutical sector, including through improved offers by patent holders to supply the country in need. To meet that end, Members are required to inform the TRIPs Council of actions taken under the prospective mechanism. This will also increase transparency and enable other Members to ensure that the medicines being exported actually reach the intended country and are not diverted into other markets.

B. *Legal Options*

Since the Doha Agreement, legal discourse concerning possible legal mechanisms for redressing the lack of access to medicines in the developing countries has arisen. Four main solutions have been proposed to the problem set forth in paragraph 6:[46] an amendment to Article 31(f);[47] a waiver with regard to Article 31(f);[48] a moratorium on dispute settle-

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[46] The first three solutions are categorized as "Article 31-base solutions." *See* Doha Declaration, *supra* note 4, para. 6.

[47] Some developing country Members advocate the deletion or revision of Article 31(f). *See* Joint Communication from the African Group in the WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/351, at para. 3(e) (June 24, 2002). The EU favors the specific amendment to Article 31(f). *See* Communication from the European Communities and Their Member States, *Concept Paper Relating to Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/339, Sec. III.1 at 4 (Mar. 4, 2002); Communication from the European Communities and Their Member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/352 (June 20, 2002).

[48] See Second Communication from the United States, Paragraph 6 of the Doha Declaration of the TRIPs Agreement and Public Health, IP/C/W/358 (9 July 2002).

ment;[49] or an authoritative interpretation of Article 30.[50] The choice between the options will be worked out politically. Whatever the potential legal solution adopted by the WTO, it should live up to the above criteria. Additionally, the process of making the solution should inspire the engagement and participation of the civil society for the sake of fostering public scrutiny of governmental policies on intellectual property protection.

1. Article Thirty-One Based Solution

a. *The Amendment to Article 31(f)*

To overcome the possible restrictions on exporting products manufactured and/or sold under a compulsory license, Article 31(f) could be deleted or amended Amending 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 license the need to address a paragraph 6 situation; and (c) the granting in the exporting country of a compulsory license upon request of an interested party.[51]

According to the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement), and the TRIPs Agreement, there are four ways to amend the TRIPs Agreement. First, amendments to Article 4 of the Agreement shall take effect only upon acceptance by all Members.[52] Second, amendments to provisions of the Agreement, "of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two-thirds of the Members and thereafter for each other Member upon acceptance by it."[53] Third, "amendments to provisions of the Agreement . . . of a nature that would not alter the rights and obligations of the

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[49] See Communication from the United States, *Moratorium to Address Needs of Developing and Least Developed Members with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector*, IP/C/W/396 (Jan. 14, 2003).

[50] Communication from the United Arab Emirates, *Paragraph 6 of the Doha Declaration of the TRIPs Agreement and Public Health*, IP/C/W/354 (June 24, 2002); Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, *Paragraph 6 of the Doha Declaration of the TRIPs Agreement and Public Health*, IP/C/W/355 (June 24, 2002).

[51] *See* Essential Drugs and Medicines (EDM), *supra* note 29, at 27.

[52] WTO Agreement, *supra* note 1, art. X

[53] *Id.*

Members, shall take effect for all Members upon acceptance by two thirds of the Members."[54] Fourth,

> Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.[55]

To date, the Ministerial Conference/General Council has not submitted any amendments of the WTO Agreement or the Multilateral Trade Agreements to the Members for acceptance in accordance with Article X of the WTO Agreement.[56] Normally the TRIPs Council can initiate the procedure for amendment of the TRIPs Agreement by submitting to the Ministerial Conference/General Council a proposal to amend the Agreement under Article X:1 of the WTO Agreement.[57] An amendment to Article 31(f) is of a nature that would alter the rights and obligations of the Members under the TRIPs Agreement, and therefore shall take effect for the Members that have accepted them upon acceptance by two-thirds of the Members in the Fifth Ministerial Conference according to the preceding analysis of the TRIPs amendment procedure.

Additionally, Article X:7 of the WTO Agreement provides that a Member may accept an amendment by depositing an instrument of acceptance with the Director-General of the WTO within the period of acceptance specified by the Ministerial Conference/General Council.[58] In practice, this means that the Member delivers a document to the WTO

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[54] *Id.*

[55] TRIPs Agreement, *supra* note 1, art. 71.

[56] *See* Note by the Secretariat, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, IP/C/W/363/Add.1, para. 20-1, at 5 (July 23, 2002).

> Two proposals to amend the DSU were submitted to the Third Session of the Ministerial Conference held in Seattle in 1999, one by Canada, Costa Rica, Czech Republic, Ecuador, the European Communities and its member States, Hungary, Japan, Korea, New Zealand, Norway, Peru, Slovenia, Switzerland, Thailand and Venezuela in respect of footnotes 6 and 7 of the DSU and the other by Turkey that proposed adding a new paragraph to Article 10 of the DSU.

Id.

[57] WTO Agreement, *supra* note 1, art. X. Article X:1 envisages also a way of initiating the process of amending the relevant agreements. Any Member of the WTO may initiate a proposal to amend the provisions of the WTO Agreement or the Multilateral Trade Agreements in Annex 1 thereto, including the TRIPs Agreement, by submitting such proposal to the Ministerial Conference/General Council. Amendments to the provisions of the Multilateral Trade Agreements in Annexes 2 and 3 are regulated in Article X:8 of the WTO Agreement. *Id.* at X:8.

[58] *Id.* art. X:7

Secretariat in which it establishes its intention to be bound by the amendment. It delivers the document after completion of the steps necessary under the domestic legal system. For many Members, these steps involve approval by the legislature. Therefore, an amendment to Article 31(f) entails ratification at the national level.

b. *A Waiver with Regard to Article 31(f)*

Advocates argue that a waiver is the most expeditious solution because it could provide legal security and still avoid the need for either amendment or authoritative interpretation of the TRIPs Agreement.[59] The conditions for a waiver could be set out in advance to define the circumstances in which they would apply. Obviously there would be a need to set these out very clearly and unambiguously to the satisfaction of all WTO members.

As to the waiver procedure, the Ministerial Conference/General Council has authority to waive an obligation imposed on a Member by the WTO Agreement or any of the Multilateral Trade Agreements, including the TRIPs Agreement.[60] Waiving the TRIPs obligations would require procedures at both the TRIPs council level and the Ministerial Conference/General Council levels.

Initially a request for a waiver must be submitted to the Council overseeing the relevant agreement for consideration during a time-period which shall not exceed ninety days.[61] Thus, a request for a waiver concerning the TRIPs Agreement must be submitted initially to the TRIPs Council. In practice, individual Members have requested that most waivers be submitted to one of the Councils, but there have been cases where the request for a collective waiver intended to apply to a number of Members has been inferred from the need for such a waiver that was realized during the work of the relevant Council.[62]

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[59] *See* Jacques H.J. Bourgeois and Thaddeus J. Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPs* and Public Health—The Waiver Solution, 6 J. WORLD INTELL. PROP. 835-64 (2002).

[60] *See* WTO Agreement, *supra* note 1, art. IX:3. To date, there have been 138 decisions on waivers or extensions of waivers. Most of them (115) extend the time-limits of waivers granted earlier. All of the decisions concern obligations under multilateral agreements on trade in goods, except for one waiver that has been granted in relation to obligations under the TRIPs Agreement.

[61] *See* WTO Agreement, *supra* note 1, art. IX:3(b).

[62] Sometimes individual waivers are granted following more standard terms that have been negotiated to apply to more than one Member. The Collective waiver refers to a waiver that covers several Members. *See* Decision on Waiver, *Preferential Tariff Treatment for Least-Developed* Countries, WT/L/304 (June 15, 1999); The Introduction of Harmonized System 2002 Changes into WTO Schedules of Tariff Concessions, WT/L/469 (May 13, 2002); Least-Developed Country Members – Obligations under Article 70.9 of the TRIPS Agreement with respect to Pharmaceutical Products, WT/L/478 (July 8, 2002).

Procedures at the Ministerial Conference/General Council can be further broken down to waiver decision-making and review of multi-year reviews. After the relevant Council has considered a draft waiver it forwards the draft to the Ministerial Conference/General Council for consideration pursuant to the practice of decision-making by consensus.[63] In exceptional circumstances, the Ministerial Conference/General Council may decide to waive an obligation imposed on the TRIPs Agreement, provided that any such decision shall be taken by three-fourths of the Members.[64] In addition, the decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate.[65]

Regarding a waiver granted for a period of more than one year, the Ministerial Conference/General Council shall review it not later than one year after it was granted, and thereafter annually until the waiver terminates. In each review the Ministerial Conference/General Council shall examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. On the basis of the annual review, the Ministerial Conference/General Council may extend, modify or terminate the waiver.[66]

In general, the terms and conditions governing the application of waivers vary depending on the substance of the waiver. However, there are some procedural terms and conditions that can be found in several waivers, such as those relating to the aforementioned reviews of multi-year waivers or consultation among affected Members. Many procedural terms are aimed at providing transparency with regard to the application of the waiver, and they often include requirements concerning notifications to the WTO.[67]

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[63] *See* WTO Agreement, *supra* note 1, art. IX:1. To date, all decisions in the WTO concerning waivers, or any other matter, have been agreed to by consensus. The practice has been that where a WTO body has failed to reach consensus on a matter, it has held further consultations in hopes of reaching a consensus.

[64] WTO Agreement, *supra* note 1, art. IX:4. A decision to grant a waiver with respect to any obligation subject to a transition period or a period for staged implementation that the requesting Member has not performed by the end of the relevant period shall be taken only by consensus.

[65] *Id.*

[66] *Id.* If the General Council were to decide, as a result of the annual review, to modify or terminate the multi-year waiver under review, or extend it beyond the term set out in the waiver itself, it would need to make a decision to that effect in accordance with Article IX of the WTO Agreement. Such a decision would normally require consensus; however, to date, no proposals have been made regarding the extension, modification or termination of multi-year waivers during their review.

[67] *See* Note by the Secretariat, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Information on Waivers*, IP/C/W/387, para.21, at 5 (Oct. 24, 2002).

c. *A Moratorium on Dispute Settlement*

The United States 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.[68]

The WTO Agreement does not have any specific provisions concerning decisions on moratoria.[69] Under the WTO Agreement, however, upon the request of a Member, the Ministerial Conference/General Council has the authority to take decisions on all matters under any of the Multilateral Trade Agreements in accordance with the specific requirements for decision-making in the WTO Agreement and in the relevant Multilateral Trade Agreement.[70] Therefore, the Ministerial Conference/General Council is entitled to make a decision on a moratorium on a dispute arising from the Article 31(f) of the TRIPs Agreement.[71]

Normally, a decision to grant a moratorium on dispute settlement shall be taken only by consensus at the meeting of the Ministerial Conference/General Council.[72] Like the waiver procedures, a decision by the Ministerial Conference/General Council granting a moratorium on dispute settlement shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the moratorium will terminate. Similarly, the Ministerial Conference/General Council shall direct the relevant Council to review

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[68] *See* Second Communication from the United States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/358 (July 9, 2002).

[69] Professor Abbott has noted that, in practice, there are ways that a form of moratorium can be established, but the point remains that this is not a mechanism expressly provided for in the WTO Agreement. *See* Frederick M. Abbott, *Legal Options for Implement Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health,* Summary of Oral Presentation at Quaker United Nations Office (QUNO), Norway Ministry of Foreign Affairs Meeting at Utstein Monastery, Norway (July 20-23, 2002).

[70] *See* WTO Agreement, *supra* note 1, art. IV:1.

[71] With regard to the WTO practice, the Doha Ministerial Conference agreed to extend the moratorium concerning certain types of complaints under the dispute settlement system originally provided under Article 64.2 of the TRIPs Agreement. Another example of a moratorium on dispute settlement concerns telecommunication accounting rates. *See* Report of the Group on Basic Telecommunications, S/GBT/4, para.7 (15 February 1997).

[72] WTO Agreement, *supra* note 1, art. IV:1. Article IV:1 provides that where a decision cannot be arrived at by consensus it shall be decided by voting and be taken by a majority of the votes cast. This rule shall not be applicable to the decision-making moratorium. Because Article 64.3 of the TRIPs Agreement provides that any decision of the Ministerial Conference to approve such recommendations or to extend the moratorium on the non-violation complaints shall be made only by consensus, the approved recommendations shall be effective for all Members without further formal acceptance process.

the moratorium on dispute settlement not later than the expiration date. Finally, the Ministerial Conference/General Council, on the basis of the report made by the relevant Council, may extend, modify, or terminate the moratorium on dispute settlement. Such decisions shall be made only by consensus, and approved recommendations shall be effective for all Members without a formal acceptance process.[73]

2. Article Thirty-Based Solution

Article 30 provides for limited exceptions to patent rights that do not conflict with the normal exploitation of the patent.[74] Some developing country Members propose that the TRIPs Council make an authoritative interpretation under Article 30 of the TRIPs Agreement that recognizes the right of Members to allow the production, without the consent of the patent holder, in order to address public health needs in another country.[75] Under this proposed solution no amendment to TRIPs is required, nor is a compulsory license in the exporting country enabling the WTO Members to use "limited exceptions" provided for in this Article to export products manufactured. The exceptions Members could rely on: 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 a market at low prices by a third party may not conflict with such exploitation; 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; and would positively "take account of the legitimate interests of third parties" (consumers in the importing country).[76]

The Ministerial Conference/General Council has exclusive authority to adopt interpretations of the WTO Agreement and the Multilateral Trade

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[73] *Id.* art. IX:4.

[74] TRIPs Agreement, *supra* note 1, art. 30.

> Members may provide *limited exceptions* to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a *normal exploitation* of the patent and do not unreasonably prejudice the *legitimate interests* of the patent owner, taking account of the legitimate interests of third parties.

Id. (emphasis added).

[75] *See* Communication from the United Arab Emirates, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/354 (June 24, 2002); Communication from the Permanent Mission of Brazil, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, IP/C/W/355 at 1 (June 24, 2002) (Developing countries who made the proposal include Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela).

[76] See TRIPs Agreement, *supra* note 1, art. 30.

Agreements, including the TRIPs Agreement.[77] The Council can exercise this authority on the basis of a recommendation by the Council overseeing the functioning of the relevant agreement;[78] in case of the TRIPs Agreement, the Council will consider on the basis of a recommendation by the TRIPs Council. If a decision concerning interpretation cannot be arrived at by consensus, the decision by the Ministerial Conference/General Council to adopt an interpretation must be taken by a three-fourths majority of the Members.[79] If there were an interpretation of Article 30 of the TRIPs Agreement, WTO Members would vote on it in the Ministerial Conference/General Council. It would not be necessary to send it back to the national parliaments for consideration.

C. *Making the Choice*

Article 31 of the TRIPs Agreement, entitled Other Use Without Authorization of the Right Holder, establishes procedures and conditions regarding the grant of compulsory licenses. Footnote 7 to Article 31 states "'[o]ther use' refers to use other than that allowed under Article 30."[80] The plain meaning of footnote 7 is that an exception under Article 30 and a compulsory license under Article 31 are different legal mechanisms to which different rules and procedures apply. Combined with the preceding analysis on the various aspects of the procedure requirements, therefore, it is obvious that Article 31-based and Article 30-based solutions are fundamentally different. Although the choice between the options will be worked out politically, it is important to examine which solution would be most effective, sustainable, transparent, and legally secure according to the foregoing criteria.

With respect to Article 31-based solutions, although supported by many developed country Members, there are still certain visible defects inherent to the solutions.

1. Procedural Defects

A waiver or dispute settlement moratorium is temporary. In the context of Article 31(f) of the TRIPs Agreement, the waiver or dispute moratorium should be granted for a period of more than one year. According to the preceding analysis, with regard to a multi-year waiver

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[77] *See* WTO Agreement, *supra* note 1, art. IV:2. The Appellate Body has noted, on a number of occasions, that the Ministerial Conference and the General Council have exclusive authority to adopt interpretations of the WTO Agreement and the Multilateral Trade Agreements.

[78] *See id.* The last sentence in paragraph 2 of Article IX provides that the paragraph shall not be used in a manner that would undermine the amendment provisions in Article X. In other words, the validity of interpretation decisions that go so far as to amend provisions of WTO Agreements could be challenged on this basis.

[79] *See* WTO Agreement, *supra* note 1, art. IX:2.

[80] *See* TRIPs Agreement, *supra* note 1, art. 31 n.7.

granted for a period of more than one year, the Ministerial Conference/ General Council shall review it not later than one year after it was granted, and thereafter annually until the waiver terminates. In each annual review, the Ministerial Conference/General Council shall examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. The Ministerial Conference/General Council, on the basis of the annual review, may extend, modify, or terminate the waiver.[81] Therefore, some Members may challenge the waiver of obligation annually under Article 31(f) of the TRIPs Agreement and therefore the waiver might terminate, in several years. The dispute settlement moratorium is similar because the only decision-making option is a consensus, on the basis of the review report made by the TRIPs Council, and the Ministerial Conference/General Council might modify or terminate the moratorium on dispute settlement. Hence, if the waiver or dispute settlement moratorium merely serves a transition function it is not sustainable, economical, and, more importantly, does not facilitate long-lasting access to the essential health-related pharmaceuticals.

Though the potential amendment to Article 31(f) of the TRIPs Agreement is permanent, apart from the submitting and voting procedures it should still undergo the additional national ratification by Members. Rules on ratification of a treaty amendment are not uniform and vary with the complex and diverse constitutional laws found in each Member state. As a general proposition, many constitutional systems would take the view that an amendment that substantially alters rights and obligations is, in essence, a new agreement that parliament must approve; while a minor or technical amendment could be undertaken solely as an executive act. In the United States, there was debate in Congress (and other forums) about whether the States should ratify the treaty embodying the Uruguay Round results and therefore the constitutional requirements regarding amendments are not determined.[82] Designed to protect the United States interests,[83] the emergence of Uruguay Round Agreements Act (URAA) further complicated this matter by requiring that the United States Trade Representative (USTR) consult with Congress

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[81] *See id.* art. 31. If, as a result of the annual review, the General Council were to decide to modify or terminate the multi-year waiver under review, or extend it beyond the term set out in the waiver itself, it would need to make a decision to that effect in accordance with Article IX of the WTO Agreement. Such a decision would normally require consensus. To date, however, no proposals have been made regarding the extension, modification or termination of multi-year waivers during their review. *See* Note by the Secretariat, *supra* note 67, para.24.

[82] *See* John H. Jackson, *The Great 1994 Sovereignty Debate: United States Acceptance and Implementation of the Uruguay Round Results*, 36 COLUM. J. TRANSNAT'L L. 159 (1997).

[83] *See id.* at 186.

before voting on an interpretation, amendment or waiver, but does not expressly address whether an amendment must thereafter be submitted to Congress for approval.[84] Debates over whether an amendment voted upon in the Ministerial Conference must be submitted to Congress for further approval can be argued either way; and the result might not be the same in all circumstances. Moreover, if the pharmaceutical manufacturing groups or other interest groups in the United States consider an amendment to the TRIPs Agreement to be adversely affecting their rights under the TRIPs Agreement, the groups would challenge the power of USTR to act alone as a matter of constitutional law. That alone creates legal insecurity regardless of the ultimate outcome. Furthermore, an industry lobby might persuade members of Congress that a vote on the amendment is required, and then seek to defeat the amendment. If the amendment is not ratified domestically, the legal dilemma will again loom large and all the endeavors to arrive at consensus on the amendment would eventually turn out to be in vain. Hence, considering the uncertainty of ratification at the national level, any amendment to Article 31(f) of the TRIPs Agreement would be legally insecure and time-consuming.

2. Potential Difficulties in the Use of Compulsory Licensing

An Article 31-based solution aims at enabling the prospective exporting Members to overcome the restriction under Article 31(f) to export products manufactured under a compulsory license. It does not, however, necessarily mean that the solution fully dismantles the exporting barrier created by Article 31(f) of the TRIPs Agreement. Instead, many developing county Members remain unable to efficiently and effectively use compulsory licensing under this solution.

Although the TRIPs Agreement allows Members to grant compulsory licenses subject to certain procedures and conditions, developing country Members have made limited use of this system.[85] Studies indicate that

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[84] *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994) [hereinafter Final Act].

[85] Ironically, it is the developed countries that have been the most active users of compulsory licensing. Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until the late 1980s. This resulted in the price of licensed drugs being 47% lower than in the United States in 1982. *See* F.M.SCHERER & JAYASHREE WATAL, POST- TRIPS OPTIONS FOR ACCESS TO PATENTED MEDICINES IN DEVELOPING COUNTRIES, (WHO, Commission on Macroeconomics and Health, Working Group Paper 1, 2001). Shortly after the September 11 attack, both the United States and Canada were significantly threatened by the anthrax attacks. To meet the challenge of severe bioterrorist attack, Canada overrode the German pharmaceutical company Bayer's patent for Cipro, an antibiotic to treat anthrax, and ordered a million tablets of a generic version from a Canadian company. More severely threatened by the bioterrorism-related anthrax attacks, the U.S. government

developing country Members have not used the compulsory license as a tool to address public health issues for a number of reasons,[86] including that the effective implementation of compulsory licensing requires that certain preconditions relating to administrative, financial and technical capacities be met, and these conditions are often not met in developing countries. The licensee must have the know-how to reverse engineer and manufacture the drug without the cooperation of the patent owner, and must also foresee a sufficiently large market to justify the costs of investment and manufacture and adequate remuneration to the patentee. Compulsory licensing must be "predominantly for the domestic market."[87] Developing country Members have feared that sanctions might be threatened, bilaterally or multilaterally. Developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons. Finally, as noted earlier, an Article 31-based solution only overcomes the restriction of predominant supply for the domestic market, it does not equip developing country Members with increased administrative, financial and technical capacities to effectively implement compulsory licensing, nor does it provide enough incentives to the generic pharmaceuticals to produce and sell low-price drugs to the Members lacking pharmaceutical manufacturing capacities.

Moreover, it is anticipated that the requirement of the issuance of a compulsory license in the country of export would be subject to bureaucratic delay based on challenges from patent holders and pressures from developed country governments. Shortly after the Doha Declaration on TRIPs and Public Health was adopted, the largest pharmaceutical companies directed an effort to undermine the Declaration, attempting to divide developing countries, and to fashion new and dangerous precedents that were designed to undermine the use of compulsory licensing, even in cases where there were enormous social costs for not addressing abuses of patent rights.

In comparison with an Article 31-based solution, an Article-30 based solution has the following advantages. The Article 30-based solution is permanent. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members.[88] If there were an interpretation submitted by the TRIPs Council, WTO Members would vote on it in the Ministerial Conference/General Council. It would not be necessary to

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won a major price concession from Bayer A.G. for its antibiotic Cipro after the Bush administration threatened to override the drug's patent and allow generic production *See* Keith Bradsher & Edmund L. Andrews, *U.S. Says Bayer Will Cut Cost of Its Anthrax Drug,* N.Y. TIMES, October 24, 2001, at B7.

[86] *See* Abbott, *supra* note 5, at 14; CIPR Final Report, *supra* note 27, at 49-50.

[87] *See* TRIPs Agreement, *supra* note 1, art. 31(f).

[88] *See* WTO Agreement, *supra* note 1, art. IX: 2.

return it back to the national parliaments for consideration. Since it does not need to be ratified at the national level, an Article 30-based approach is an expeditious solution identified by paragraph 6 of the Doha Declaration. Meanwhile, once the interpretation is adopted by the Members, it would be in effect for a long time and it would not undergo review which might lead to a waiver or a moratorium.

Considering the legitimate interests of third parties, the Article 30-based solution is economically feasible. In the event of a national public health emergency in a Member lacking pharmaceutical manufacturing capacities, some Members may provide limited exceptions to the exclusive rights conferred by a patent. The exceptions are limited and do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. In addition, it could be limited to only the health problems that the Doha declaration addresses.

The Article 30-based solution would avoid double remuneration to patent owners. If the importing Member issues a license and the exporting Member provides reasonable remuneration,[89] then the interests of the patent owner are in fact taken into account. In the cases where there is no patent in the importing country, the economic consequences to the patent holder are likely to be insignificant, and in any case could be addressed by an Article 30 solution. This approach would avoid problems of double compensation where patents exist in both the producing and exporting countries, and would only fail to provide compensation when consumption took place in countries where the inventor did not have a patent (typically in smaller markets of marginal economic importance). This ensures that the inventor benefits when the product is used in countries where the inventor obtained a patent, and it permits patients to seek the most efficient suppliers of medicines and other medical technologies.

Finally, the Article 30-based solution would ensure that the exporting Member's use of limited exceptions will not be successfully challenged by the potential application of non-violation complaints. Non-violation complaints do not require a violation of an obligation of an agreement. Accordingly, a waiver of an obligation does not affect the availability of these types of complaints.[90] Although non-violation complaints are cur-

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[89] WTO Agreement, *supra* note 1, art. IX:4. Section V of this article explains the exporting Member, rather than the importing Member, should provide adequate remuneration to patent owners.

[90] Final Act, *supra* note 84 at para. 3. Paragraph 3 reads as follows:

> Any Member considering that a benefit accruing to it under GATT 1994 is being nullified or impaired as a result of: the failure of the Member to whom a waiver was granted to observe the terms or conditions of the waiver, or the application of a measure consistent with the terms and conditions of the waiver may invoke the provisions of Article XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding.

rently not applicable to TRIPs-related disputes,[91] there is still the possibility that this will be applied to TRIPS-related disputes. Subject to the interpretation adopted by the Members and the Doha Declaration, the use of limited exceptions is out of the dimension of the potentially applicable non-violation complaints. Compared with the waiver, the Article 30-based solution is more legally secure.

On October 23, 2002, the European Parliament adopted Amendment 196 to the European Medicines Directive stating:

> Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.[92]

The European Parliament Amendment 196 is only 52 words, but it provides the correct policy framework to balance the objectives of Paragraph 4 of the Doha Declaration, while protecting the legitimate interests of patent owners. This amendment provided the precise solution that the TRIPs Council should have adopted.

V. INTERPRETATION OF ARTICLE THIRTY OF THE TRIPS AGREEMENT

Among the WTO Agreements, the TRIPs Agreement is probably the most difficult to interpret.[93] Underlying the superficial certainty of the TRIPs Agreement, substantive prescriptions exist in the gulfs of interpretative difference regarding the meaning of many of its rules.[94] The wording of Article 30 of the TRIPs Agreement is particularly ambiguous and this provision has no direct counterpart in the Paris Convention or the common law of WTO Members pre-dating the Uruguay Round negotiations; therefore, there is substantial uncertainty regarding how its criteria

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Id. para. 3. Therefore, the concept reflected in paragraph 3(b) has to be considered as a reference to non-violation under article XXIII:1(b) and (c).

[91] *See* TRIPs Agreement, *supra* note 1, arts. 64.2, 64.3. Pressed to conclude the Uruguay Round, negotiators simply placed a moratorium on such claims in order to allow further investigation. As a result, the above two paragraphs limit the availability of non-violation complaints until 2001. At the Doha Ministerial Conference, the TRIPs Council was instructed to continue its examination of the scope and modalities for non-violation complaints. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPs Agreement. *See Implementation-Related Issues and Concerns*, WT/MIN(01)/17, at para. 11.1 (Nov. 14, 2001).

[92] Council Directive 2001/83/EC, art. 1, 2001 O.J. (L311) 67.

[93] Oliver Cattneo, *The Interpretation of the TRIPS Agreement –Considerations for the WTO Panels and Appellate Body*, 3 J. WORLD INTELL. PROP. 627, 679 (2000).

[94] Frederick M. Abbott, *WTO Dispute Settlement and Agreement on Trade-Related Aspects of Intellectual Property Rights*, *in* INTERNATIONAL TRADE LAW AND THE GATT/WTO DISPUTE SETTLEMENT SYSTEMS 415 (Kluwer Law International, 1997).

should be applied.[95] Article 30, however, must be interpreted so as to allow the making, sale and export of patented products to address public health needs in some developing country Members. An authoritative interpretation adopted by the Ministerial Conference/General Council would be useful in providing legal security and predictability for operation of a prospective mechanism established under the TRIPs Agreement.

A. *Basic Principles of the Interpretation*

1. Principle of Protecting Public Health

With the introduction of the Doha Declaration, the gradual realization of public health becomes a clearly stated purpose of the Agreement. In light of these guidelines, Members may 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,[96] for example, development of medicines. The TRIPs Agreement is intended to achieve a balance between the protection of intellectual property rights and other social and economic policies; therefore, Members must have the necessary flexibility to adjust intellectual property laws to maintain the desired balance.

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* of the purpose of the TRIPs Agreement in relation to public health issues, which requires that the Agreement not prevent Members from taking measures to protect public health.[97] Accordingly, Article 30 of 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."[98]

2. Principle of Good-Faith Interpretation

The Doha Declaration requires that 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.[99] The fundamental rule of treaty interpretation as set out in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (Vienna Conven-

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[95] *See generally* Abbott, *supra* note 31.

[96] *See* TRIPs Agreement, *supra* note 1, art. 8.1 When formulating or amending their laws and regulations, Members should ensure that such measures are consistent with the provisions of the TRIPs Agreement.

[97] *See* Doha Declaration, *supra* note 4, para. 4.

[98] *Id.*

[99] *See id.* para. 5(a).

tion)[100] has attained the status of a rule of customary or general international law.[101]

In the framework of the TRIPs Agreement, which incorporates certain provisions of the major pre-existing international instruments on intellectual property, the TRIPs Council may have recourse for purposes of interpreting specific TRIPs provisions. Guided by the key elements of treaty interpretation defined in Articles 31 and 32 of the Vienna Convention, the TRIPs Council should examine the provisions in the context of objectives and principles highlighted by the TRIPS Agreement, rather than merely refine themselves to a restrictive textual approach.

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[100] Vienna Convention on the Law of Treaties, May 23, 1969, art. 31 & art. 32, 1155 U.N.T.S. 331, 340. The Vienna Convention then sets out two rules regarding the interpretation of treaties:

> (1) A treaty shall be interpreted *in good faith* in accordance with the *ordinary meaning* to be given to the terms of the treaty *in their context* and *in the light of its object and purpose.*
> (2) The context for the purpose of the interpretation of a treaty shall comprise, *in addition to the text, including its preamble and annexes*:
> (a) *any agreement relating to the treaty* which was made between all the parties in connection with the conclusion of the treaty;
> (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an *instrument related to the treaty.*
> (3) There shall be taken into account, together with the context:
> (a) any *subsequent agreement* between the parties regarding the interpretation of the treaty or the application of its provisions;
> (b) any *subsequent practice* in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
> (c) any *relevant rules of international law* applicable in the relations between the parties.
> (4) A special meaning shall be given to a term if it is established that the parties so intended.
> Article 32: Supplementary Means of Interpretation
> Recourse may be had to *supplementary means* of interpretation, including the *preparatory work* of the treaty and the *circumstances of its conclusion*, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:
> (a) leaves the meaning ambiguous or obscure; or
> (b) leads to a result which is manifestly absurd or unreasonable.

Id. art. 31.

[101] *See United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, p. 17. *See also* Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, 1 November 1996, p. 11; Appellate Body Reports, *India—Patents*, para. 46; *European Communities—Customs Classification of Certain Computer Equipment*, WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68AB/R, 22 June 1998, para. 84; *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, 6 November 1998, para. 114; *see also* James Cameron & Kevin R. Gray, *Principles of International Law in the WTO Dispute Settlement Body*, 50 INT'L COMP. L. Q. 254-56 (2001).

a. *Meaning of Treaty Terms "In Context"*

In the case of Article 30, the context is not restricted to the text and Preamble of the TRIPs Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPs Agreement. Any agreement between the parties within the meaning of Article 31(2) of the Vienna Convention should also be considered.[102] Thus, as the Council will have occasion to elaborate further below, Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention)[103] is an important contextual element for the interpretation of Article 30 of the TRIPs Agreement. As a consequence of the extended context that has to be taken into account when interpreting provisions of the TRIPs Agreement, the TRIPs Council, in considering the negotiating history of the Agreement, may go beyond the negotiating history of the TRIPs Agreement proper and also inquire into that of the incorporated international instruments on intellectual property.[104]

b. *The Object and Purpose of the Treaty*

Article 31 of the Vienna Convention states that, in interpreting particular terms in a treaty, the treaty interpreter must give regard to the "object and purpose" of the treaty as whole.[105] In the context of the TRIPs Agreement, the TRIPs Council should consider the "object and purpose" in determining the meaning of the terms in Article 30, for example "limited exceptions," "normal exploitation," and "legitimate interests." Therefore, the TRIPs Council should recognize the underlying public policy objectives of national systems for the protection of intellectual prop-

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[102] Vienna Convention, *supra* note 100, art. 31(2).

[103] Article 9(2) of the Berne Convention stipulates that "[i]t shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in *certain special cases*, provided that such reproduction does not conflict with *a normal exploitation* of the work and does not *unreasonably prejudice the legitimate interests of the author*." Berne Convention for the Protection of Literary and Artistic Works, *opened for signature* Sept. 9, 1886, art. 9(2), S. Treaty Doc. No. 99-27, 828 U.N.T.S. 221 at 229 (revised at Paris July 24, 1971) (emphasis added). When interpreting the Limitations and Exceptions in Article 13 of the TRIPs Agreement, the Panels of U.S. Copyright Act, Panels Established at the Request of the E.C., WT/DS160/6 (Aug. 6, 1999) and U.S. Omnibus Appropriations Act, Report of the Panel, WT/DS176/R (Aug. 6, 2001) made references to the Article 9(2) of the Berne Convention.

[104] *See India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R, adopted on 5 May 1997, paras.1.4–1.6; Report of the Panel, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, paras.7.1-7.3 (March 17, 2000); Note by the Secretariat, *United States—Section 110(5) of the U.S. Copyright Act,* WT/DS160/R, paras. 6.43-6.45 (February 4, 1999); Report of the Panel, *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, paras. 1.1-1.3 (August 6, 2001).

[105] Vienna Convention, *supra* note 100, art. 31.

erty, including developmental and technological objectives.[106] Simultaneously, it should also recognize the special needs of the least-developed country Members with respect to maximum flexibility in the domestic implementation of laws and regulations to enable them to create a sound and viable technological base.[107] Most importantly, the TRIPs Council should largely refer to Article 7 of the TRIPs Agreement, which unambiguously contains the object and purpose of the TRIPs Agreement.[108] Therefore, the Council should reemphasize that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology; to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare; and to a balance of rights and obligations.[109]

c. *Additional Interpretive Sources*

Other than the texts of the WTO Agreements themselves, no source of law is as important as the reports adopted by the GATT/WTO Dispute Settlement Panels as well as the Appellate Body.[110] As Abbott, Cottier & Gurry have remarked:

> The TRIPs Agreement is unique in that it establishes minimum standards applicable to the enforcement of legislation by WTO Members. . . . The reference in the DSU to use of "customary rules of interpretation of international law" is rather important in respect to TRIPS Agreement dispute settlement. The unique character of the TRIPS Agreement will almost certainly result in a greater reliance by dispute settlement panels on sources of law outside the WTO/GATT texts, and outside WTO/GATT panel decisions, than has been the practice in regard to interpretation of the GATT 1947.[111]

The TRIPs Council may make reference to the reports of the Canada-Generic Pharmaceuticals case,[112] U.S. Copyright Act case,[113] and U.S. Omnibus Appropriations Act case.[114] When interpreting Article 30, the

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[106] *See* TRIPs Agreement, *supra* note 1, Preamble.

[107] *See id.*

[108] TRIPs Agreement, *supra* note 1, art. 7.

[109] *See id.* art. 7.

[110] *See* D. Palmeter and P. C. Mavroidis, *The WTO Legal System: Source of Law*, 92 AM. J. INT'L L. 398, 400 (1998).

[111] *See* THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS 719, 721 (Frederick Abbott et al. eds., 1999).

[112] *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, Mar. 17, 2000.

[113] *United States—Section 110(5) of the U.S. Copyright Act*, Feb. 4, 1999, WT/DS160/R.

[114] *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R, Aug. 6, 2001.

TRIPs Council should be guided by the GATT/WTO jurisprudence, but it is not bound by it.[115]

Intellectual property protection and international trade regulation must respect and abide by international human rights law. As an element of States' obligations to act in good faith in fulfilling their treaty obligations, the interpretation of treaties such as the TRIPs Agreement must proceed on the assumption that States who are already bound by international legal obligations to protect and promote human rights would not enter into other treaties, such as the WTO agreements, with the intent of violating those existing obligations, which are of the highest order, derived as they are from the UN Charter and the Universal Declaration on Human Rights (UDHR)[116] and International Covenant on Economic, Social and Cultural Rights (ICESCR).[117] One such principle directly relevant to the question of interpreting the TRIPs Agreement in the light of international human rights law is the general principle of *in dubio mitius*, which holds that restrictions upon States' sovereignty as independent states cannot be presumed; States can only be presumed to have given up their discretion to act if they have explicitly consented to such restrictions. This principle has been interpreted to mean that "if the wording of a treaty provision is not clear, in choosing between several admissible interpretations, the one which involves the minimum of obligations for the parties should be adopted."[118]

B. *Basic Ingredients of the Interpretation*

Article 30 does not enumerate the scope of exceptions that were under negotiation at WIPO and GATT during the Uruguay Round. On the contrary, Article 30 is formulated as a balance of factors among stakeholders. Discretion whether to use the exceptions under Article 30 should be in the hands of the Member that would grant the compulsory licensing. However, the following content of the interpretation would help prevent Members from fully carrying out obligations to protect intellectual property rights under the TRIPs Agreement.

1. Pharmaceutical Product Coverage

Article 30 authorizes "limited exceptions," meaning that Members may deviate from general rules of the patent protection under the TRIPs Agreement within the established legal boundaries. When a WTO Member uses "limited exceptions" under Article 30 of the TRIPs Agreement,

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[115] Cattaneo, *supra* note 93, at 670.

[116] Universal Declaration of Human Rights, G.A. Res. 217 U.N. GAOR, 3d Sess., at 71, U.N. Doc. A/810 (1948).

[117] International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc. A/6316 (1966).

[118] *See* Frontier between Turkey and Iraq (Turkey v. Iraq), 1925 P.C.I.J. (ser. B) No. 12, at 25 (Nov. 21, 1925).

it is of great significance to determine the coverage of the exporting pharmaceutical products in order to guarantee that this action does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner. The WHO Report observes:

> 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.[119]

The African group argued that the coverage should include medicines, related technical processes, and related technical equipment, whereas some WTO Members, for example Japan, maintained that the scope of the products should be limited to the treatments of diseases listed in the Declaration, namely HIV/AIDS, malaria and tuberculosis.[120] On one hand, a broad-based scope of products may prejudice the legitimate interests of the pharmaceutical product patent owner and discourage new research and development for new drugs. On the other hand, a narrow-based scope of products merely covering the treatments of HIV/AIDS, malaria and tuberculosis may impede the resolution of public health crises resulting from diseases other than the aforementioned. The Doha Declaration does not refer only to situations that relate to serious public health problems like HIV/AIDS, malaria and tuberculosis, but it relates also to all other public health policy problems.[121] Paragraphs 4 and 5 recognize the need for flexibility for this purpose, including the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[122] Therefore, the best coverage should be refined to the patented pharmaceutical products conducive to addressing public health problems. In addition, the patented pharmaceutical products associated with the treatments of HIV/AIDS, malaria and tuberculosis should be afforded considerable importance. While the

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[119] *See* Essential Drugs and Medicines (EDM), *supra* note 29, at 21.

[120] *See* Note by the Secretariat, *Proposals on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, IP/C/W/363, at 4 (July 11, 2002).

[121] Doha Declaration, *supra* note 4, para.1.

[122] *Id.* paras. 4, 5.

TRIPs Council determines the scope of the products, it could make reference to the Essential Drugs List issued by WHO.[123]

2. Eligible Beneficiary Importing Members

Due to insufficient GNP, limited government financial capacity, and a lack of well-established pharmaceutical industries and sophisticated pharmaceutical technologies, many developing country Members, especially least-developed country Members, should be the beneficiary importing Members. These eligible developing country and least-developed country Members are vulnerable to grave public health crises yet have insufficient or no manufacturing capacities in the pharmaceutical sector. Since none of the developed country Members face the above mentioned difficulties, developed country Members should not be included in this scope.

Least-developed country Members listed in the report annually issued by the World Bank should be deduced automatically to have insufficient or no manufacturing capacities in the pharmaceutical sector. Secondly, as to developing country Members, it is appropriate to allow these Members to determine whether they have insufficient or no manufacturing capacities in the pharmaceutical sector. These Members should then promptly submit reports on the assessment of their manufacturing capacities of certain pharmaceuticals that address their domestic public health problems.

3. Eligible Exporting Members

Clearly, the Doha Declaration was directed at the needs of developing and least-developed Members. Therefore, it would seem appropriate that the solution be limited to developing and least-developed Members. Failure to do so would undermine what potential there could be under the solution for deserving Members to expand their pharmaceutical production capacity by supplying other developing and least-developed Members. If the solution were available to producers in the developed world, there might be little opportunity for producers in developing and least-developed Members to supply pharmaceuticals under this mechanism.

Owing to the fact that the vast majority of low-price generic drugs are produced in some developing country Members, the eligible exporting Members should include developing country Members with sufficient manufacturing capacities in the pharmaceutical sector as requested by the eligible exporting Members that are afflicted with grave public health problems. If the supply of certain pharmaceuticals were beyond the manufacturing capacities in developing country Members, a requesting country would need to have its medicines supplied by a developed country Member.

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[123] *See* Essential Drugs and Medicines (EDM), *The WHO Model List of Essential Medicines*, *at* http://www.who.int/medicines/organization/par/edl/eml.shtml (last visited May 8, 2003).

Article 31(h) of the TRIPs Agreement ambiguously provides that, in light of a compulsory license, the right holder will be paid adequate remuneration in the circumstances of each case.[124] In light of the term "limited exceptions" used in Article 30, analogous with granting compulsory licenses, the right holder also should be appropriately compensated. Although there is an inherent contradiction between the use of "limited exceptions," which aims to increase competition and public welfare, and a profit-based standard for compensation that would preserve the monopoly right of the patent,[125] the patent holder should be willing to accept remuneration lower than normal in the case of WTO Member's use of "limited exceptions" to address public health problems.

Article 30 is silent on the issue of remuneration and it neither compels nor prohibits Members from establishing a form of compensatory adjustment when using the exception rules contained in their domestic patent laws. In order to obviate the problem of double remuneration, the burden should fall on the exporting Members to make effective use of "limited exceptions." The TRIPs Council should establish guidelines for calculating remuneration. Simultaneously, it is important to establish an international fund to financially assist the exporting Members that assume the remuneration burden.

4. Reasonable Safeguards Against Trade Diversion

Reasonable safeguards against trade diversion aim at preventing Members from abusing rights that would undermine the legitimate interests of related right holders. The exporting Members shall ensure that the entirety of the requested production is directly exported to the eligible importing Members and prevent diversion of the relevant pharmaceuticals into their domestic markets. In addition, these Members shall make a binding confirmation regarding the quality and delivery condition of the relevant pharmaceuticals. Meanwhile, the importing Members should take necessary measures to ensure that pharmaceutical products are domestically sold or distributed and not re-exported to other Members.

5. Establishment of Transparent Procedures

Considerable importance should be attached to the establishment of a set of fully transparent procedures for the purpose of keeping a balance of rights and obligations in the intellectual property protection system and accelerating the pace of addressing public health problems. Both importing and exporting Members shall carry out the obligations of publication and notification of relevant information, and provide consulting service under Article 63 of the TRIPs Agreement. The procedures state

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[124] TRIPs Agreement, *supra* note 1, art. 31(h)

[125] *See* Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement—Two Proposals*, 4 J. WORLD INTELL. PROP. 323, 331 (2001).

that importing Members should provide information pertaining to the granting of compulsory licenses on the basis of public health needs and the assessment of their manufacturing capacities in the pharmaceutical sector to the TRIPs Council in the shortest time possible. Equally, the exporting Members should provide information to the TRIPs Council, without any delay, pertaining to the request of the importing Members and the process of manufacturing and delivering pharmaceuticals. Therefore, with the foregoing publicly available information, both the TRIPs Council and the interested Members will be kept well-informed and can monitor the on-going actions.

VI. CONCLUSION

Intellectual property protection under the TRIPs Agreement, whose very function is to promote the innovation and marketing of new drugs by providing incentives for research and development, is legitimate when it completely takes the developing country Members' essential interests into account and improves their access to essential drugs. Intellectual property protection should keep a balance between the need to provide incentives to reward and spur innovation and the need to ensure that society benefits from having maximum access to new creations. Just as too little protection of intellectual property rights can impede innovation and trade, so can too much protection undermine fundamental human rights.

It should be noted that, while emphasizing the scope in the TRIPs Agreement to take measures to promote access to medicines, the Doha Declaration also recognizes the importance of intellectual property protection for the development of new medicines and reaffirms the commitments of WTO Members in the TRIPs Agreement. In fact, many developing country Members with insufficient or no manufacturing capacities in the pharmaceutical sector would face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. In light of this fact, the solution to this issue should ensure that those Members will have access to essential drugs on one hand, and should keep incentive to research and develop new drugs on the other hand. Given the merits of the Article 30-based solution as discussed in the proceeding analysis, the TRIPs Council should adopt this solution and make relevant interpretation pertaining to the exceptions contained in this article.