

TRIPS, ACCESS TO MEDICINES AND THE “NORTH-SOUTH” CONFLICT AFTER DOHA: THE END OR THE BEGINNING?

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INTRODUCTION

THE AGREEMENT ON *TRADE-RELATED ASPECTS of Intellectual Property Rights (TRIPS)*¹ is widely recognized as having established new patterns of Intellectual Property (IP) protection, especially regarding patent protection.² The abundant literature discussing *TRIPS* repeatedly emphasizes the tension between developed and developing countries' positions on an effective level and adequate scope of international IP protection,³ and the question of who will define “adequate” is a recurring theme.

Setting new, much stronger standards of IP protection (especially in comparison to the previous level set by WIPO Conventions),⁴ *TRIPS* sharpened and intensified the strain between IP rights, particularly patents on pharmaceuticals and public health issues. The mechanisms of exception from patent protection provided in *TRIPS*, such as a compulsory license mechanism, proved unworkable for developing countries lacking sufficient manufacturing capacity.⁵ This controversy resulted in the Doha Declaration on *TRIPS* and Public Health (Doha

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¹ WTO, *Trade-Related Aspects of Intellectual Property Agreement*, 15 April 1994, arts. 1-2, online: WTO <http://www.wto.org/english/docs_e/legal_e/27-TRIPS_01_e.htm> [*TRIPS*].

² Leslie Gladstone Restaino & Katrine A. Levin, “Accord may provide means to stop copycat drugs: Under *TRIPS* Agreement, WTO has more power to pressure countries not in compliance” (14 May 2001) 23:38 Nat'l. L. J. C6., Col.1 at 2-3.

³ Frederick M. Abbot, “The *TRIPS* Agreement, Access to Medicines and the WTO Doha Ministerial Conference” Occasional Paper 7 Quaker UN Office (8 September 2001) at 3, online: Medecins Sans Frontieres <<http://www.accessmed-msf.org/upload/ReportsandPublications/19920011223306/Fred%20Abbott%20paper%20on%20TRIPS.pdf>>.

⁴ Monique L. Cordray, “GATT v. WIPO” (1994) 76 J. Pat & Trademarks Off. Soc'y 121 at 124-25.

⁵ Thomas A. Haag, “*TRIPS* Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?” (2002) 84 J. Pat. & Trademark Off. Soc'y 945 at 950.

Declaration).⁶ It was adopted primarily as a response to developing countries' demands to respond to public health crises and to make a compulsory license mechanism under *TRIPS* workable, which would allow countries lacking sufficient pharmaceutical manufacturing capacities to import generic versions of patented drugs.

This paper investigates the balance between IP protection, particularly the balance between pharmaceutical patents and public health issues, reached as a result of the Doha Declaration. Part I analyzes the process of *TRIPS*' creation, stressing the tension between the interest of developed nations in strengthening IP protection to combat trade in counterfeit goods and intellectual property rights (IPR) infringement that deter investments in the development of IP-related products, and developing countries' interest in providing access to affordable drugs in times of public health crises. Part II examines this balance as established by the *TRIPS Agreement*. Part III focuses on the Doha Declaration and its attempt to balance patent rights with access to affordable pharmaceuticals in public health crises. The World Trade Organization (WTO) General Council decision of 30 August 2003 was supposed to implement the Doha Declaration's instructions in regards to the problem of developing countries' inability to provide affordable drugs in cases of public health emergencies. This paper concludes that due to its vague language and lack of clearly outlined mechanism, the decision failed to achieve the appropriate balance between the interests of developed and developing countries. Therefore, the problem of developing countries' inability to use the compulsory license mechanism proposed in *TRIPS* was not solved, but has been reiterated.

I. INTELLECTUAL PROPERTY RIGHTS PROTECTION PRIOR TO *TRIPS*

THE AGREEMENT ON *TRADE-RELATED ASPECTS of Intellectual Property Rights (TRIPS)* was enacted on 1 January 1995, as a part of the Final Act of the new *WTO Agreement*. It emerged from the Uruguay Round of trade negotiations on the *General Agreement on Tariffs and Trade (GATT)*.⁷ *TRIPS* is considered to be the only multilateral agreement that creates minimum standards of international IPR

⁶ WTO, *Declaration on the TRIPS agreement and public health*, WTO Doc. WT/MIN(01)/DEC/2 (2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.htm>[*Doha Declaration*].

⁷ The trade negotiations of the Uruguay Round occurred between 1986 - 1994, concluding with the formation of the WTO and signing of the Final Act on April 1994 at the ministerial meeting in Marrakesh (Morocco). See "WTO legal texts," online: WTO <http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPS>.

protection, providing a relatively detailed and specific enforcement system and applying the WTO's dispute settlement system to IP-related disputes.⁸

a) WIPO-Regulated Intellectual Property Conventions: Virtues and Flaws

The World Intellectual Property Organization (WIPO) Convention, which created WIPO, came into force in 1970.⁹ As of today, 183 States are members of WIPO. Its two primary objectives are the global promotion and protection of IP rights and the administration of IP Unions, such as the *Paris Convention for the Protection of Industrial Property* (1883) (*Paris Convention*) and the *Berne Convention for the Protection of Literary and Artistic Works* (1886) (*Berne Convention*).¹⁰

The *Paris Convention* offers a broad interpretation of the "industrial property" it applies to, including patents, utility models, industrial designs, trademarks, trade names, service marks, and others.¹¹ One of the most important clauses provided by the Convention is the national treatment clause in regard to persons (as opposed to the national treatment clause provided in *GATT* in regard to goods), stating that nationals of any country of the Union (and some countries outside the Union¹²) enjoy the same level of IPR protection as nationals of the host-country according to its national laws.¹³ The main criticism of the national treatment clause is that if a country provides no IP protection to its nationals, it has no obligation to provide any protection for the nationals of other countries.¹⁴

In relation to patents, the *Paris Convention* also created the possibility of granting compulsory licenses to prevent the abuses in

⁸ WTO, "Overview: the TRIPS Agreement," online: WTO <http://www.wto.org/english/tratop_e/TRIPS_e/intel2_e.htm>.

⁹ *Convention Establishing the World Intellectual Property Organization*, Stockholm 14 July 1967, art. 1, online: WIPO <http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html>.

¹⁰ See also "Basic Facts about WIPO," online: WIPO <http://www.wipo.int/about-wipo/en/gib.htm#P29_4637>.

¹¹ *Paris Convention for the Protection of Industrial Property*, signed on 20 March 1883, arts. 1 (2)-(3) online: WIPO <http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P71_4054> [*Paris Convention*].

¹² *Ibid.*, art. 3.

¹³ *Ibid.*, art.2(1).

¹⁴ *Supra* note 4 at 123.

exercising exclusive rights,¹⁵ but it was heavily restricted to certain cases only.¹⁶

Contrary to the *Paris Convention*, the *Berne Convention* (which concentrates mostly on copyrights) determines minimum standards of protection¹⁷ and defines the term of protection for IP.¹⁸ Similar to the *Paris Convention*, the *Berne Convention* provides for national treatment. The *Berne Convention's* national treatment clause is considered to be more efficient than the *Paris Convention*. Under the *Berne Convention*, the protection of author's rights in each member country should be unconditional and independent of the existence of such protection in the country of origin.¹⁹

One of the most controversial issues, particularly for developed countries, is the lack of effective enforcement mechanisms under the WIPO Unions.²⁰ The United States General Accounting Office Report describes WIPO's attempts to ensure strong worldwide IP protection as "unsuccessful," and tends to accuse developing countries of attempting to weaken the level of international IP protection.²¹

With respect to dispute settlement, both the *Paris* and *Berne Conventions* refer disputes to the International Court of Justice.²² However, both Conventions allow members to declare the provisions as non-binding.²³ Quite apart from the political and diplomatic considerations (*i.e.*, the affected country perceiving this as an unfriendly gesture), the length and complexity of the procedure itself turns the mechanism into a *de facto* impractical one.²⁴ On the other hand, weak

¹⁵ *Paris Convention*, *supra* note 11, art. 5A(2).

¹⁶ *Ibid.*, art. 5A(4).

¹⁷ *Berne Convention for the Protection of Literary and Artistic Works*, 9 September 1886, art. 2(1), online: WIPO <http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html#P492_95713> [*Berne Convention*].

¹⁸ According to the *Berne Convention*, literary and artistic work of the author is protected during the author's life and for 50 years after his death. *Ibid.*, art. 7.

¹⁹ *Ibid.*, art. 5 and Summary of the *Berne Convention*, online: WIPO <http://www.wipo.int/treaties/en/ip/berne/summary_berne.html#f1>.

²⁰ *Supra* note 4 at 131.

²¹ U.S., General Accounting Office, *Report to Selected Congressional Subcommittees: International Trade: Strengthening Worldwide Protection of Intellectual Property Rights* (NSIAD-87-65) (Washington, D.C.: United States General Accounting Office, April 1987) at 25, online: The Government Accountability Office <<http://archive.gao.gov/d2t4/132699.pdf>>.

²² Unless the countries involved in a dispute agree on some other method of settlement. See *Paris Convention*, *supra* note 11, art. 28(1) and note 17, art. 33(1).

²³ *Paris Convention*, *supra* note 11, art. 28(2) and *Berne Convention*, *supra* note 17, art. 33(2).

²⁴ *Supra* note 4 at 131.

or almost non-existent enforcement and dispute resolution mechanisms, along with the national treatment clause, might be considered as an expression of the right of a country to adhere to certain political, economic, and social systems as the State sees fit.²⁵ Moreover, State sovereignty grants the country a right to decide which level of IP protection to provide within its own territory.²⁶ Some conclude that neither of the WIPO Conventions, and specifically not the *Paris Convention*, would have been adopted had it not been for their flexible regimes, as there was much disagreement among member States over the suitable multilateral level of IP protection.²⁷

b) Intellectual Property Protection under GATT (1947)

One of the main objectives of the earliest *GATT Agreement (1947)* was to provide a multilateral trading system with minimum barriers to trade.²⁸ The essential principles of this “old” *GATT* were the most favoured nation principle (any favour or privilege granted to one contracting party should be granted to all contracting parties),²⁹ national treatment clause (no less favoured treatment to a foreigner than the one provided to a national),³⁰ trade liberalization and transparency of trade rules.³¹

With such a clear intent to protect trade, the only mention of IPR protection in the *GATT* was a mere hint that the Contracting Party may adopt measures for the protection of patents, trademarks and copyrights, as well as measures against trade in counterfeit goods, only if they are

²⁵ R. Dhanjee & L. Boison de Chazournes, “Trade Related Aspects of Intellectual Property Rights (*TRIPS*): Objectives, Approaches and Basic Principles of the *GATT* and of Intellectual Property Conventions” (1990) 24:5 *J. World Trade* 5 at 6.

²⁶ *Ibid.*

²⁷ According to this argument, the only chance to establish some IP rules, rather than discard the whole idea of international IP protection, was to allow States (being in different levels of development) the freedom to adhere to their chosen economic and political regimes). *Ibid.* at 7.

²⁸ *Ibid.* at 6, also see “. . . Being desirous of contributing to these objectives by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce . . .” See *General Agreement on Tariffs and Trade*, 30 October 1947, 58 U.N.T.S. 187, Can.T.S. 1947 No. 27, (entered into force 1 January 1948), online: WTO <http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm> [*GATT 1947*].

²⁹ *GATT 1947, ibid.*, art. I(1).

³⁰ *GATT 1947, ibid.*, art. III(1).

³¹ Adrian Otten, “The Trade-Related Intellectual Property Rights Agreement (*TRIPS*)” (Video presentation WTO Webcasting), online: WTO <http://www.wto.org/english/res_e/webcas_e/webcas_e.htm#TRIPS>.

“necessary to secure compliances with laws or regulations which are not inconsistent with the provisions of this Agreement . . .”³² In other words, only when these measures do not pose any barrier to free trade are they allowed to be pursued. Therefore, it might be concluded that *GATT* considered IP protection as an obstacle to trade and, therefore, addressed IP issues as a secondary matter, while its primary concern was trade in tangible, not intangible (IP) goods.³³

One of the main reasons that the U.S. insisted on incorporating IPR protection in the Uruguay Round of trade negotiations in the new *GATT 1994* was the relatively effective dispute settlement and enforcement mechanisms provided by *GATT*. Dispute settlement mechanisms that were in existence at the launch of the 1986 Uruguay Round had gradually developed on the basis of Articles XXII – XXIII of *GATT 1947*.³⁴ An effective measure available under Article XXIII(2) is a suspension of the application of any concession or obligation that the offending country was entitled to under the Agreement.³⁵

Although *GATT*'s dispute settlement regime was more efficient than the WIPO dispute settlement mechanism, it retained its deficiencies. A major flaw was a consensus requirement to refer a dispute to a panel of experts. Parties to the dispute could participate in the dispute settlement process and, therefore, could successfully block a decision to refer the dispute to the panel.³⁶

c) United States Efforts to Strengthen the Level of International Intellectual Property Protection

Ever since the Diplomatic Conference for the Revision of the Paris Convention for the Protection of Industrial Property (Paris Convention Conference held in 1980-1984 under a patronage of WIPO), in which

³² *GATT 1947*, *supra* note 28, art. XX(d).

³³ *Supra* note 25 at 6-7.

³⁴ While art. XXII(2) established a mechanism for consultations between the contracting parties if a “satisfactory solution” to a dispute had not been found prior to that, art. XXIII provided a mechanism that allowed contracting parties to settle disputes arising between other contracting parties. The contracting parties that participated in a dispute settlement procedure of other parties’ dispute produced a report that was to be adopted consensually. This dispute settlement regime evolved to another version of dispute resolution procedure where, instead of contracting parties, a panel of independent experts prepared reports including their recommendations that were submitted to the *GATT* Council. See WTO, “Historic development of the WTO dispute settlement system,” online: WTO <http://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c2s1p1_e.htm>.

³⁵ *GATT 1947*, *supra* note 28, art. XXIII(2) and *supra* note 4 at 133.

³⁶ *Supra* note 31 and note 4 at 133.

fundamental disagreements among the parties as to the scope and application of IP protection were revealed anew, the U.S. began to revise its IP policy.³⁷ While developing countries argued that the international standards of patent protection under the *Paris Convention* were too high to allow a proper balance between the protection of patent holders' rights and public interests with economic development requirements, the U.S. attempted to create a global system of IP protection to prevent trade in counterfeit goods.³⁸ During the *Paris Conference*, developing countries proposed the revision of the existing IPR system to achieve differential treatment and to weaken global IP protection.³⁹ Despite its explicit protest, the U.S. (along with the UK) failed to advance its agenda of strengthening the international IP level.⁴⁰

Meanwhile, the U.S. recognized the increasing impact of foreign piracy on the U.S. economy.⁴¹ With huge investments in research and development and as the largest producer of copyrighted works, the U.S. realized that better protection of IP was necessary both within the U.S. and abroad.⁴² New technologies allowed for the relatively easy and rapid spread of pirated copies of innovations.⁴³ The U.S. General Accounting Office report of April 1987 officially recognized that:

. . . such piracy

- (1) limits the ability of firms and individuals to obtain returns on their investments of time and resources in developing patented innovations, trademarked products, and copyrighted works,
- (2) deprives legitimate businesses of sales, profits, and the ability to provide employment, and
- (3) can threaten public health and safety.

In the long term, piracy undermines the patent and copyright systems as mechanisms for encouraging

³⁷ Susan K. Sell, "Intellectual Property as a Trade Issue: From the Paris Convention to GATT" (1989) 13:4 Legal Studies Forum 407.

³⁸ The attempts to prevent trade in counterfeit goods started at the Tokyo Round of Trade Negotiations of GATT (1973-1979), but failed due to developing countries' opposition. Based on Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd ed. (London: Sweet & Maxwell, 2003) at 7-8.

³⁹ Sell, *supra* note 37 at 409-10.

⁴⁰ *Ibid.* at 410-11.

⁴¹ *Ibid.* at 411.

⁴² Richard A. Morford, "Intellectual Property Protection: A United States Priority" (1989) 19:2 Ga. J. Int'l & Comp. L. 336.

⁴³ *Ibid.*

innovation and creativity and the trademark system as an indicator to consumers of quality products and services.⁴⁴

According to the International Trade Commission, foreign infringements of IPR caused estimated losses of 43-61 billion dollars to U.S. companies.⁴⁵

There were numerous additional developments and a number of interrelated reasons, both within the U.S. and within the multilateral and bilateral levels, for raising IP issues in the 1996 Uruguay Round of *GATT* negotiations. One major development was the creation of the Intellectual Property Committee (IPC) in March, 1986.⁴⁶ As well, bilateral consultations were initiated by the U.S. with countries that had unsatisfying (according to the U.S.) levels of IP protection.⁴⁷ Additionally, the U.S. extended the Generalized System of Preferences for developing countries under the *Trade and Tariff Act* of 1984.⁴⁸ On 23 August 1988,

⁴⁴ *Supra* note 21. The report presents compelling data showing that combined losses of 82 firms that suffered from foreign piracy, and especially from unauthorized use of patents, accounted for \$50 million in lost sales during 1982. According to the International Intellectual Property Alliance (IIPA), piracy of copyrighted works in ten different countries amounted to \$1 billion in losses as compared to 1985. The Pharmaceutical Research and Manufacturers Association of America (PhRMA) reported the same statistics in 1985, stating that one of its member-companies lost \$27 million in potential sales on one patented product because unlicensed copies were sold in five developing countries.

⁴⁵ *Supra* note 42 at 336-37.

⁴⁶ Being a coalition of 12 major U.S. companies from various IP-oriented industries including Bristol-Myers, DuPont, FMC Corporation, General Electric, Hewlett-Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer, Rockwell International, Warner Communication, the IPC's first and foremost goal was to act towards an enclosure of the IP protection issues in the Uruguay Round. After the Uruguay Round launched, the IPC along with European and Japanese business groups worked closely on convincing the international community of the necessity of the multilateral IP agreement in GATT framework. See Carol J. Bizli, "Towards an Intellectual Property Agreement in the GATT: View from the Private Sector" (1989) 19:2 Ga. J. Int'l & Comp. L. 343; *supra* note 4 at 137-38.

⁴⁷ In these countries, piracy and the unauthorized use of patented inventions have raised concerns of American manufacturers; therefore, to make these countries revise their IP policies, the U.S. threatened with various trade sanctions, which were effective enough to bring Hungary, Taiwan, and Singapore to strengthen the IP protection in their national laws. See Sell, *supra* note 37 at 414-15.

⁴⁸ Under the new conditions, the U.S. President could determine if a country whose IP laws succeeded to provide effective IP protection to foreign nationals was a beneficiary developing country. As a result, such a country could enjoy various benefits in tariffs and trade transactions with the U.S. See *Trade and*

President Reagan signed the *Omnibus Trade and Competitiveness Act*.⁴⁹ These amendments granted the U.S. Trade Representative (USTR) the power to identify “priority foreign countries”⁵⁰ that have “the most onerous or egregious”⁵¹ IP policies and, therefore, deny adequate IP protection to the U.S. right owners trading with them. “Special 301” empowered the USTR to retaliate against these countries through various trade sanctions.⁵² Therefore, by incorporating various trade sanctions and amending trade laws to increase the enforcement of new IP policy, the U.S. obviously sought an opportunity to connect IP issues to trade issues.⁵³ The wide-scale GATT agenda⁵⁴ was the perfect forum for the U.S. to enhance IP issues from intangible rights with minimum enforcement to trade-related issues connected to the GATT’s relatively effective enforcement and dispute resolution mechanisms and GATT’s “more fluid mechanism for adopting new measures . . .”⁵⁵

d. Emergence of the TRIPS Agreement in the Uruguay Round of Trade Negotiations

The question that should be asked and answered next is whether connecting IP rights to trade issues was the right thing to do. In other

Tariff Act of 1984, Pub. L. 98-573, 98 Stat. 2948, (passed as H.R. 3398) and also Sell, *supra* note 37 at 418.

⁴⁹ *Omnibus Trade and Competitiveness Act* of 1988, Pub. L. No. 100-418. [*Omnibus Act of 1998*]. Paragraphs 1301 and 1303 of *Omnibus Act of 1998* amended sections 301 and 182 of the *Trade and Tariff Act* of 1974 respectively (amendments known as “Super 301” and “Special 301,” 19 U.S.C. § 2420 (a)-(b) and 19 U.S.C. § 2242 (respectively). See also Dylan A. MacLeod, “U.S. Trade Pressure and the Developing Intellectual Property Law of Thailand, Malaysia and Indonesia” (1992) 26:2 U.B.C.L.Rev.343 at 346-48.

⁵⁰ 19 U.S.C. § 2242 (a)(2).

⁵¹ *Ibid.*, § 2242 (b)(1)(A).

⁵² *Ibid.*, § 2242 (b)(1) and also Judith H. Bello & Alan H. Holmer, “Update: Special 301” (1990-1991) 14 *Fordham Int’l L. J.* 874 at 874-75 and Susan Sell, “Post-TRIPS developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property” (2001-2002) 14 *Fla. J. Int’l L.* 193 at 197 [Sell, “Post-TRIPS developments”].

⁵³ Solomon F. Balraj, “General Agreement on Tariffs and Trade: The effect of the Uruguay Round multilateral trade negotiations on US intellectual property rights” (1992) 24:1 *Case W. Res. J. Int’l L.* 63.

⁵⁴ TRIPS negotiating group was one of 14 negotiating groups on various topics that were established under the Group of Negotiation on Goods, which reported to the highest body — the Trade Negotiations Committee — that supervised all of the Negotiations. See Gervais, *supra* note 38 at 12.

⁵⁵ Based on *supra* note 4 at 139.

words, was the GATT negotiations forum the right forum for raising IP issues?

On 11 April 1986, the U.S. (along with Japan) submitted a wide-scale proposal to the Preparatory Committee.⁵⁶ The Committee was to recommend the general program of negotiations and effectively establish the basis of discussions at the Ministerial Conference.⁵⁷ While for the U.S. the inclusion of IP issues in the GATT agenda was the foremost condition for participation in the negotiations, many participating countries (mostly developing ones) were absolutely opposed to linking IP protection to trade issues.⁵⁸ Developing countries claimed time and again that State sovereignty extended to the right to decide the appropriate level of IP protection available within a State's territory.⁵⁹ Moreover, they questioned the economic profitability of stronger IP protection and argued that the GATT forum was not the correct forum for the evolution of IP issues.⁶⁰

The fundamental differences between the developed countries⁶¹ and underdeveloped countries (led by Brazil and India) were not settled during the Preparatory Committee's meetings prior to the launch of the Uruguay Round.⁶² Eventually, the text of Colombia and Switzerland was adopted as a basis for a future Ministerial Declaration conferring the

⁵⁶ Gervais, *supra* note 38 at 10.

⁵⁷ WTO, *Decision on the Establishment of the Preparatory Committee for the World Trade Organization* at para. 8(c), online: WTO <http://www.wto.org/English/docs_e/legal_e/58-dpcwto_e.htm>.

⁵⁸ The group of countries named "the group of ten" (ten developing countries) submitted a draft communication to the Preparatory Committee, in which the countries argued against the inclusion of the IP issues in the GATT Negotiations. See Azza El Shinnawy, "A Reading into the TRIPS Track Road" (Autumn 2003) 10:3 Newsletter of the Economic Research Forum, for the Arab Countries, Iran & Turkey, online: the Estuarine Research Federation <http://www.erf.org.eg/nletter/Newsletter_Vol10_Autumn03/P16-17.pdf> and also Chakravarthi Raghavan, News Release, "New Efforts of Consensus over Ministerial Meeting?" *International Foundation for Development Alternatives* (26 August 1986), online: South-North Development Monitor <<http://www.sunsonline.org/trade/process/during/86/08280086.htm>>.

⁵⁹ Frank Emmert, "Intellectual Property in the Uruguay Round - Negotiating Strategies of the Western Industrialized Countries" (1989-1990) 11 Mich. J. Int'l L. 1317 at 1353-354.

⁶⁰ *Ibid.* at 1358-359.

⁶¹ The group of developed countries expanded later to the "group of forty," including industrialized as well as 20 developing countries, chaired by Colombia and Switzerland. See T. N. Srinivasan, *Developing Countries and the Multilateral Trading System - from GATT to the Uruguay Round and the Future*, (Delhi: Oxford University Press, 1998) at 30-31.

⁶² *Ibid.*

mandate for the Uruguay negotiations.⁶³ This proposal extended the scope of topics in GATT negotiations to “trade-related aspects of intellectual property rights, including trade in counterfeit goods” but only where the measures to enforce IPR “do not themselves become barriers to legitimate trade.”⁶⁴

The fact that no basic consensus was reached regarding the scope of the issues to be included in the mandate of the future Ministerial Conference had not influenced the outcome of the Preparatory Committee’s meetings, for TRIPS was nonetheless included in the agenda that resulted from the Preparatory Committee’s report. However, the dilemma of GATT as the right forum for strengthening the global level of IP protection remained unresolved and, therefore, a more profound analysis of countries’ positions became necessary. No consensus on this issue was reached in the Punta Del Este Ministerial meeting that launched the Uruguay Round either; the only solution the Ministers were able to achieve was the adoption of a solution proposed by the Group of Experts.⁶⁵ This decision stressed that the existing provisions of WIPO treaties were not sufficient to protect contracting parties from the growing impact of trade in counterfeit goods and that there would be a need to create an effective regime of IP protection.⁶⁶ However, the decision had also determined, once again, that a measure of protection against trade in counterfeit goods should not pose a barrier to legitimate trade.⁶⁷

The question of an appropriate scope of IPR that should be included in the GATT framework was discussed again at the very beginning of discussions of the Negotiation Group on Trade-Related Aspects of IPR, including Trade in Counterfeit Goods.⁶⁸ During the meeting, numerous countries stated that the Negotiating Group (NG) should seek a proper

⁶³ Gervais, *supra* note 38 at 10-11.

⁶⁴ GATT, *Ministerial Declaration on the Uruguay Round*, MIN.DEC of 20 September 1986, online: GATT <<http://gatt.stanford.edu/bin/object.pdf?91240152>> [*Ministerial Declaration on the Uruguay Round*] and Gervais, *supra* note 38 at 10-11.

⁶⁵ The group of experts was created in 1984 following a Ministerial Declaration adopted in the 38th Session at Ministerial Level in November 1982 in Geneva. See GATT, *Ministerial Declaration, Quantitative restrictions and other non-tariff measures* (29 November 1982), 38th Sess., online: <<http://www.jus.uio.no/lm/wto.gatt.thirty.eighth.session.ministerial.declaration.1982/non.tariff>> and also *supra* note 53 at 63.

⁶⁶ Gervais, *supra* note 38 at 8-9.

⁶⁷ Ministerial Declaration on the Uruguay Round, *supra* note 64. See also Gervais, *supra* note 38 at 8-9.

⁶⁸ WTO, Meeting of the Negotiating Group (held on 23 September 1987), WTO Doc. MTN.GNG/NG11/3 (8 October 1987), online: WTO <<http://docsonline.wto.org>>.

balance between adequate IP protection and its effective enforcement and the risk that such protection would pose a barrier to international trade.⁶⁹ However, the NG is entitled to consider “the whole range of intellectual property protection rights,” as opposed to only specific aspects.⁷⁰ Several participants were of the opinion that the mandate given to the NG by the Ministerial Declaration of Punta Del Este did not allow the discussion to evolve beyond trade in goods. Therefore, in their view, the NG was not authorized to deal with such issues as setting a higher level of IP protection or strengthening the enforcement procedures. The advocates of the narrow approach claimed that the only aspects of IP that the Negotiating Group was authorized to discuss were the consequences of IPR protection on trade in goods where they caused barriers to legitimate trade.⁷¹ Some participants argued that connecting GATT’s mandate with the relevant provisions of WIPO treaties on IPR protection would be totally inappropriate and would lead to the wide-range “code approach” to GATT, which was not quite the desired result.⁷²

During the period of the Secretariat’s examinations, the negotiations progressed very slowly.⁷³ The age old differences between developed countries (the U.S., Switzerland, the EU, and Japan) desiring broad IP protection, and developing countries (Thailand, Mexico, and Brazil) fearing that strong IP protection would deter technology transfer and increase prices of goods (including drugs), remained unresolved for the most part.⁷⁴ Nor at the later conference in Montreal could substantial agreement be achieved on the text.⁷⁵

In light of the final results — the broad scope of the IP protection constituted in *TRIPS* — it could be stated that from the beginning, developing countries had no real choice but to succumb to the pressure of developed countries. Therefore, the question of whether the GATT forum was indeed the right forum to strengthen international IP standards is doomed to stay a matter of opinion. Obviously, the answer to this question would depend on a State’s disposition on the map of

⁶⁹ *Ibid.*

⁷⁰ WTO, *Meeting of the Negotiating Group* (held on 25 March 1987), WTO Doc. MTN.GNG/NG11/1 (10 April 1987) at 2, online: WTO <<http://docsonline.wto.org>>.

⁷¹ *Ibid.*

⁷² *Ibid.* Being the only multinational agreement that set up international trade rules, GATT not only served as a code of rules but also allowed parties to negotiate on adding and improving such rules in order to reduce barriers to international trade. GATT also provided a broad exposure of various trade-related aspects, therefore offering a possibility for package deals, *i.e.*, making concessions in more developed areas of trade. See *supra* note 59 at 1344-345.

⁷³ Gervais, *supra* note 38 at 13-14.

⁷⁴ *Ibid.* at 13-14.

⁷⁵ Srinivasan, *supra* note 61 at 33.

international trade. IP issues were akin to some “abstract” unsubstantial issues under the WIPO Conventions. After the Uruguay Round, IP issues became related to trade and turned into a “trade-related” topic in the frame of the wide-ranging GATT agenda. Moreover, the IPR issue became connected to the GATT’s enforcement and dispute resolution mechanisms, which obliged more than one hundred member states of the newly created WTO. It can be stated that this transformation definitely served the economic interests of developed countries (hosting most of the IPR owners). Did it also serve the economic interests of developing countries? Not likely, at least not in the short-term. The WIPO Conventions had no intention of establishing multilateral trade rules, but instead sought to lessen possible conflicts between the members as a result of different national IP regimes.⁷⁶ In doing so, they allowed the countries as much freedom as possible (considering their weak enforcement system) to implement IP laws as they saw fit, based on national treatment and non-discrimination clauses.⁷⁷ There are opinions that numerous developing countries agreed to sign *TRIPS* hoping that this would finally satisfy U.S. (particularly, U.S.-based multinational corporations) plans for reaching a high level of international IP protection.⁷⁸

Interestingly enough, the same argument that had been used by developing countries as a contra-argument to the inclusion of IP issues in the GATT agenda can be used to support an argument that IP issues should indeed be connected to the GATT forum, and, therefore, to trade. This argument being that GATT negotiations had a wide-scale agenda that covered various trade topics. The broad spectrum of trade topics discussed during the Uruguay Round negotiations provided numerous opportunities to retaliate and to be compensated for different concessions and renunciations.⁷⁹ Potentially, bargains among developing and developed countries could have been made in various fields where developing countries were able to compete, such as textiles or agriculture.⁸⁰

Eventually, the Chairman of the Negotiating Group along with the Secretariat, and with support from Arthur Dunkel, the Director General of GATT at the time, presented a final draft of *TRIPS* in December,

⁷⁶ *Supra* note 25 at 6.

⁷⁷ *Ibid.*

⁷⁸ Peter Drahos, “Expanding Intellectual Property’s Empire: the Role of FTAs” (November 2003), online: [Bilaterals.org](http://www.bilaterals.org) <http://www.bilaterals.org/IMG/doc/Expanding_IP_Empire_-_Role_of_FTAs.doc>.

⁷⁹ Robert E. Hudec, “GATT and the Developing Countries” (1992) 1:67 *Colum. Bus. L. Rev.* 67 at 75.

⁸⁰ *Ibid.*

1991.⁸¹ It has been suggested that this text, which was by and large similar to the adopted *TRIPS*, was much less a result of the consensus on the disputable issues reached in the negotiations, but more of an attempt by the Director-General and the Secretariat to meet a deadline and prevent the failure of the Uruguay Round due to unresolved IP issues.⁸² It seems, based on the previous analysis, that *TRIPS* was designed and shaped by a group of developed countries led by the U.S., as the final draft of *TRIPS*, for the most part, was based on their proposal.

The question is whether developing countries concluded a “worthy deal” by consenting to sign *TRIPS*. What kind of balance had been achieved during such dramatically complicated and problematic negotiations? There are opinions that developing countries themselves were not united in their attempt to counteract bilateral and unilateral pressure from the U.S.⁸³ For example, numerous developing countries had their reasons to join the Group of Forty (led by Switzerland and Colombia) instead of sticking to the opposition of The Group of Ten (led by India and Brazil).⁸⁴ Toward the 1990s, as a result of a debt crisis created by constant borrowing, stagnated economies, failure of inward-oriented economies that saw the success of neighbouring countries achieved by opening their markets to trade, some developing countries realized (or perhaps were forced to realize) that this was a good time to abolish trade barriers and to adopt “market-oriented economic policy.”⁸⁵ The way the final act of the Uruguay Round was constructed (as one package of obligations) and the way the final draft of *TRIPS* was presented (as a “take-it-or-leave-it” offer by the GATT Director-General)⁸⁶ suggest, at the very least, that the bargain developing countries had struck was shifted. The developing countries made concessions in the IP area, *i.e.*, they accepted the fact that IP issues were negotiated and that the broad scope of IP protection was incorporated into the Final Act. However, all developing countries have received was a “one size for all”

⁸¹ Gervais, *supra* note 38 at 24.

⁸² Sergio Escudero, “International Protection of Geographical Indications and Developing Countries,” online: South Centre <<http://www.southcentre.org/publications/geoindication/toc.htm#TopOfPage>>; see also William O. Hennessy, “‘Holy Spirits’ – Part II” *IPFrontline.com* (22 February 2005), online: IPFrontline.com <<http://www.ipfrontline.com/depts/article.asp?id=2160>>; and also Chakravarthi Raghavan, “*TRIPS* – Dunkel’s New Text Seen As More Partial to US,” online: South-North Development Monitor <<http://www.sunsonline.org/trade/areas/intellect/04070189.htm>>.

⁸³ Srinivasan, *supra* note 61 at 35.

⁸⁴ *Ibid.*

⁸⁵ *Ibid.* at 35-36 and *supra* note 79 at 74.

⁸⁶ William O. Hennessy, *supra* note 82.

package, which they had a “choice” to adopt or to leave the *GATT*⁸⁷ and that gave them access to the developed countries’ markets.⁸⁸ All in all, it can be concluded that neither developed nor developing countries would have signed the *TRIPS* as it appears in its final version had it been the only agreement in the Uruguay Round of trade negotiations.⁸⁹

II. ANALYZING TRIPS

AS THE “MOST COMPREHENSIVE MULTILATERAL agreement on intellectual property,”⁹⁰ *TRIPS* created a new balance, connecting IP issues to trade and intensifying the strain between IP protection and public health. In this paper, the analysis will concentrate mainly on patent protection in general, and on pharmaceutical patents specifically. However, the scope of obligations and basic principles of *TRIPS* will be discussed briefly since they contribute to the understanding of the new principles conferred by *TRIPS*.

a. New Aspects of International Intellectual Property Protection According to TRIPS

Substantively, *TRIPS* determines seven main areas of IPR: copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and protection of undisclosed information (trade secrets).

Four main WIPO Conventions — the *Paris*, *Berne*, and *Rome Conventions*, and the *Treaty on International Property in Respect of Integrated Circuits* — are the foundation of *TRIPS*.⁹¹ Contrary to the *Paris Convention* (which did not establish minimum standards for patent protection), *TRIPS* states in Article 1.1 that members may (but are not obliged to) apply more extensive protection in their national laws, but they are obliged to adopt the standards required by the Agreement.⁹² By requiring members to comply with certain provisions of the *Paris Convention* (regarding scope, availability, and use of IP rights), *TRIPS*

⁸⁷ *Supra* note 79 at 76.

⁸⁸ Laurence R. Helfer, “Regime shifting: the *TRIPS* Agreement and new dynamics of international intellectual property lawmaking” (2004) 29:1 *Yale J. Int’l L.* 1 at 3.

⁸⁹ *Supra* note 82.

⁹⁰ *Supra* note 8.

⁹¹ *TRIPS*, *supra* note 1 and *Paris Convention*, *supra* note 11, arts. 1-12, 19.

⁹² Pedro Roffe *et al.*, “Resource book on *TRIPS* and Development: an authoritative and practical guide to the *TRIPS* Agreement” *INCTAD-ICTSD Capacity – Building project on IPRs* at 19-24, online: [IPRsonline.org](http://www.iprsonline.org) <<http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>>.

engages all countries, even those who were not parties to the *Paris Convention*, in the WTO framework.⁹³

Additionally, *TRIPS* preserves the national treatment clause, also an element of the *Paris* and *Berne Conventions*.⁹⁴ According to *TRIPS*' national treatment clause, which is related to persons (owners of IPRs) as opposed to goods, member States cannot discriminate against "the nationals" of other member States and must grant them no less favorable IP protection than they would to their own nationals.⁹⁵

Another significant clause introduced in *TRIPS* is a most-favored-nation (MFN) clause, which provides that if the nationals of one State are granted any advantage, favour, privilege, or immunity, then nationals of every other member State should be granted the same advantage.⁹⁶ The MFN clause was not included in the WIPO Conventions because it was presumed that the national treatment clause sufficed to ensure that member States would not prefer other nationals to their own.⁹⁷ The MFN clause in *TRIPS* attempts to remain consistent with existing regional agreements⁹⁸ by exempting advantages, privileges, or immunities that were in existence according to international bilateral agreements, provisions of the *Berne Convention*, the *Rome Convention* and others.

The patent section of *TRIPS* (Section 5, Articles 27–34) is considered to be a huge success for the U.S. It defines the availability and scope of patent protection (in the broadest manner possible) at the international level, rather than referring this task to the national laws of members, which occurred under the *Paris Convention*.⁹⁹ Article 27.1 determines that patents shall be available for products and processes without discrimination as to the field of technology, place of invention, or the place of production (whether the product is imported or produced locally).¹⁰⁰ This Article has a special impact on pharmaceutical patents. In the "pre-*TRIPS*" era, numerous countries (mostly developing and least-developed ones) did not provide patent protection for pharmaceuticals in their national laws; however, this will have to change upon full implementation of *TRIPS*.¹⁰¹

⁹³ Gervais, *supra* note 38 at 94-95.

⁹⁴ *TRIPS*, *supra* note 1, art. 3.1.

⁹⁵ *Supra* note 92 at 62.

⁹⁶ *TRIPS*, *supra* note 1, art. 4.

⁹⁷ *Supra* note 92 at 63.

⁹⁸ *Ibid.* at 63-64.

⁹⁹ Gervais, *supra* note 38 at 220.

¹⁰⁰ *Supra* note 92 at 356.

¹⁰¹ Considering the transitional periods, this will not happen in least-developed countries, for example, until 2016. See *TRIPS*, *supra* note 1, arts. 66, 65.4 and the Decision of the Council for *TRIPS* of 27 June 2002, online: WTO <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm#texts_decisions> and also Leslie Gladstone Restaino & Katrine A. Levin, "Accord may provide

Article 27.1 determines that inventions must be new, involve an inventive step, and be non-obvious. Articles 27.2 and 27.3 of *TRIPS* determine exceptions from patentability in cases where commercial exploitation of an invention (and not the invention itself) may endanger *ordre public* or morality and where the exception is needed to protect human, animal or plant life, public health, or the environment.¹⁰² While Article 27.2 apparently relates to certain inventions, Article 27.3 determines special categories of inventions that might be excluded from patent protection (although countries are free to determine whether they will exclude these inventions or not).¹⁰³

Article 28 of *TRIPS* defines the exclusive rights that patents will confer – prevention from making, using, offering for sale, selling and importing of the patented product or process by third parties.

Another important “innovation” introduced by *TRIPS* in Article 33 is the minimum term of protection, which is 20 years from a filing date. Although developed countries, especially the U.S., wanted to prolong the patent protection term for products requiring governmental approval (for example, the relatively long period needed to approve drugs for marketing is counted into the patent term, although exclusive rights can not be exercised during this period without official governmental approval), this position was not adopted.¹⁰⁴ Therefore, *TRIPS* did indeed create relatively clearer and more effective mechanisms with respect to patent protection, which makes the *Agreement* the “most important multilateral instrument in the field.”¹⁰⁵

b. Enforcement and dispute settlement mechanisms in TRIPS

Prior to *TRIPS*, there was no clear enforcement mechanism for IPR: the issue was subject to national regulations.¹⁰⁶ According to the vision of developed countries, as soon as *TRIPS* became applicable in developing countries, enforcement mechanisms would ensure quick and complete compliance with the *Agreement* and its implementation in national laws

means to stop copycat drugs: Under *TRIPS* Agreement WTO has more power to pressure countries not in compliance” (2001) 23:38 Nat'l. L. J. C6., Col.1 at 2-3, and *supra* note 92 at 356.

¹⁰² Gervais, *supra* note 38 at 222.

¹⁰³ *Ibid.*

¹⁰⁴ *Supra* note 92 at 424.

¹⁰⁵ Gervais, *supra* note 38 at 220.

¹⁰⁶ *Ibid.* at 287.

by “orderly and effective means.”¹⁰⁷ Article 7 of *TRIPS* introduces a general “envelop” for the protection and enforcement of IPR, stating that its main purpose is to contribute to the promotion of technological innovation and technology transfer to the mutual advantage of producers and users “in a manner conducive to social and economic welfare . . .”¹⁰⁸ Accordingly, Part III of *TRIPS* (Articles 41-61) determines the enforcement procedures, and Part IV (Article 62, which will not be discussed here) constitutes the Acquisition and Maintenance of IPR. Article 41.1 of *TRIPS* sets out that the enforcement mechanism will be applicable to “any act of infringement” of all IPR covered by *TRIPS*.¹⁰⁹ However, not all measures are equally strong and deemed to be effective, *e.g.*, criminal procedures are required to be applied only in cases of “wilful trademark counterfeiting or copyright piracy on a commercial scale.”¹¹⁰

On the weaker, more ambiguous side of the enforcement procedures are obligations to provide fair and equitable civil judicial procedures (Article 42) and to present “reasonably available evidence” (Article 43.1).¹¹¹ Generally, in most of the enforcement provisions, members are required to authorize judicial authorities to take action to enforce protection of IPR; and in some cases, to prevent any infringement from happening (Article 50), as well as to prevent the entry of infringing goods into the State. However, judicial authorities are given considerable discretion in applying this authorization.¹¹²

Although enforcement regulations in *TRIPS* are unprecedented and appear to be effective, they generate much criticism.¹¹³ A particularly poignant argument is that although judicial authorities of member States are empowered, they are not obliged to authorize any action to enforce IPR in national legal systems.¹¹⁴ The system is permissive, not mandatory.

¹⁰⁷ J.H. Reichman & David Lange, “Bargaining around the *TRIPS* Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions” (1998-1999) 9 *Duke J. Comp. & Int’l L.* 11 at 14.

¹⁰⁸ *TRIPS*, *supra* note 1, art. 7.

¹⁰⁹ *Supra* note 92 at 579.

¹¹⁰ *TRIPS*, *supra* note 1, art. 61.

¹¹¹ *Supra* note 92 at 587 – 88.

¹¹² *Ibid.* at 576.

¹¹³ The drafters of *TRIPS* attempted to create a harmonized international intellectual property system with relatively high standards of IPR protection that would promote both “the global interests of the technology-exporting countries, and immunized these interests from disruptive exercises of the territorial sovereignty . . .” Apparently, this was to be achieved by establishing “detailed enforcement standards” for the first time in international conventions. *Supra* note 107 at 20.

¹¹⁴ *Supra* note 92 at 576.

In addition to the detailed enforcement mechanisms, *TRIPS* provides a dispute settlement and prevention system, which is embodied in Part V (Articles 63-64). Article 64.1 applies (with certain exceptions) to a combined dispute settlement model of Articles XXII – XXIII of the new *GATT (1994)* and a Dispute Settlement Understanding (Annex 2 of the Final Act of *WTO Agreement*).¹¹⁵

Contrary to the dispute settlement under the old *GATT*, in which there were no timeframes and a party was able to block a ruling of the panel, the new Dispute Settlement (DS) mechanism under the WTO sets out detailed procedures and relatively strict timetables (no more than one year until the first ruling and 15 months if a case goes to the Appellate Body).¹¹⁶ Additionally, the new system is not as dependent on the consent of parties involved. The panel's decision is adopted automatically unless there is a consensus to decline the ruling.¹¹⁷ The panel is now established (by the Dispute Settlement Body — DSB) only after the parties have made an attempt to settle their dispute through a consultative process,¹¹⁸ which is designed to assist in a mutual resolution without resorting to a panel. If the panel is established and renders a decision, failure to comply within a “reasonable period of time” may result in trade sanctions imposed by the panel.¹¹⁹

Not all members who signed onto the “Uruguay package” are obliged to implement the *TRIPS* provisions simultaneously. First, the general extenuation of one year to implement *TRIPS* is given to all members (Article 65.1 of *TRIPS*).¹²⁰ Existing pharmaceutical patents and agricultural chemical products are an exception, as these products enjoy patent protection from the *WTO Agreement's* date of entry into force (Article 70(8)(a) of *TRIPS*).¹²¹ Developing countries received four more years of transitional period, *i.e.*, five years from the date of entry into force of *TRIPS*, during which time they are not obliged to comply with the *Agreement* (Article 65.2). The exceptions are the national treatment clause (Article 3) and the MFN clause (Article 4), which entered into force one year after *TRIPS* was signed.¹²² Least-developed countries, whose

¹¹⁵ Gervais, *supra* note 38 at 340-41.

¹¹⁶ WTO, “Understanding the WTO: Settling disputes: A unique contribution,” online: WTO

<http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm>.

¹¹⁷ *Ibid.* and see also WTO, “Understanding on rules and procedures governing the settlements of disputes,” online: WTO

<http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#Understanding> [Understanding on rules].

¹¹⁸ Understanding on rules, *ibid.*

¹¹⁹ *Supra* note 116.

¹²⁰ Also *supra* note 92 at 712.

¹²¹ Gervais, *supra* note 38 at 349.

¹²² *Ibid.*

special needs and requirements regarding economic and financial restrictions and a need for flexibility in creation of efficient technological infrastructure had been considered, were allowed an additional transitional period of five years more than the developing countries.¹²³

Although enforcement and dispute settlement mechanisms can be criticized for being ineffective and for allowing developing and least-developed countries to free-ride on the economic and technological advantages provided by industrialized members,¹²⁴ many consider these mechanisms a “cornerstone of today’s globalized research, development, production and trade.”¹²⁵

III. WHAT HAS GONE WRONG IN THE “FAIRY-TALE”?

a. Difficulties with the implementation of TRIPS’ mechanisms on issues related to access to patented pharmaceuticals

Considering the controversial negotiations of *TRIPS* and its broad scope of IP protection, it was not expected to operate smoothly;¹²⁶ however, one area of *TRIPS* has caused especially deep and painstaking discrepancies. This has occurred despite the fact that it was one of the very issues that initiated the revision of the U.S. IP policy, which led to *TRIPS*’ creation. This area is patented pharmaceuticals.

Patents are one of the most significant factors responsible for raising the costs of medicines, particularly when compared to the costs of generic drugs that are manufactured under competition.¹²⁷ For example, in cases where life-saving drugs for pandemics such as AIDS, tuberculosis, or malaria are needed, patent protection can limit access to drugs by making them unaffordable. This is primarily a consequence of monopoly pricing, whereas competition would engender affordability.¹²⁸

¹²³ *TRIPS*, *supra* note 1, art. 66.1.

¹²⁴ See *supra* note 107 at 20-21.

¹²⁵ Joseph Straus, “Bargaining around the *TRIPS* Agreement: The case for ongoing public-private initiatives to facilitate worldwide intellectual property transactions,” Editorial Comment (1998-1999) 9 *Duke J. Comp. & Int’l L* 91 at 95.

¹²⁶ *Ibid.* at 95.

¹²⁷ Adam Lewinberg, *Access to Medicines Guide: Guide for Policymakers and Researchers: Understanding the challenge — Making Essential Medicines Available to the World’s Poor*, (Toronto: Centre for Innovation Law and Policy, 2003), online: CILP <<http://www.innovationlaw.org/English/Access-to-Medicines-Guide.html>>.

¹²⁸ *Ibid.*, online: CILP <<http://www.innovationlaw.org/English/Access-to-Medicines.html>>.

By strengthening international patent protection, *TRIPS* has inevitably had a significant impact on access to life-saving pharmaceuticals in developing countries.¹²⁹ In particular, poor countries that have no pharmaceutical manufacturing capacities and countries afflicted with pandemics that were, until now, dependent on the importation of life-saving drugs from countries that provided no patent protection for pharmaceuticals.

Approximately three million people died from HIV/AIDS in 2001; 2.3 million of these deaths occurred in Sub-Saharan Africa.¹³⁰ Nearly 1.7 million people worldwide died from tuberculosis in the same year, with as many as 10.2 million new cases arising in 2005.¹³¹

It is common knowledge that most of these deaths are preventable, that life-saving drugs do exist, and that the problem is the inaccessibility of these drugs primarily for patients in countries afflicted with the diseases. In the Uruguay Round, developing countries were concerned that raising international IP standards, particularly, strengthening patent protection for pharmaceuticals, would decrease access to much-needed medicines.¹³² Developed countries, for their part, argued time and again that only effective patent protection would create the necessary incentives for costly investments in research and development needed to create innovative, effective drugs.¹³³ However, a study conducted on the relationship between pharmaceutical innovations and the burden of disease in developed and developing countries showed that pharmaceutical companies have no viable incentives (or, at best, very weak incentives) to develop drugs to cure infectious diseases afflicting developing countries. This is due to the lack of potential profits and remuneration for such investments,¹³⁴ since potential clients in

¹²⁹ *Supra* note 127.

¹³⁰ Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy," *Report of the Commission on Intellectual Property Rights*, (September 2002) at 1, online: Commission on Intellectual Property Rights <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf>.

¹³¹ *Ibid.*

¹³² *Ibid.* at 29.

¹³³ Henry Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries" (July 2002) at 4, online: Duke University <<http://www.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf>> and also C. Correa, "*TRIPS* and R&D Incentives in the Pharmaceutical Sector" (November 2001) Commission on Macroeconomics and Health, Paper No. WG2: 11 at 5-6, online: WHO <http://www3.who.int/whosis/cmh/cmh_papers/e/pdf/wg2_paper11.pdf>.

¹³⁴ Frank R. Lichtenberg, "Pharmaceutical Innovation and the burden of disease in developing and developed countries" *Commission on Intellectual Property*

developing countries simply do not have the income to pay for these products.

Partly as compensation for the concessions made by developing countries in the Uruguay Round negotiations, and partly in response to developing countries' (especially South Africa's) efforts to find ways to alleviate the hardship of access to HIV/AIDS drugs,¹³⁵ *TRIPS* offers mechanisms of exceptions to patent protection.

Article 30 of *TRIPS* sets out general exceptions to the exclusive patents rules. They are permissible if they do not "unreasonably conflict with a normal exploitation" of patents and do not "unreasonably prejudice" patent owners' and third parties' interests.¹³⁶ Additionally, Article 31 of *TRIPS* provides a more specifically designed mechanism, which has been applied particularly on the importation of pharmaceuticals — the compulsory license mechanism.¹³⁷ Compulsory licenses allow a government to grant a license to exploit a patent (or another IP right) without authorization from the patent right's owner.¹³⁸ This mechanism is generally used to limit certain powers of rights owners when these powers conflict with the public interest.¹³⁹ Accordingly, Article 8 of *TRIPS* permits members to adopt measures "necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance."¹⁴⁰ Moreover, it could be

Rights, Innovation and Public Health (CIPIH) Study Summaries (2004), online: CIPIH <<http://www.who.int/intellectualproperty/studies/StudySummaries.pdf>>.

¹³⁵ Sell, "Post-*TRIPS* developments," *supra* note 52 at 209.

¹³⁶ *TRIPS*, *supra* note 1, art. 30.

¹³⁷ See also Rosalyn S. Park, "The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients" (2002) 11 *Minn. J. Global Trade* 125 at 131-32.

¹³⁸ Adi Gillat, "Compulsory Licensing to Regulated Licensing: Effects on Conflict between Innovation and Access in the Pharmaceutical Industry" (2003) 58 *Food Drug L. J.* 711 at 712.

¹³⁹ *Supra* note 92 at 461.

¹⁴⁰ *TRIPS*, *supra* note 1, art. 8. See also *supra* note 137 at 132. Although it should be stated that any interpretation conferred by arts. 7-8 should be confined within the *TRIPS* boundaries. In other words, the effect of these articles is limited. Article 7 states: "the protection and enforcement of intellectual property rights should contribute . . ." One possible interpretation is that such a protection will not guarantee the desired results, *i.e.*, the promotion of technological innovation and technology transfer, but will only lead toward these results. Also, art. 8 requires that the measures undertaken for the protection of public health and nutrition, the promotion of the public interest, and the prevention of the abuse of IP rights by right holders should be consistent with the Agreement. Thus, art. 8 restrains the discretion of the member-countries to adopt the measures they consider necessary for the protection of public health in that these measures will not violate the *TRIPS* provisions. See Roffe *et al.*, *supra* note 92 at part 1.20 at 126-27.

argued that compulsory licenses may be used to allow manufacturing of generic versions of patented pharmaceuticals during a public health crisis, in which the public interest would prevail over the private interests of patent owners.

This exception to patent protection, known as a compulsory license, must be authorized by a government or a governmental agency and it must comply with the requirements of Article 31 of *TRIPS*.¹⁴¹ Apparently, according to the title of Article 31 and its footnote, a compulsory license clause shall constitute “other use” than the one allowed under Article 30.¹⁴² Therefore, it is clear that under Article 30, which provides only a general framework of exceptions, the similar unauthorized use of a patented invention would not be available.

This conclusion becomes a significant barrier if a country wishes to request an authorization to manufacture a drug under a compulsory license, but does not meet the requirements of Article 31. Although Article 30 tends to broaden the scope of permissible exceptions by adding that “legitimate interests of third parties” should be considered once a State wishes to apply the exception mechanism, it is clear from Article 31 that the grant of a compulsory license should be restricted to the conditions defined in Article 31 only.¹⁴³ This obvious distinction between the two Articles is designed to specify rules for granting a compulsory license under Article 31 (*e.g.*, for a specific patent, to a specific company). This is instead of incorporating this mechanism in a more general framework such as legislation or an amendment, which could evolve from Article 30.¹⁴⁴

Thus far, the picture looks bright and positive. Along with strengthening patent protection, *TRIPS* provides flexibilities (general as well as specific) to allow countries to respond to their public health problems. However, developing countries, particularly countries that implemented *TRIPS* in 2000 and 2005, do not rush to use this mechanism. Why then is the compulsory license mechanism, one of the few flexibilities found in *TRIPS*, not used, especially by countries where public health problems are so evident?

Many developing countries, along with Non-Governmental Organizations (NGOs), consider Article 31 (and in some cases Article 30 as well) as permitting the manufacture and import of generic versions of patented drugs in cases of public health crisis, such as the AIDS crisis in South Africa.¹⁴⁵ Horribly affected by the AIDS pandemic (as many as

¹⁴¹ Gervais, *supra* note 38 at 242.

¹⁴² *TRIPS*, *supra* note 1, art. 31.

¹⁴³ *Ibid.*

¹⁴⁴ *Supra* note 92 at 462.

¹⁴⁵ *Supra* note 137 at 133.

19.94 percent of its 21 million adult population suffer from AIDS),¹⁴⁶ South Africa passed the *Medicines and Related Substances Control Amendment Act* in 1997.¹⁴⁷ The Act authorized the Minister of Health to grant compulsory licenses for the supply of cheaper generic drugs to protect public health “notwithstanding anything contrary contained in the Patent’s Act.”¹⁴⁸ The South African law was challenged by the U.S. as violating *TRIPS* because Section 15C allows the Minister of Health to go beyond the strict definition of the conditions of the compulsory license clause set out in Article 31 of *TRIPS* and to permit the grant of compulsory licenses beyond *TRIPS*’ limitations.¹⁴⁹

What are the limited conditions under which a compulsory license to produce a generic version of a patented drug can be granted? From the point of view of the generic companies and developing countries, one of the restrictive requirements is that under Article 31(b), the user of a compulsory license is required to obtain a permit from the right owner “on reasonable commercial terms and conditions.”¹⁵⁰ This means that a compulsory license can be granted only when a future user fails to obtain such authorization from the right’s owner “within [a] reasonable period of time.”¹⁵¹ This clause may possibly neutralize the exception altogether. For example, a patent holder, as the sole person who can sell, distribute, and use his invention while bargaining the license to authorize manufacturing of the invention, would probably ensure the highest possible remuneration for trading his/her exclusive rights.¹⁵² However, Article 31(b) offers a waiver of this requirement in cases of national emergency, other circumstances of extreme urgency, or in cases of public non-commercial use (in each case the right holder shall be notified, but prior negotiation is not required).¹⁵³ Article 31(b) appears to explicitly authorize grants of compulsory licenses in the case of a public health crisis. Furthermore, it leaves each country with the ability to decide what

¹⁴⁶ Theodore C. Bailey, “Innovation and Access: The role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs” (2001) *J.L. Tech. & Pol’y* 193 at 195-96.

¹⁴⁷ *Medicines and Related Substances Control Amendment Act of 1997*, online: Department of Health <<http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf>>.

¹⁴⁸ *Supra* note 146 at 200-01.

¹⁴⁹ *Ibid.* at 201 and see also Kara M. Bombach, “Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the *TRIPS* Agreement” (2001) 19 *B.U. Int’l L.J.* 273.

¹⁵⁰ *TRIPS*, *supra* note 1, art. 31(b).

¹⁵¹ *Ibid.*

¹⁵² *Supra* note 146 at 202.

¹⁵³ Gervais, *supra* note 38 at 250-51.

constitutes “cases of national emergencies,” since national emergency is not defined in the article.¹⁵⁴

Article 31(f) creates the main problem for developing countries lacking sufficient pharmaceutical manufacturing infrastructure and requesting to grant compulsory licenses to import generic versions of patented pharmaceuticals to increase access to drugs in times of national health emergencies. This article was one of the main factors leading to the Doha Declaration on *TRIPS* and Public Health adopted on 14 November 2001.¹⁵⁵ The problem is that Article 31(f) authorizes the use of a compulsory license “predominantly for the supply of the domestic market of the member authorizing such use,” except in cases where a compulsory license is granted to remedy an anti-competitive practice.¹⁵⁶ Therefore, countries that lack pharmaceutical manufacturing abilities and cannot produce generic drugs locally will not be able to use the proposed mechanism of compulsory licensing without infringing *TRIPS*. This is because the possibility of exporting drugs produced under a compulsory license, where such export constitutes the main use of the compulsory license, is not covered by Article 31(f).¹⁵⁷

Many argue that Article 30 provides an alternative mechanism for granting a compulsory license to export generic versions of patented drugs to the country in need.¹⁵⁸ However, the scope of Article 30 was interpreted narrowly by a decision of the panel in Canada’s case.¹⁵⁹ In this dispute, the EU challenged several sections of the *Canadian Patent Act*. The panel stated that “limited exception” under Article 30 should acquire the narrowest interpretation possible, and the exact scope was to be interpreted in each specific case.¹⁶⁰ Accordingly, a patent owner’s exclusive right allowed him to prevent competition that significantly endangered his economic remuneration from the patent.¹⁶¹ In regard to the requirement to consider interests of third parties while determining

¹⁵⁴ *Ibid.* at 251 and *TRIPS*, *supra* note 1, art. 31(b).

¹⁵⁵ *Supra* note 6.

¹⁵⁶ *TRIPS*, *supra* note 1, art. 31(k).

¹⁵⁷ Gervais, *supra* note 38 at 252. In other words, the export under a compulsory license is allowed as a marginal component in the production intended for the domestic market. The language of the provision suggests that a government may not authorize the export of products under a compulsory license unless the license provides that more than 50 percent of the product will be produced for the domestic market. See Roffe *et al.*, *supra* note 92 at 474.

¹⁵⁸ *Supra* note 5 at 952-53.

¹⁵⁹ *Ibid.* at 965-66. See also WTO, *Canada — Patent Protection of Pharmaceutical Products: Complaint by European Communities and their member States*, WTO Doc. WT/DS114R (17 March 2000), online: WTO <<http://docsonline.wto.org>> [*Canada case*].

¹⁶⁰ Gervais, *supra* note 38 at 243.

¹⁶¹ *Ibid.*

whether an exception under Article 30 unreasonably prejudices the legitimate interests of the patent owner, the panel ambiguously stated that “legitimate interests” of a patent owner and third parties should be balanced in accordance with “relevant public policies or other social norms.”¹⁶²

Foreseeing the difficulties in addressing public health emergency situations under *TRIPS*, developing countries initiated high-level consultations on the authoritative interpretation of *TRIPS*.¹⁶³ They sought to balance the demands to provide high levels of IP protection with a solution to the public health controversy.¹⁶⁴ In response, at the Fourth Ministerial Conference in Doha, Qatar in 2001, the Declaration on *TRIPS* and Public Health was adopted. The Declaration was supposed to solve the problem of access to drugs in developing and least-developed countries under the flexibilities of the *TRIPS Agreement*.

Unlike *TRIPS*, which was for the most part created by developed countries and not fully negotiated, this Declaration was preceded by profound discussions, with participation from WHO representatives, representatives of the brand-name industry, and generic manufacturers.¹⁶⁵ In light of the extensive involvement in the negotiation process, the Declaration on *TRIPS* and Public Health was expected to be more balanced and should have incorporated the interests of all players from all sectors in regard to the implementation of *TRIPS*.

¹⁶² *Canada case*, *supra* note 159 at para. 7.69.

¹⁶³ Some developing countries that had no pharmaceutical patent protection should implement the *TRIPS* requirements on 1 January 2016. See *TRIPS*, *supra* note 1, arts. 65-66 and WTO, Press Release, WTO Doc. Press/301, “Decision of the Council for *TRIPS* of 27 June 2002” (28 June 2002), online: WTO <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm#texts_decisions>.

¹⁶⁴ Kenneth C. Shadlen, “Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO” (Fall 2004) 39:3 *Studies in Comparative International Development* 76 at 78.

¹⁶⁵ WTO, “*TRIPS* Council’s discussion on ‘Intellectual Property and access to medicines’” (20 June 2001), online: WTO <http://www.wto.org/english/tratop_e/TRIPS_e/counciljun01_e.htm>, and also see WTO, “Governments share interpretations on *TRIPS* and public health” (20 June 2001), online: WTO <http://www.wto.org/english/news_e/news01_e/TRIPS_drugs_010620_e.htm>.

b. Doha Declaration on TRIPS and Public health and General Council's decision of 30 August 2003 — attempts to reach a feasible balance or hasty decisions to hide the leaks?

Indeed, the implementation of the WTO Agreements was the key issue at the Doha Ministerial Conference.¹⁶⁶ Paragraph 17 of the Ministerial Declaration (adopted on 14 November 2001) stressed the importance of “implementation and interpretation of the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)* in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.”¹⁶⁷ The Ministers adopted a separate Declaration on the *TRIPS Agreement and Public Health (Doha Declaration)*, in which, along with the recognition of “the gravity of the public health problems afflicting many developing and least-developed countries” and the recognition of the importance of IP protection for development of new medicines, the Ministers emphasized that *TRIPS* should not prevent members from taking measures to protect public health.¹⁶⁸ To this purpose, members were encouraged to use flexibilities provided in *TRIPS*.¹⁶⁹ The Declaration even provided members with reasonably detailed instructions as to how to interpret those flexibilities. For example, each member is entitled to determine the suitable grounds for granting compulsory licenses (Paragraph 5 (b)), and each member can state what a “national emergency” is, while pandemics (AIDS, tuberculosis, and malaria are clearly stated in the Declaration as cases of pandemics) are automatically proclaimed a “national emergency or other circumstances of extreme urgency.”¹⁷⁰ Developed countries were made responsible for promoting and encouraging technology transfer to least-developed countries. As well, the decision to grant least-developed countries an additional extenuation period for complying with the patent section of *TRIPS* until 1 January 2016, was reaffirmed.¹⁷¹

An important question that remained unresolved (and was left for the *TRIPS* Council to deal with) was how to make the compulsory license

¹⁶⁶ See WTO, “The Doha Declaration explained,” online: WTO <http://www.wto.org/English/tratop_e/dda_e/dohaexplained_e.htm>.

¹⁶⁷ WTO, *Ministerial Declaration*, WTO Doc. WT/MIN(01)/DEC/1 (20 November 2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#TRIPS>.

¹⁶⁸ *Supra* note 6 at para. 1.

¹⁶⁹ *Ibid.* at paras. 1-4.

¹⁷⁰ *Ibid.* at para. 5(c).

¹⁷¹ *Ibid.* at para. 7.

feasible for developing countries with no manufacturing capacities (or with insufficient manufacturing infrastructure) in the pharmaceutical field — the Paragraph 6 problem. In other words, the Declaration stated clearly that Article 31(f) of *TRIPS* prevents some developing countries from effectively using the compulsory licensing mechanism to alleviate public health crises.¹⁷² For developing countries, the Doha Declaration and its interpretation of *TRIPS* constituted a great and promising success: there appeared to be the opportunity to shift *TRIPS*' unbalanced mechanisms (from developing countries' point of view) to their side and to permit the export of lower-priced patented drugs in cases of public health emergencies.¹⁷³

Following the instructions of the Ministerial Conference, the *TRIPS* Council intended to complete the "mission" set out in Paragraph 6 of the Doha Declaration and to find a satisfying solution to the Paragraph 6 problem before the end of 2002.¹⁷⁴ The *TRIPS* Council held several meetings in which members' representatives were heard.¹⁷⁵ Notwithstanding the final decision, the representatives of numerous developing and least-developed countries, such as Kenya, Zimbabwe, India, Brazil, Sri Lanka, Pakistan, Malaysia, Indonesia, China, Argentina, Peru, Uganda and others, as well as representatives of some developed countries, such as the U.S., the EU, Japan, Canada, Switzerland, and Norway, had the opportunity to present their positions. The representative of the World Health Organization (WHO),¹⁷⁶ emphasized that *TRIPS* should be interpreted and implemented in a way that would support the protection of public health and promotion of access to medicines.¹⁷⁷ The WHO representative stated that the Doha Declaration "marked a watershed in international trade and demonstrated that a rules-based trading system should be compatible with public health interests."¹⁷⁸ These developments indicated that the *TRIPS* Council's solution for the Paragraph 6 problem would integrate the approaches and views of developed and developing countries and would strike a proper balance to alleviate the tension between the need for strong IP protection to create incentives for the creation of new effective medicines and public health issues.

¹⁷² *Supra* note 5 at 951-52.

¹⁷³ *Ibid.* at 952.

¹⁷⁴ *Ibid.*

¹⁷⁵ WTO, General Council, *Minutes of Meeting* (held on 5-7 March 2002), WTO Doc. IP/C/M/35, online: WTO <<http://docsonline.wto.org>>.

¹⁷⁶ *Ibid.* at 28-29.

¹⁷⁷ *Ibid.*

¹⁷⁸ *Ibid.* at 29.

By mid-June 2002, the Secretariat of the TRIPS Council received five communications on the Paragraph 6 problem.¹⁷⁹ The U.S. proposal suggested adherence to the narrowest possible interpretation of TRIPS provisions, *i.e.*, to limit a solution of the Paragraph 6 problem only to patented pharmaceuticals needed to treat pandemics referred to in the Doha Declaration solely, such as AIDS, tuberculosis, malaria and others. Additionally, the U.S. insisted on informing patent holders if a country applied for the use of the product under a compulsory license to allow the patent holder to offer the product at lower prices. Additionally, the U.S. wanted strict safeguard mechanisms to ensure that the compulsory license mechanism would not be used to re-sell and re-distribute exported products.¹⁸⁰ In an effort to shift the emphasis to the general poverty of the countries most likely to use the compulsory license mechanism proposed in TRIPS,¹⁸¹ the U.S. claimed that for many people in the world, drugs would still be unaffordable and that “at any price and under any TRIPS-related solution there would still involve a cost.”¹⁸²

Four suggestions were offered to make the compulsory license mechanism under TRIPS workable:

- 1) a broad interpretation of Article 30 authorizing export/import of patented products under compulsory license;
- 2) an amendment of Article 31 in order to authorize such use of the mechanism;
- 3) a waiver of Article 31(f) requirements; or
- 4) a dispute settlement moratorium to determine non-compliance with Article 31(f).¹⁸³

Of these solutions, the U.S. favoured the moratorium or the waiver.¹⁸⁴

¹⁷⁹ WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, (11 July 2002), WTO Doc. IP/C/W/363, online: WTO <<http://docsonline.wto.org>>.

¹⁸⁰ WTO, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Communication from the United States* (14 March 2002), WTO Doc. IP/C/W/340, online: WTO <<http://docsonline.wto.org>> [WTO, “Paragraph 6 Communication from the U.S.”] and *ibid.*

¹⁸¹ WTO, “Paragraph 6 Communication from the U.S.,” *ibid.* at 1-2.

¹⁸² *Ibid.* at 2.

¹⁸³ *Supra* note 5 at 953-54.

¹⁸⁴ *Supra* note 179 at 17.

Proposals from the African Group and the Group of developing countries¹⁸⁵ suggested the broadest possible interpretation of *TRIPS* as a solution to the Paragraph 6 problem. As to the scope of products that could be exported under a compulsory license mechanism, they claimed that pharmaceuticals should not be limited to drugs for the treatment of specific conditions mentioned in the Doha Declaration, but should include, aside from medicines, related technical equipment and processes.¹⁸⁶ Moreover, the beneficiary importing countries' list should not be limited — every country that needs to address a public health crisis should be able to use the mechanism.¹⁸⁷ The African Group and the Group of developing countries also hoped that the safeguards intended to prevent abuse of the compulsory license mechanism would not be overly burdensome or costly and would not complicate or limit the flexibilities of *TRIPS*.¹⁸⁸ As to the legal solutions for the Paragraph 6 problem, the African Group's proposal differed from the proposal of the Group of developing countries. The African Group proposed either to revise all the provisions of Article 31 or to remove or neutralize the Article 31(f) provision and thereafter apply the remaining provisions of Article 31 as they stand.¹⁸⁹ The Group of developing countries proposed to interpret Article 30 in a way that would authorize the export of generic versions of patented products under compulsory licenses.¹⁹⁰

Interestingly enough, the EU proposal mediated between the U.S. and African and developing countries' groups. The EU stated that:

. . . even when manufactured under a compulsory license, medicines may still be unaffordable for certain segments of the population in poor countries. After all, production of medicines, even by a manufacturer other than the patent holder, always has a cost, and manufacturers have to make a reasonable return on investment if they are to stay in business. Second, any solution that emerges from the discussions in the *TRIPS* Council would never be a panacea for the problem of access to medicines. It is widely agreed that improving such access requires a mix of complementary measures in different areas. These measures include: public financing of drugs purchases;

¹⁸⁵ Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand, and Venezuela.

¹⁸⁶ *Supra* note 179 at 4.

¹⁸⁷ *Ibid.* at 5.

¹⁸⁸ *Ibid.* at 9.

¹⁸⁹ *Ibid.* at 13.

¹⁹⁰ *Ibid.*

strengthened health care systems, including the infrastructure for distributing drugs and monitoring their usage; improved information and education; and increased research and development.¹⁹¹

Within this framework, the EU suggested that the scope of patented products available for issuing compulsory licenses should not be limited solely to the drugs referred to in the Doha Declaration, but that these pharmaceutical products (including products manufactured through patented processes) should be related to public health crises afflicting numerous developing and least-developed countries.¹⁹² The EU (contrary to the U.S.) was willing to admit that in some cases, the product for which a compulsory license was needed could not be patented in the country that requested a license and could still be subject to a compulsory license.¹⁹³ Also, the EU held a more flexible opinion as to the safeguards necessary to prevent abuses and trade diversions resulting from the use of the compulsory license mechanism. Although acknowledging the necessity of such safeguards, the EU added that its complexity should be reasonable;¹⁹⁴ however, the EU did not determine what exactly constitutes the term “reasonable.” As to the legal solution, the EU proposed the elimination of Article 31(f) and the application of the remaining provisions of Article 31 as written.¹⁹⁵

Overall, an analysis of the proposed solutions suggests the one-sidedness of the U.S. proposal. It is obvious that the U.S. proposal almost completely ignores the essence of the Doha Declaration, which emphasized “the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹⁹⁶ By proposing the solution that advocates for the narrowest possible interpretation of *TRIPS* (solely according to its agenda — to provide stronger IP protection) with only slight alterations in favour of public health issues, the U.S. provided a “narrow” solution that is mostly inapplicable in cases slightly different from those explicitly stated in the Doha Declaration. Restricting the solution to those diseases stated in the Declaration, such as HIV/AIDS, tuberculosis, malaria, and other currently existing epidemics, will result in ignoring the same problem of access to affordable drugs for

¹⁹¹ WTO, *Concept paper relating to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/C/W/339 (4 March 2002) at 1-2, online: WTO <<http://docsonline.wto.org>>.

¹⁹² *Supra* note 179 at 4.

¹⁹³ *Ibid.* at 6.

¹⁹⁴ *Ibid.* at 9.

¹⁹⁵ *Ibid.* at 13.

¹⁹⁶ *Supra* note 6 at para. 1.

treatments of many other infectious diseases that could evolve into pandemics in the future.

What the U.S.-proposed solution ignores, for the most part, is that patentees would not be interested in supplying the markets of poor developing countries with sufficient quantities of their products because they would not receive an adequate return for their investment, given the countries' inability to pay the high price of patented pharmaceuticals.¹⁹⁷ This problem could have been possibly solved, and the prices possibly lowered, by generic competition in the export of pharmaceuticals produced in countries that had lower levels of patent protection of drugs prior to *TRIPS* (such as India and Brazil).¹⁹⁸ However, after 1 January 2005, this solution (helpful or not) is no longer possible.

Equally, the U.S. proposal was so abundantly laden with safeguards as to make the process bureaucratically burdensome. There is a considerable doubt as to the probability that such a mechanism would serve the purposes of public health protection. The reasons for all the complex and burdensome safeguards proposed by the U.S. are quite understandable. It is necessary to provide procedures to ensure that the compulsory license mechanism not be abused and to prevent diversions of the drugs exported under a compulsory license, such as re-selling and re-exporting, and, therefore, circumventing patent protection of the original drugs. However, a reasonable balance should be kept so as not to abolish the opportunity of developing countries to use the proposed mechanism. The U.S. proposal fails to relate to the humanitarian essence of the instructions given in the Doha Declaration and to the need of *TRIPS* to be "part of the wider national and international action," as well as to address public health problems.¹⁹⁹

Similarly, the proposal of the African Group and the Group of developing countries is not a perfect model of an objective solution either. Concentrating on the broadest possible interpretations of *TRIPS*' flexibilities, the proposals basically ignore the fact that paragraphs 4-5 of the Doha Declaration stated that each provision of *TRIPS* should be read in light of the expressed objectives of the Agreement.²⁰⁰ According to

¹⁹⁷ *Supra* note 180 at 13.

¹⁹⁸ As Dr. Karim Laouabdia of Medecins Sans Frontieres (MSF) said of the campaign for access to essential medicines, "We were able to increase the number of people we treat because generic competition lowered the prices of first line medicines . . . That was before full *TRIPS* implementation." Where will affordable second-line drugs come from now?" from "MSF to WTO: Re-think access to life-saving drugs now", (24 October 2005), online: MSF <http://www.msf.org/msfinternational/invite.cfm?objectid=224B1730-E018-0C72-091E8829E29F80E6&component=toolkit.article&method=full_html>.

¹⁹⁹ *Supra* note 6 at paras. 1-2.

²⁰⁰ *Ibid.* at para. 5(a).

Article 7 of *TRIPS*, these objectives are “the protection and enforcement of intellectual property rights” contributing to the promotion of technology transfer.²⁰¹ On the other hand, it could be stated that the same Article 7 determines that the technology transfer should contribute “to the mutual advantage of producers and users . . . and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”²⁰² Proposing to waive obligations under Article 31(f) or to interpret Article 30 as the one that authorizes the use of a compulsory license, the African Group admits in its proposal that there would be no other means to cause the investor/patent owner to voluntarily export drug or medical technology needed to fight a public health crisis in the poor country. This is because the purchasing power of the poor country is so low that there would be no substantial return on investment and no profit.²⁰³ In these conditions, even if the requirements of Article 31(f) are waived and an exportation of generic versions of patented drug is allowed under a compulsory license clause, the requirement to adequately remunerate the right holder (Article 31(h)) would still be in the way of the African Group’s vision of the compulsory license mechanism’s operation. According to the African Group’s proposal, members will provide for “just compensation to the right holder”;²⁰⁴ however, the interpretation of the term “just” remains ambiguous.

Another shortcoming of the African Group’s and the Group of developing countries’ proposals is that neither suggests the provision of effective safeguards against trade diversions, re-exporting, and re-selling the medicines exported under a compulsory license mechanism. While the African Group recommended providing suitable regulations in domestic law, which would allow a patent holder whose patent was infringed and whose product was re-exported without his permission to seek remedies, the Group of developing countries suggested placing this responsibility solely on the patent owners themselves.²⁰⁵

Here again, the unsolvable nature of the problem is obvious: how to balance IP protection with public health issues, as well as balance the position of developed countries with that of developing nations. Neither *TRIPS* nor the Doha Declaration has been able to provide some clear solution. Both texts, in their efforts to incorporate the positions of developed and developing countries (*TRIPS* being more in line with developed countries, while the Doha Declaration tries to relate to the

²⁰¹ *TRIPS*, *supra* note 1, art. 7.

²⁰² *Ibid.*

²⁰³ WTO, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Joint Communication from the African Group in the WTO*, WTO Doc. IP/C/W/351 (24 June 2002) at 1, online: WTO <<http://docsonline.wto.org>>.

²⁰⁴ *Supra* note 179 at 15.

²⁰⁵ *Ibid.* at 10.

position of developing ones) seem to go farther away from a feasible solution to the problem of access to affordable drugs in developing countries in times of health crises.

The question remains as to whether this balanced solution was reached in the General Council's Decision of August 2003. The WTO Director-General, Supachai Panitchpakdi, called the *TRIPS* Council decision of 30 August 2003 (the Decision)²⁰⁶ "a historic agreement for the WTO." He added: "It proves once and for all that the organization can handle humanitarian as well as trade concerns."²⁰⁷ According to the General Council Chairperson, Carlos Perez del Castillo (the Uruguay Ambassador), the decision should be used in good faith for the solution of public health problems rather than for commercial use, so as to prevent medicines from falling into the wrong hands.²⁰⁸

Indeed, the Decision attempts to incorporate the position of developed countries and developing ones based on the communications submitted to the *TRIPS* Council examined above. A definition of "pharmaceutical product" in the Decision includes not only medicines, but also products produced through patented processes.²⁰⁹ This definition unifies the EU as well as the African Group and the Group of developing countries' (both of them will be referred to as "developing countries") proposals.²¹⁰ The definition of eligible importing country is based on the developing countries' proposal, although with slight alterations. Any least-developed country will be automatically eligible to use a compulsory license mechanism and any other country will be eligible to do so following a notification to the *TRIPS* Council.²¹¹ For its part, the U.S. proposed to limit the number of eligible importing countries to the developing and least-developed countries affected with the diseases mentioned in the Doha Declaration and who have no, or insufficient, manufacturing capacity.²¹² The definition of eligible exporting country was adopted against the U.S.'s advice as well, and includes any country that produces a needed medicine. The U.S. had advised to exclude any developed

²⁰⁶ WTO, General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Doc. WT/L/540 and Corr.1 (1 September 2003), online: WTO <http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm>.

²⁰⁷ WTO, Press Release, WTO Doc. Press/350/Rev.1, "Decision removes final patent obstacle to cheap drug imports" (30 August 2003), online: WTO <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>.

²⁰⁸ *Ibid.*

²⁰⁹ *Supra* note 206 at para. 1(a).

²¹⁰ *Supra* note 179 at 4.

²¹¹ *Supra* note 206 at para. 1(b). See also *supra* note 179 at 5.

²¹² *Supra* note 179 at 5.

country so as to create incentives for the developed country to participate in future technology transfers.²¹³

Although the Decision adopts a solution that was proposed by developing countries (a waiver of Article 31(f)), the numerous safeguards ensuring that no abuses and trade diversions will be possible under an amended compulsory license mechanism make the process of acquiring a compulsory license disproportionately burdensome for a country facing public health crisis. The safeguards include: the specification of the expected quantities;²¹⁴ evidence required of every importing country (except a least-developed one) to establish a lack or insufficiency of manufacturing capacities, with no detailed instructions as to the kind of evidence that would satisfy this requirement;²¹⁵ various notifications required from an exporting member;²¹⁶ and the general instruction for members to ensure that the products imported under a compulsory license will be used for public health purposes.²¹⁷

Based on this analysis, the Decision attempts to integrate competing interests, in that it tries to improve the flexibilities that were introduced by *TRIPS*, proven not to be feasible for developing countries. The U.S.-proposed solution to the Paragraph 6 problem is the logical extension of the *TRIPS* negotiations: lop-sided and clearly in favour of the U.S. Interestingly, although the views and approaches of developing countries were incorporated in the Decision, it appears to remain unworkable for them, particularly for developing countries facing a public health crisis. One of the possible explanations could be the argument presented by the EU: the solution to the Paragraph 6 problem must be multifaceted, consisting of public financing and strengthening the public care systems in developing countries so as to improve the possibility of the delivery of the drugs into the right hands, technology transfer, etc.²¹⁸

CONCLUSION

BEING CREATED, BY AND LARGE, BY DEVELOPED COUNTRIES and, at least in the short-term, for developed countries, *TRIPS* is an explicit expression of the age-old tensions between industrialized and developing nations. This tension is greatly emphasized in the “collision” of IP protection and public health issues. Throughout the patent section of *TRIPS*, there are various mechanisms that aim to strengthen patent protection, followed by attempts to provide some

²¹³ *Supra* note 206 at para. 1(c) and note 179 at 8.

²¹⁴ *Supra* note 206 at paras. 2(a)(i) & 2(b)(i).

²¹⁵ *Ibid.* at para. 2(a)(ii).

²¹⁶ *Ibid.* at para. 2(c).

²¹⁷ *Ibid.* at paras. 4-5.

²¹⁸ *Supra* note 191.

flexibilities as a response to developing countries' demands (such as mechanisms for exception from patentability in Articles 27(2)-(3), or a general exception from patent protection in Article 30). However, even these flexibilities reflect an attempt to "alleviate" the consequences of granted exceptions. For example, one of the purposes of a compulsory license clause could be to provide developing countries with access to affordable drugs, but the mechanism turned out to be unworkable for developing and least-developed countries with insufficient manufacturing capacities in the pharmaceutical field.

As a response to this problem, the Doha Declaration on *TRIPS* and Public Health was adopted. It could be suggested that since it was based on consultations with and communications from developed and developing countries, testimonies of representatives from NGOs and industry, as well as from academia, the Doha Declaration introduces a much more balanced mechanism regarding *TRIPS* implementation. Unfortunately, the Declaration left the problem of access to patented medicines in developing countries lacking sufficient manufacturing capacities for the *TRIPS* Council to resolve.

Although the Decision of the *TRIPS* Council attempts to maintain the "tone" of Doha Declaration, *i.e.*, shifting the balance to the side of developing countries, it is evident that the influence of the developed countries' proposals prevailed in the Decision. In contrast as to what happened in *TRIPS*, in which most of the substantive definitions and provisions were determined by developed countries, in the Decision, the African Group's and the developing countries' proposals were the basis for substantial definitions. Even the final solution (waiving Article 31(f) and allowing the export of generic versions of patented drugs) had been proposed by developing countries (and the EU). As for the procedural provisions, the developed countries were the ones to determine the rules and procedures, according to which the mechanism of compulsory license will operate. The difficulty is that in determining how compulsory licenses will work in times of a public health crisis, the numerous rules and procedures deemed to protect production exported under compulsory licenses from trade diversions and abuses are most likely to prevent developing countries from using the mechanism.

It can be concluded that the balance between IP protection and public health issues, which apparently was shifted to the side of developing countries by the Doha Declaration, is most likely to return to its origins, *i.e.*, to the side of developed countries, as it was established under *TRIPS*. Although the implications of a stronger level of IP protection provided by *TRIPS* are designed for the long-run, the flexibilities in *TRIPS*, at least those related to the improvement of access to patented medicines in developing countries in times of public health crisis, seem to be remarkably short-term in nature.