A HOLE IN THE BUCKET: THE WORLD TRADE ORGANIZATION'S ENDEAVOR TO STRIKE A GLOBAL BALANCE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND THE NEED FOR ACCESS TO ESSENTIAL MEDICINES IN DEVELOPING NATIONS

INTRODUCTION

Epidemic diseases and the contemporary medicines used to combat them have created curious opponents in the global intellectual property fray: at odds are the pharmaceutical-manufacturing industry that produces these drugs, and the developing nations that stand to benefit the most from their use. The critical needs of developing nations for access to essential medicines have long been at issue with the objectives of the pharmaceutical industry, which seeks to protect its intellectual property rights and to profit from the billions of dollars it invests annually in research and development.[1] The least-developed countries (LDC's)[2] are at greatest risk in this regard because they are typically unable to purchase or pay royalties for the right to produce essential medications that are protected by patents. These nations are beleaguered with infectious diseases such as HIV/AIDS, tuberculosis, and malaria, in epidemic proportions.[3] However, pharmaceutical manufacturers assert that they could not continue to invest in the research and development of such drugs absent protection of the intellectual property

1. The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that its member companies invested an estimated $33.2 billion on research and development in 2003. *See* PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2004 vii (2004), http://www.phrma.org/publications (last visited Dec. 17, 2004) [hereinafter PHRMA PROFILE].

2. The Economic and Social Council of the United Nations utilizes three criteria to identify least-developed countries: (1) low income, characterized by a three-year mean estimated gross domestic product per capita of less than $750; (2) low quality of life, taking into consideration nutrition, health, education, and adult literacy; and (3) high economic vulnerability, attributable to factors such as an instability in agricultural production, instability in the export of goods and services, and displacement of a significant proportion of the population by natural disasters. United Nations, The Criteria for the Identification of the LDCs, *at* http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm (last visited Dec. 17, 2004).

3. *See* World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, at Appendix A, *infra* [hereinafter Doha-TRIPS Declaration]. *See also* THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA, THE GLOBAL FUND BROCHURE 5 (2004), http://www.theglobalfund.org/en/about/publications/brochure (last visited Dec. 17, 2004).

rights that allow them to recover their investments.[4] This conflict has polarized governments, political leaders, non-governmental organizations (NGO's), activists, and businesses globally. Two oft-quoted international figures illustrate the broad divergence of opinion on this issue:

> The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."
>
> — Indira Gandhi, former Prime Minister of India.[5]

> Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people."
>
> — Kofi Annan, UN Secretary General.[6]

From its establishment as a forum for international trade negotiations, the World Trade Organization (WTO) has inserted itself into this dispute and sought to resolve the conflict through a series of negotiations intended to balance the interests of its members.[7] This paper will examine the progression of the events which, to date, have characterized

4. *See, e.g.*, Alan F. Holmer, President and Chief Executive Officer, PhRMA, Address before the Economist's Second Annual Pharmaceuticals Roundtable (Nov. 20, 2002), *available at* http://www.phrma.org/publications/publications/20.11.2002.629.cfm (last visited Dec. 17, 2004) (stating that the pharmaceutical industry vigorously protects its intellectual property rights in order to ensure that it has the means to produce new life-saving medicines).

5. Indira Gandhi, Address before the World Health Assembly (May 1982).

6. Press Release, United Nations, Secretary-General Announces Steps by Leading Drug Companies to Improve AIDS Treatment Access to Developing Countries, SG/SM/7764, *at* http://www.un.org/News/Press/docs/2001/sgsm7764.doc.htm (last visited Dec. 17, 2004).

7. Acronyms which appear frequently throughout this document include:
DSB – Dispute Settlement Body
DSU – Dispute Settlement Understanding
GATT – General Agreement on Tariffs and Trade
IP – Intellectual property
LDC's – Least-developed countries
NGO's – Non-governmental organizations
PhRMA – Pharmaceutical Research and Manufacturers of America
TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO – World Health Organization
WTO – World Trade Organization

the WTO's approach to the issue—from its initial, ostensible support of strong intellectual property rights, to its gradual retreat to a position in favor of more attention to the public health needs of developing nations. It will further examine: (1) whether the WTO has the legitimate authority to implement these goals, and (2) whether the WTO has collectively assembled a framework that can effectively serve to accomplish these goals.

I. OVERVIEW OF THE CONFLICT

A. Epidemics in Developing Nations

A substantial majority of the world's least-developed countries are situated in sub-Saharan Africa.[8] In a December 2004 collaborative report, the United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) noted that in the these African nations, over 2.3 million people succumbed to AIDS in 2004, and another 25.4 million were living with the human-immunodeficiency virus (HIV).[9] With 7.4 percent of the population infected, this region has the highest prevalence of HIV/AIDS in the world.[10] Further, while the sub-Saharan African nations are home to just over ten percent of the world's population, nearly two-thirds of all people living with HIV are members of these nations.[11]

It has been noted that while "HIV/AIDS . . . is the biggest single cause of mortality in developing countries, [tuberculosis] and malaria claim almost as many

8. The United Nations presently categorizes fifty countries as least-developed; of these, forty are located in sub-Saharan Africa. *See* United Nations, List of Least Developed Countries, http://www.un.org/special-rep/ohrlls/ldc/list.htm (last visited Dec. 17, 2004).

9. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS (UNAIDS) AND WORLD HEALTH ORGANIZATION (WHO), 2004 AIDS EPIDEMIC UPDATE 2, *at* http://www.unaids.org/wad2004 (last visited Dec. 17, 2004) [hereinafter AIDS EPIDEMIC UPDATE].

10. *Id.*

11. *Id.* at 19.

lives."[12] The Global Fund to Fight AIDS, Tuberculosis, and Malaria reports: "[i]n 2003, about 3 million people died of AIDS, three-quarters in sub-Saharan Africa alone. Another 5 million were newly infected."[13] In addition, "[e]ach year, nearly 2 million people die of [tuberculosis], despite the availability of inexpensive treatments that are effective in up to 95% of cases,"[14] while "[m]alaria kills more than 1 million people a year, with 90% of these deaths occurring in Africa, mostly in children under 5 years of age."[15]

From these figures, it is evident that developing countries, particularly the LDC's, stand to benefit the most from access to essential medicines.[16] Advocates of initiatives to facilitate access to these medicines in developing nations include multinational organizations such as Oxfam America,[17] the Consumer Project on Technology,[18] the Third World Network,[19] and Doctors Without Borders/Médecins Sans Frontières.[20] These organizations attribute poor access to such medicines largely to the failures of the pharmaceutical industry, arguing that drug prices set by the industry are too high, and

12. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 30 (2002), *at* http://www.iprcommission.org/graphic/documents/final_report.htm (last visited Dec. 17, 2004) [hereinafter CIPR REPORT].

13. The Global Fund, Fighting AIDS, *at* http://www.theglobalfund.org/en/about/aids/default.asp (last visited Dec. 17, 2004).

14. The Global Fund, Fighting Tuberculosis, *at* http://www.theglobalfund.org/en/about/tuberculosis/default.asp (last visited Dec. 17, 2004).

15. The Global Fund, Fighting Malaria, *at* http://www.theglobalfund.org/en/about/malaria/default.asp (last visited Dec. 17, 2004).

16. The term "essential medicines" is derived from the World Health Organization's list of Essential Drugs and Medicines. WHO categorizes essential medicines as "those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness." WHO, Essential Drugs and Medicines Policy, *at* http://www.who.int/medicines (last visited Dec. 17, 2004). *See also* Essential Medicines, WHO Model List (revised April 2003), *available at* http://www.who.int/medicines/organization/par/edl/expcom13/eml13_en.pdf (last visited Dec. 17, 2004).

17. Oxfam America, http://www.oxfamamerica.org (last visited Dec. 17, 2004).

18. The Consumer Project on Technology, http://www.cptech.org (last visited Dec. 17, 2004).

19. The Third World Network-Africa, http://www.twnafrica.org (last visited Dec. 17, 2004).

20. Doctors Without Borders/Médecins Sans Frontières, http://www.doctorswithoutborders.org (last visited Dec. 17, 2004).

research and development is not targeted to the specific needs of these nations.[21] It has been suggested that the pharmaceutical industry is unwilling to invest in the development of medications to combat diseases which are present in developing nations, unless those diseases are also common to developed nations, where the potential for a return on the industry's investment is more probable.[22] The paucity of medications that have been manufactured to treat tropical diseases over the last twenty-five to thirty years supports this assertion.[23]

B. Intellectual Property Concerns in the Pharmaceutical-Manufacturing Industry

In the United States, pharmaceutical manufacturers estimate that it takes an average of ten to fifteen years and greater than $800 million to advance a single medicine from the level of a research idea to an FDA-approved drug.[24] Additionally, only one out of every five medicines that advances to the level of clinical trials is actually approved for patient use by the FDA.[25] Hence, "[t]he process is long, risky, fraught with failure, and ultimately expensive. Failure at the clinical trial stage could completely nullify 15 years of painstaking work by pharmaceutical research company scientists."[26]

In view of this investment, the pharmaceutical industry is very attentive to optimally utilizing and enforcing its intellectual property (IP) rights in those medications which it is actually able to bring to market. Further, it has been suggested that the

21. *See, e.g.*, Doctors Without Borders/Médecins Sans Frontières, *Research and Development System Failing to Meet Health Needs of Developing Countries, at* http://www.doctorswithoutborders.org/pr/2004/11-16-2004.shtml (last visited Dec. 17, 2004).
22. CIPR REPORT, *supra* note 12, at 32.
23. *See Id.* (citing Patrice Trouiller, et. al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-health Policy Failure*, 359 LANCET 2188, 2188-94 (2002)).
24. *See* PHRMA PROFILE, *supra* note 1, at 2.
25. *Id.* at 3.
26. *Id.*

industry is particularly susceptible to violations of its IP rights because the vast bulk of the expense of producing pharmaceuticals lay in the cost of the research and development.[27] The actual production costs are very low, as most drugs are manufactured from inexpensive, basic chemicals; thus, where IP protection is absent or not adequately enforced, competitors can produce identical medicines at substantially less cost than the companies which invested heavily in their development.[28] For this reason, the pharmaceutical-manufacturing industry has lobbied for strong intellectual property protection throughout the world.[29] Developed nations, especially the United States, have historically responded to this lobby abroad through international forums like the World Trade Organization.[30]

II. OVERVIEW OF THE WORLD TRADE ORGANIZATION

A. The GATT Years

The WTO formally came into existence on January 1st, 1995, its primary objective being "to help trade flow smoothly, freely, fairly and predictably" throughout the world.[31] In its first decade, the original membership of seventy-five nations nearly doubled,[32] and today member nations account for over 97% of global trade.[33] Although the WTO is a relatively young international organization, its roots are significantly older. Near the end

27. DONALD G. RICHARDS, INTELLECTUAL PROPERTY RIGHTS AND GLOBAL CAPITALISM: THE POLITICAL ECONOMY OF THE TRIPS AGREEMENT 141 (2004).
28. *Id.*
29. *Id.*
30. *See Id.*
31. WTO, THE WORLD TRADE ORGANIZATION IN BRIEF 7 (2003), *available at* http://www.wto.org/english/res_e/doload_e/inbr_e.pdf (last visited Dec. 17, 2004).
32. WTO, UNDERSTANDING THE WTO 112 (3d ed. 2003), *available at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf (last visited Dec. 17, 2004). For a frequently-updated source of this information, *see also* WTO, Members and Observers, *at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Dec. 17, 2004).
33. THE WORLD TRADE ORGANIZATION IN BRIEF, *supra* note 31, at 7.

of World War II, a proliferation of international organizations occurred in response to a growing multinational consensus favoring the view that improving international social and economic relations might prevent another world war.[34] During this period, the United Nations came into existence and the Allied nations held the Bretton Woods Conference.[35] This conference spawned the International Monetary Fund (IMF) and the World Bank (IBRD), and opened the door to discussions concerning the formation of an international trade organization.[36] Soon after, the General Agreement on Tariffs and Trade (the GATT)[37] was formed to serve as a multilateral trade agreement, to be administered by the newly-chartered International Trade Organization (ITO).[38] However, the United States ultimately concluded that the ITO was overly-restrictive, and Congress declined to ratify the agreement; as a result, the ITO never came into force.[39] Thus, a multinational trade agreement existed in the GATT, but no formal intergovernmental organization was present to oversee it. Despite the failure of the ITO to take root, the GATT was adopted by a multitude of countries, and through numerous rounds of

34. JOHN H. JACKSON, THE WORLD TRADE ORGANIZATION: CONSTITUTION AND JURISPRUDENCE 15 (1998).

35. *Id.* The Bretton Woods conference took place in the resort town of Bretton Woods, New Hampshire, in July 1944. It was attended by all forty-four of the Allied nations. *See* Wikipedia, Bretton Woods System, *at* http://en.wikipedia.org/wiki/Bretton_Woods_Conference (last visited Dec. 17, 2004).

36. *See* JACKSON, *supra* note 34, at 15-16.

37. General Agreement on Tariffs and Trade, October 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 187 [hereinafter GATT 1947].

38. JACKSON, *supra* note 34, at 17.

39. *Id.* Notably, the charter for the ITO was drafted by same nation which eventually triggered its demise: the United States. Upon its submission to the Havana Conference in 1948, the charter was accepted and signed by fifty-four nations. However, the United States Senate decided that the scope of the ITO was too ambitious, and in 1951 President Truman announced that the United States would not ratify the charter. Other key nations followed the example of the United States, and in due course the ITO collapsed. *Id. See also* M. RAFIQUL ISLAM, INTERNATIONAL TRADE LAW 4-5 (1999).

negotiation, it evolved into the central instrument that governed multilateral international trade for nearly half a century.[40]

One of the failings of the GATT, if it could be described as such, lay in its dispute settlement provisions.[41] Despite its evolution, the GATT was, at its core, nothing more than an agreement among nations regarding trade; it was never intended to serve as a governing body.[42] Under the GATT, a consensus among all signatories was required to modify the Agreement, and this applied even in cases of dispute settlement.[43] Thus, when a GATT dispute resolution panel reached a determination, the unsuccessful party could effectively veto the decision by simply refusing to agree to it.[44] This issue was one of the items on the agenda for resolution during the eighth round of negotiations under the GATT, known as the Uruguay Round.[45]

B. The Uruguay Round

The Uruguay Round began in September of 1986 and did not conclude until April of 1994.[46] It has been described as "the largest, most far-reaching, longest, and most contentious round of multilateral trade negotiations ever undertaken,"[47] as well as "the most important event in recent world economic history."[48] Several defining agreements emerged from the Uruguay Round, but one item in particular that resulted from a

40. *See* JACKSON, *supra* note 34, at 17-20. The GATT began with twenty-three signatories in 1947 and grew to 123 nations at the time of the commencement of the Uruguay Round. *See* UNDERSTANDING THE WTO, *supra* note 32, at 16.
41. *See* DAVID PALMETER & PETROS C. MAVROIDIS, DISPUTE SETTLEMENT IN THE WORLD TRADE ORGANIZATION 9 (2004).
42. *Id.; see also* JACKSON, *supra* note 34, at 16.
43. PALMETER & MAVROIDIS, *supra* note 41, at 9.
44. *See Id.*
45. *Id.* at 12.
46. *Id.* at 11.
47. *Id.*
48. Leonard Bierman, Donald R. Fraser, & James W. Kolari, *The General Agreement On Tariffs And Trade: World Trade From A Market Perspective*, 17 U. PA. J. INT'L ECON. L. 821, 845 (1996).

proposal well into the negotiations proved to be highly significant: the charter for the World Trade Organization.[49] The conclusion of the Uruguay Round took place in Marrakesh, Morocco, and hence the final document signed there was designated the Marrakesh Agreement Establishing the World Trade Organization, commonly referred to as the WTO Agreement. [50]

Fundamentally, the agreements formed under the GATT during its forty-seven year tenure were designed to remove barriers to trade in goods caused by tariffs and quotas.[51] The WTO Agreement, by contrast, was constructed more broadly. It includes provisions for the establishment of separate councils to oversee trade in goods, services, and the intellectual property aspects of international trade. Specifically, the WTO Agreement is composed of sixteen articles and four annexed agreements. The articles set forth the administrative provisions of the Agreement, including, inter alias, the scope, structure, and function of the WTO, as well as provisions for accession to and withdrawal from the WTO.[52] The annexed agreements furnish the substantive aspects of the Agreement and provide provisions for dispute settlement and monitoring of trade practices among member nations.

Annex 1 forms the primary substantive portion of the Agreement, and is itself divided into three subsections which define the broad aspects of trade covered by the

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49. JACKSON, *supra* note 34, at 15-16, 27. The Ministerial Declaration which opened the Uruguay Round of Multilateral Trade Negotiations made no reference to the formation of a new organization to replace the GATT. The proposal to form the WTO came almost two years into the negotiations. *Id.* at 27. *See also* WTO/GATT Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, Sept. 20, 1986, 25 I.L.M. 1623 (1986).

50. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 5 (1994), 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

51. *See* UNITED STATES MISSION TO THE UNITED NATIONS IN GENEVA, THE BRIEFING BOOK ON INTERNATIONAL ORGANIZATIONS IN GENEVA 70 (Wendy Lubetkin & Katharine Mann eds., 2004), *available at* http://www.genevabriefingbook.com/chapters/wto.pdf.

52. WTO Agreement, *supra* note 50, arts. I-XVI.

WTO: goods (Annex 1A), services (Annex 1B), and trade-related intellectual property matters (Annex 1C).[53] Annex 1A, known as the Multilateral Agreement on Trade in Goods, incorporates the entirety of GATT 1994[54] as well as twelve other agreements.[55] Annex 1B is the General Agreement on Trade in Services (GATS),[56] and Annex 1C is known as the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).[57] The latter section, TRIPS, is the most relevant to the intellectual property issues discussed below.

Annex 2 is known as the Understanding on Rules and Procedures Governing the Settlement of Disputes, or Dispute Settlement Understanding (DSU).[58] This section of the WTO Agreement provides the rules for the Dispute Settlement Body (DSB), which functions to resolve disputes among members.[59]

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53. *Id.*, Annex 1A, 1B, 1C.

54. The GATT was first formed in 1947 and revised periodically through many rounds of negotiations that took place during in its 47-year history. In 1994 the GATT was entirely replaced with a new version of the agreement, in order to bring its provisions into line with the decisions reached in the Uruguay Round of trade negotiations. To distinguish the two distinct agreements, the original GATT is often referred to as GATT 1947 and the agreement which replaced it is known as GATT 1994. Thus, the GATT continues to exist as an integral part of the WTO Agreement. UNDERSTANDING THE WTO, *supra* note 32, at 19.

55. Multilateral Agreement on Trade in Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 20 (1994); 33 I.L.M. 1144, 1154 (1994) [hereinafter Multilateral Agreement].

56. General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 325 (1994); 33 I.L.M. 1144, 1168 (1994) [hereinafter GATS].

57. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 365 (1994); 33 I.L.M. 1144, 1197 (1994) [hereinafter TRIPS].

58. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 404 (1994), 33 I.L.M. 1144, 1226 (1994) [hereinafter DSU].

59. *Id.*

Annex 3 is known as the Trade Policy Review Mechanism (TPRM).[60] This section of the Agreement provides a means for the WTO to monitor national trade policies in order to encourage transparency domestically and multilaterally.[61] The Trade Review Policy Board, which was created under this agreement, performs reviews of member nations' trade practices regularly.[62] The frequency of such reviews depends upon the amount of trade in which a member engages: those countries that engage in the most trade are reviewed frequently, while those nations that are less-active in international trade are reviewed less-often.[63]

Finally, Annex 4 consists of two Plurilateral Trade Agreements,[64] which are the only remaining optional agreements in the WTO—agreements that members may, but are not required to join.[65] These include agreements on trade in civil aircraft and on government procurement, and they are only binding on those members that choose to accept them.[66] Prior to the Uruguay Round, similar side agreements commonly existed as optional agreements, many of which were established during the Tokyo Round.[67] The Uruguay Round, however, advocated a "single package" approach, whereby nations accepting the Uruguay Round were required to embrace the entire agreement, with the

60. Trade Policy Review Mechanism, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 3, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 434 (1994) [hereinafter TPRM].

61. UNDERSTANDING THE WTO, *supra* note 32, at 12, 53.

62. *Id.* at 53.

63. *Id.* The largest trading powers of the world (the United States, Japan, the European Union, and Canada) are examined as often as every two years, while LDC's are reviewed, at most, every six years. *Id.*

64. Plurilateral Trade Agreements, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 4, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 438 (1994) [hereinafter Plurilateral Agreements]. The WTO Agreement originally contained two additional plurilateral agreements, both of which were terminated in 1997: the International Dairy Agreement, and the International Bovine Meat Agreement. *Id.*

65. PALMETER & MAVROIDIS, *supra* note 41, at 14.

66. *Id.*

67. *See* JACKSON, *supra* note 34, at 7.

exception of the Annex 4 agreements.[68] This is particularly relevant in regard to TRIPS, since TRIPS was one of the most contentious aspects of the framework assembled during the Uruguay Round,[69] yet its ratification was ultimately compulsory for membership in the WTO.

III. INTELLECTUAL PROPERTY PROVISIONS IN THE WTO AGREEMENT

A. Origins in the Uruguay Round

It has been argued that the influences of the political and economic forces surrounding the Uruguay Round of trade negotiations resulted in an agreement which was as much the product of a hegemonic struggle as it was the product of enlightened thinking.[70] This is particularly evident in light of the inclusion of TRIPS in the World Trade Agreement. The optimistic view may be that the ministers who took part in the Uruguay Round recognized that just as tariffs and quotas could create barriers to trade, so too could a lack of intellectual property protection, and thus TRIPS was included. The more critical view suggests that TRIPS would never have been discussed during the Uruguay Round—and it certainly would not have been included in the final agreement—but for the fact that the United States would never have ratified the WTO absent its inclusion.[71] In any event, it is generally agreed that while TRIPS is well-constructed in terms of setting forth international standards for IP protection, several of its provisions "clearly display the characteristics of a difficult compromise reached during the Uruguay

68. *Id.*
69. *See* DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS 30 (2002) (noting that TRIPS had become a central stumbling block to the progress of the negotiations by the mid-term of the Uruguay Round).
70. *See* RICHARDS, *supra* note 27, at 124.
71. *See Id.* at 25.

Round negotiations."[72] That the Uruguay Round negotiations were long, difficult, and fraught with setbacks is further evidence of this.[73] The Ministerial Declaration which opened the Uruguay Round provided: "[t]he Multilateral Trade Negotiations will be concluded within four years."[74] However, this proved to be ambitious, as the contentious negotiations did not conclude for nearly eight years.[75]

Historically, the protection of intellectual property rights has primarily been a concern of the developed nations, which advocate the view that intellectual property protection leads to innovation, stimulation of economic growth, the transfer of technology, and ultimately, social welfare.[76] Developing countries have traditionally considered such rights to be either unimportant or, in some cases, an actual hindrance to economic growth.[77] Specifically, it has been suggested that many developing nations view IP regimes as a means for developed nations to maintain their dominance in the global market, and to prevent technological development in other nations.[78] Indeed, in the least-developed countries, the enforcement of IP rights may be viewed as a financial burden: such nations typically do not have the economic resources to develop their own technology, and the cost of implementing IP enforcement protocol may be prohibitive to them.[79] Finally, some commentators have suggested that developed nations like the United States have behaved pharisaically in attempting to force developing nations to

72. MATTHEWS, *supra* note 69, at 66.
73. PALMETER & MAVROIDIS, *supra* note 41, at 12-13.
74. WTO/GATT Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, Sept. 20, 1986, 25 I.L.M. 1623, 1624 (1986).
75. Negotiations formally concluded on December 13, 1993.
76. *See* Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 46-47 (1999).
77. *See Id.* at 52-53*; see also* MATTHEWS, *supra* note 69, at 31 (discussing the resistance of developing countries to strong protection of intellectual property rights which might impede the transfer of technology and elevate the cost of pharmaceuticals).
78. *See* McCabe, *supra* note 76, at 52-53.
79. *See Id.* at 54-55.

implement IP regimes.[80] They attribute this notion to the fact that countries like the United States did not respect the IP rights of other industrialized nations when they themselves were developing.[81]

As early as the GATT Ministerial Meeting in 1982,[82] the United States pushed for the development of an agreement on intellectual property rights concerning counterfeit goods.[83] The escalation of trade in counterfeit goods in the 1970's had produced a strong lobby in Washington and abroad, buoyed by corporations which were feeling the ill-effects of this trade.[84] Developing countries like India and Brazil argued that the inclusion of such an agreement in the GATT was unnecessary because a forum already existed in the World Intellectual Property Organization (WIPO) to address these concerns.[85] However, developed nations like the United States were unsatisfied with WIPO as a vehicle to expand their intellectual property rights internationally because WIPO was established as a one-country, one-vote forum, and the majority of its membership consisted of developing nations.[86] Further, the vast majority of WIPO's

80. Kumariah Balasubramaniam, *Access to Medicines: Patents, Prices, and Public Policy—Consumer Perspectives*, *in* GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT 105 (Peter Drahos & Ruth Mayne eds., 2002).

81. *Id.*

82. The 1982 GATT Ministerial Meeting was part of the intermediate negotiations leading up to the Uruguay Round. It was held to attend to the unresolved issues that remained following the end of the previous GATT round, the Tokyo Round. *See* MATTHEWS, *supra* note 69, at 9.

83. *Id.*

84. *Id.* at 8-9, 12.

85. *Id.* The World Intellectual Property Organization (WIPO) is one of the specialized agencies of the United Nations. It was formally established as part of the UN by the Convention Establishing the World Intellectual Property Organization, which was signed at Stockholm in 1967. Its two objectives are: (1) "to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization"; and (2) "to ensure administrative cooperation among the Unions." The current mandate of WIPO is primarily focused on promoting and harmonizing intellectual property laws around the world. *See* Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3; *see also* WIPO, Medium-Term Plan for WIPO Program Activities - Vision and Strategic Direction of WIPO, http://www.wipo.int/about-wipo/en/dgo/pub487.htm (last visited Dec. 17, 2004).

86. *See* MATTHEWS, *supra* note 69, at 10-11. Although the WTO is also a one-member, one-vote organization, the United States was able to assert substantial influence in expanding IP protection during

budget is derived through the services it provides (e.g., international patent applications), rather than through international contributions, and thus it is far less-susceptible to hegemonic manipulation.[87] Hence, developing nations were able to successfully block the development of expansive intellectual property treaties which might have emerged under WIPO.[88]

When it became clear that the United States and other developed nations would not be able to push multilateral intellectual property initiatives through WIPO, they shifted their focus to a new strategy: linking intellectual property to trade.[89] This was initially achieved through a series of bilateral agreements formed with developing nations during the mid-1980's, and later the approach became integral to the developed nations' position in the Uruguay Round.[90] These agreements essentially gave developing countries wider access to U.S. markets in exchange for increased protection of intellectual property rights in those nations.[91] The fact that the Ministerial Declaration at the opening of the Uruguay Round called for a discussion of counterfeit goods and intellectual property rights among its objectives is reflective of the predominance of these agreements.[92]

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the Uruguay Round by binding agreements involving intellectual property rights to agreements involving international trade. Thus, through their dominance in world trade, developed nations like the United States had greater than the sum of their individual votes during the Uruguay Round negotiations. *See Id.* at 12.

87. RICHARDS, *supra* note 27, at 117.
88. *Id.*
89. MATTHEWS, *supra* note 69, at 12.
90. *Id.* at 12, 16-17.
91. *Id.* at 32-33.
92. *See Id.* at 17. The relevant section of the Ministerial Declaration states:

> In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines. Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with

Throughout the Uruguay Round, the United States continued to cultivate new bilateral trade and intellectual property agreements with developing nations engaged in the negotiations.[93] This enabled the United States to prevent an organized resistance to the inclusion of intellectual property among the developing nations, and thus intellectual property rights remained a key component of the negotiations.[94] Through this approach and through the strength of its tripartite alliance with Europe and Japan,[95] the United States succeeded in shepherding through the Uruguay Round what would become the broadest international intellectual property agreement in history.[96]

B. TRIPS

TRIPS was the first international agreement to make intellectual property rules a compulsory constituent of a multilateral trading system.[97] It has been described as "undoubtedly the most significant milestone in the development of intellectual property… " in the twenty-first century.[98] Further, the inclusion of TRIPS as part of the "single package" of the WTO Agreement effectively resulted in an unparalleled, mandatory globalization of intellectually property rights among its signatories.[99]

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international trade in counterfeit goods, taking into account work already undertaken in the GATT.

WTO/GATT Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, Sept. 20, 1986, 25 I.L.M. 1623, 1625 (1986).

93. MATTHEWS, *supra* note 69, at 32-33.
94. *Id.*
95. *See Id.* at 42.
96. DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 3 (1998).
97. UNDERSTANDING THE WTO, *supra* note 32, at 39.
98. GERVAIS, *supra* note 96, at 3.
99. *See generally* MATTHEWS, *supra* note 69, at 1-6. *But cf.* RICHARDS, *supra* note 27, at 5 (noting that although TRIPS is designed to create international minimum standards for the protection of intellectual property rights, it does not seek to harmonize these rights per se, because member nations are free to design their own systems, which may award even broader protections).

TRIPS was designed with three central features: it established minimum standards for the protection of intellectual property rights; it described procedures and remedies to be utilized in the enforcement of these rights; and it provided for the application of the WTO dispute settlement mechanism to issues arising under TRIPS.[100] Additionally, it established two fundamental principles to be applied by all member nations: national treatment and most-favored nation treatment.[101]

National treatment, which was a well-established principle in international IP law prior to TRIPS, may be described as "[t]he policy or practice of a country that accords the citizens of other countries the same intellectual-property protection as it gives its own citizens, with no formal treaty of reciprocity required."[102] National treatment functions well as an international principle because "it allows countries the autonomy to develop and enforce their own laws, while meeting the demands for international protection. Effectively, national treatment is a mechanism of international protection without harmonization."[103]

Had the drafters of TRIPS limited its requirements to national treatment, however, TRIPS would have been much narrower in scope. Under national treatment, a member nation need only provide as much protection for intellectual property to other members as it offers domestically.[104] For example, under national treatment, those nations that did not grant patents for pharmaceuticals to their own nationals would not have to recognize

100. PETER GALLAGHER, GUIDE TO THE WTO AND DEVELOPING COUNTRIES 181 (2000).
101. TRIPS, arts. 3, 4.
102. BLACK'S LAW DICTIONARY 1054 (8th ed. 2004).
103. LIONEL BENTLY & BRAD SHERMAN, INTELLECTUAL PROPERTY LAW 5 (2001), *reprinted in* BLACK'S LAW DICTIONARY 1054 (8th ed. 2004).
104. RICHARDS, *supra* note 27, at 142.

patents issued to nationals of other member nations.[105] However, TRIPS expanded IP rights by imposing minimum standards for the protection of all of the forms of intellectual property that are covered under the agreement.[106] Further, with respect to patentable subject matter, Article 27 of the TRIPS Agreement requires that members make "patents . . . available for any inventions, whether products or processes, in all fields of technology."[107] Thus, even contentious subject matter not previously protected under the intellectual property laws of many nations is protected under TRIPS, including pharmaceuticals.[108]

Most-favored nation treatment is "[t]he practice or policy of automatically and unconditionally granting any intellectual-property protection, advantage, favor, privilege, or immunity that by treaty is extended to nationals of any member country to the nationals of all member countries"[109] Such treatment is to be awarded even when it is more-favorable to others than it is to a member's own nationals.[110]

In assembling the substantive provisions of TRIPS, the drafters chose to integrate several established subject-specific international intellectual property agreements, with very few modifications.[111] Included in TRIPS were nearly all of the provisions of the Paris Convention, the Berne Convention, and the Rome convention.[112] With the addition

105. Notably, as late as 1988, forty-eight countries among the WIPO members did not provide patent protection for pharmaceutical products. MATTHEWS, *supra* note 69, at 185 n.5.

106. TRIPS, *supra* note 57, arts. 9-39.

107. *Id.*, art. 27(1).

108. RICHARDS, *supra* note 27, at 141.

109. BLACK'S LAW DICTIONARY 1035 (8th ed. 2004).

110. WTO, A Summary of the Final Act of the Uruguay Round, *at* http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement (last visited Dec. 17, 2004).

111. GERVAIS, *supra* note 96, at 25-26.

112. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, last revised at Stockholm, July 14, 1967, 828 U.N.T.S. 221 [hereinafter Berne Convention]; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]; International Convention for the Protection of

of several new provisions that accounted for contemporary IP subject matter, TRIPS encompassed a broad range of intellectual property, including copyright, patents, trademarks, trade secrets, industrial designs, geographical indicia and integrated circuit layouts.[113]

Finally, Article 68 of the TRIPS Agreement establishes the Council for Trade-Related Aspects of Intellectual Property Rights, which serves to monitor members' compliance with their obligations under the Agreement and provides the opportunity for consultations on matters related to TRIPS.[114]

C. TRIPS Provisions Beneficial to Developing Countries

Presently, approximately two-thirds of the WTO members are categorized as developing countries, and many of these are considered least-developed.[115] The preamble of the WTO Agreement leaves little doubt that the trade interests of these developing countries are well-represented in the Agreement, "[r]ecognizing . . . that there is a need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth of international trade commensurate with the needs of their economic development."[116]

Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome, Italy on Oct. 26, 1961, 496 U.N.T.S. 43 [hereinafter Rome Convention].

113. GALLAGHER, *supra* note 100, at 181.

114. TRIPS, *supra* note 57, art. 68.

115. UNDERSTANDING THE WTO, *supra* note 8, at 32. Member nations in the World Trade Organization may be classified as developed, developing, or least-developed countries. Those countries categorized as least-developed "are defined according to a UN list" but "[t]here are no WTO definitions of 'developed' and 'developing' countries." For purposes of the WTO, "members announce for themselves whether they are 'developed' or 'developing' countries . . . [and] . . . other members can challenge the decision of a member to make use of provisions available to developing countries." *See* World Trade Organization, *Who are the Developing Countries in the WTO?*, *at* http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Dec. 17, 2004) (describing these categorizations).

116. WTO Agreement, *supra* note 50, pmbl., para. 2.

One of the issues recognized by the drafters of the WTO Agreement was the risk that the requirement to enforce intellectual property rights in developing nations would be initially burdensome to developing countries and could impede humanitarian interests, particularly in least-developed countries. TRIPS was constructed in a manner directed to balancing these interests. This mandate is evident in Article 7, which states:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[117]

Concessions for developing countries and LDC's supportive of this mandate are scattered throughout TRIPS. These concessions may be viewed as falling into three broad categories: (1) transitional provisions, which are described in fairly specific terms; (2) ambiguous loophole provisions, which leave greater room for interpretation; and (3) highly-contentious yet thinly-worded provisions related to parallel importation and compulsory licenses.

1. Transitional Provisions – The transitional provisions embodied in TRIPS provide a kind of grace period for member nations acceding to the Agreement, so that they may adjust before implementing its terms.[118] The inclusion of these provisions was necessary to encourage developing countries and LDC's to adopt the Agreement, as these nations argued that they needed more time to modify their economies and legal systems

117. TRIPS, *supra* note 57, art. 7.
118. *See* MATTHEWS, *supra* note 69, at 72.

to make implementation viable.[119] Articles 65 and 66 of TRIPS set forth these rules: developed countries are permitted one year following their effective date of membership to reach compliance with the requirements of TRIPS; developing countries are permitted five years; and LDC's are permitted up to eleven years.[120] These grace periods are limited in the case of national treatment and most-favored nation treatment, which must both be in effect within a year following a member nation's effective date of membership.[121] Thus, after its first year of membership in the WTO, a nation cannot implement IP policies domestically or for the benefit of select WTO members without providing those benefits to all members.

Additional extensions are also possible. LDC's, for example, may be granted extensions to the eleven-year period for implementation by simply making a "duly motivated request . . . " to the TRIPS Council for such an extension.[122] Article 65(4) also provides for a further extension of up to five years for implementation of protection of any technology that the member has no protection for at the time of application for membership.[123] Thus, if a nation does not permit patent protection for pharmaceuticals prior to its accession to the WTO, it need not enforce other members' pharmaceutical patent rights until the conclusion of this added period. This is, in fact, one of the two most common invocations of this rule: many developing nations which seek membership in the WTO have previously offered no protection for either pharmaceutical or

119. Peter L. Farkas, *Trade-Related Aspects of Intellectual Property: What Problems with Transition Rules, What Changes to U.S. Law, How has Congress Salvaged 337?*, *in* THE WORLD TRADE ORGANIZATION: A MULTILATERAL FRAMEWORK FOR THE 21ST CENTURY AND U.S. IMPLEMENTING LEGISLATION 465 (Terence P. Stewart ed., 1996).

120. TRIPS, *supra* note 57, arts. 65(1), 65(2), 66(1).

121. *Id.*, art. 65(1).

122. *Id.*, art. 66(1).

123. *Id.*, art. 65(4).

agrochemical technologies.[124] Under this and the other transitional provisions, any LDC that invokes all of its transitional rights will have until at least 2016 to implement an intellectual property regime which protects these technologies.

During the Uruguay Round, the inclusion of such generous transition periods was a difficult pill for the developed nations to swallow, and perhaps rightfully so: it is believed that each year that member nations delay the implementation of their duties under TRIPS, the industries of developed countries like the United States lose billions of dollars in revenue.[125] However, these provisions were very likely the final key to securing the incorporation of TRIPS in the WTO Agreement, and therefore the developed nations agreed to their inclusion.[126]

2. Loophole Provisions – TRIPS contains several loophole provisions which could benefit developing nations by adding flexibility to the Agreement, but they may ultimately serve to leave too much to interpretation. For example, Article 8 states that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Agreement."[127] No elaboration is provided, yet the broadest interpretation of this provision would seem to suggest that IP rights should generally surrender to public health needs. Similarly, Article 27 seems to clearly identify the full breadth of patentable technology under TRIPS as "any inventions, whether

124. *See* MATTHEWS, *supra* note 69, at 74.
125. Farkas, *supra* note 119, at 465.
126. *Id.*
127. TRIPS, *supra* note 57, art. 8(1).

products or processes, in all fields of technology . . . "[128] yet it also contains an escape clause:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[129]

This ambiguously-stated provision, read broadly, suggests that wherever public order, the environment, human life, animal life, or plant life are at stake, a patent-holder's rights may be ignored. Finally, Article 30 is even less-enlightening, providing:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[130]

The drafters provide no further elaboration in regard to what is meant by "limited exceptions," nor do they offer any insight into how a member nation should interpret the highly-flexible terms "unreasonably" or "normal exploitation." These latter phrases would seem to provide qualifying language to tighten the loopholes, but even this language is ultimately indistinct and therefore subject to a wide range of interpretation, providing room for conflict rather than flexibility.[131]

3. Parallel Imports and Compulsory Licenses – The most frequently-cited provisions, which are also the most controversial, are the provisions in TRIPS which

128. *Id.*, art. 27(1).
129. *Id.*, art. 27(2).
130. *Id.*, art. 30.
131. *See* RICHARDS, *supra* note 27, at 156-57.

permit parallel importation and compulsory licenses. These provisions provide potentially very useful tools to developing countries, but they may frustrate the interests of industrialists, particularly within the pharmaceutical industry, because they provide broad escape clauses for developing nations which do not honor IP rights for pharmaceuticals.

(a) Parallel Imports – The concept of parallel importation is most easily understood through its corollary, a doctrine known as exhaustion.[132] This doctrine applies the rule that the rights of an intellectual property owner over goods end once those goods have been placed on the market legally.[133] This is also referred to as the first-sale doctrine, particularly in the United States.[134] In regard to patents, this doctrine asserts the view "that the buyer of a patented article has the right to use, repair, and resell the article without interference from the patentee."[135] In regard to copyright-protected works, "the purchaser of a physical copy of a copyrighted work, such as a book or CD, may give or sell that copy to someone else without infringing the copyright owner's exclusive distribution rights."[136] Thus, to an extent, the IP right-holder's privileges do not extend past the first sale.[137]

132. Carlos M. Correa, *Pro-competitive Measures Under TRIPS*, *in* GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT 43 (Peter Drahos & Ruth Mayne eds., 2002).

133. *Id.*

134. *Id.* at 43-44.

135. BLACK'S LAW DICTIONARY 667 (8th ed. 2004).

136. *Id.*

137. This is not to say that all of a right-holder's privileges terminate upon the sale of a good; for example, a copyright-holder still has the right to prevent others from copying or reproducing his work without authorization. Similarly, a patent-holder may generally continue to prevent others from making, using, or selling his invention without permission, even after he has licensed a particular manufacturer to produce the patented article. He cannot, however, prevent subsequent sales of individual goods manufactured under such a license as they change hands from owner to owner.

It is common in some nations for right-holders to form contractual agreements for the sale of goods which limit a buyer's rights to export or resell those goods.[138] This is customary in the United States, the European Union, and Japan.[139] In other nations, however, these restrictions are not permitted and exhaustion is automatic.[140] Where exhaustion exists, parallel importation may legally follow:

> Parallel imports (PI), also called gray-market imports, are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. This owner is typically a licensed local dealer. For example, it is permissible for a trading firm to purchase quantities of prescription drugs in Spain and import them into Sweden or Germany without the approval of the local distributor owning licensed patent rights.[141]

The legal status of the act of parallel importation depends upon a country's law regarding the territorial extent of exhaustion.[142] Where a country establishes a policy of *national* exhaustion, exclusive rights terminate upon first sale within a country, but right-holders may still exclude parallel imports from other nations.[143] This is essentially a "government-enforced territorial restriction on international distribution."[144] By contrast, when a country implements a policy of *international* exhaustion, exclusive rights are

138. MATTHEWS, *supra* note 69, at 48.
139. *Id.*
140. *Id.; see also* Correa, *supra* note 132, at 43-44.
141. KEITH E. MASKUS, PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES, FINAL REPORT TO WORLD INTELLECTUAL PROPERTY ORGANIZATION 2 (2001), *available at* http://www.wipo.org/about-ip/en/studies/pdf/ssa_maskus_pi.pdf (last visited Dec. 17, 2004).
142. *Id.* at 3.
143. *Id.*
144. *Id.*

terminated following the first sale anywhere and parallel imports cannot be excluded thereafter.[145]

The text of TRIPS leaves open the question of whether parallel importation is permissible or subject to restriction. Parallel imports are not mentioned in TRIPS; however, Article 6 does make reference to the doctrine of exhaustion, stating simply "[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[146]

From a strict reading of this provision, it would appear that nothing in TRIPS forbids parallel importation, provided that national treatment and most-favored nation treatment are implemented. The WTO's silence on this issue has been the cause for much dispute in the pharmaceutical industry. Parallel importation of pharmaceuticals typically occurs when a low-cost generic version of a drug is manufactured under license for use in a specific region, but it is shipped without authorization to another market where it can compete with the higher-priced proprietary supply of the same drug.[147] This is particularly relevant to the pharmaceutical industry, which is built substantially on price discrimination, whereby manufactures seek to shield affluent markets from lower-priced imports originating in less-affluent markets.[148] It has been noted:

> [I]t pays to charge a different price across two markets if the elasticity of demand in those markets differs at a common price. The market with the

145. *Id.* Maskus adds: "[a] third possibility is regional exhaustion, under which rights end upon original sale within a group of countries, thereby allowing parallel trade among them, but are not ended by first sale outside the region." *Id.*

146. TRIPS, *supra* note 57, art. 6.

147. *See* RICHARDS, *supra* note 27, at 155-56.

148. MATTHEWS, *supra* note 69, at 49.

> low elasticity of demand—that is, where price can be raised without causing a lot of consumers to exit the market—will be charged the higher price. The high elasticity market—where a price increase causes a larger loss of consumers—will receive the lower price.[149]

(b) Compulsory Licenses – Equally frustrating to the pharmaceutical industry are the provisions in Article 31, which permit the issuance of compulsory licenses.[150] Under this Article, a member nation may authorize its nationals to use the subject matter of a patent without the permission of the right-holder, subject to several conditions. However, even the most-restrictive of these qualifying conditions can be met with little difficulty "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[151] Neither of the key phrases in this safety valve are defined by TRIPS: there is no explanation as to what constitutes a "national emergency," nor "extreme urgency," and thus interpretation is again left largely open. In any event, under such circumstances, only two relatively firm conditions must be met prior to authorization under Article 31. First, the patent holder must be adequately compensated for the use of his rights.[152] Second, the amount of this compensation and the legal validity of the decision to grant such authorization must be subject to "judicial review or other independent review by a distinct higher authority in that Member."[153]

For obvious reasons, the compulsory licensure provisions in Article 31 are particularly adaptable to pharmaceutical patents, particularly for those pharmaceuticals which are used to treat life-threatening illnesses. Member nations experiencing critical

149. Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 63 (2002) (citing FREDERIC M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 14-19 (Rand McNally 2d ed 1980)).

150. TRIPS, *supra* note 57, art. 31.

151. *Id.*, art. 31(b).

152. *Id.*, art. 31(h).

153. *Id.*, art. 31(i), (j).

health crises can authorize their nationals to produce such medications with minimal bureaucratic obstruction, and largely at their own discretion, since the decision to give such authorization is subject only to domestic review. Depending upon one's viewpoint, this may be regarded as either a great humanitarian boon or an unwarranted, total abrogation of the pharmaceutical industry's rights to control its intellectual property.

(c) The South-African Government/Pharmaceutical Companies Case – The liberal use of both parallel imports and compulsory license was tested in 1998 when forty-two international pharmaceutical companies brought suit against the South African government in the Pretoria High Court in South Africa.[154] At issue was a provision of the South African Medicines and Related Substances Control Amendment Act 1997, which seemed to permit the South African Health Minister to issue compulsory licenses, allow parallel imports, and abolish patent rights in order to gain less-expensive access to essential medicines.[155] The pharmaceutical companies argued, inter alias, that the powers granted to the Health Minister through the Act were in conflict with several of the provisions of Article 31 of TRIPS.[156] The United States also complained through its trade minister, asserting that the Act was in conflict with Articles 6, 27, and 28, and 31 of

154. *See* Sarah Büchner, *The South African Government/Pharmaceutical Companies Case: Background and Issues*, Tralac Trade Briefs, at http://www.tralac.org/scripts/content_print.php?id=20#issue (last visited Dec. 17, 2004); *see also* Tshimanga Kongolo, *Public Interest Versus Pharmaceutical Industry's Monopoly in South Africa*, 4 JOURNAL OF WORLD INTELLECTUAL PROPERTY 609-627 (2001).

155. MATTHEWS, *supra* note 69, at 114-115. *But see* David Benjamin Snyder, *South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 DICK. J. INT'L L. 175, 183-84 (1999) (stating that although the Act is subject to interpretation, close examination suggests that it does not give the Minister of Health the power to abrogate patent rights; rather it merely permits the parallel importation of pharmaceuticals).

156. MATTHEWS, *supra* note 69, at 115.

the TRIPS Agreement.[157] However, in the face of massive public protest both domestically and abroad, the United States chose not to bring the matter before the WTO Dispute Settlement Body and the pharmaceutical manufacturers ultimately withdrew from the suit.[158]

IV. INTERPRETING TRIPS

A. The Doha-TRIPS Declaration

Eventually, the WTO's competing objectives of providing strong intellectual property rights and protecting public health needs lead to more incessant demands for a more detailed interpretation of the thinly-worded TRIPS Agreement, particularly by the developing nations. The issue of whether exceptions to patent rights could be made in the case of a public crises dominated the core debate that lead to the Fourth WTO Ministerial Conference in Doha, Qatar, which took place in November 2001.[159] The Doha Conference resulted in a Ministerial Declaration designating a work programme[160] for another round of trade negotiations, and it also produced a separate Ministerial Declaration, the Declaration on the TRIPS Agreement and Public Health (the Doha-TRIPS Declaration).[161] The intention of this separate declaration, diplomatically stated by the WTO, was to "respond to concerns about the possible implications of the TRIPS

157. *Id*.
158. *Id.;* Büchner, *supra* note 154.
159. Preceding the Fourth Ministerial Conference in Doha were the Singapore Ministerial (1996), the Geneva Ministerial (1998), and the Seattle Ministerial (1999). The Cancún Ministerial followed in 2003, and the Sixth Ministerial will be held in Hong Kong in December 2005. WTO, Ministerial Conferences, at http://www.wto.org/english/thewto_e/minist_e/minist_e.htm (last visited Dec. 17, 2004).
160. The British spelling of "programme" is used by the WTO.
161. Doha-TRIPS Declaration, *supra* note 3.

Agreement for access to medicines" and to interpret TRIPS in a manner supportive of public health.[162]

In the Declaration, the WTO noted both sides of the issue, stating "[w]e recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics . . ." and "[w]e recognize that intellectual property protection is important for the development of new medicines."[163] However, the substance of the Declaration serves primarily to loosen the restraints of intellectual property rights over access to essential medicines. In substance, paragraph 5 of the Declaration addressed the most frequently-cited issues, with a strong focus on issues related to pharmaceuticals. Specifically, it affirmed the right of member nations to grant compulsory licenses "and the freedom to determine the grounds upon which such licences are granted," and further noted that members have the right to determine for themselves what constitutes a "national emergency" or "extreme urgency," noting that public health crises caused by epidemics can meet this determination.[164] The Declaration also affirmed the permissibility of parallel importation by stating that "each member [is] free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."[165] Finally, the Declaration added a blanket provision stating that no LDC was required to implement IP rights for pharmaceuticals until at least 2016.[166]

162. World Trade Organization, *The Doha Declaration Explained, at* http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Dec. 17, 2004).
163. Doha-TRIPS Declaration, *supra* note 3, at paras. 1, 3.
164. *Id.* at paras. 5(b), (c).
165. *Id.* at para. 5(d).
166. *Id.* at para. 7.

Significantly, the Ministerial Council recognized that developing countries with poorly-developed manufacturing sectors might not be able to make use of compulsory licenses to produce needed medicines when such licenses were authorized.[167] Although other member nations with better manufacturing capabilities would be able to produce enough medicines under compulsory license to support the needs of the less-industrialized nations, this was not permissible under TRIPS. Article 31(f) states that "any such use [of compulsory licenses] shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[168] Further, Article 31(h) requires that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."[169] To address these issues, paragraph 6 of the Doha-TRIPS declaration mandated that "the Council for TRIPS . . . find an expeditious solution to this problem and . . . report to the General Council before the end of 2002."[170]

B. Implementation of paragraph 6 of the Doha-TRIPS Declaration

Members of the TRIPS Council were deadlocked over how to resolve the paragraph 6 issue.[171] The mandated deadline was missed, and negotiations failed in both

167. *Id.* at para. 6. Notably, it has been observed that only about a dozen of the developing countries actually have a manufacturing sector which is developed enough to produce substantial quantities of pharmaceuticals. Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73, 78 (2004) (hereinafter Matthews/WTO Decision).

168. TRIPS, *supra* note 57, art. 31(f).

169. *Id.*, art. 31(h).

170. Doha-TRIPS Declaration, *supra* note 3, at para. 6.

171. Press Release, WTO News, Decision Removes Final Patent Obstacle to Cheap Drug Imports, *at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited Dec. 17, 2004).

November 2002 and February 2003.[172] Much of the disagreement was over the scope of medicines which could be produced under compulsory licenses, and which diseases could constitute valid public health problems for purposes of the provision.[173] The United States sought to limit the scope of the provision to medicines used to treat HIV/AIDS, malaria, and tuberculosis, while developing nations and NGO's lobbied for broader coverage.[174] Ultimately, the United States conceded the issue, and this proved to be the critical factor to breaking the deadlock.[175] Just days prior to the start of the Fifth Ministerial Conference in Cancún, an agreement was reached and the General Council announced the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Decision).[176]

Under the terms of the Decision, Articles 31(f) and 31(h) may be temporarily waived with respect to pharmaceuticals if certain conditions are met. Notably, these waivers are only applicable until TRIPS can be amended to replace these provisions and such amendments take effect for member states utilizing the waivers.[177]

Article 31(f), which expresses the requirement that compulsory licenses be used predominantly for the supply of the domestic market of the member authorizing the license, may be waived for the production and export of pharmaceuticals to eligible importing members.[178] To qualify as "eligible," importing members must demonstrate to the TRIPS Council that they have inadequate manufacturing ability in the pharmaceutical

172. Markus Nolff, *Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding its Implementation: An "Expeditious Solution"?*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 291, 293 (2004).

173. *See* Matthews/WTO Decision, *supra* note 167, at 92.

174. *Id.* at 86-87.

175. *Id.* at 94.

176. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, at Appendix B, *infra* [hereinafter Decision].

177. *Id.*, para. 11.

178. *Id.*, para. 2.

sector for the products that they require; in the case of LDC's, this is presumed.[179] Additional requirements exist to monitor the use of this waiver. The exporting and importing members must notify the TRIPS Council of their intentions to apply the waiver, and they must provide details concerning the type and quantity of product to be manufactured and exported, the countries which will be involved in the exporting and importing, and the duration of the license(s) granted.[180]

A waiver of Article 31(h) is also available in the Decision.[181] This waiver provides what may be fundamentally a solution to a technical difficulty, in the sense that payment of adequate remuneration to the right-holder is waived for the *importing* member when remuneration is paid to the right-holder by the *exporting* member.[182] This simply avoids payment of double-compensation to the right-holder, which would technically be required under 31(f).

The Decision also contains obligations which must be met in order to prevent misuse of the waivers. Products generated utilizing these waivers must be specifically marked and distinguishable from otherwise-identical proprietary products, and prior to shipment, the licensee must post information on a website concerning these distinguishing features and the quantities and destinations to be supplied.[183] Exporters may manufacture only the amount necessary to meet the needs of the importing member, and the full inventory produced must be exported to that member.[184] Further, the Decision seeks to limit profiteering through illicit parallel trade by requiring that

179. *Id.*, ANNEX.
180. *Id.*, paras. 2(a)(i), 2(a)(iii), 2(c).
181. Decision, *supra* note 176, at para. 3.
182. *Id.*
183. *Id.*, para. 2(b)(ii), 2(b)(iii).
184. *Id.*, para. 2(b)(i).

"importing Members . . . take reasonable measures within their means . . . to prevent re-exportation of the products that have actually been imported into their territories under the system," and "members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions."[185]

One other notable provision in the Decision is the inclusion of a definitional section, which sets forth the meaning of "pharmaceutical product" for purposes of the Decision.[186] According to the Decision, this includes "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha-TRIPS] Declaration."[187] Paragraph 1 of the Doha-TRIPS Declaration, in turn, recognizes "public health problems" to mean those "afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[188] This definition is clearly subject to some interpretation, as the Untied States anticipated during the negotiations. It seems to suggest that the umbrella of public health problems should include, but not necessarily be limited to, infectious epidemic diseases. The phrasing "public health problems" and "afflicting many developing and least-developed countries" suggests that illnesses such as obesity and the common cold

185. *Id.*, para. 4, 5.
186. Decision, *supra* note 176, at para. 1(a).
187. *Id.*, para. 1(a).
188. Doha-TRIPS Declaration, *supra* note 3, at para. 1.

might be included as well.[189] Thus, the reach of the decision is potentially broad, and ultimately subject to interpretation.

C. Subsequent Deliberations by the Council for TRIPS

The Council for TRIPS was instructed to begin work on negotiations regarding the manner in which TRIPS would be amended to incorporate the concepts inherent in the Decision, with a view to adoption of the amendment by June 2004.[190] Much of the Council's time was initially invested in resolving technical questions in regard to how the waivers might be incorporated into TRIPS, and hence the deadline was extended to March 2005.[191] Negotiations at the Council's last meeting of 2004, held December 1st and 2nd, seem to indicate that the agreement on the Decision announced by the General Council in August 2003 is still tenuous. At the final meeting, the African Group (composed of all African WTO members) submitted a proposal for the amendment which was criticized by the United States and other developing nations for failing to incorporate several of the provisions agreed to in the earlier Decision.[192] The developed nations further asserted that the African Group, through its proposed amendment, sought to re-open the negotiations which had been delicately-balanced in August 2003.[193] The African Group countered that it sought only to simplify the text by removing sections that are redundant in view of TRIPS.[194]

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189. Matthews/WTO Decision, *supra* note 167, at 87.
190. Decision, *supra* note 176, at para. 11.
191. Bridges Weekly Trade Digest, *TRIPS Council Considers Public Health, Biodiversity, at* http://www.ictsd.org/weekly/04-12-08/story1.htm (last visited Dec. 17, 2004).
192. *Id.*
193. *Id.*
194. *Id.*

V. ANALYSIS

The disagreement encountered at the final TRIPS Council meeting of 2004 suggests that the balance of rights sought in TRIPS is not yet settled, even within the WTO. If the WTO delegates cannot reach a meeting of the minds on these sensitive issues, it seems unlikely that the international community as a whole will respond to the call to enforce such rights. Indeed, much of the legitimacy of the WTO may be attributed to its members' perception and to the public's perception of its ability to make decisions that are fair and reasonable.[195] While the international community expects its representatives in the WTO to make rational decisions through careful negotiation, the transparency of the WTO may expose the fragility of these decisions and potentially undermine the public's view of the efficacy of the organization.

However, the ability of the WTO to meet its goal of balancing intellectual property rights with increased access to essential medicines in developing nations is a product not only of its legitimacy, but also of the feasibility of achieving this end, despite the numerous peripheral factors which frustrate it. Hence, the issue may be broadly described as one of both legality and practicality.

A. Legitimacy/Legality of the WTO and its Decisions

1. Legitimacy: Democracy and Globalization – The most frequent criticism of the authority of the WTO, and of international organizations generally, is that it is violative

195. *See* Lawrence D. Roberts, *Beyond Notions of Diplomacy and Legalism: Building a Just Mechanism for WTO Dispute Resolution*, 40 AM. BUS. L.J. 511, 527 (2003) (stating that "[a]n efficient system is one that, all other interests being equal, achieves its objectives as rapidly as possible . . ." and "[t]he organization relies upon the ability of enumerated criteria to greatly enhance the perceptions of legitimacy of the World Trade Organization as a whole."); *see also* Donald McRae, *What is the Future of WTO Dispute Settlement?*, 7 J. INT'L ECON. L. 3, 13-14 (2004).

of traditional notions of democracy because it shifts decision-making further away from the hands of the populace.[196] The now-cliché phrase "faceless bureaucrats" has been often-used to voice this criticism by alluding to the fact that the decisions of the WTO in dispute settlement proceedings are made by a panel of "experts" selected by the WTO, who, under the rules of the DSU, cannot be members of any of the nations that are parties to a given dispute.[197] Hence, almost without fail, the experts will be chosen from developing nations and rarely from the United States, which is often a party to disputes in the WTO.[198] It is noted, however, that the WTO offers some balance to this in the fact that it has a standing Appellate Body to reconsider panel decisions, and thus the members of this body may be more recognizable over time.[199]

Another theory suggests that traditional notions of democracy may not be suitable in an age of globalization.[200] As the impact of the policies of one nation come to affect the people of other nations more profoundly, it becomes impossible to function under the customary ideal of a state-centered democracy in which all persons affected by a policy will have some say in its establishment and governance.[201] It is beyond the scope of this work, but interesting nonetheless, to consider that as democracy spreads throughout the world and harmonization emerges, a loss of individual rights may occur.

In any event, measuring the legitimacy of the WTO in terms of its effect on the democratic rights of the populace of its member nations is ultimately a question of perspective. Accession to the WTO by a nation is, in a democratic nation, arguably a part

196. Peter M. Gerhart, *The Two Constitutional Visions of the World Trade Organization*, 24 U. PA. J. INT'L ECON. L. 1, 6-7 (2003).

197. *See* Matthew Schaefer, *National Review of WTO Dispute Settlement Reports: In the Name of Sovereignty or Enhanced WTO Rule Compliance?* 11 STJJLC 307, 333-336 (1999).

198. *Id.*

199. *Id.*

200. Gerhart, *supra* note 196, at 4.

201. *See Id.* at 74.

of the democratic process. The decision of the United States Senate not to ratify the Havana Charter and the accompanying International Trade Organization in the early 1950's is an example of the exercise of this process.[202] However, from a state-centered view, a democratic accession to an arguably non-democratic organization does not ultimately legitimize that organization.

2. Legality: Sources of Law – The primary source of law which provides the authority of the WTO is the WTO Agreement itself, including its annexes. Treaties are recognized sources of law, per the 1969 Vienna Convention on the Law of Treaties (Vienna Convention).[203] The Vienna Convention itself is largely a codification of the pre-existing customary law on treaties, and because of this, it is believed that most of its provisions are binding on even those nations which are not formally parties to it.[204] Article 2 of the Vienna Convention notes that a treaty is fundamentally "an international agreement concluded between States in written form and governed by international law…"[205] Further, Article 5 of the Vienna Convention notes: "[t]he present Convention applies to any treaty which is the constituent instrument of an international organization and to any treaty adopted within an international organization without prejudice to any relevant rules of the organization."[206] The WTO Agreement satisfies all of these provisions: it exists between States, it is written, and it is an instrument of an international organization, namely the WTO.

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202. *See supra* notes 38, 39 and accompanying text.

203. Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 332 [hereinafter Vienna Convention].

204. *See* Michael Lennard, *Navigating by the Stars: Interpreting the WTO Agreements*, 5 J. INT'L ECON. L. 17, 17-18 (2002). *See also Frederic* L. Kirgis, *Reservations to Treaties and United States Practice*, The American Society of International Law, *at* http://www.asil.org/insights/insigh105.htm#_ednref3 (last visited Dec. 17, 2004).

205. Vienna Convention, *supra* note 196, art. 2, 1155 U.N.T.S. at 333.

206. *Id.*, art. 5, 1155 U.N.T.S. at 334.

Of course, other sources of international law exist beyond treaties. These include custom and principle as the other two primary sources of law, and judicial decisions and the works of recognized scholars as secondary sources. These are succinctly stated in Article 38(1) of the Statute of the International Court of Justice:

> a. *international conventions*, whether general or particular, establishing rules expressly recognized by the contesting states;
>
> b. international *custom*, as evidence of a general practice accepted as law;
>
> c. the general *principles* of law recognized by civilized nations;
>
> d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as *subsidiary means* for the determination of rules of law.[207]

Notably, it has been argued that the WTO Agreement has as its basis of authority elements of all four of these sources of international law, at least for the purposes of dispute settlement in the WTO, if not more.[208] This conclusion draws a connection between customary law and the WTO Agreement through Article 3.2 of the Dispute Settlement Understanding, which states that the DSU "serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements *in accordance with customary rules* of interpretation of public international law."[209] The connection to general principles of law, it is argued, may be found in the DSB's panel decisions and appellate body decisions, which have

207. Statute of the International Court of Justice, June 26, 1945, art. 38(1), 59 Stat. 1055, 1060 (emphasis added).

208. *See* PALMETER & MAVROIDIS, *supra* note 41, at 50 (stating that "all of the subparagraphs of Article 38(1) are potential sources of law to be drawn on in WTO dispute settlement").

209. *Id.* at 65 (emphasis added).

periodically cited recognized principles of international law.[210] Finally, secondary sources of law may presumably be found in the references that DSB panels make to the decisions of earlier panels and appellate bodies, as well as to the teachings of qualified GATT and WTO legal publicists.[211]

This argument is not accepted by all legal scholars, however; most agree that the WTO's authority is simply treaty-based, and likely subject to construal in view of Articles 31 and 32 of the Vienna Convention, which provide guidelines for interpreting treaties.[212] Article 31(1) is the provision most-commonly cited: "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[213] This provision suggests that treaties should be read first in view of the text on its face, and then interpreted in the context of the intentions of the drafters. Article 32 adds the stipulation that when the meaning of the treaty is unclear subsequent to its contextual interpretation, "[r]ecourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion."[214] This approach is applicable not only to implementing the obligations of members of the WTO, but also in reaching determinations in DSB panels. However, it has been argued that the views of those scholars who extend this interpretive license to include "all sources of international law referred to in Article 38 of the International Court of Justice Statute . . . are, at the least, strained ..."[215]

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210. *Id.* at 68-69.
211. *Id.* at 51-64, 66-68.
212. *See, e.g.*, Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT'L L. 123, 137 (2004).
213. Vienna Convention, *supra* note 196, art. 31(1), 1155 U.N.T.S. at 340.
214. *Id.*, art. 32, 1155 U.N.T.S. at 340.
215. Lennard, *supra* note 204, at 36-37.

3. Ministerial Declarations – In regard to TRIPS and its pronouncements on intellectual property rights, the most contentious legitimacy/legality issues are manifest in the debate concerning the legal value of WTO Ministerial Declarations, particularly the Doha-TRIPS declaration and its subsequent implementation, discussed *supra.* The Doha-TRIPS Declaration states very plainly that its interpretation of TRIPS is grounded in customary principles of international law, vis-à-vis the provisions of Article 31 and 32 of the Vienna Convention: "[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[216] In this manner, the General Council sought to validate its reading of the TRIPS agreement in a light more-favorable to public health concerns, and arguably, less-favorable to IP right-holders.

In view of this, some have suggested that the Doha-TRIPS declaration is legally binding as long as it does not directly contradict any of the textual provisions of TRIPS, which it does not seem to do.[217] However, while some of the statements in the Doha-TRIPS Declaration are fairly direct, *e.g.*, "[e]ach Member has the right to grant compulsory licences,"[218] one might argue that some of the flexible, interpretive language of the Doha-TRIPS Declaration bases its legality in the equally-flexible, ambiguous mandate expressed in several of the loophole provisions of TRIPS. For example, as noted *supra*, Article 8 of the TRIPS Agreement states that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the

216. Doha-TRIPS Declaration, *supra* note 3, at para. 5(a).
217. Sykes, *supra* note 149, at 54.
218. Doha-TRIPS Declaration, *supra* note 3, at para. 5(b).

provisions of this Agreement."[219] The most nearly-matched Doha-TRIPS Declaration states, in turn: "while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[220] Although the second statement (the interpretive statement) seems to be logically supported by the presumed intent of the first statement (the textual statement) it is troublesome that both statements are ultimately somewhat ambiguous. Eventually the language begins to look less-interpretive and more impressionistic.

Ostensibly, the key to resolving the legality of the Doha-TRIPS Declaration is to simply amend TRIPS, in clear language. Provisions for doing so exist in both the TRIPS Agreement and in the WTO Agreement itself.[221] This is unlikely to occur, however. The persistent disagreement among the Council for TRIPS regarding pharmaceuticals seems to indicate that the ambiguous language of TRIPS may well be (and may well continue to be) the product of tortuous negotiations, rather than built-in flexibilities.

B. Practical Considerations

1. The Effect of the Principles Set Forth in TRIPS – The WTO's efforts may be equally befuddled by the practical effects of implementing the substantive provisions of TRIPS. The use of both parallel imports and compulsory licenses, which were authorized in TRIPS and affirmed in the Doha-TRIPS Declaration, may prove to be the most unpredictable variables included in the Agreement. At first blush, it would seem that

219. TRIPS, *supra* note 57, art. 8(1).
220. Doha-TRIPS Declaration, *supra* note 3, at para. 4.
221. TRIPS, *supra* note 57, arts. 71(1), 71(2); WTO Agreement, *supra* note 50, art. X, para. 6.

these tools should provide a predictably high success rate in facilitating access to cheaper medicines in developing nations. However, the use of each carries the possibility of untoward consequences which may result in frustrating the efforts of both sides.

First, it is possible that the use of compulsory licenses will ultimately serve as an additional disincentive to the pharmaceutical industry to produce the drugs necessary to fight diseases in developing countries. As noted above, it has already been suggested that the industry has a track record of not investing in the development and production of medications which have no market in developed nations.[222] If the industry finds that the vast majority of such drugs become the subject of compulsory licenses, it may choose to discontinue its investment in these products. It is notable that even the development and production of medicines to treat HIV/AIDS could diminish as a side-effect of the use of compulsory licenses; notwithstanding the prevalence of HIV in the United States and the profitable market there for HIV/AIDS drugs, most AIDS sufferers in developing countries are of a different genetic profile than those in developed countries, and therefore require different medications.[223]

Similarly, the use of parallel imports will likely disrupt the price discrimination around which the pharmaceutical industry has built its business model. As parallel importation becomes more commonplace among WTO member nations, the outcry in nations where it is not permitted may expand as well. The United States has already experienced the growing pains of this phenomenon in response to the expanding availability and demand for cheaper drugs in Canada and Mexico. Pfizer, the world's largest research-based pharmaceutical company, recently discontinued drug shipments to

222. *See supra* note 23 and accompanying text.
223. Matthews/WTO Decision, *supra* note 167, at 74.

some Canadian wholesalers and e-pharmacies in order to prevent re-importation of the drugs into the United States where they would compete in the higher-priced market.[224]

In addition to the potential long-term effects of compulsory licensure and parallel importation, there is some evidence that illicit activity may play a role in frustrating both parties' needs. First, it has been noted that parallel importation may lead to the production of dangerous counterfeit medicines. One PhRMA spokesperson noted: "We don't believe parallel importing is proper. A lot of parallel imports come from places like India, and half the time [the drugs have] no active ingredients. It's killing patients, causing drug resistance, and giving false hope."[225] Second, there is evidence that an illicit gray-market is emerging, which may be hidden in the guise of legal parallel imports. Verification of this appeared in 2002 when HIV medications, manufactured by the British company GlaxoSmithKline and bound for sub-Saharan Africa, were diverted back to Europe and resold for substantial profits.[226]

In light of the foregoing, it is possible to imagine that the well-intended use of parallel imports and compulsory licenses may in fact lead to greater opportunities for misuse. These are variables over which the WTO has little control once the wheels of TRIPS are set in motion.

2. Resources – Another practical limitation to the WTO's efficacy may be its limited resources. The WTO's resources in terms of financial and human capital may be strained in the foreseeable future. In comparison to its Bretton Woods companions, the

224. Brian Gorman, *The Drug Cost Conundrum*, *at* http://www.fool.com/news/commentary/2004/commentary040318BG.htm (last visited Dec. 17, 2004).

225. Liz Highleyman, *Access for Countries*, 14 BETA 12, 14 (2004), *available at* http://www.sfaf.org/treatment/beta/b48/b48.pdf (last visited Dec. 17, 2004).

226. Gregory Crouch, *Europeans Investigate Resale of AIDS Drugs*, N.Y. TIMES, Oct. 29, 2002, *at* http://www.accessmed-msf.org/prod/publications.asp?scntid=71120021459554&contenttype=PARA& (last visited Dec. 17, 2004).

WTO is woefully under-funded, and potentially under-staffed. In 2004, the WTO had a budget of 162 million Swiss francs, or about $141 million U.S. dollars, and it supported a Secretariat staff of approximately six-hundred persons.[227] By contrast, the International Monetary Fund has a budget of $800 million and 2,680 professional staff,[228] and the World Bank has a staff of approximately 9,300 employees and an annual operating budget in the billions of dollars.[229]

One of the significant areas where the WTO might feel the impact of its financial constraints is in its ability to utilize experts.[230] Dispute panels are typically composed of three to five appointed experts from different countries who resolve disputes through treaty interpretation, but additional expert assistance may be needed to resolve more technical matters, including, inter alias, matters related to health issues.[231] The appointment of such experts is specifically authorized in Article 13(2) of the DSU, and may include consultations or advisory opinions.[232] These experts can prove to be an expensive resource, but they are often needed to clarify complex matters which may have significant bearing on a panel decision. Further complicating the issue is the growing case load in the DSB; it has been suggested that the WTO may quickly become a victim of its own success.[233] One author comments, "[t]he DSB has become so popular with

227. World Trade Organization, What is the WTO?, *at* http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Dec. 17, 2004).

228. THE BRETTON WOODS COMMITTEE, CRITICAL ISSUES FORUM, THE WORLD TRADE ORGANIZATION: SHOULD WE RETOOL OR RESTRUCTURE? 10, *available at* http://www.brettonwoods.org/WTO%20Critical%20Issues%20Forum.pdf (last visited Dec. 17, 2004).

229. The World Bank Group, About US, *at* http://web.worldbank.org/WBSITE/EXTERNAL/EXTABOUTUS/0,,pagePK:50004410~piPK:36602~theSitePK:29708,00.html (last visited Dec. 17, 2004).

230. Sarah Hogg & Mahmud Nawaz, *Economic Considerations and the DSU*, *in* DISPUTE RESOLUTION IN THE WTO 66-67 (James Cameron & Karen Campbell eds., 1998).

231. *See Id.*

232. DSU, *supra* note 58, at art. 13(2).

233. JAMES CAMERON & KAREN CAMPBELL, *Introduction*, *in* DISPUTE RESOLUTION IN THE WTO 20 (1998).

states that it is already overburdened . . . [n]o international dispute settlement has ever had to cope with this level of demand." This demand is attributed to the efficiency of the WTO's dispute settlement system,[234] which is characterized by mandatory deadlines for the various phases of the settlement process. Additionally, the DSB panel is appointed by "negative" consensus; that is, a panel will be established to settle a dispute automatically, unless there is a consensus to the contrary among the members.[235] Further, once a panel had issued its report, that report will be also be adopted automatically, unless there is a consensus to the contrary.[236] It is hard to imagine how this could happen in view of the fact that the "winning" member would have to join in the consensus to not adopt the panels decision in its favor.

As a practical matter, the WTO's limited resources could have a genuine impact on its ability to properly manage disputes involving the pharmaceutical industry. It is foreseeable that a diverse set of technological issues could arise, ranging from epidemiological questions to the need to interpret complex econometric analyses. In such cases, the number of "experts" required might be significant, and the number of cases which emerge could also be significant, particularly if member nations remain conflicted and TRIPS remains ambiguous.

3. Diplomatic Considerations and Public Opinion – The South-African Government/Pharmaceutical Companies Case discussed above provides a good lesson in the effects that political pressure may have on the WTO's attempts to balance IP rights and access to medicine.[237] The case was ultimately ripe for a WTO panel report and the

234. *Id.* at n.4.
235. PALMETER & MAVROIDIS, *supra* note 41, at 15.
236. *Id.*
237. *See supra* note 154 and accompanying text.

pharmaceutical-manufacturers may well have prevailed in their claims. Nevertheless, the United States chose diplomacy over pursuing the issue, and the right-holders were unable to use the WTO as a forum.

Private parties have no direct voice in the WTO; unless a member government chooses to pursue an issue, the issue will not be heard before a panel. This is one of the awkward aspects of the WTO, particularly for business interests in industrialized countries. Under the WTO system, industries are often likely to feel the impact of a member government's decisions more than any other party. This applies in the case of a member government's decision not to pursue a matter of concern to its business nationals before the WTO, as in the aforementioned case, and it also applies in the scenario where a member government takes actions violative of its duties under the WTO Agreement, which ultimately impact industry. A good illustration of the latter is the recent steel tariff incident in the United States. In March 2002, the United States placed a tariff on imported foreign steel, purportedly to allow American steel companies to restructure and become more competitive with foreign steel-producers.[238] President Bush was forced to rescind these tariffs in December 2003, shortly after the WTO Appellate Body affirmed a dispute panel's report ruling that the tariffs were illegal.[239] European nations and Japan were poised to place substantial tariffs on American goods including textiles, computers, and farm products.[240] During the twenty-one months in which the steel tariffs were in place, the effects were felt most strongly by the domestic steel-consuming manufacturing

238. *See* Joseph Curl and Jeffrey Sparshott, *Bush Rescinds Steel Tariffs*, THE WASHINGTON TIMES, Dec. 5, 2003, *available at* http://www.washtimes.com/national/20031204-111447-5080r.htm (last visited Dec. 17, 2004); *see also* The Knowledge@Wharton Team, *U.S. Steel Users Claim Tariffs Protect a Few at the Expense of the Majority*, *at* http://www.trilla.com/Wharton_Feb_12.htm (last visited Dec. 17, 2004).

239. *Id.*

240. *Id.*

industries in the United States, where reportedly over 200,000 jobs were lost.[241] Still greater impact might have been felt by American industries if the United States had not lifted its tariffs and the other developed nations had moved forward with their threatened trade sanctions.

CONCLUSION

A much-cited 2001 study in the Journal of the American Medical Association analyzed the relationship between patent protection and access to HIV/AIDS drugs in fifty-three African countries, concluding that patents and patent law were not a significant barrier to treatment access.[242] The study noted that a number of other de facto barriers had a greater impact on the access to these medicines.[243] These barriers included "poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales tax, and, above all, lack of sufficient international financial aid to fund antiretroviral treatment."[244]

Additionally, a joint study by the WTO and the WHO noted: "it is important to keep the extent of the problem in perspective. The vast majority of the 300 or so drugs on WHO's Model List of Essential Drugs are not under patent protection in any country."[245] On the balance, these two studies suggest that the cost of essential medications is probably more prohibitive to access than the enforcement of intellectual property rights.

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241. *Id.*

242. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 15 JAMA 1886 (2001), *available at* http://www.iipi.org/activities/Research/antiretroviral_article.pdf (last visited Dec. 17, 2004).

243. *Id.*

244. *Id.*

245. WORLD TRADE ORGANIZATION / WORLD HEALTH ORGANIZATION, WTO AGREEMENTS & PUBLIC HEALTH 96, *available at* http://www.who.int/media/homepage/who_wto_e.pdf (last visited Dec. 17, 2004).

The World Trade Organization's effort to balance intellectual property rights with the needs of the public is not novel. It is reflective of the most fundamental principles of patent law, which seeks to provide inventors with enough incentive to encourage investment in innovation, while simultaneously enabling the public to reap the rewards of this innovation.[246] Under the patent system used by most nations, and indeed, under the stated minimum requirements of TRIPS, this is achieved by granting inventors what is essentially an exclusive license to their own inventions for a limited period of time. Following the expiration of this period, the right to the invention returns to the public domain so that society may benefit freely from its usefulness.

The patent system is a good model and the goal of applying a similar model to facilitating essential humanitarian needs in the face of a pandemic is a noble one. In the long term, strong protection of IP rights will probably provide the incentive necessary to continue to invest and innovate in the life-saving drugs that are needed in poverty-stricken nations. However, in the short term, this goal may not yet be achievable, as the world is in the process of moving toward global harmonization, but it is still vastly diverse. A rigid framework would probably not work, and in this sense, the WTO's plan is not ill-conceived: deferring strong protection of IP rights long enough for the developing world to adjust, grow, and begin to manage its health crisis may ultimately succeed if member nations can form stable agreements which meld flexibility with clarity.

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246. This idea was well-stated by the United States Supreme Court in *Aronson v. Quick Point Pencil Co.* in 1979:

> First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.

440 U.S. 257, 262 (1979).

However, more is required. Greater cooperation among member nations on both sides of the equator will do much to facilitate these goals, both in negotiation and in practice. Drug manufacturers have begun to supply lower-priced medications in recognizable shapes and colors so that they are readily identifiable; it will be up to both the developed and the developing nations to ensure that they are not diverted from their intended recipients. More investment is needed universally: it is needed in the WTO so that it can make wise decisions; it is needed for research and the development of new drugs; and perhaps most critically, it is needed in the poorest nations where poverty is the greatest barrier to access.