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Alexandra G. Watson

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INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS: DO TRIPS' FLEXIBILITIES PERMIT SUFFICIENT ACCESS TO AFFORDABLE HIV/AIDS MEDICINES IN DEVELOPING COUNTRIES?

ALEXANDRA G. WATSON*

Abstract: The World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement seeks to standardize intellectual property laws around the world. TRIPS is controversial because, in effect, it limits access to affordable HIV/AIDS medicines in nations where they are desperately needed. This Note argues that although TRIPS' compulsory licensing provision is an invaluable tool for improving access to affordable medicines, a tiered-pricing scheme in concert with a ban on parallel imports would help secure universally lower drug prices.

INTRODUCTION

The notion of international protection for intellectual property rights stirs up emotional dilemmas.¹ Pharmaceutical companies invest billions of dollars to research and develop innovative new medicines, and the only way to recoup these costs and incentivize future research is to grant companies temporary monopolies on their innovations and allow them to charge high prices for patented medicines.² At the same time, the World Health Organization estimates that half the population in regions of Africa and Asia lacks access to essential medicines.³ Further, patent protection itself is a foreign concept in many of these nations, and forcing them to abide by international intellectual property

* Alexandra G. Watson is a Senior Note Editor for the *Boston College International & Comparative Law Review*.

¹ See *A Gathering Storm: Drugs Companies' Patents Are Under Attack*, *ECONOMIST*, June 9, 2007, at 100.

² See John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 *WIDENER L. SYMP. J.* 175, 187 (2001).

³ Scott Lucyk, *Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement*, 38 *OTTAWA L. REV.* 191, 193 (2006).

agreements seems to be an unfair imposition of Western values.⁴ The question remains: How can pharmaceutical companies be compensated adequately for their exorbitant expenses and, at the same time, poor nations be ensured access to affordable HIV/AIDS medicines?⁵

Given the increasing interconnectedness of global markets, protecting intellectual property on an international scale has become a critical concern for the World Trade Organization (WTO).⁶ In response to pressure from developed countries such as the United States, the WTO passed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994.⁷ Each of the more than 150 WTO member-states was required to ratify the Agreement.⁸ TRIPS attempts to create a global intellectual property consensus by requiring nations to establish minimum baseline intellectual property laws.⁹ The Agreement also provides exceptions for rare circumstances.¹⁰

A crucial flexibility contained in TRIPS is compulsory licensing, which is the process by which a government compels a patent-holder to license its rights to a generic manufacturer in exchange for compensation.¹¹ Global health advocates praise the increased use of compulsory licensing because it leads to lower-priced medicines, but drug executives insist that the method was intended to be used only as a last resort during emergencies.¹²

This Note first discusses the WTO's adoption of TRIPS and several subsequent initiatives and outlines the flexibilities that they provide. Next, this Note highlights the controversies surrounding TRIPS and compulsory licensing and it introduces possible improvements. Finally, this Note analyzes how effectively TRIPS achieves its competing goals

⁴ Naomi Bass, *Implication of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Law in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 205 (2002).

⁵ Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 A. BUS. L.J. 353, 356 (2004).

⁶ See Harrelson, *supra* note 2, at 175.

⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, Annex 1C, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS]; see Sherman & Oakley, *supra* note 5, at 362; Bass, *supra* note 4, at 196.

⁸ TRIPS, *supra* note 7, art. 1.

⁹ See *id.* art. 33.

¹⁰ *Id.* art. 31.

¹¹ *Id.*; see Bass, *supra* note 4, at 198–99.

¹² *A Gathering Storm*, *supra* note 1, at 100.

and proposes ways to enhance the current international intellectual property system.

I. BACKGROUND

A. *TRIPS and Its Progeny: A Chronology of Initiatives*

International intellectual property rights are not a new idea.¹³ The Paris Convention, signed in 1883, was an early international agreement to address the subject.¹⁴ Nevertheless, it merely required nations to offer the same patent protection to foreign inventors that they provided to domestic innovators.¹⁵ Moreover, there was no mode of enforcement and thus the Convention was essentially a guideline that nations were free to ignore.¹⁶ In 1967, the World Intellectual Property Organization (WIPO) was formed, but it was criticized for favoring the needs of developing nations and failing to provide substantial international intellectual property protections.¹⁷ These disappointing initiatives ultimately led to the formation of the WTO and the adoption of the TRIPS agreement.¹⁸

Following proposals by the United States and Japan, as well as years of negotiations, the WTO adopted TRIPS during the 1994 Uruguay Round negotiations.¹⁹ TRIPS protects various types of intellectual property, including pharmaceuticals, by mandating that signatories adopt patent laws conforming to the minimum standards enunciated in the Agreement.²⁰ Specifically, TRIPS requires member-states to provide at least twenty years of patent protection for innovators.²¹ Nevertheless, the Agreement also allows for exceptions in rare circumstances.²² Most significantly, TRIPS lists the situations in which a country may engage in compulsory licensing, a process by which a government authorizes a manufacturer to produce a patented item without the patent-owner's

¹³ See Harrelson, *supra* note 2, at 178.

¹⁴ See *id.* at 178–79.

¹⁵ *Id.*

¹⁶ See *id.*

¹⁷ See Bass, *supra* note 4, at 195.

¹⁸ See *id.* at 195–96.

¹⁹ See KATHERINA GAMHARTER, ACCESS TO AFFORDABLE MEDICINES 9 (2004).

²⁰ *Id.* at 16.

²¹ TRIPS, *supra* note 7, art. 33.

²² *Id.* art. 31.

permission.²³ TRIPS also contains dispute settlement provisions, a feature that its predecessors lacked.²⁴

In response to questions from developing countries about how strictly TRIPS would be interpreted, the WTO issued a Declaration on TRIPS and Public Health at a conference in Doha, Qatar, in 2001.²⁵ The Doha Declaration clarified various aspects of TRIPS and generally loosened developing nations' obligations under the Agreement.²⁶ Specifically, it stated that TRIPS "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."²⁷ This was considered a major victory for developing nations.²⁸ The Declaration also extended the deadline for developing nations to comply with TRIPS' requirements until 2016.²⁹

In August 2003, the WTO General Council addressed another lingering issue: the fact that nations lacking manufacturing capabilities were unable to use TRIPS' compulsory licensing provision.³⁰ TRIPS Article 31(f) requires that compulsory licensing be used "predominantly" to supply goods to a nation's domestic market.³¹ This serves to limit compulsory licensing in the developing world, as many poorer nations lack the technological resources to produce pharmaceuticals.³² The WTO's 2003 decision addressed this deficiency by creating a waiver for TRIPS Article 31(f), allowing member-states to export generic drugs to poorer nations.³³ The 2003 decision is frequently referred to as the

²³ *Id.*

²⁴ *Id.* art. 64; Harrelson, *supra* note 2, at 178–79.

²⁵ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm [hereinafter Doha Declaration]; see Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 BRANDEIS L.J. 623, 635–36 (2007); see also GAMHARTER, *supra* note 19, at 121–31 (describing lengthy negotiation process).

²⁶ See Sherman & Oakley, *supra* note 5, at 358–59.

²⁷ Doha Declaration, *supra* note 25, para. 4.

²⁸ See Sherman & Oakley, *supra* note 5, at 379–80.

²⁹ Doha Declaration, *supra* note 25, para. 7.

³⁰ See Decision of General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr. 1, at para. 2 (Aug. 30, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [hereinafter Paragraph Six Decision]; L. Danielle Tully, *Prospects for Progress: The TRIPS Agreement and Developing Countries After the Doha Conference*, 26 B.C. INT'L & COMP. L. REV. 129, 142–43 (2003) (describing Doha Declaration's limited usefulness in developing nations).

³¹ TRIPS, *supra* note 7, art. 31(f).

³² See Whobrey, *supra* note 25, at 636.

³³ See Paragraph Six Decision, *supra* note 30, para. 2; Whobrey, *supra* note 25, at 636.

Paragraph Six Decision because the sixth paragraph of the Doha Declaration specifically identified the manufacturing capabilities issue.³⁴

Perhaps unsurprisingly, the United States agreed to the Paragraph Six Decision on the condition that the exportation method was to be used solely to address public health needs and was not for commercial purposes.³⁵ This extra condition led some public health groups to conclude that the Decision was doomed because developing countries, many of which lack organized governmental infrastructures, would be discouraged by the bureaucratic “red tape.”³⁶ The Decision contains other restrictions, as well; for instance, states that utilize the compulsory licensing provisions must fulfill notification obligations and follow several other complicated steps.³⁷

Since the Paragraph Six Decision was issued, many developed countries have pledged not to use the waiver provision to import cheap generic drugs.³⁸ Several other countries have announced that they will not use the waiver unfairly but instead will utilize it only during national emergencies.³⁹ Perhaps as a result of the pervasive perception that developed countries will exert pressure on nations that use the new mechanism, only one country has done so thus far.⁴⁰ In October 2007, Canada issued a compulsory license for the production and export of a generic AIDS medicine to Rwanda.⁴¹

In December 2005, WTO members agreed to incorporate the 2003 waivers into the TRIPS Agreement permanently.⁴² The amendment will

³⁴ See Doha Declaration, *supra* note 25, para. 6; World Trade Organization, Frequently asked questions: Compulsory licensing of pharmaceuticals and TRIPS, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Nov. 21, 2008).

³⁵ See Elizabeth Becker, *Poor Nations Can Purchase Cheap Drugs Under Accord*, N.Y. TIMES, Aug. 31, 2003, at 1.

³⁶ *Id.*

³⁷ Paragraph Six Decision, *supra* note 30, para. 2; see GAMHARTER, *supra* note 19, at 275.

³⁸ Paragraph Six Decision, *supra* note 30, n.3; World Trade Organization, TRIPS and Public Health: The Situation in Late 2005, http://www.wto.org/english/tratop_e/trips_e/health_background_e.htm (last visited Nov. 21, 2008).

³⁹ TRIPS and Public Health: The Situation in Late 2005, *supra* note 38.

⁴⁰ See John Boscariol, *Canada Is First to Grant WTO Compulsory License for Export of Generic Drug*, MONDAQ BUS. BRIEFING, Nov. 2, 2007.

⁴¹ *Id.*; *Canada Allows Apotex to Manufacture Generics for Rwanda*, PHARMA BUS. DAILY BULL., Oct. 10, 2007; World Trade Organization, TRIPS and Public Health ‘Paragraph 6’ System: Notifications by Importing WTO Members, http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm [hereinafter WTO Notifications] (last visited Nov. 21, 2008).

⁴² See World Trade Organization, Fact Sheet: TRIPS and Pharmaceutical Patents (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm [hereinafter WTO Fact Sheet]; Whobrey, *supra* note 25, at 637–38.

enter into force when two-thirds of WTO members ratify it, which was originally expected to occur by the end of 2007.⁴³ In December 2007, the General Council decided to extend the deadline by two years until the end of 2009.⁴⁴ Thus far, eighteen members, including the United States and the European Union (EU), have officially accepted the amendment.⁴⁵

B. TRIPS' Flexibilities in Detail: Compulsory Licensing and Parallel Importation

The TRIPS Agreement permits compulsory licensing in a section entitled, "Other use without authorization of the right holder."⁴⁶ According to the Agreement, the entity or individual applying for a compulsory license first must attempt to obtain a voluntary license from the patent-holder.⁴⁷ If that effort is unsuccessful, the government may issue a compulsory license and the license-user must provide the patent-owner with monetary compensation.⁴⁸

Nevertheless, TRIPS permits exceptions during national emergencies and other urgent situations.⁴⁹ In these instances, the user is not obliged to make an initial attempt to secure a voluntary license.⁵⁰ The Doha Declaration further loosened this national emergency exception by allowing nations to develop their own definitions of "national emergency."⁵¹ In addition, TRIPS previously reserved compulsory licensing for domestic uses, but the 2003 Paragraph Six Decision made it possible for developing nations to import copies of drugs that they are incapable of manufacturing domestically.⁵²

Parallel importation is another crucial avenue of drug access for developing nations.⁵³ This occurs when a manufacturer sells a medicine

⁴³ World Trade Organization, Countries accepting amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Nov. 21, 2008); Whobrey, *supra* note 25, at 637–38.

⁴⁴ Countries accepting amendment of the TRIPS Agreement, *supra* note 43.

⁴⁵ *Id.*; Andrew Bounds, *World News: EU Paves Way for Access to Generic Medicines*, FINANCIAL TIMES EUROPE, Oct. 25, 2007, at 3.

⁴⁶ TRIPS, *supra* note 7, art. 31. Although the words "compulsory licensing" do not appear in the TRIPS Agreement, the WTO has stated that the practice falls under this broad heading. WTO Fact Sheet, *supra* note 42.

⁴⁷ *See* TRIPS, *supra* note 7, art. 31(b).

⁴⁸ *Id.* art. 31(b), (h).

⁴⁹ *Id.* art. 31(b).

⁵⁰ *Id.*

⁵¹ Doha Declaration, *supra* note 25, para. 5(c).

⁵² *See* Paragraph Six Decision, *supra* note 25.

⁵³ *See* Harrelson, *supra* note 2, at 192.

to different countries at varying prices, and a buyer purchases the drug from the country with the lowest price.⁵⁴ Thus, if a patent-holder sold a drug to country A for \$1.00 and country B for \$5.00, and a company buys the drug cheaply in country A and imports it into country B, parallel importing has occurred.⁵⁵ The legal principle behind parallel importation is “exhaustion;” once a company sells a batch of its product, it no longer has any rights over the batch; and thus its rights have been exhausted.⁵⁶ By extension, there are no restrictions on what the new owner of the product can do with it.⁵⁷ While the doctrine of exhaustion is recognized on a national level, the concept of ‘international exhaustion’ is hotly contested.⁵⁸

Because the issue is so divisive, TRIPS does not expressly permit or prohibit the practice of parallel importation.⁵⁹ In fact, the Agreement explicitly states, “[N]othing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”⁶⁰ The Doha Declaration reiterated that member-states can address parallel importation on an individual basis according to their domestic policy goals.⁶¹ Currently, parallel importation is a common practice, especially within the European Union.⁶²

II. DISCUSSION

A. *General Tension over TRIPS*

TRIPS has been a source of controversy since its inception.⁶³ Some developing countries protest that patents are a Western concept and TRIPS forces Western values on their cultures.⁶⁴ Indeed, some cultures in developing nations value shared knowledge and reject the competitiveness embodied in TRIPS.⁶⁵ Furthermore, intellectual property laws

⁵⁴ Whobrey, *supra* note 25, at 632-33.

⁵⁵ See WTO Fact Sheet, *supra* note 42, at 5; Whobrey, *supra* note 25, at 632-33.

⁵⁶ WTO Fact Sheet, *supra* note 42, at 5.

⁵⁷ See *id.*

⁵⁸ See HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO 230 (2007).

⁵⁹ See WTO Fact Sheet, *supra* note 42, at 5; Sherman & Oakley, *supra* note 5, at 373.

⁶⁰ TRIPS, *supra* note 7, art. 6.

⁶¹ Doha Declaration, *supra* note 25, para. 5(d).

⁶² See Harrelson, *supra* note 2, at 193.

⁶³ See Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 134 (2002); Bass, *supra* note 4, at 199-201; Whobrey, *supra* note 25, at 624.

⁶⁴ See Bass, *supra* note 4, at 205.

⁶⁵ See *id.*

may seem unnecessary in developing countries with few resources and low levels of technological development.⁶⁶ Developing countries object most forcefully to the implementation of Western values in an area of great concern to them: access to affordable pharmaceuticals.⁶⁷ Justifiably, these nations fear that TRIPS will limit access to crucial medications by raising prices.⁶⁸

By stark contrast, the United States, other developed nations, and the pharmaceutical industry have complained that TRIPS is too lenient.⁶⁹ In particular, they oppose the transitional grace periods for compliance provided to developing countries and TRIPS' built-in flexibilities, such as compulsory licensing.⁷⁰ Indeed, the United States' insistence on an additional statement in the Paragraph Six Decision regarding commercial use exemplifies its tough approach to TRIPS.⁷¹

B. *The Debate over Compulsory Licensing*

The controversy over compulsory licensing, especially in the context of desperately needed HIV/AIDS pharmaceuticals, rightly has been referred to as "an emotional battleground."⁷² Of all HIV-infected patients, eighty-nine percent live in the poorest ten percent of all nations.⁷³ In the United States, the annual cost of HIV/AIDS drugs is more than \$10,000, a cost which is far beyond the means of almost all patients in developing countries.⁷⁴ Therefore, compulsory licensing has clear appeal because it lowers prices.⁷⁵

Interestingly, developing countries can benefit from compulsory licensing even when they do not implement the method.⁷⁶ In the past, mere threats to issue compulsory licenses have motivated pharmaceutical companies to quickly drop their prices.⁷⁷ In 2001, for instance, Brazil threatened to issue a compulsory license for an AIDS drug

⁶⁶ Whobrey, *supra* note 25, at 629.

⁶⁷ See Bass, *supra* note 4, at 205.

⁶⁸ See *id.* at 204–05.

⁶⁹ *Id.* at 205.

⁷⁰ *Id.* at 205–06.

⁷¹ See Becker, *supra* note 35, at 1.

⁷² Harrelson, *supra* note 2, at 189.

⁷³ *Id.*

⁷⁴ See *id.* at 190.

⁷⁵ See *id.* at 190–91.

⁷⁶ See Bonita de Boer, *TRIPS, AIDS & Generic Drugs*, Aug. 8, 2007, www.avert.org/generic.htm; TRIPS and Public Health: The situation in late 2005, *supra* note 38.

⁷⁷ See Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, N.Y. TIMES, Sept. 1, 2001, at C1.

produced by Swiss pharmaceutical company Roche Holding, and the company reacted by lowering its prices to about thirty percent of the price in the United States.⁷⁸ To the relief of the pharmaceutical industry, Brazil agreed to the discount; drug companies had feared that other developing nations would follow Brazil's example and issue compulsory licenses for much-needed medicines.⁷⁹

Unfortunately, compulsory licensing suffers from several notable shortcomings, including the fact that many poor nations do not employ the method for fear of trade sanctions or business repercussions.⁸⁰ Indeed, developed countries and pharmaceutical companies have not hesitated in the past to exert pressure on nations with weak intellectual property laws.⁸¹ As evidenced by the fact that only one country has used the new Paragraph Six method in the years since its adoption, nations are cautious about potentially exposing themselves to a mountain of international pressure.⁸² This remains a pressing problem, as many developing countries lack pharmaceutical manufacturing capabilities.⁸³

The United States' actions toward Brazil's intellectual property laws exemplify the developed world's approach to weak intellectual property regimes. In 1987, even before TRIPS was enacted, the United States imposed "Special 301" sanctions on Brazil because it considered Brazil's flimsy intellectual property laws and failure to denounce piracy of pharmaceuticals to be unacceptable.⁸⁴ The sanctions consisted of a one hundred percent tariff on Brazilian imports to the United States.⁸⁵ After the passage of TRIPS, Brazil enacted its Industrial Property Law in an attempt to meet its new obligations under the Agreement.⁸⁶ This new law required that foreign goods seeking Brazilian patent protection be produced at least partially within Brazil.⁸⁷ As a result, the United States filed a complaint with the WTO in 2001.⁸⁸ Ultimately, the United States withdrew its complaint following much international pressure.⁸⁹

⁷⁸ *Id.*

⁷⁹ *See id.*

⁸⁰ *See* Harrelson, *supra* note 2, at 189.

⁸¹ *See* Whobrey, *supra* note 25, at 624.

⁸² *See* Boscarior, *supra* note 40; Rich, *supra* note 77, at C1.

⁸³ *See* Whobrey, *supra* note 25, at 636.

⁸⁴ *See* Bass, *supra* note 4, at 206–07.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *See id.* at 208 (describing the United States' allegation that the Industrial Property Law violated TRIPS Article 27, which prohibits discrimination against foreign manufacture of goods).

⁸⁹ *See* Bass, *supra* note 4, at 208.

The international community also took a strong stance against one of South Africa's laws.⁹⁰ In 1997, South Africa passed the Medicines and Related Substances Control Amendment Act (Medicines Act), which empowered the Minister of Health to use sweeping measures, such as unrestricted compulsory licensing, during health emergencies.⁹¹ The United States and various organizations considered these provisions to be TRIPS violations, and as a result, the United States placed South Africa on its "watch list" in 1998 and attempted to challenge the Medicines Act before the WTO.⁹² Furthermore, upon passage of the Medicines Act, the Pharmaceutical Manufacturers' Association (PMA) of South Africa filed a lawsuit against the South African government on behalf of forty domestic and international drug companies.⁹³ In response to public pressure, the United States removed South Africa from its list in 2001 and issued a statement acknowledging the AIDS epidemic, and the PMA dropped its suit.⁹⁴ Nevertheless, the United States has continued to closely monitor South Africa's patent protections.⁹⁵

More recently, Thailand was targeted for the perceived weaknesses in its intellectual property practices.⁹⁶ In January 2007, Thailand approved a compulsory license for an AIDS drug, thereby allowing its domestic drug makers to copy the patent-holder's formula and sell the medicine in Thailand at a low price.⁹⁷ Shortly thereafter, the United States elevated Thailand to its "priority watch list" and EU Trade Commissioner Peter Mandelson wrote a letter to the nation attacking its weak intellectual property standards.⁹⁸ Even more devastatingly, the patent's owner, Abbott, announced that it would no longer sell seven of its newest products in Thailand, including a highly desirable heat-stable AIDS medicine.⁹⁹ The United States claimed that its actions were based on Thailand's cumulative disregard for intellectual property, as well as

⁹⁰ See *id.* at 210–13.

⁹¹ *Id.* at 210–11.

⁹² See *id.* at 211–12; Sherman & Oakley, *supra* note 5, at 395.

⁹³ Park, *supra* note 63, at 137.

⁹⁴ See Bass, *supra* note 4, at 212; Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES, Apr. 20, 2001, at A1.

⁹⁵ See Harrelson, *supra* note 2, at 185.

⁹⁶ Lara Santoro, *Forget the Patents on AIDS Drugs; Third World Nations Have the Right, and the Duty, to Produce Generic Versions*, L.A. TIMES, Oct. 9, 2007, at 17.

⁹⁷ *Id.*

⁹⁸ See *id.*

⁹⁹ Keith Alcorn, *Abbott To Withhold New Drugs from Thailand in Retaliation for Kaletra Compulsory License*, Mar. 15, 2007, <http://www.aidsmap.com/en/news/00C7641B-57F5-4AB8-8876-9040425D4464.asp>.

its failure to include all stakeholders in the discussions leading up to the issuance of the license.¹⁰⁰ It did, however, acknowledge Thailand's legal right under TRIPS to issue a compulsory license.¹⁰¹

Thus there is a strong international perception that developed nations and the pharmaceutical industry will react swiftly and harshly to what they perceive to be intellectual property infractions.¹⁰² The threat of trade sanctions or other business repercussions is alarming to developing nations that are already in desperate economic positions.¹⁰³ As a result, developing countries are hesitant to issue compulsory licenses, especially for Paragraph Six purposes.¹⁰⁴

Besides instilling fear of sanctions in developing countries, another drawback to compulsory licensing is that it arguably destroys the pharmaceutical companies' incentives to research and develop medicines to treat the diseases that strike developing countries.¹⁰⁵ If the pharmaceutical industry's fears are realized and compulsory licensing becomes a common practice, it could be "the last blow" to the drug industry's attempts to cure diseases of the developing world, which are overlooked even today.¹⁰⁶ One Doctors Without Borders report reads, "For [some] diseases there is no treatment: no effective medicine exists and nobody is looking for a cure."¹⁰⁷ Indeed, pharmaceutical companies will not invest in new medicines unless there is an economic incentive to do so, and pervasive compulsory licensing may destroy this motivation.¹⁰⁸

A related weakness is that compulsory licensing allows and perhaps even encourages free-riding.¹⁰⁹ That is, an inventor invests a huge amount of money into researching and developing new medicines, and another company simply copies the formula and makes a significant

¹⁰⁰ See GOV'T ACCOUNTABILITY OFFICE, U.S. TRADE POLICY ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION (NOV. 1, 2007) (detailing the United States' argument that Thailand failed to follow proper procedure when issuing compulsory licenses).

¹⁰¹ *Id.*

¹⁰² See Sherman & Oakley, *supra* note 5, at 398.

¹⁰³ See *id.*

¹⁰⁴ See Rich, *supra* note 77, at C1; Boscariol, *supra* note 40.

¹⁰⁵ Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 392-93 (2000).

¹⁰⁶ See *A Gathering Storm*, *supra* note 1, at 100.

¹⁰⁷ Singham, *supra* note 105, at 392.

¹⁰⁸ See *id.* at 392-93.

¹⁰⁹ See *id.* at 363, 390.

profit from its sales.¹¹⁰ In this sense, some argue that compulsory licensing is anti-competitive and takes an economic toll on society.¹¹¹

Another realistic danger is that middle-income nations will take advantage of compulsory licensing to the detriment of poorer developing countries.¹¹² As one member of the Gates Foundation stated, "Brazil is not Rwanda, which cannot afford to pay."¹¹³ Further, some argue that the prices of drugs created by compulsory licensing are not low enough to justify the massive intrusion on patent rights.¹¹⁴ Indeed, the prices of generic drugs are reduced, but they are still far beyond the means of many developing nations.¹¹⁵

C. Other Options: Parallel Importation and Tiered Pricing

Parallel importation is another method through which developing countries can obtain affordable pharmaceuticals.¹¹⁶ Supporters of parallel importation contend that once a product has been sold, manufacturers can no longer control what happens to it, and thus an importing country is free to resell the products at a higher price if it so chooses.¹¹⁷ An attractive quality of parallel importation is that, unlike the type of compulsory licensing widely used in the world today, it does not require countries to have domestic manufacturing capabilities; rather, nations can simply import the cheapest version of a drug that they can find.¹¹⁸

The United States and other developed countries fundamentally oppose the practice of parallel importation, arguing that it destroys the monopoly a patent-holder has on its innovation and undermines the patent system.¹¹⁹ Opponents further hold that parallel importation eliminates any incentive to offer lower prices to developing nations, a tactic which is further described below.¹²⁰

¹¹⁰ *See id.*

¹¹¹ *See id.* at 391.

¹¹² *See A Gathering Storm, supra* note 1, at 100.

¹¹³ *Id.*

¹¹⁴ *See Singham, supra* note 105, at 390.

¹¹⁵ *See Harrelson, supra* note 2, at 175.

¹¹⁶ *See id.* at 192–95.

¹¹⁷ *See Whobrey, supra* note 25, at 632–34.

¹¹⁸ Sherman & Oakley, *supra* note 5, at 375. It should be noted that compulsory licensing under the 2003 Paragraph Six Decision also does not necessitate domestic manufacturing facilities. Nevertheless, as stated previously, this type of compulsory licensing has only been employed on one occasion since the decision was issued. *See Boscarion, supra* note 40.

¹¹⁹ *See Harrelson, supra* note 2, at 194.

¹²⁰ *See id.*; Sherman & Oakley, *supra* note 5, at 375.

Furthermore, it is debatable whether parallel importation even benefits poor patients in developing countries.¹²¹ The primary beneficiaries of parallel importation are often the importers themselves, who proceed to raise the price of the drug and resell it to patients at an unreduced rate.¹²² In addition, the governments of some developing nations are corrupt and the poor patients are often unable to reap the benefits of parallel importation.¹²³ In other instances, developed countries purchase lower-priced drugs intended for the developing world, which is arguably unfair.¹²⁴

Tiered pricing is another option, inextricably linked to parallel importation, which may help make medicines more affordable in the developing world.¹²⁵ In a tiered pricing scheme, drug companies charge less for patented medicines in developing nations than they do in developed countries.¹²⁶ The TRIPS Agreement does not address tiered pricing, although differential pricing can lead to parallel importation, as explained above.¹²⁷ Tiered pricing already exists to a fairly large extent in the world, especially in relation to vaccines and contraceptives, but questions remain as to whether it can solve access problems in the developing world and whether it should be mandated by TRIPS.¹²⁸

The chief argument against tiered pricing is that sales in developing countries would not be profitable for pharmaceutical companies, which rely on large profits to offset their exorbitant research and development costs.¹²⁹ Furthermore, tiered pricing also can negatively affect profits in developed countries.¹³⁰ When distributors in one nation realize that a drug is available for a lower price in another country, there is an incentive for the distributor to buy the drug cheaply and resell it for a higher price.¹³¹ Opponents of tiered pricing therefore argue that because it is difficult, if not impossible, to keep lower-priced

¹²¹ See Sherman & Oakley, *supra* note 5, at 375; Harrelson, *supra* note 2, at 194.

¹²² See Sherman & Oakley, *supra* note 5, at 375.

¹²³ See Whobrey, *supra* note 25, at 633.

¹²⁴ See *A Gathering Storm*, *supra* note 1, at 100.

¹²⁵ See Harrelson, *supra* note 2, at 195.

¹²⁶ *Id.*

¹²⁷ See Harrelson, *supra* note 2, at 196; see generally TRIPS, *supra* note 7.

¹²⁸ See Sherman & Oakley, *supra* note 5, at 373; World Health Organization & World Trade Organization, Report of the Workshop on Differential Pricing and Financing of Essential Drugs, April 2001, at 3, available at http://www.wto.org/english/tratop_e/TRIPS_e/hosbjor_report_e.pdf [hereinafter Report on Differential Pricing].

¹²⁹ See Harrelson, *supra* note 2, at 196.

¹³⁰ See Sherman & Oakley, *supra* note 5, at 374–75.

¹³¹ See *id.*

drugs within the country for which they are intended, this alternative is not a viable solution.¹³²

III. ANALYSIS

As it exists, TRIPS fairly effectively achieves its dual goals of facilitating access to affordable medicines and protecting intellectual property on an international scale.¹³³ Nevertheless, one of TRIPS' most significant mechanisms, the Paragraph Six method of compulsory licensing, has been used on only one occasion.¹³⁴ Therefore, it is premature to conclude that TRIPS has effectively struck a balance between its competing aims.¹³⁵ That is, if developing nations routinely used the Paragraph Six provision and imported from other countries medicines created using compulsory licenses, the pharmaceutical industry would likely be outraged.¹³⁶ Accordingly, TRIPS will need to be continuously evaluated in the coming years.¹³⁷ In the meantime, prices are still high and many developing nations are too intimidated to issue compulsory licenses, and thus, several additional provisions would help improve medicine access.¹³⁸

First, TRIPS or a supplementary WTO declaration should mandate a tiered pricing scheme based on gross domestic product.¹³⁹ Tiered pricing allows nations with limited resources to pay lower prices for much-needed pharmaceuticals.¹⁴⁰ Differential pricing already exists, but researching developing countries' buying power and standardizing price tiers would benefit patients in poor nations.¹⁴¹ To offset higher prices for medicines in developing countries, an incentive such as tax credits should be offered to those nations.¹⁴² Research reflects that tiered pricing's impact on pharmaceutical profits would be insignificant because eighty to ninety percent of global sales occur in the thirty

¹³² See Harrelson, *supra* note 2, at 196.

¹³³ See Whobrey, *supra* note 25, at 642.

¹³⁴ See WTO Notifications, *supra* note 41.

¹³⁵ See Rich, *supra* note 77, at C1.

¹³⁶ See *A Gathering Storm*, *supra* note 1, at 100. At present, many pharmaceutical executives are furious that developing nations are issuing compulsory licenses. The Paragraph Six mode of compulsory licensing is arguably more objectionable to executives because any developing nation can use it, not just those that have pharmaceutical manufacturing facilities. See Paragraph Six Decision, *supra* note 30, para. 2; Boscarion, *supra* note 40.

¹³⁷ See Bass, *supra* note 4, at 222.

¹³⁸ See Whobrey, *supra* note 25, at 638–39.

¹³⁹ See *id.* at 640–41.

¹⁴⁰ See *id.*

¹⁴¹ See *id.*

¹⁴² See *A Gathering Storm*, *supra* note 1, at 100.

wealthy countries that make up the Organization for Economic Cooperation and Development (OECD).¹⁴³ That is, sales in developing countries are so low—likely because medicines are too expensive—that lowering prices in that sector of the world would not have a major impact on cost recovery.¹⁴⁴

In concert with the pricing scheme, TRIPS also should reflect an explicit ban on parallel importation.¹⁴⁵ This ban would allow the differential pricing plan to function as intended because it would prevent middle-income countries from abusing the system and buying cheaper drugs for purely commercial reasons.¹⁴⁶ This would avoid loss of profits to pharmaceutical companies through their sales to developed nations because these nations would be prevented from importing cheaper drugs from developing nations.¹⁴⁷ The WTO also would need to develop regulations and sanctions to ensure that parallel importation did not occur.¹⁴⁸ Strict supply-chain management by purchasers and use of different trademarks and packaging may also help prevent trade diversion.¹⁴⁹ Thus, pharmaceutical companies could recoup their research and development costs and continue to develop new medicines in the meantime.¹⁵⁰

A recent European Community (EC) regulation incorporated a similar combination of initiatives.¹⁵¹ In 2003, the EC adopted a differential pricing scheme, which was accompanied by a ban on trade diversion (or parallel importation) of certain named medicines.¹⁵² The EC regulation has been criticized, however, for its rigid pricing scheme and the fully voluntary nature of participation.¹⁵³ Indeed, only one pharmaceutical company used the pricing scheme in the year after its entry

¹⁴³ See Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AM. J.L. & MED. 159, 160 (2006).

¹⁴⁴ See *id.*

¹⁴⁵ See Whobrey, *supra* note 25, at 641.

¹⁴⁶ See *A Gathering Storm*, *supra* note 1, at 100.

¹⁴⁷ See Whobrey, *supra* note 25, at 641.

¹⁴⁸ See GAMHARTER, *supra* note 19, at 258. The European Community has enacted a tiered pricing scheme and the devices it has adopted to prevent parallel importation, such as the temporary suspension of trade, could guide the WTO in this area. See *id.*

¹⁴⁹ Report on Differential Pricing, *supra* note 128, at 21.

¹⁵⁰ See Whobrey, *supra* note 25, at 640–41.

¹⁵¹ See Council Regulation 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, O.J. (L 135), 3 June 2003, 5–11 (EC); GAMHARTER, *supra* note 19, at 252.

¹⁵² See Council Regulation 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, O.J. (L 135), 3 June 2003, 5–11 (EC); GAMHARTER, *supra* note 19, at 252.

¹⁵³ See GAMHARTER, *supra* note 19, at 260.

into force.¹⁵⁴ Thus, although it has not been a major success, the EC regulation forms a useful starting point for the WTO.¹⁵⁵

Likewise, the International Intellectual Property Institute (IPI), a non-profit organization devoted to promoting the use of the intellectual property system as a tool for economic growth, has proposed a comparable plan.¹⁵⁶ The IPI's proposal includes: (1) the division of nations into price-sectors based on ability to pay; (2) the adoption of appropriate prices for each segment; and (3) the development of a system of international subsidies.¹⁵⁷ The IPI has stressed that a key to its plan is prohibition of parallel importation.¹⁵⁸

As a final observation, generic drug makers operate sophisticated manufacturing facilities and their technological capabilities are becoming increasingly advanced.¹⁵⁹ It is predicted that soon they will be able to produce novel drugs and obtain their own patents.¹⁶⁰ Somewhat ironically, a board member of one of India's large generic drug companies stated, "[w]e are very supportive of intellectual-property rights, as innovations must be given their reward."¹⁶¹ This new development bodes well for access to affordable medicines because many generic manufacturers are located in developing countries.¹⁶²

CONCLUSION

The TRIPS Agreement was a major accomplishment and the international community's efforts to improve it, although often marked by controversy, indicate a crucial shift in focus from trade issues to public health.¹⁶³ Despite its numerous shortcomings and drawbacks, compulsory licensing remains an invaluable tool, especially because the mere threat to use it has triggered pharmaceutical companies to significantly reduce their prices.¹⁶⁴ Nevertheless, because many developing countries fear sanctions and business repercussions and refuse to issue compulsory licenses, additional measures are needed to ensure access to af-

¹⁵⁴ *Id.*

¹⁵⁵ *See id.*

¹⁵⁶ *See* Harrelson, *supra* note 2, at 197-98; International Intellectual Property Institute, FAQs, http://www.iipi.org/nav_faqs/faqs.asp (last visited Nov. 21, 2008).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *See A Gathering Storm*, *supra* note 1, at 100.

¹⁶⁰ *See id.*

¹⁶¹ *See id.*

¹⁶² *See id.*

¹⁶³ *See* Lucyk, *supra* note 3, at 216.

¹⁶⁴ Rich, *supra* note 77, at C1.

fordable HIV/AIDS medicines. A standardized tiered pricing scheme accompanied by a ban on parallel imports would help secure universally lower prices for developing countries.

An overarching criticism of TRIPS is that its flexibilities, such as compulsory licensing, are intended to be used only on a temporary basis, but the problem of access to affordable pharmaceuticals is structural and therefore permanent.¹⁶⁵ Indeed, securing lower prices does not guarantee access to vital medicines, but it is a critical piece of a complex puzzle. Nevertheless, it is encouraging to note that the international community is prepared to amend the TRIPS agreement if the need arises.

¹⁶⁵ See GAMHARTER, *supra* note 19, at 276.

