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Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under the Doha Declaration

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**COMPULSORY LICENSING OF PATENTED PHARMACEUTICALS:
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DECLARATION***

By Aileen M. McGill†

ABSTRACT

In response to concerns that patent protection for pharmaceuticals negatively affected world health, the World Trade Organization (WTO) issued the Doha Declaration in 2001, allowing member nations to issue compulsory licenses for patented pharmaceuticals during a public health crisis. The terms of this declaration allow countries to determine what constitutes a public health crisis, what terms are appropriate for compulsory licenses, and what medications they should be entitled to produce.

This article argues that the Doha Declaration has not served countries most in need of inexpensive medications: least developed countries with high rates of HIV/AIDS. The terms of the Doha Declaration are too broad, allowing countries to issue compulsory licenses for medications that do not treat life-threatening illnesses, such as Viagra and Plavix. Many countries have seen a dramatic drop in Foreign Direct Investment (FDI) as a result of extensive compulsory licensing of patented pharmaceuticals, making least developed countries hesitant to invoke the terms of the Doha Declaration for fear of similar losses in FDI. To safeguard the interests of countries facing severe health crises, the WTO should establish an administrative body to determine when a country may issue compulsory licenses of patented pharmaceuticals.

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INTRODUCTION

The balance between the rights of patent holders of pharmaceuticals and public health has become a heated source of debate in the past half century. Although medications for HIV/AIDS and other deadly diseases exist, strong patent protection for pharmaceuticals has enabled drug companies who engineered these medications to price them in order to maximize profits, at high prices beyond the reach of poor people in least developed countries.¹ “Profits over patients or patients over profits? Patents or people?”² many have questioned, rebuking the greed of these behemoth pharmaceutical companies who maintain exclusive rights over lifesaving treatment.

The tension between access to medication and intellectual property protection is more complicated than these outcries profess. The cross-section of intellectual property rights and public health needs encompasses a vast array of diverse ideologies and economic incentives among developed and developing countries. Standards for intellectual property rights, including patent rights for pharmaceuticals, were established internationally through the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) adopted by the WTO following the Uruguay Round Agreements in 1994.³ Although some international agreements previously governed

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¹ The cost for antiretroviral treatment is approximately \$10,000 to \$15,000 per patient per year. See Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 426, 446-47 (2003) (discussing how Bayer’s sale of its anti-anthrax drug at a heavily discounted price ultimately led to a WTO ministerial meeting where members recognized the “deleterious effects of widespread intellectual property recognition on the ability of poor people to obtain essential drugs.”).

² *Patients Before Profits: TRIPS and Trade Rules on Intellectual Property*, OXFAM AMERICA (on file with Wake Forest Intellectual Property Law Journal), available at http://web.archive.org/web/20071011133029/http://oxfamamerica.org/whatwedo/issues_we_work_on/trade/news_publications/trips/art4190.html (last visited May 3, 2009).

³ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 33 I.L.M. 1197, 1869 U.N.T.S. 299 [hereinafter TRIPS]. For a useful guide to TRIPS, including its economic implications for WTO member nations, see generally MICHAEL BLAKENEY, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT* (1996).

intellectual property protection between other countries—namely, the Berne Convention,⁴ the Paris Convention,⁵ and others—TRIPS is unique because it binds any country to its system of intellectual property protection if that country wants to participate in international trade through the WTO. Membership in the WTO requires adherence to TRIPS.⁶

TRIPS supporters, primarily developed countries and drug companies, heralded it as a positive step in combating piracy, counterfeiting, and patent infringement worldwide, protecting the rights of intellectual property holders.⁷ Its critics are quick to note that the scope of patent protection for pharmaceuticals varied tremendously between countries prior to the adoption of TRIPS due to both theoretical perspectives of the rights inherent in intellectual creation and the health and economic circumstances within developing countries.⁸ The uniform standards established by TRIPS did not correspond to the ideals of many countries, and continue to create problems with nations that disagree with its terms who have sought to circumvent patent protection whenever possible.

Because of the trade advantages of WTO membership, countries with diverse social, economic, and healthcare needs have reluctantly signed on to this universal system of intellectual property rights under standards largely advocated by economic powerhouses, such as the United States, acting under lobbying pressure from drug companies.⁹ Patent protection under TRIPS guarantees patent holders the right to exclusive use of their medication for twenty years with no

⁴ Berne Convention for the Protection of Literary and Artistic Works, Sept. 28, 1979, 102 Stat. 2853, 1161 U.N.T.S. 3.

⁵ Paris Convention for the Protection of Industrial Property, *opened for signature* Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 303. For a list of contracting parties, see World Intellectual Property Organization, Contracting Parties to the Paris Convention, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Nov. 13, 2009).

⁶ The obligations of compliance for TRIPS apply equally to all WTO member nations, though developing countries were given a buffer period to come into compliance. See TRIPS, *supra* note 3, art. 65; see also World Trade Organization, Overview: the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 13, 2009).

⁷ See generally Mark A. Groombridge, *The TRIPS Trade-Off: Reconciling Competing Interests in the Millennium Round*, 2 J. WORLD INTELL. PROP. 991 (1999) (discussing both the successes of TRIPS and residual issues in implementation).

⁸ For a discussion of the ways in which initial compliance with TRIPS may impose a significant burden on developing countries, see *id.* at 1003-05.

⁹ Clark A.D. Wilson, *The TRIPS Agreement: Is it Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?*, 10 J. TECH. L. & POL'Y 243 (2005).

limit on price.¹⁰ Advocates of strong patent protection argue that exclusive patent rights are necessary to incentivize research and development of medications.¹¹ But are we giving patent holders more protection than they need to create incentives to produce these medications? Has intellectual property protection become a tool for abuse instead of advancement? Can we find a way to reconcile intellectual property rights with public health and humanitarian concerns?

In light of these questions and the increasing evidence that patent protection was negatively affecting world health by erecting a barrier between sick people and the medication they need, the WTO amended TRIPS in 2001 under the Doha Declaration to broaden the criteria to facilitate compulsory licensing of patented pharmaceuticals for countries facing a public health crisis.¹² Furthermore, countries that lack domestic pharmaceutical production abilities may import these medications from countries that produce the medications for them for this purpose.¹³ Since the Doha Declaration's passage, compulsory licensing or threats of compulsory licensing have issued from a number of countries, seeking to use the Doha Declaration's terms to combat a variety of diseases from AIDS¹⁴ to Anthrax¹⁵ to

¹⁰ TRIPS, *supra* note 3, art. 28.

¹¹ See, e.g., Vishal Gupta, *A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement*, 13 CARDOZO J. INT'L & COMP. L. 631, 631 (2005) (noting that "the very thing that limits access to these medicines, 'the right to exclude others from making, using, offering for sale or selling the invention,' is also what promotes innovation in the first place.").

¹² World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

¹³ World Trade Organization General Council, *Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003) [hereinafter *Implementation of Paragraph 6*].

¹⁴ Brazil has been the leader in using compulsory licensing or threats of compulsory licenses to negotiate reduced prices for HIV/AIDS medications. A number of other countries including South Africa, India, and Thailand have similarly used compulsory licenses to produce generic forms of HIV/AIDS antiretroviral therapies. For a comprehensive list of countries that have issued compulsory licenses for the production of pharmaceutical products, including ARVs to treat HIV/AIDS, see JAMES PACKARD LOVE, RECENT EXAMPLES OF THE USE OF COMPULSORY LICENSES ON PATENTS, KNOWLEDGE ECOLOGY INT'L (2007), available at http://www.keionline.org/misc-docs/recent_cls.pdf.

¹⁵ In 2001, the United States threatened Bayer that it would issue compulsory licenses for the production of Ciproflaxin, an antibiotic that treats Anthrax, if Bayer did not match the price for generic versions of the drug. The United States intended to stockpile the drug in fear of a bioterrorist attack. See Keith Bradsher, *U.S. Says Bayer will Cut Cost of its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001, at B7.

heart disease.¹⁶ Regardless of the severity of their situation, ability to pay for medications, or connection to the medication at issue, countries have declared a public health crisis in order to produce generic versions of patented formulas under the terms of the Doha Declaration.¹⁷

While the goal of the WTO to increase access to medication during public health emergencies is a good one, the terms of this provision have led to unfettered discretion by nations to dictate the terms of their own compulsory licensing programs.¹⁸ The WTO intended, through this agreement, to ensure that countries facing public health crises that lacked the ability to pay for pharmaceuticals at patent prices, would be able to invoke these terms to ensure that their citizens had access to medication.¹⁹ Because member nations may dictate when they are entitled to compulsory licensing for a wide range of pharmaceutical products, however, countries have invoked compulsory licensing for a range of conditions that may go beyond the definition of a “public health crisis” the WTO intended.²⁰ This unchecked discretion has created a negative association with compulsory licensing, and may be hurting the very countries needing access to life-saving medications most: least developed countries facing severe public health crises that lack domestic pharmaceutical production capacity.

This article argues that the Doha Declaration should be revised to increase checks on when countries may issue compulsory licenses for pharmaceuticals. Particularly, it argues that the discretionary terms of the Doha Declaration are hurting least developed countries that lack domestic pharmaceutical production capacity because past negative

¹⁶ In 2007, Thailand announced it would issue a compulsory license to a domestic pharmaceutical production company to begin production of Plavix, a blood thinner that prevents heart disease. LOVE, *supra* note 14, at 13.

¹⁷ See generally *id.* (outlining a number of recent examples of the use of compulsory licenses, in both developed and developing economies).

¹⁸ The Doha Declaration permits countries to “grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Doha Declaration, *supra* note 12, ¶ 5(b).

¹⁹ Under the Doha Declaration paragraph 4, the WTO “affirm[ed] 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.” *Id.* ¶ 4.

²⁰ Doha Declaration paragraph 5(c) gives countries the authority to determine what constitutes a public health crisis for purposes of invoking compulsory licenses. “Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” *Id.* ¶ 5(c).

publicity, political repercussions, and negative economic consequences of compulsory licensing have made these countries hesitant to invoke its terms. Part I addresses different countries' interpretations of what intellectual property rights should entail, how the globalization of intellectual property protection standards was dominated by developed countries, particularly the United States, and how this has led to backlash from countries who disagree with its terms through extensive compulsory licenses. Part II discusses the applicable agreements governing patent protection and compulsory licensing and how these terms have been used by both developed and developing countries. Giving developing countries a louder voice than they had in the formation of TRIPS in the scope of pharmaceutical patent protection is a wise goal of the WTO. However, discretionary compulsory licensing of patented pharmaceuticals is likely not the appropriate means to ensure these countries receive the medications they need or the voice in the WTO they deserve. Countries that have issued compulsory licenses widely prior to the adoption of TRIPS, under conditions that the Doha Declaration permits, have seen dramatic decreases in FDI. These negative consequences have made other countries facing health crises hesitant to import medication under compulsory licensing out of fear of similar negative economic effects. Unchecked discretion for compulsory licensing has made compulsory licenses a dirty word for economic development and erected a barrier between generic drugs and the least developed countries that need them.

In conclusion, this article proposes how decision-making by a WTO member body could prevent the abuses of the compulsory licensing program in the Doha Declaration. In this framework, the WTO, through representatives from all member nations, will act to ensure that the amendments adopted through the Doha Declaration benefit those most in need of life-saving medication.

I. COUNTRIES VIEW INTELLECTUAL PROPERTY AND THE ADOPTION OF TRIPS DIFFERENTLY.

A. THE APPROPRIATE LEVEL OF PATENT PROTECTION FOR PHARMACEUTICALS VARIES BETWEEN DEVELOPED AND DEVELOPING COUNTRIES BASED ON THEIR THEORETICAL IDEALS AND ECONOMIC NEEDS.

Countries perceive the scope of protection for intellectual property rights differently based on differing values pertaining to

public welfare and the relative importance of private property rights.²¹ Some countries, such as the United States, afford intellectual property holders the full panoply of rights that they give to owners of real estate or chattel: the rights to possess, improve, transfer, exclude others, and most importantly, the right to waste.²² There are no exceptions or limitations for patented pharmaceuticals, such that one who has invented a lifesaving medication no less than one who has invented a widget machine has the right to both exclude others from using that formula and choose not even to produce that medication if he chooses.²³ This legal right reflects how the United States views the individual right to property ownership, even ownership in one's ideas, as an important human right and a necessary component of our capitalist system.

The United States' patent system uses this grant of property rights as the counterweight in the delicate balance with society's benefits of full disclosure of those ideas and a rich public domain when patent protection expires. Granting strong, guaranteed property protection in new creations, the public receives the benefit of knowing that new developments are not kept secret in return for the inventor's legal monopoly over the implementation of these ideas.²⁴ Society receives the benefit of full disclosure of these ideas, which may often spawn new ideas and new creations. The full disclosure of new ideas may be the strongest benefit of patent rights; the question within any patent system arises as to what incentives are necessary to ensure that people research and develop new ideas and continue to disclose them to the public.

Other countries' patent systems reflect an ideal in which private property rights do not play so dominant a role in their intellectual property systems. Rather, patent protection is meant not only to encourage innovation by rewarding innovators with certain

²¹ See generally PARAMESWARAN NARAYANAN, PATENT LAW (4th ed. 2006) (explaining the patent systems of various countries).

²² "No patent owner otherwise entitled to relief for infringement . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . (4) refused to license or use any rights to the patent." 35 U.S.C. § 271(d) (2006). This statute authorizes a patent holder the right to bring a claim for infringement against an infringing party even if the patent holder has not used the rights of the patent. See *id.* This statute was part of the Patent Misuse Reform Act of 1988. *Id.* (originally enacted as Patent Misuse Reform Act of 1988, Pub. L. No. 100-703, 102 Stat. 4674).

²³ Patentable subject matter includes pharmaceutical products and the process involved in making them. 35 U.S.C. § 101 (2006).

²⁴ One of the requirements for patentability is full disclosure of the patent, with adequate descriptions enabling one having prior skill in the art to practice the patent. 35 U.S.C. § 112 (2006).

rights, but also to enrich the economy, provide jobs, and ensure that new and useful inventions are widely produced.²⁵ Failure to produce the patented product, in most countries, is considered an abuse of the monopoly rights granted to the patent holder; laws in those countries provide for compulsory licensing and even revocation of the patent, in some cases, where the patent holder does not “work” the patent.²⁶

India is one interesting case example of a country that has interpreted patent rights very differently from the United States. In India, patent holders are required to work the invention within the country so as to establish “a new industry . . . which would profitably employ the labour and capital of the country and thus increase the national wealth.”²⁷ As one commentator notes, “patent systems are not created in the interests of the inventor but in the interests of the national economy.”²⁸ Under this governmental goal of granting patents only where it benefits the country, as a whole, Indian patent law explicitly prohibits the patenting of pharmaceuticals, believing that monopoly power over a medication is not in the public interest.²⁹ Many other countries have forbidden patent protection for pharmaceuticals at some point in the twentieth century or have broad exceptions for pharmaceuticals, including Austria, Brazil, Bulgaria, Canada, Chile, the Czech Republic, Denmark, Germany, Hungary, Italy, Japan, the Netherlands, Pakistan, Poland, Spain, Sweden, and Switzerland.³⁰ India does, however, provide a patent for the process of creating the pharmaceutical product, ensuring that its inventor may receive some exclusive rights to his process,³¹ though compulsory licenses for patents relating to medicines, including such process, may be obtained by an interested party.³² On the whole, India represents a broad class of countries that consider patent protection to be a tool for

²⁵ See NARAYANAN, *supra* note 21.

²⁶ Brazilian law, for example, requires patents to have industrial application such that the invention “can be made or used in any kind of industry.” Código de Propriedade Industria [C.P.I.] tít. I arts. 8, 9, 15 (Braz.), *translated at* http://www.inpi.gov.br/menu-esquerdo/marca/dirma_legislacao/oculto/LEI9279INGLES.pdf. Likewise, a compulsory license may be granted if the patentee does not produce the patent in Brazil. *Id.* art. 68 § 1(I).

²⁷ NARAYANAN, *supra* note 21, at 3.

²⁸ *Id.* at 3-4 (citing 1 ALOYS JOHN MICHEL, THE WORLD’S PATENT LAWS 15 (1945)).

²⁹ *Id.*

³⁰ *Id.*; see also J.W. BAXTER, WORLD PATENT LAW AND PRACTICE 73-76 (2d ed. 1968) (discussing countries which do not provide pharmaceuticals full patent protection).

³¹ NARAYANAN, *supra* note 21, at 3-4 (citing 1 ALOYS JOHN MICHEL, THE WORLD’S PATENT LAWS 15 (1945)).

³² *Id.*

public good with decreased emphasis on personal property rights in innovation.

B. AMERICAN VIEWS OF STRONG PATENT PROTECTION FOR PHARMACEUTICALS DOMINATED TRIPS DUE TO THE LOBBYING POWER OF THE PHARMACEUTICAL INDUSTRY AND THE TRADE INFLUENCE OF THE UNITED STATES.

The United States was the strongest supporter of linking intellectual property requirements with world trade and used TRIPS to ensure that countries would be required to comply with patent protection under American ideals.³³ The goal of harmonizing intellectual property protection worldwide has largely been a product of the shift in the American economic system from an industrial to a knowledge-based economy. Countries such as China, India, and other developing countries have taken over the manufacturing and industrial components of international trade.³⁴ The United States now exports primarily entertainment, attractive brand names,³⁵ and innovation,³⁶ including products created by the multi-billion dollar pharmaceutical company that lobbied heavily for the passage of TRIPS.³⁷ The United States' economy relies on profits from innovation.³⁸ Thus, the United States pushed heavily to pass a system of intellectual property protection that embodied our strong private property rights in patents and ensured its adoption worldwide by linking it to the benefits of the WTO.³⁹

The TRIPS agreement, as adopted, reflects the broad property rights of the American intellectual property system. In fact, the agreement parallels American law almost exactly. First, TRIPS

³³ CARLOS M. CORREA, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS; A COMMENTARY ON THE TRIPS AGREEMENT (2007).

³⁴ China, for example, dominates the world in manufacturing, producing two-thirds of the world's copiers, microwaves, DVD players, shoes, and toys. Fareed Zakaria, *Does the Future Belong to China?*, NEWSWEEK, May 9, 2009, at 28.

³⁵ See Burt Helm, *Best Global Brands*, BUSINESSWEEK, Sept. 29, 2008, at 56. Four out of the five most valuable brands are American companies. These brands are Coca-Cola, IBM, Microsoft, and GE, while Nokia, a Finnish company, is the fifth most profitable. *Id.*

³⁶ See *id.* (noting that three of America's four most valuable international brands, IBM, Microsoft, and GE are companies known for developing new technology).

³⁷ GAIL E. EVANS, LAWMAKING UNDER THE TRADE CONSTITUTION: A STUDY IN LEGISLATING BY THE WORLD TRADE ORGANIZATION (vol. 14, 2000).

³⁸ See Helm, *supra* note 35, at 56-60 (listing the most valuable international brands; a number of the American brands contained on the list are known for developing new and cutting edge products and technologies).

³⁹ CORREA, *supra* note 33.

requires a minimum term of twenty years of patent protection,⁴⁰ similar to American law at that time⁴¹ and longer than most other countries' patent protection prior to TRIPS.⁴² Second, there is no "local working" requirement for patent holders, and it does not authorize compulsory licensing if a patentee fails to work the patent locally,⁴³ a policy directly at odds with most countries.⁴⁴ The United States did not want their patented ideas to be put to use through manufacturing in other countries under compulsory licensing terms which did not maximize the profits of its drug companies.⁴⁵ Local working has been a source of dispute and unrest between Brazil and the United States for some time, and is still relatively unresolved.⁴⁶ Finally, TRIPS does not make exceptions for the patenting of pharmaceuticals or pharmaceutical processes, unlike the terms of India's laws and those of many other countries.⁴⁷ Pharmaceuticals receive the same patent protection as other products.⁴⁸

The terms of TRIPS favor producers of patented products, primarily developed countries, and the United States in particular, and American pharmaceutical companies.⁴⁹ This outcome should not be surprising given that executives from many of the highest grossing American pharmaceutical companies were members of the U.S. President's Advisory of Committee on Trade Policy and Negotiations

⁴⁰ TRIPS, *supra* note 3, art. 33.

⁴¹ Prior to TRIPS, American law gave patent holders seventeen years of protection. The law was amended in 2006 to comply with TRIPS. 35 U.S.C. § 154(a)(2) (2006).

⁴² See, e.g., The Patents Act, 1970, No. 39 of 1970, § 53(1)(a)-(b), Acts of Parliament, 1970 (India) available at <http://www.wipo.int/clea/en/details.jsp?id=2393> (providing a patent term of either seven or fourteen years depending upon the nature of the patented invention).

⁴³ TRIPS, *supra* note 3, art. 27, 28.

⁴⁴ See NARYANAN, *supra* note 21 (discussing the patent laws of various countries).

⁴⁵ See Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 459-60 (2009) (stating that compulsory licenses oppose a profit-maximizing strategy); Angela Foster, *Compulsory Licensing After Ebay*, N.J. LAW. MAG., June 2009, at 43.

⁴⁶ See Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 380-81 (2002).

⁴⁷ See NARYANAN, *supra* note 21 (discussing the patent laws of various countries); see also Versão em Inglês [C.P.I.] tit. I art. 43 (Braz.) (providing wide exceptions for infringement relating to medical products), translated at www.inpi.gov.br/menu-esquerdo/marca/dirma_legislacao/oculto/LEI9279INGLES.pdf.

⁴⁸ GERMÁN VELÁSQUEZ & PASCALE BOULET, WORLD HEALTH ORG., GLOBALIZATION AND ACCESS TO DRUGS: IMPLICATIONS OF THE WTO/TRIPS AGREEMENT 3 (1999), available at <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf>.

⁴⁹ Wilson, *supra* note 9, at 264.

(ACTPN), and directly supported TRIPS.⁵⁰ James R. Enyart, Director of International Affairs at Monsanto, defended the lobbying of the pharmaceutical and biotech industry and noted: “The rules of international commerce are far too important to leave up to government bureaucrats and their academic advisers. But governments, not businessmen, make rules and they only listen when the chorus gets big enough and the singing gets loud enough.”⁵¹ The voice of pharmaceutical companies undoubtedly has had a loud and permanent effect on international intellectual property rights.

II. THE DOHA DECLARATION HAS NOT GIVEN LEAST DEVELOPED COUNTRIES A SIGNIFICANT ROLE IN INTERNATIONAL PATENT POLICY, AND IT HAS LED COUNTRIES TO INVOKE COMPULSORY LICENSING FOR SCENARIOS THAT MAY HAVE BEEN BEYOND THE SCOPE OF THE WTO’S INTENDED USE.

A. THE WTO ISSUED THE DOHA DECLARATION TO BROADEN THE TERMS UNDER WHICH COUNTRIES MAY ISSUE COMPULSORY LICENSES, INTENDING TO FACILITATE ACCESS TO LIFESAVING MEDICATIONS IN PUBLIC HEALTH CRISES.

Medications to treat life-threatening illnesses such as HIV/AIDS are available but pharmaceutical companies have priced them out of reach of those hardest hit by these illnesses and may continue to do so under TRIPS.⁵² HIV/AIDS has been the focus of this controversy due to its devastating toll on many least developed countries, the fact that many of its treatments are still under patent protection, and the high prices charged by pharmaceutical companies that hold these patent rights. Although treatments for other illnesses have been affected by TRIPS, this paper will use HIV/AIDS as an

⁵⁰ Peter Drahos, *Global Property Rights in Information: The Story of TRIPs at the GATT*, 13 PROMETHEUS 6, 8 (1995). See James Thon Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. GENDER, RACE & JUST. 267, 268 (2003) (noting that “[s]trong patent protection is . . . the primary U.S. foreign policy position on how to facilitate access to essential medicines under patents held by U.S. and western pharmaceutical corporations.”). This policy position reflects the lobbying pressure of the pharmaceutical industry.

⁵¹ James R. Enyart, *A GATT Intellectual Property Code*, 25 LES NOUVELLES 53 (1990).

⁵² The cost of a year’s supply of anti-retroviral drugs in the United States far exceeds the income of the average person infected by HIV/AIDS in developing countries. Joseph, *supra* note 1, at 428.

example to illustrate some of the consequences of reduced access to medications under patent protection.

Developing countries, particularly countries in sub-Saharan Africa, have been the hardest hit by HIV/AIDS. According to the United Nations, Africa “remains the most severely affected region,”⁵³ with approximately twenty-two million out of thirty-three million people worldwide living with HIV at the end of 2007.⁵⁴ Sixty-one percent of women and 90% of children living with HIV/AIDS worldwide are in sub-Saharan Africa.⁵⁵ Furthermore, life expectancy at birth has dropped below forty years in seven African countries: Central African Republic, Lesotho, Malawi, Mozambique, Swaziland, Zambia, and Zimbabwe.⁵⁶

Although there is no cure for HIV/AIDS, anti-retroviral (ARV) drugs have been available since 1996, and have been shown to be very effective in improving the quality of life and prolonging life for those infected with HIV.⁵⁷ ARV therapies, which are still under patent protection, cost between \$10,000 and \$15,000 per person in the United States, a price that far exceeds the reach of citizens of sub-Saharan Africa.⁵⁸ Patent rights and the ability to price medications at these high prices, thus, have prevented citizens in developing countries from accessing such medications that could allow them to live longer, healthier lives.

In response to the AIDS crisis as well as other diseases worldwide and the patented medications available to treat them, the WTO convened in 2001 in Doha, Qatar, to draft an amendment to TRIPS.⁵⁹ The WTO did not override the terms of TRIPS, but

⁵³ WHO, UNAIDS, & UNICEF, JOINT REPORT, TOWARDS UNIVERSAL ACCESS: SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR, PROGRESS REPORT 2009 7 (2009), http://www.who.int/hiv/pub/tuapr_2009_en.pdf. [hereinafter JOINT REPORT].

⁵⁴ UNAIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC – EXECUTIVE SUMMARY 4-5 (2008), http://data.unaids.org/pub/GlobalReport/2008/JC1511_GR08_ExecutiveSummary_en.pdf.

⁵⁵ GLOBAL AIDS ALLIANCE, FACT SHEET: GLOBAL AIDS STATISTICS (2009), http://aidsalliance.3cdn.net/83e598ec.dabca06971_fbm6bnx9s.pdf.

⁵⁶ Beatriz Pavon, *Development Crisis: AIDS Slashes Life Expectancy in 23 African Countries*, U.N. CHRON., Sept.–Nov. 2004, at 54 (discussing the decreased life expectancy and negative economic impacts on African countries with high rates of HIV/AIDS).

⁵⁷ Joseph, *supra* note 1, at 427.

⁵⁸ *Id.* at 428.

⁵⁹ See Doha Declaration, *supra* note 12. The WTO stated that they sought, through this declaration to “reiterat[e] our commitment to the TRIPS agreement” but “affirm[ed] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health” *Id.* ¶ 4.

amended them to enable countries to access medications in a wider variety of circumstances under royalty terms that the country issuing the compulsory license may determine.⁶⁰ Articles 30 and 31 of the original TRIPS agreement allow member nations to issue compulsory licenses to third parties to satisfy local needs.⁶¹ They require, however, that compulsory licensing take place only after efforts have been made to obtain authorization from the patent holder, a requirement that can be waived “in the case of a national emergency or other circumstances of extreme emergency.”⁶² The Doha Declaration broadens the conditions under which member nations can issue compulsory licenses, recognizing each member nation’s “freedom to determine the grounds upon which such licenses are granted.”⁶³ Under this provision, countries may dictate the royalties they pay to pharmaceutical companies in any situation it deems appropriate without attempting to negotiate with the patent holder prior to issuing the license.⁶⁴

One challenge the WTO encountered in drafting this amendment was ensuring that countries that lacked domestic pharmaceutical production capabilities would still be able to make use of compulsory licensing of the patented pharmaceuticals they needed. Most of the least developed countries that are unable to afford patented medications also lack a facility within its borders capable of producing generic forms of these medications. For example, about 80% of developing countries lack a functional pharmaceutical sector capable of domestic production of ARV drugs to treat HIV/AIDS.⁶⁵ This dilemma, articulated in paragraph 6 of the Doha Declaration, called on “the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council.”⁶⁶ The Council responded through a waiver known as the Decision of 30 August 2003

⁶⁰ *Id.* ¶ 5(c). Under Doha Declaration paragraph 5(b), “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” *Id.* ¶ 5(b). This provision authorizes countries to determine the royalties they should pay to patent holders.

⁶¹ TRIPS, *supra* note 3, arts. 30-31.

⁶² *Id.* art. 31.

⁶³ Doha Declaration. *supra* note 12, ¶ 5(b).

⁶⁴ See Arvind Panagariya, *Developing Countries at Doha: A Political Economy Analysis*, in GLOBAL TRADE POLICY 9; 11 (Peter Lloyd and Chris Milner eds., 2003) (2002).

⁶⁵ CARLOS M. CORREA, IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 1 (2004), http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf; WHO, THE WORLD MEDICINES SITUATION (2004), http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf.

⁶⁶ Doha Declaration, *supra* note 12, ¶ 6.

(Waiver Decision).⁶⁷ This decision, adopted permanently through Article 31*bis* of TRIPS,⁶⁸ allows countries with pharmaceutical production capabilities to export generic forms of patented drugs to a country that lacks domestic pharmaceutical production capacity under conditions identical to those as if the importing country were to produce the drugs themselves.⁶⁹

B. THE WTO DELIBERATELY LEFT THE DEFINITION OF
“PUBLIC HEALTH CRISIS” AND “PHARMACEUTICAL
PRODUCT” VAGUE SO AS NOT TO OBSTRUCT BARRIERS
TO UNFORESEEABLE PUBLIC HEALTH NEEDS IN TIMES
OF CRISIS.

In drafting the Doha Declaration, the WTO struggled in defining what scope of diseases and medications should be covered by compulsory licensing allowances. “From the outset [of the] Paragraph 6 mandate, developing countries demanded that the solution to this problem be applied broadly to both diseases and treatments.”⁷⁰ The United States tried to restrict its scope to HIV/AIDS, malaria, tuberculosis, and a small group of infectious diseases.”⁷¹ The European Committee also “proposed that the declaration be limited to ‘grave’ public health problems,” invoking the possibility of “WTO intervention to determine the gravity of [a] nation’s public health crises for compulsory licensing purposes.”⁷²

In a move uncharacteristic of prior TRIPS negotiations, developing countries prevailed in their push for broad, discretionary interpretation of the scope of diseases covered by the terms of the Doha Declaration.⁷³ As Abbott and Reichman note, “[t]here is no public health justification for denying patients access to treatments for certain diseases because trade officials have decided that some diseases should be on (or off) an official list.”⁷⁴ Indeed, a pre-determined list of diseases that may benefit from compulsory licensing is not in the public’s best interest; diseases that threaten public health

⁶⁷ *Implementation of Paragraph 6, supra* note 13.

⁶⁸ World Trade Organization General Council, Protocol Amending the TRIPS Agreement, ¶ 1, WT/L/641 (Dec. 6, 2005).

⁶⁹ World Trade Organization General Council, Annex to the Protocol Amending the TRIPS Agreement, ¶¶ 1-2, WT/L/641 (Dec. 6, 2005).

⁷⁰ Frederick M. Abbott & Jerome H. Reichman, *The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT’L ECON. L. 921, 936 (2007).

⁷¹ *Id.*

⁷² *Id.*

⁷³ Doha Declaration, *supra* note 12, ¶ 5(c).

⁷⁴ Abbott & Reichman, *supra* note 70, at 936-37.

mutate, evolve, and present unforeseeable degrees of gravity, mortality, contagiousness, and treatability.

This agreement was intended to provide nations with the discretion to determine what conditions constitute a public health crisis.⁷⁵ Paragraph 5(b) states that “[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”⁷⁶ This expansive language appears to indicate that countries can and should grant compulsory licenses under its own terms for any pharmaceutical product. However, the following paragraph states that “[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁷⁷ While the WTO did not limit compulsory licensing to “HIV/AIDS, tuberculosis [and] malaria” as the United States had advocated, it indicated that this declaration intended to target “epidemics” and “circumstances of extreme urgency.”⁷⁸ It would be unusual for the WTO to give member nations the authority to make determinations as to a “national emergency or other circumstances of extreme urgency” if it intended for countries to issue compulsory licenses under *any* circumstances.⁷⁹

Similarly, the scope of pharmaceuticals that may be produced in generic form under a compulsory license was deliberately left undefined in the Doha Declaration.⁸⁰ Both the Waiver Decision and the pending Amendment establish broad subject matter that may be furnished under this system, encompassing any product of the pharmaceutical sector including vaccines and diagnostic kits.⁸¹ By extending the terms broadly enough to encompass existing products that do not treat life-threatening illnesses, the WTO may have signaled its intent to allow wide, discretionary use of compulsory licensing.⁸² However, it is more likely that the absence of a list or class of

⁷⁵ See Doha Declaration, *supra* note 12, ¶ 5(c) (“Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises . . . can represent a national emergency or other circumstances of extreme urgency.”).

⁷⁶ *Id.* ¶ 5(b).

⁷⁷ *Id.* ¶ 5(c).

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ See generally *id.* (The Doha Declaration does not articulate a list of medications or class of medications that may be produced through compulsory licenses).

⁸¹ Abbott & Reichman, *supra* note 70, at 937.

⁸² See *id.* (“Paragraph 1 of the Doha Declaration does not contain any limitation on the application of the Declaration to specific diseases or medicines.”).

predetermined medications subject to compulsory licensing was not intended to grant discretionary usage of these terms under any circumstances. Rather, similar to its refusal to limit what diseases may constitute a national emergency, the WTO did not want to limit what treatments should be available to combat such a crisis.⁸³ The availability of vaccines and diagnostic kits may be a valuable asset during a national health emergency; indeed, vaccines have been used by governments, including the United States, to prevent the spread of a contagious disease.⁸⁴

Developing countries prevailed on both accounts, in leaving the scope of diseases and pharmaceutical products unlimited in the Doha Declaration. However, this ambiguity has not led to extensive benefits for least developed countries facing the most severe health crises, specifically sub-Saharan African countries suffering from HIV/AIDS.⁸⁵ Subsequent events have revealed that neither least developed countries nor the United States predicted the terms that would maximize their best interests.⁸⁶

C. COUNTRIES HAVE CAPITALIZED UPON THIS AMBIGUITY
BY INVOKING COMPULSORY LICENSING FOR A WIDE
VARIETY OF CONDITIONS AND FEARS OF FUTURE
CHRONIC HEALTH PROBLEMS.

The absence of limits on what products and diseases may be covered by the Doha Declaration has had mixed consequences.

1. Positive Outcomes

First, larger developing countries with domestic pharmaceutical production capabilities have used the Declaration either to produce generic forms of patented ARVs or as leverage in negotiating significantly lower prices for ARVs from pharmaceutical companies, facilitating better treatment and more affordable prices for

⁸³ See KATHLEEN S. SWENDIMAN, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2009 (detailing a history of the United States' use of vaccinations to control disease outbreaks).

⁸⁴ During the Swine Flu outbreak of 1976, the United States government ordered the vaccination of hundreds of thousands of U.S. citizens in an effort to create "herd immunity" to this highly contagious disease before it became uncontainable. Justin Lessler et al., *Transmissibility of Swine Flu at Fort Dix, 1976*, 4 J. R. SOC. INTERFACE 755, 759-60 (2007).

⁸⁵ Abbott & Reichman, *supra* note 70, at 937.

⁸⁶ See *id.*, at 938-39 (explaining why developing countries are hesitant to utilize the system and the United States' reaction to the Anthrax scare in 2001).

poor people infected with HIV.⁸⁷ India has been the international leader in producing generic forms of patented medications and has created a thriving industry of exporting these medications to countries that invoke compulsory licensing under the Doha Declaration.⁸⁸ India, though technically a “developing country,” has made enormous, unprecedented strides in pharmaceutical innovation and production.⁸⁹ India now produces generic forms of hundreds of patented pharmaceuticals, innovations that have provided the people of India with lifesaving medications at substantially reduced costs, established a sustainable, profitable industry and enabled some countries around the world to import these medications at reduced cost under the terms of the Doha Declaration.⁹⁰

Brazil is one such case. Brazil has led the world in ensuring that its citizens have access to medications by establishing public access to AIDS treatment.⁹¹ Brazil has traditionally used its public manufacturing facilities to produce older forms of ARVs no longer covered by patent.⁹² However, several important ARVs, developed as “second-line treatment” to overcome resistance to the original ARVs, were subsequently patented in Brazil by foreign drug companies and could not be produced locally without offending TRIPS prior to the Doha Declaration.⁹³ The original cost of the patented form of these medications was beyond the reach of Brazil’s public health budget.⁹⁴ Until 2007, Brazil was able to use the threat of compulsory licensing under the Doha Declaration to pressure foreign drug companies to significantly lower the prices of these second-line ARVs to an amount Brazil could afford.⁹⁵ In April 2007, Brazil authorized a compulsory license for Efavirenz, an ARV produced by Merck.⁹⁶ Although Brazil had negotiated a reduced price for Efavirenz, from \$580 to \$400 per year per patient, Brazil was able to import a generic version of

⁸⁷ For a list of countries that have produced ARVs under compulsory licenses, see LOVE, *supra* note 14.

⁸⁸ India’s history of pharmaceutical production precedes TRIPS, as India has, for many years, sought to make access to medications widespread and affordable. The first planning commission established for this purpose was set up in 1950. PLANNING COMM’N FIRST FIVE YEAR PLAN, intro., *available at* <http://planningcommission.nic.in/plans/planrel/fiveyr/1st/1pintro.htm>.

⁸⁹ *Id.*

⁹⁰ Abbott & Reichman, *supra* note 70, at 949.

⁹¹ *Id.* at 951.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

Efavirenz from India for only \$165 per year, saving the country an estimated \$30 million in public health expenditures.⁹⁷

The ability of countries such as Brazil and India to produce generic ARVs to ensure their citizens have access to these medications has been a positive outcome of the Doha Declaration. Although countries such as Brazil, India, and Thailand are often labeled “developing countries,” in TRIPS negotiations, their perspective represents a distinct class of developing countries that is bridging the gap under TRIPS, largely by way of their domestic pharmaceutical production abilities.

2. Some Negative Consequences

Another use of threats of compulsory licensing illustrates the inconsistencies in countries’ interpretations of when they may issue compulsory licenses. The United States used compulsory licensing as leverage against pharmaceutical companies as soon as it felt threatened by the possibility of a public health emergency.⁹⁸ In 2001, following the September 11th terrorist attacks, a small number of citizens were infected with Anthrax, and three people died as a result.⁹⁹ In response, the United States threatened to issue compulsory licenses to produce and stockpile Ciproflaxin, an antibiotic patented by the German pharmaceutical company Bayer, forcing the company to sell the drug to the United States and Canada at heavily discounted prices.¹⁰⁰ Some commenters have noted that the North American response may have been “legitimate in the circumstances.”¹⁰¹ The United States felt exceptionally vulnerable following September 11th and believed that this action was a necessary response to the threat of a full-blown bioterrorist attack.¹⁰² Regardless, this move reflects the

⁹⁷ Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, SCI. MAG., May 11, 2007, at 816; Braz. Ministry of Health Press Office, *Efavirenz: Questions About Compulsory Licensing* (Apr. 25, 2007), <http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITEMID74BBB449C36442B9B92D6ACC1D9DFC21ENIE.htm>.

⁹⁸ See generally Taiowa A. Oriola, *Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy*, 2007 U.ILL. J. L. TECH & POL’Y, 287 (discussing the negotiated price reductions of Ciproflaxin and Tamiflu as examples of the United States using threats of patent breach to coerce drug companies into allowing generics of critical drugs).

⁹⁹ Francis X. Clines, *U.S. Officials Voice New Worry After Traces of Anthrax Taint Off-Site White House Mailroom*, N.Y. TIMES, Oct. 24, 2001, at A1, B6.

¹⁰⁰ See Bradsher, *supra* note 15, at B7 (noting that Bayer would charge the government approximately what a generic producer of the drug would have charged the government).

¹⁰¹ E.g., Joseph, *supra* note 1, at 447

¹⁰² *Id.* at 446.

blatant hypocrisy of the United States and the unequal consequences of unlimited compulsory licensing provisions in light of prior actions by the United States government.

In 1997, four years prior to the Anthrax scare in the United States, the South African government passed the South African Medicines and Related Substances Control Amendment Act of 1997.¹⁰³ This law “introduce[d] a legal framework to increase the availability of affordable medicines in South Africa”¹⁰⁴ through “generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines.”¹⁰⁵ The South African government specifically hoped to begin production of generic forms of patented ARVs to treat the millions of its citizens infected with HIV at that time.¹⁰⁶ Forty pharmaceutical companies, with the support of the United States, sued the South African government, claiming the Act violated TRIPS.¹⁰⁷ The drug companies eventually dropped the suit but it was a public relations disaster for the United States government and the WTO, prompting massive protests and outrage against the WTO.¹⁰⁸

The actions of the United States reflect how countries have used compulsory licenses to maximize their own best interests while ignoring or actively rebuking another country’s attempts to do the same. The Anthrax scare was a situation not on par with the HIV/AIDS crisis in Sub-Saharan Africa.¹⁰⁹ Nonetheless, the Doha Declaration, by giving countries the ability to negotiate their own circumstances and own terms of compulsory licensing, has given countries an escape door from TRIPS whenever they feel it is in their best interest irrespective of the gravity of their healthcare needs.

Allowing countries to issue compulsory licenses for health situations notably less dire than those in other parts of the world due to their economic and political muscle decreases credibility for the policy overall. Furthermore, this unchecked flexibility garners resistance and

¹⁰³ Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.).

¹⁰⁴ Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27, 30 (2002).

¹⁰⁵ *Id.*

¹⁰⁶ See NAT’L BD. OF TRADE, THE WTO DECISION ON COMPULSORY LICENSING 21 n.29 (2008), available at http://www.kommers.se/upload/Analysarkiv/Arbetsomr%C3%A5den/WTO/Handel%20och%20skydd%20f%C3%B6r%20imateriella%20r%C3%A4ttigheter%20-%20TRIPS/Rapport%20The_WTO_decision_on_compulsory_licensing.pdf (noting South Africa introduced this law at a time when it was the country with the largest population of individuals living with HIV/AIDS).

¹⁰⁷ Hoen, *supra* note 102, at 30.

¹⁰⁸ NAT’L BD. OF TRADE, *supra* note 106, at 21 n.29.

¹⁰⁹ Joseph, *supra* note 1, at 447.

suspicion from the pharmaceutical companies who hold patents on many lifesaving medications, erecting a barrier between least developed countries and the medications they need to combat the most serious health crises. The United States' loud criticism of South Africa's steps towards producing generic ARVs, and its later threats of compulsory licensing over Cipro, negatively affected the reputation of compulsory licensing programs.¹¹⁰ This dispute pitted pharmaceutical companies against countries seeking to issue such licenses, a negative consequence that has a rippling effect on least developed countries.¹¹¹

Developing countries with domestic pharmaceutical production abilities have issued compulsory licenses for medications that do not treat life-threatening illnesses, which may go beyond the scope of the TRIPS compulsory licensing allowances and the Doha amendments, although the terms of the Doha Declaration technically allow such actions.¹¹² These compulsory licenses have had negative economic and public health consequences for both these countries and their lesser developed neighbors.¹¹³ The act of compulsory licensing is "retrospective in nature" and necessarily only applies to intellectual property that already exists.¹¹⁴ Some have posited that pharmaceuticals that have been created with an eye on the reward granted for full patent protection would have never been developed in the face of compulsory licensing.¹¹⁵ From an economic standpoint, "a compulsory license is predicated on the assumption that beneficial health effects from the limitation will be significant, outweighing the loss of any innovation investment."¹¹⁶ Thus, the public benefit achieved in improving and prolonging life should outweigh the economic loss of decreased return on innovation investments. Although the countries that are home to the majority of companies that hold patents on pharmaceuticals typically (though not always) do not issue compulsory licenses for those drugs, least developed countries may nonetheless suffer from overuse of compulsory licensing through the fear of decreased FDI.

¹¹⁰ NAT'L BD. OF TRADE, *supra* note 106, at 21.

¹¹¹ *Id.* at 21 n.29.

¹¹² See, e.g., Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 306-07 (2008) (discussing Egypt's issuance of a compulsory license for the erectile dysfunction drug Viagra).

¹¹³ See *id.* at 308-09 (explaining how Egypt's compulsory licensing scheme can undermine the strength of the Egyptian pharmaceutical industry, which supplies pharmaceuticals throughout the Middle East and North Africa).

¹¹⁴ *Id.* at 291.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

Viagra in Egypt is one such example. Egyptian law strongly favors compulsory licensing, allowing the Minister of Health to grant compulsory licenses when the quantity of medicine fails to meet national need, the price is outside the reach of most consumers, or simply because the high prices are politically burdensome.¹¹⁷ Their laws governing compulsory licensing are broad, ambiguous, and generally afford the government wide discretion to issue compulsory licenses.¹¹⁸ In 2002, after years of effort, Pfizer received regulatory approval to enter the Egyptian market with Viagra, a drug treating erectile dysfunction.¹¹⁹ Two months after Pfizer's entry into the Egyptian market, under pressure from local well-connected drug manufacturers, the government granted authorization to all companies to produce Viagra that applied to do so.¹²⁰ Although Pfizer was furious, Egypt noted they were legally allowed to issue compulsory licensing under these conditions given that, as a developing country, they were not required to comply with TRIPS until 2005 (the broadened terms of the Doha Declaration would equally have permitted such an action).¹²¹ They also argued that reducing the cost of Viagra would benefit the poor.¹²² Pfizer immediately halted their construction of a manufacturing facility in Egypt, and a Pfizer Middle Eastern representative remarked that allowing generic Viagra to be sold will "send a chill down foreign investor's spines."¹²³ Indeed, largely as a result of extensive compulsory licensing, FDI in Egypt decreased from \$948 million in 1987¹²⁴ to \$509.4 million in 2001-02.¹²⁵ Although FDI has increased since that time, these increases have been dominated by investments in petroleum.¹²⁶ Pharmaceutical companies have deliberately avoided investing in Egypt, a missed opportunity for a country that relies heavily on FDI.¹²⁷

¹¹⁷ Law on the Protection of Intellectual Property Rights, art. 23(2) (2002) (Egypt).

¹¹⁸ Bird & Cahoy, *supra* note 112, at 305.

¹¹⁹ *Id.* at 306

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.* (citing Richard A. Castellano, Note, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 289 (2006)).

¹²⁴ Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH* 44 (Carsten Fink and Keith E. Maskus eds., 2005).

¹²⁵ Egyptian Ministry of Investment, Foreign Direct Investment, <http://www.investment.gov.eg/en/Investment/pages/foreigninvestment.aspx> (last visited Nov. 12, 2009).

¹²⁶ *Id.*

¹²⁷ Sahar Aziz, *Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment*

This scenario took place prior to the Doha Declaration, and prior to the time Egypt was required to come into compliance with TRIPS.¹²⁸ However, the terms of the Doha Declaration expanded TRIPS to allow countries the freedom to “determine the grounds upon which such [compulsory] licenses are granted.”¹²⁹ Thus, under the expansive terms of the Doha Declaration, countries may issue compulsory licenses for pharmaceuticals at their discretion, and would permit Egypt to issue this type of compulsory license.

Thailand has also made extensive use of compulsory licensing under the allowances provided in the Doha Declaration. In November, 2006, Thailand announced its intention to issue compulsory licenses for the ARV efavirenz, eliciting international praise for these steps towards improving treatment of HIV/AIDS.¹³⁰ After receiving an overwhelmingly positive international response, Thailand issued two more compulsory licenses, one for another ARV, Kaletra, and one in February 2007 for Plavix, a blood thinner that has been proven to prevent heart disease.¹³¹

Additionally, Thailand has announced that it is considering breaking the patents of eleven other drugs, many of which do not treat life-threatening conditions.¹³² Simultaneously, private investment in Thailand fell dramatically between 2005 and 2007.¹³³ Gross private investment growth fell from 10.6% to .5% in 2007, its lowest since 2000.¹³⁴ The primary cause of this decline was the dramatic decline of FDI, the main supporter of private investment growth, which declined by \$10 billion in 2007.¹³⁵ Widespread compulsory licensing of pharmaceuticals is not the only factor affecting the decline in FDI in Thailand,¹³⁶ but it has had a strong negative impact on FDI. FDI has “transferred amazingly little tacit knowledge and technology, as only a

Policy: A Case Study of Egypt’s Pharmaceutical Industry, 10 ILSA J. INT’L & COMP. L. 1, 22 (2003).

¹²⁸ *Id.* at 14.

¹²⁹ Doha Declaration ¶ 5(b).

¹³⁰ Stephanie Skees, *Thai-ing Up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand’s AIDS Epidemic?*, 19 PACE INT’L L. R. 233, 235 (2007).

¹³¹ *Id.*

¹³² James Hookway & Nicholas Zamiska, *Thai Showdown Spotlights Threat to Drug Patents*, WALL ST. J., Apr. 24, 2007, at A1; Kaiser Network, Kaiser Daily HIV/AIDS Report, Thai Government to Issue Compulsory Licenses for Two More Drugs (May 30, 2007), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=45220.

¹³³ Kirida Bhaopichitr et al., World Bank, Thailand Economic Monitor 25 (Apr. 2007), http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.* at 28

handful of companies have set up research establishments in Thailand.”¹³⁷

The Viagra scenario in Egypt and Thailand’s broad usage of compulsory licensing generally illustrate how widespread, unchecked discretionary compulsory licensing may have poignant negative economic effects on the countries that issue them where they do not convey dramatic health benefits. Looking back at the formation of TRIPS, negotiations by the United States have been widely dominated by lobbying pressure from pharmaceutical companies. Given that this voice prevailed in TRIPS negotiations, we often consider lobbying by American pharmaceutical companies to be the only private voice in this discussion, and largely to blame for the strong patent rights in TRIPS. However, developing countries, such as Egypt, are subject to many of the same lobbying pressures of the United States. The decision of the Egyptian government to issue compulsory licenses for Viagra was the product of intense pressure from generic drug manufacturers.¹³⁸ Additionally, “the chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of Parliament at the time the compulsory license was issued.”¹³⁹

The terms of the Doha Declaration do little to subdue the lobbying influence of localized interests that often exert powerful pressure over their national governments. Decision-making at the national level will represent the interests of the most powerful voices in those governments. This observation is not to say that national governments will always put the interests of private companies over citizens most needing access to lifesaving medication. Brazil, as previously discussed, has made access to lifesaving medications a top priority and has used compulsory licensing for that purpose, especially pertaining to HIV/AIDS, with limited negative effects on FDI.¹⁴⁰ However, many countries, including the United States, Egypt, and others are subject to strong influences of private parties that have a stake in patent protection and compulsory licensing.¹⁴¹ The terms of the Doha Declaration as they currently stand may authorize too much

¹³⁷ *Id.* at 7.

¹³⁸ Bird & Cahoy, *supra* note 112, at 306.

¹³⁹ *Id.* at 307.

¹⁴⁰ Robert Bird and Daniel Cahoy have noted how “[u]nlike Egypt, Brazil’s compulsory license statute does not appear to come at a price of lost FDI.” *Id.* at 316. They attribute this outcome to Brazil’s skillful negotiations with the United States, and the fact that WTO issues compulsory licenses primarily for anti-AIDS drugs. *Id.* at 311-17.

¹⁴¹ *Id.* at 300-11.

leeway in giving governments a carte blanche to appropriate any patented medication under any circumstance.

Citizens of the most underdeveloped countries have suffered as a result of the discretionary allowances of the Doha Declaration. In this sense, the Doha Declaration has failed at achieving its most fundamental goal of “support[ing] WTO Members’ right to protect public health and, in particular, promot[ing] access to medicines for all.”¹⁴² As previously noted, about 80% of developing countries lack a functional pharmaceutical sector capable of producing ARVs.¹⁴³ In August 2003, the General Council of the WTO adopted a decision to implement the terms of Paragraph 6 of the Doha Declaration, providing criteria aimed at facilitating access to ARVs for least developed countries lacking pharmaceutical production facilities.¹⁴⁴ Under this decision, least developed countries may obtain generic drugs from other countries that have amended their patent legislation to produce generic drugs solely for export to countries most in need of them.¹⁴⁵ Two forms of notification are required by the Waiver Decision and Amendment.¹⁴⁶ First, countries, except those on the least developed countries list, must file a general notification of intent to make use of this system as an importing country.¹⁴⁷ Least developed countries are exempt from this requirement and are thus already eligible to use the system, but they must notify the WTO of their intent to use the Waiver Decision for the importation of specific drugs.¹⁴⁸

The WTO has done a great deal to encourage eligible importing countries, especially least developed countries, to use this system. Systematically and procedurally, the system should maximize and clear channels between least developed countries and exporting countries. Any least developed country without domestic production capabilities may invoke its terms, subject to some notification requirements. The burdens of such notification, procedurally, are minimal, facilitated by World Bank standard forms prepared for this purpose.¹⁴⁹

¹⁴² Doha Declaration ¶ 4.

¹⁴³ CORREA, *supra* note 65.

¹⁴⁴ *Implementation of Paragraph 6*, *supra* note 13.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 2.

¹⁴⁸ *Id.*

¹⁴⁹ Frederick M. Abbott & Rudolph van Puymbroeck, *Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, WORLD BANK WORKING PAPER NO. 61 (2005).

Although the Waiver Decision intended to increase access for least developed countries, these countries, particularly countries lacking domestic pharmaceutical production capacity, have hesitated to invoke its terms. Some countries, such as Ghana, Guinea, and Eritrea have issued compulsory licenses since 2005 but not under the terms of the Waiver Decision.¹⁵⁰ Ghana later expressed an interest to Canada as its supplier for the importation of generic pharmaceuticals, both for itself and for neighboring countries, though they have not followed through with this system.¹⁵¹ In 2007, Rwanda became the first and only country to date to follow through with the implementation of the Waiver Decision.¹⁵²

The reasons for the hesitance on the part of least developed countries to import inexpensive generic ARVs under the terms of the Waiver Decision are not clear, but commentators have speculated that political backlash and fear of economic sanctions have made the channels between least developed countries and eligible exporting countries tenuous.¹⁵³ “[I]n requiring eligible importing countries to deposit a general notification of intent to use, opponents of the system may in fact have imposed a political barrier that limits its usefulness.”¹⁵⁴ Particularly, some commentators have speculated that concern for adverse reaction from trading partners and the fear of appearing hostile to FDI has caused developing countries to delay issuing compulsory licenses or importing generic drugs under the Waiver Decision.¹⁵⁵

Developing countries’ fear of appearing hostile to FDI is a result of the dramatic decrease in FDI from pharmaceuticals in countries, such as Egypt, that have invoked compulsory licenses for medications in non-emergency situations. Of course, not all of Egypt’s decreased FDI can be attributed to Viagra. The Viagra situation was part of a general policy in Egypt of lax intellectual property protection for a wide variety of intellectual property, including copyrighted and trademarked goods that discouraged foreign companies from entering the Egyptian market.¹⁵⁶ But issuing a compulsory license to this product encouraged Pfizer to retract its

¹⁵⁰ LOVE, *supra* note 14.

¹⁵¹ NAT’L BD. OF TRADE, *supra* note 106.

¹⁵² Alexandra G. Watson, Note, *International Intellectual Property Rights: Do TRIPS’ Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries*, 32 B.C. INT’L & COMP. L. REV. 143, 147 (2009); see generally LOVE, *supra* note 14 (providing international background on waiver).

¹⁵³ Abbott & Reichman, *supra* note 70, at 938.

¹⁵⁴ *Id.* at 939.

¹⁵⁵ *Id.* at 956.

¹⁵⁶ Bird & Cahoy, *supra* note 112, at 308.

investment, and undoubtedly played a role in future companies' decisions not to enter the Egyptian market.

Allowing countries to issue compulsory licensing for pharmaceuticals that treat non life-threatening conditions sends a message to *other* countries that compulsory licensing of pharmaceuticals will negatively affect their country's well-being through decreased FDI. "Developing countries have more to 'prove' in regards to the quality of their national intellectual property rights system than high income countries and [are] also more sensitive to losses of investment."¹⁵⁷ Given the "negative climate around compulsory licenses in general,"¹⁵⁸ countries facing extreme poverty, limited FDI, and high infection rates of HIV/AIDS may opt not to invoke their rights under the Waiver Decision to import generic ARVs.

Providing ARVs to least developed countries with severely high rates of HIV/AIDS will likely increase FDI in those countries in the long-term. Least developed countries "attract virtually no FDI . . . due to low productivity, education, skills," and an underdeveloped infrastructure.¹⁵⁹ Countries that have historically struggled to build a sustainable infrastructure for economic growth now face the additional obstacle of a population in which one in five citizens is infected by HIV¹⁶⁰ and life spans are cut by as much as ten to twenty years.¹⁶¹ Scholars note that "[t]o the extent that these countries can marshal effective investments in infrastructure, capital, education, and skills, their per-capita income levels will rise over time."¹⁶² ARVs are the essential first step to building this infrastructure. Countries have not and cannot function under the HIV rates that have taken such a toll on their public welfare. Finding a way to ensure its population is healthy and economically productive will have long-lasting public health and economic benefits. "[A] compulsory license is predicated on the assumption that the beneficial health effects from the limitation will be significant, outweighing the loss of any innovation investment."¹⁶³ Unfortunately, other countries, including Egypt, Thailand, and the United States, are responsible for the "negative climate" surrounding

¹⁵⁷ NAT'L BD. OF TRADE, *supra* note 106, at 12.

¹⁵⁸ *Id.*

¹⁵⁹ Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT'L L. 109, 124 (1998).

¹⁶⁰ UNAIDS, *supra* note 54, at 4.

¹⁶¹ See STEFAN DE VYLDER, SOCIO-ECONOMIC CAUSES AND CONSEQUENCES OF HIV/AIDS 12 (Sida 1998); Pavon, *supra* note 56, at 54.

¹⁶² Maskus, *supra* note 159, at 125.

¹⁶³ Bird & Cahoy, *supra* note 112, at 291.

compulsory licenses in general, causing least developed countries to hesitate before importing generic ARVs. While compulsory licensing is not a comprehensive answer to global health,¹⁶⁴ for countries devastated by HIV, importing generic ARVs is the necessary first step to rebuilding a sustainable future.

Facilitating access to ARVs in least developed countries lacking domestic production capabilities will require more than streamlined administrative procedures through the Waiver Decision. The WTO needs to act to preserve the credibility of TRIPS compulsory licensing terms, so least developed countries do not fear negative political or economic consequences when they invoke its terms to provide their dying citizens with lifesaving medications.

CONCLUSION

The WTO should consider revising the Doha Declaration through clearer guidance and requirements for countries issuing compulsory licenses, with the goal of ensuring that least developed countries facing the most severe health crises benefit most from this declaration.

The flexibility and lack of clarification in the Doha Declaration as to what constitutes a public health crisis and what products may be subject to compulsory licensing have done more harm than good for the countries most in need of inexpensive lifesaving medications. Giving countries the flexibility to determine what constitutes a public health crisis and what pharmaceuticals they should have the rights to produce through compulsory licensing has diminished credibility for this policy, decreased FDI in many countries, and consequently erected barriers between least developed countries and the lifesaving medications they need.

I do not believe a pre-determined list of diseases and products available to treat them should be imposed to limit compulsory licensing. Although a number of diseases currently pose serious threats to public health, particularly HIV/AIDS, we have no way of predicting what diseases will threaten public health in the future, nor do we have the foresight to know what currently available medications or those later developed will be necessary to combat such a crisis. However, I believe the WTO should impose greater checks on decision-making for the terms that may be used for countries to issue compulsory licenses. If the WTO is truly looking to “harmonize

¹⁶⁴ See, e.g., Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AMER. MED. ASSN. 1886, 1891 (2001) (discussing the impacts of poverty on limited access to ARVs).

intellectual property rights” through TRIPS, the discretionary terms of the Doha Declaration are a step away from such harmonization. Discretionary compulsory licensing has favored countries with domestic pharmaceutical production capacity and the economic and political muscle to threaten compulsory licensing to force pharmaceutical companies to drastically lower prices.¹⁶⁵ In the long term, it has not truly benefited many developing countries that have seen a decrease in FDI. The backlash and controversy surrounding compulsory licensing has led least developed countries to tread lightly before invoking its terms to import generic drugs.

An administrative body through the WTO with representatives from both developed and developing countries may be in a better position to determine when countries may issue compulsory licenses. Developing countries deserve a louder voice in WTO decision-making for compulsory licensing, overall. While the terms of the Doha Declaration favored the position taken by developing countries, subsequent usage of those terms has primarily benefited developing countries with pharmaceutical production capabilities such as India and Brazil, and developed countries such as the United States. Giving all member nations an equal voice in guiding WTO policy through decision-making of when compulsory licensing may occur will give least developed nations a louder voice in making decisions that ultimately affect their access to lifesaving medication. Compulsory licensing should not be so negatively perceived that countries in a public health crisis fear political backlash and economic downturn if they invoke its terms. The victims in this economic and political tug of war will be the citizens of least developed countries infected with HIV that do not have access to the most recent and most effective ARVs because their countries have delayed importing generic drugs. While access to ARVs has increased in recent years, the United Nations estimates that 58% of people infected with HIV are still not being treated with ARVs.¹⁶⁶ The best way that countries will secure access to these patented medications will be through imports of generics under the Waiver Decision.

Undoubtedly, TRIPS does not represent the best interests of every member nation in the WTO. The strong influence of American pharmaceutical companies over these negotiations, and the fact that the agreement directly reflects American ideals regarding intellectual property rights reveal that TRIPS may not be wise international policy,

¹⁶⁵ See *supra* notes 91-95 and accompanying text.

¹⁶⁶ JOINT REPORT, *supra* note 54, at 4.

especially with respect to developing countries.¹⁶⁷ However, broad, discretionary compulsory licensing has not and will not reconcile the entire system of strong intellectual property rights with the disparate ideals regarding the balance between private property rights and public welfare.

¹⁶⁷ See Charles T. Collins-Chase, *The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT'L L. 763 (2008) (discussing the negative effects of strong patent rights on developing countries with high rates of HIV/AIDS).