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Are We There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication

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ARE WE THERE YET? TAKING “TRIPS” TO BRAZIL AND EXPANDING ACCESS TO HIV/AIDS MEDICATION

INTRODUCTION

On May 4, 2007, President Luiz Inácio Lula da Silva of Brazil signed a decree to import a generic version of the Merck owned HIV/AIDS drug Efavirenz.¹ This unprecedented decree was issued after failed negotiations with Merck, during which Brazil’s health ministry rejected an offer by the company to lower the drug’s price by thirty percent.² Brazil cited the compulsory licensing provision in the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”), claiming that this provision allows the government to override pharmaceutical patents in cases of national emergency or public interest.³

TRIPS is the international trade agreement that gives pharmaceutical companies patent rights in every member nation of the World Trade Organization (“WTO”).⁴ Patent protection provides the patent owner a temporary monopoly to exclusively produce and sell a certain medication.⁵ Patent rights are important because they allow pharmaceutical companies to recoup and make a profit on the high research and development costs invested in making a drug, thus incentivizing the creation of new medication.⁶ However, due to the owner’s temporary monopoly power, patent rights allow the patent holder to charge prices for the drug that may be prohibitively high for some developing nations.⁷ Acknowledging the

1. *Compulsory License Issued for Merck’s Efavirenz*, 21 World Intell. Prop. Rep. (BNA) No. 6 (June 2007) [hereinafter BNA Report].

2. *Id.*

3. *Id.*

4. See WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO: THE AGREEMENTS 17 (2007), http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm#understanding_chapter (download Chapter 2: The Agreements for pdf version). [hereinafter UNDERSTANDING THE WTO: THE AGREEMENTS].

5. FREDERIC M. SCHERER, THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING 84–85 (1977).

6. *Id.* at 84.

7. See Mark C. Lang, *What a Long, Strange “TRIPS” It’s Been: Compulsory Licensing From the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration*, 3 J. MARSHALL REV. INTELL. PROP. L. 331, 331 (2004) (discussing how one of the main reasons for the high HIV/AIDS infection rate in developing countries is the high prices of pharmaceutical products produced by Western companies). *But see* Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5 NW. J. INT’L HUM. RTS. 1, 1–5 (2006) (arguing that the focus on patent regulation is largely misguided because many factors, such as

prohibitive costs of essential medicines to developing countries due to patents, certain flexibilities and exceptions were written into the TRIPS agreement.⁸

One such flexibility is the compulsory licensing provision.⁹ The compulsory licensing provision allows developing countries to produce or buy generic versions of the patented medication, thus reducing the cost of the medicine.¹⁰ The compulsory licensing provision has been invoked more than a dozen times, including by economically deprived countries with very high rates of HIV infection.¹¹ However, middle-income countries like Brazil have frequently used the threat of the compulsory licensing provision in order to have stronger bargaining power in their negotiations with pharmaceutical companies.¹² Brazil's recent use of the provision to import generic HIV/AIDS medication has created heated controversy as to the meaning and intent of the provision. The pharmaceutical industry argues that as a middle-income country with a relatively low rate of HIV infection, Brazil's use of the provision is not necessary and sets dangerous precedent by encouraging overuse of the provision.¹³

lack of proper healthcare systems and corruption, are responsible for the ongoing health crisis in the developing world). See also Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1116–17 (1996). The market does not provide a solution for optimal drug pricing in the context of developing countries. *Id.* Although pharmaceutical companies generally provide different pricing schemes to different countries (based on what “the market will bear”), this pricing scheme still creates prohibitively high drug prices for many developing countries. *Id.* at 1117. The problem is in defining what is optimal. Pharmaceutical companies want to maximize their wealth and the drug prices reflect this. However, the optimal goal of the law should be to minimize the cost of health care without ruining the pharmaceutical industry's incentives to create more drugs. See ANTHONY OGUS, *COSTS AND CAUTIONARY TALES: ECONOMIC INSIGHTS FOR THE LAW* 30–31 (2006). This price will be different than the price that pharmaceutical companies want to sell at in order to maximize profits. *Id.*

8. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 42. Governments are allowed to reduce the short term costs of intellectual property protection, such as public health problems, through the various exceptions in the TRIPS agreement. *Id.*

9. *Id.*

10. *Id.*

11. Consumer Project on Technology, Examples of Health-Related Compulsory Licensing, <http://www.cptech.org/ip/health/cl/recent-examples.html> (last visited Oct. 26, 2007) [hereinafter Consumer Tech].

12. *Id.* Brazil, in its negotiations with various pharmaceutical companies, has threatened at least three times to issue a compulsory license for generic production of the drug before the parties reached an agreement. *Id.*

13. Press Release, Merck & Co., Inc., Statement on Brazilian Government's Decision to Issue Compulsory License for STOCRIN (May 4, 2007), <http://www.merck.com/>

This Note will discuss Brazil's use of the compulsory licensing provision to import generic HIV/AIDS drugs and analyze whether Brazil's actions are consistent with the meaning and intention of the TRIPS agreement. Part I of this Note will present a brief overview of the TRIPS agreement. Part II will explain the compulsory licensing provision in the TRIPS agreement and discuss how the provision has been used in the context of producing generic HIV/AIDS drugs. Part III will discuss the recent controversy surrounding Brazil and Merck. Finally, Part IV will analyze the validity of Brazil's actions under the compulsory licensing provision and present policy arguments for and against Brazil's use of the provision. This Note argues that Brazil's recent use of compulsory licensing is valid under the TRIPS provision. It will be effective in strengthening Brazil's bargaining power with pharmaceutical companies and ensuring that Brazil continues to be able to provide HIV/AIDS treatment for its citizens.

However, the use of the compulsory licensing provision by other middle-income countries to import or produce generic HIV/AIDS medication demonstrates that the use of the provision should be evaluated on a case by case basis and may not set good policy in every circumstance. Thus, this Note concludes by arguing that the compulsory licensing provision does not provide an adequate remedy to the prohibitively high cost of medicines in developing countries. This Note adopts an additional remedy to the access problem in which the students and faculty of research universities play an important role in creating greater access to essential medicine in developing countries.

I. THE TRIPS AGREEMENT

Intellectual property rights can be defined as "the rights given to people over the creations of their minds."¹⁴ The protection of intellectual property rights has become an increasingly important concern in interna-

newsroom/press_releases/corporate/2007_0504.html [hereinafter Merck Statement]; Press Release, PhRMA, Compulsory Licensing Trend Dangerous (May 14, 2007), http://www.phrma.org/news_room/press_releases/phrma:_compulsory_licensing_trend_dangerous/ [hereinafter PhRMA Press Release].

14. WTO, Frequently Asked Questions about TRIPS, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Sept. 21, 2007). Intellectual property rights are divided into two main categories: (1) copyrights: rights granted to authors of original artistic works; and (2) industrial property: this includes protection of distinctive signs such as trademarks and industrial property such as inventions (protected by patents), industrial designs, and trade secrets. *Id.*

tional trade.¹⁵ The extent of protection afforded to intellectual property varies widely throughout the world and this can provide a source of tension in economic relations between countries.¹⁶ As a response to the ever-growing concern over intellectual property protection, the nations of the WTO negotiated the TRIPS agreement.¹⁷ The TRIPS agreement entered into force on January 1, 1995, and “is to date the most comprehensive multilateral agreement on intellectual property.”¹⁸ The agreement is an attempt by the WTO to standardize the protection of intellectual property rights throughout the world by establishing minimum levels of protection that each WTO member country must provide for the intellectual property of other WTO members.¹⁹ The preamble of TRIPS generally describes the objective of the agreement, which is to reduce the impediments to international trade while promoting the protection of intellectual property.²⁰

15. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 39. *See also* Weissman, *supra* note 7, at 1075–87 (discussing the role of the U.S. pharmaceutical industry in influencing the drafting of the TRIPS agreement and how intellectual property rights was framed as a trade issue).

16. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 39.

17. *Id.* The World Trade Organization (“WTO”) was created in 1995 as a successor to the General Agreement on Tariffs and Trade (“GATT”) established at the end of World War II. WTO, THE WORLD TRADE ORGANIZATION IN BRIEF 3 (2007), http://www.wto.org/english/res_e/download_e/inbr_e.pdf. The WTO’s objective is to help trade flow “smoothly, predictably, and freely.” *Id.* at 1. The WTO has 150 member countries, which accounts for approximately 97% of world trade. *Id.* at 7. The WTO typically makes decisions through a consensus of its members. *Id.* The WTO’s agreements are a result of negotiations between the member countries. *Id.* at 4. The 1986–94 Uruguay Round negotiations resulted in the current set of WTO agreements. *Id.* at 4. One of the agreements that was negotiated during the Uruguay Round was the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). *See* UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 39.

18. World Trade Organization, Overview: The TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Sept. 22, 2007) [hereinafter Overview of the TRIPS Agreement].

19. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 39.

20. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. The preamble of the TRIPS agreement reads: “Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.” *Id.* at 84.

The TRIPS agreement provides protection for inventions such as pharmaceutical patents.²¹ The agreement gives the pharmaceutical patent owner exclusive rights for making, using, offering for sale, selling, and importing the drug in every member nation of the WTO.²² By providing the patent holder exclusive rights to make and sell the drugs they have developed, TRIPS prevents the emergence of competition based on the reduction of production costs.²³ In this way, pharmaceutical companies hold a temporary monopoly power over the drug in all WTO member nations.

One of the main arguments for granting this monopoly power is that it provides an incentive for the future development of medicine.²⁴ By conferring a temporary monopoly over a certain drug, TRIPS allows pharmaceutical companies to recoup the research and development (“R&D”) costs of producing the drug.²⁵ If companies could not recover their R&D costs and make a profit on selling the drug, they would have less of an incentive to invest in producing the drug in the first place.²⁶ Thus universal patent protection provides a mechanism to encourage future R&D on new medicines.²⁷

21. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 41. To qualify for patent protection under the TRIPS agreement, an invention has to be new, it must be an “inventive step”, and it must have “industrial applicability.” TRIPS Agreement, *supra* note 20, art. 27(1). Patent protection over pharmaceutical drugs lasts at least twenty years and must be available for both products and processes. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 41.

22. TRIPS Agreement, *supra* note 20, art. 28.

23. Fredrick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 393, 408 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

24. Henry Grabowski, *Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 457, 462 (Keith E. Maskus & Jerome H. Reichman eds., 2005). “Patents have been found to be critically important to pharmaceutical firms in appropriating the benefits from drug innovation.” *Id.* It takes millions of dollars to develop and get approval for a new medicine. *Id.* Absent market protection, other companies could imitate the drug and free-ride on the innovator’s work. *Id.* Because imitation costs in pharmaceuticals are extremely low relative to the innovators’ costs of developing the new medicine, some form of market exclusivity is required to allow innovators to appropriate enough of the benefits from the drug innovation to cover their large R&D costs and make a profit. *Id.*

25. CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 275 (2007).

26. *Id.*

27. *Id.*

However, the exclusive monopoly power that TRIPS confers to pharmaceutical companies is problematic. Approximately two thirds of the 150 WTO member nations are developing countries.²⁸ As a result, a major issue arising out of pharmaceutical patent protection under the TRIPS agreement is how to ensure that pharmaceutical patents do not prevent sick people in these developing nations from having access to medicines.²⁹

II. THE COMPULSORY LICENSING PROVISION

Acknowledging the difficulties that developing countries may have in conforming to the TRIPS agreement, certain flexibilities and exceptions were written into the agreement.³⁰ One such exception is compulsory licensing.³¹

Compulsory licensing allows another producer to make a patented drug without the consent of the patent owner.³² Compulsory licensing helps ensure that developing countries have access to medicines while protect-

28. WTO, UNDERSTANDING THE WTO—DEVELOPING COUNTRIES 93 (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm [hereinafter UNDERSTANDING THE WTO: DEVELOPING COUNTRIES].

29. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 42.

30. UNDERSTANDING THE WTO: DEVELOPING COUNTRIES, *supra* note 28, at 93. Excluding compulsory licensing, the other three main exceptions to patent rights are: (1) article 27, permits exclusion from patentability where necessary to protect public health and the environment; (2) article 30, which permits member nations to provide limited exceptions to patent exclusivity contingent upon a showing that the interests of the patent owner are not unreasonably infringed upon; and (3) article 40, which allows a government to impose price controls or nondiscriminatory taxes. TRIPS Agreement, *supra* note 20, arts. 27(2), 30, 40(2). *See also* Weissman, *supra* note 7, at 1099. Exceptions to exclusive rights are permitted when needed to “protect public health and nutrition, and to promote the public interest in sectors of vital importance” to economic development; to prevent “abuse of intellectual property rights;” and to prevent unreasonable trade practices that “adversely affect the international transfer of technology.” TRIPS Agreement, *supra* note 20, arts. 8(1), 8(2). Flexibilities in the TRIPS agreement include extra time for lower developed and least developed countries (“LDCs”) to fulfill their commitments. *Id.* arts. 65.2, 66.

31. UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4, at 42.

32. WTO, TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET 4 (2006), http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm [hereinafter TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET]. Article 31 of the TRIPS agreement, entitled “Other Use Without Authorization of the Right Holder” is the compulsory licensing provision of the TRIPS agreement. *Id.* It allows member nations to make “use of the subject matter of a patent without the authorization of the right holder, including use by the government of third parties authorized by the government.” TRIPS Agreement, *supra* note 20, art. 31.

ing the rights of the patent holder.³³ Article 31 of the TRIPS agreement, entitled “Other Use Without Authorization of the Right Holder,” is the compulsory licensing provision of the agreement.³⁴ In the context of public health, the compulsory licensing provision is intended to permit countries to produce or import generic drugs that are more affordable than patented medications.³⁵ Because the provision is an exception to the exclusive rights of the patent holder, the use of the provision is restricted by a number of conditions aimed at protecting the rights of the patent holder.³⁶

The WTO has explicitly stated that each member nation has the freedom to determine the grounds upon which compulsory licenses may be granted.³⁷ Article 31 lists several non-exclusive grounds for granting a compulsory license: national emergency or extreme urgency; public non-commercial use,³⁸ and remedy to anti-competitive practices.³⁹ Although article 31 specifically mentions several grounds for issuing a license, it must be stressed that this list is not exclusive and it does not limit a member’s right to issue compulsory licenses based on other grounds.⁴⁰ However, the grant of a compulsory license on frivolous grounds, such as the individual interest of a competitor, is not a legitimate ground for granting a compulsory license because compulsory licenses are exceptions to patent rights and, as such, may only be used in exceptional circumstances.⁴¹

33. TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET, *supra* note 32, at 4.

34. *Id.*

35. CORREA, *supra* note 25, at 313–14.

36. TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET, *supra* note 32, at 4.

37. WTO, Ministerial Declaration of 14 November 2001, ¶ 5(b) WT/MIN(01)/DEC/2 [hereinafter Doha Declaration].

38. “Public non-commercial use,” otherwise known as “government use,” is an act by the government of a member nation to exploit by itself or through the use of a private contractor a patented invention without consent of the patent owner. CORREA, *supra* note 25, at 316.

39. *See* TRIPS Agreement, *supra* note 20, art. 31.

40. CARLOS M. CORREA, PATENT RIGHTS IN INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 210 (1998).

41. NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 232 (2002). The compulsory licensing provision should be read together with the related provisions of article 27(1) which requires member countries to make patents available for any inventions, including products or processes, and subject to the normal tests of novelty, inventiveness, and industrial applicability. *See* Overview of the TRIPS Agreement, *supra* note 18. Article 27(1) also requires that patents be enjoyed without discrimination as to the place where they were invented and whether the product is produced locally or imported. *Id.*

Although the TRIPS agreement is flexible regarding the grounds for issuing a compulsory license, the agreement subjects such licenses to a detailed list of conditions. Article 31(b) requires a country applying for a license to first attempt to negotiate a voluntary license from the patent holder under reasonable commercial terms and for a reasonable period of time.⁴² However, in situations of national emergencies, other circumstances of extreme urgency, or in cases of public non-commercial use, there is no need to try to negotiate for a voluntary license.⁴³ Additionally, under the compulsory license, adequate remuneration must still be paid to the patent holder taking into account the economic value of the authorization in each case.⁴⁴ The scope and duration of the use of the compulsory license is “limited to the purpose for which it was authorized”⁴⁵ and authorization of such use can be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur.”⁴⁶ Furthermore, article 31(f) states that a compulsory license shall be authorized “predominately for the supply of the domestic market of the Member authorizing such use.”⁴⁷ This condition has the practical effect of preventing export of generic drugs to countries that do not have sufficient pharmaceutical industries to produce the drugs themselves.⁴⁸

In November 2001, the WTO nations held the Doha Ministerial Conference (“Doha Declaration”) in order to clarify the terms and intention of the compulsory licensing provision.⁴⁹ This conference resulted in the Doha Declaration. The Doha Declaration stressed that the TRIPS agreement should be interpreted and implemented in such a manner so as to promote public health.⁵⁰ The Declaration affirmed the government’s right to use the agreement’s flexibilities, such as compulsory licensing, in order to protect public health and also clarified some of the grounds for granting a compulsory license.⁵¹ It stated that each member has the right

42. TRIPS Agreement, *supra* note 20, art. 31(b).

43. *Id.*

44. *Id.* art. 31(h).

45. *Id.* art. 31(c).

46. *Id.* art. 31(g).

47. *Id.* art. 31(f).

48. CORREA, *supra* note 25, at 321.

49. See generally Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 964–66 (2000) (discussing the wide range of interpretations that developing and developed countries attach to the language in article 31).

50. Doha Declaration, *supra* note 37, ¶ 4.

51. See Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1305 (2002) (noting that the ministerial text of the Doha Declaration intended to address

to determine what constitutes a “national emergency” or “other circumstance of extreme urgency” and that public crisis such as HIV/AIDS, tuberculosis, malaria, and other epidemics, can present such circumstances.⁵²

In addition, the Declaration recognized that some WTO members with insufficient manufacturing capacities were having difficulties making use of the compulsory licensing provision and instructed the Council for TRIPS to find an “expeditious solution to this problem.”⁵³ On August 30, 2003, in response to the Doha Declaration, WTO members adopted an amendment that solved the legal problem for exporting countries.⁵⁴ The August 30 Decision waived exporting countries’ obligations under article 31(f).⁵⁵ Under this waiver, any member country may export generic pharmaceuticals made under compulsory licenses to meet the needs of importing countries that lack manufacturing capacity to make the drug.⁵⁶

For many years, compulsory licensing was typically used as a bargaining tool for developing countries in their negotiations with pharmaceutical companies.⁵⁷ However, after the Doha Declaration in 2002, develop-

two issues: the scope of the term “public health” and the ability of nations without adequate manufacturing capacities to seek the benefits of compulsory licensing).

52. Doha Declaration, *supra* note 37, ¶ 5(c). The declaration also clarified what the grounds are for granting a compulsory license by stating that “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 related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” *Id.*

53. *Id.* ¶ 6.

54. TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET, *supra* note 32, at 6.

55. *Id.*

56. *Id.* This waiver is itself subject to several conditions. The importing member must notify the TRIPS Council of the type and quantity of licensed product, and, except in the case of a least developed country, the importing member must establish a lack of manufacturing capacity to produce the drug. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, ¶ 2(c), WT/L/540, <http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc> (Sept. 2, 2003) [hereinafter August 30 Decision]. It is unclear what a member must do in order to establish “lack of manufacturing capacity.” The Annex of the Decision sets out two alternatives: (1) the member has established that it has no manufacturing capacity in the pharmaceutical sector; or (2) the member has some manufacturing capacity in the pharmaceutical sector but it is currently insufficient to meet its needs. *Id.* In addition, in order to prevent the emergence of a black market through re-exportation of the generic drug, the Decision requires that the generic drug must be clearly distinguished through specific labeling, packaging, or product coloring. *Id.* ¶ 2. Finally, the responsibility of “adequate remuneration” to the patent holder is still applicable although it only extends to the exporting member. *Id.* ¶¶ 3–4.

57. Consumer Tech, *supra* note 11.

ing countries began utilizing the provision in order to obtain generic versions of HIV/AIDS medication.⁵⁸ In 2004, Malaysia and Indonesia became the first middle income countries to issue compulsory licenses for the importation of HIV/AIDS medications.⁵⁹ In 2006, amidst much controversy, Thailand issued a compulsory license for importation of the generic version of Efavirenz, an HIV/AIDS medication.⁶⁰ In the beginning of 2007, Thailand announced that it would issue two more compulsory licenses for the HIV/AIDS drug Kaletra and the heart disease drug Plavix.⁶¹ Then, on May 4, 2007, for the first time in Brazil's history, President Luiz Inácio Lula da Silva signed a decree issuing a compulsory license for the Merck owned HIV/AIDS drug Efavirenz.⁶²

III. THE RECENT CONTROVERSY SURROUNDING THE DISPUTE BETWEEN BRAZIL AND MERCK

A. About Brazil's HIV/AIDS Program

In order to better understand the recent controversy surrounding Brazil's actions, it is necessary to consider the factual background of the AIDS epidemic in Brazil. Acquired Immune Deficiency Syndrome ("AIDS") is caused by the Human Immunodeficiency Virus ("HIV").⁶³ First recognized in 1981, AIDS has since become a worldwide pandemic.⁶⁴ HIV kills or damages cells in the body's immune system caus-

58. *Id.* After the Doha Declaration in 2002, Zimbabwe, Mozambique, and Zambia became the first developing nations to issue a compulsory license for the production of Antiretroviral drugs ("ARVs"). *Id.* In 2005, three more low income countries issued a compulsory license for the importations of generic ARVs (Cameroon, Eritrea, and Ghana). *Id.*

59. *Id.*

60. *Id.* On November 29, 2006, Thailand's Ministry of Health, without prior negotiations with Efavirenz's producer Merck, declared that it would issue a compulsory license for the importation of Efavirenz from India and pay Merck a royalty rate of 0.5%. Brook K. Baker, *Price Cut Hand-Cuffs: Thailand Must Stand Up to Merck*, IP-HEALTH, Dec. 3, 2006, <http://lists.essential.org/pipermail/ip-health/2006-December/010273.html>.

61. Consumer Tech, *supra* note 11. On January 25, 2007, Thailand announced that it would issue compulsory licenses for Kaletra and Plavix. *Id.* The royalty rate to the patent holder under both licenses was 0.5%. *Id.* In addition, the Plavix license does not have a specific expiration date and will last until the patent has expired or there is no essential need. *Id.*

62. BNA Report, *supra* note 1.

63. See Nat'l Inst. of Health, HIV Infection and AIDS: An Overview, <http://www.niaid.nih.gov/factsheets/hivinf.htm> (last visited Sept. 29, 2007) [hereinafter NIH Fact Sheet].

64. *Id.* In 2006, there were approximately 39.5 million people living with the HIV virus worldwide and approximately 4.3 million new infections. UNAIDS, AIDS

ing sickness and death from illnesses that normally do not make healthy people sick.⁶⁵ Antiretroviral drugs (“ARVs”) have been developed to disrupt the progress of HIV.⁶⁶ ARVs have been proven to be effective at combating the virus but they are not a cure.⁶⁷ A person taking ARVs must take them for life because if treatment is stopped, the virus will become active again.⁶⁸

But the AIDS epidemic continues to devastate many developing countries.⁶⁹ Approximately 24.7 million people are infected with HIV in Sub-Saharan Africa, compared with 1.4 million people in North America.⁷⁰ So while the new drugs have lowered the rate of HIV infection in developed countries, the high cost of these drugs is not affordable for most people living with HIV/AIDS in developing countries.⁷¹ The local production or importation of generic drugs could lower the price of essential medication, making the drugs affordable for people in developing nations.⁷² A strong international patent system exacerbates the lack of access problem for developing nations by inhibiting developing nations

EPIDEMIC UPDATE 1, UNAIDS/06.29E (2006), available at http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf [hereinafter UNAIDS EPIDEMIC UPDATE].

65. NIH Fact Sheet, *supra* note 63.

66. UNAIDS: Policy and Practice—HIV Treatment, <http://www.unaids.org/en/PolicyAndPractice/HIVTreatment/default.asp> (last visited June 06, 2008).

67. *Id.*

68. *Id.*

69. UNAIDS, REPORT ON THE GLOBAL AIDS EPIDEMIC—EXECUTIVE SUMMARY 6, UNAIDS/06.20E (2006), available at http://data.unaids.org/pub/GlobalReport/2006/2006_GR-ExecutiveSummary_en.pdf. “Africa remains the global epicenter of the AIDS pandemic. South Africa’s AIDS epidemic—one of the worst in the world—shows no evidence of a decline.” *Id.*

70. UNAIDS EPIDEMIC UPDATE, *supra* note 64, at 65 (providing a global map of the number of people infected with HIV in different regions of the world).

71. WORLD HEALTH ORGANIZATION [WHO], PROGRESS REPORT: TOWARDS UNIVERSAL ACCESS—SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR 21 (2007), available at http://data.unaids.org/pub/Report/2007/20070925_oms_progress_report_en.pdf [hereinafter WHO PROGRESS REPORT]. Between 2003 and 2005, the price of first-line ARVs has decreased between 37–53% in low and middle income countries. *Id.* at 6. Between 2005 and 2006, the price has decreased an additional 10–20%. *Id.* However, the average prices paid for second line regimens remain unaffordably high in low and middle income countries where few generic alternatives are available. *Id.* at 21. In 2006, the most commonly used second-line regimen cost \$1698 in low-income countries and \$4735 in middle-income countries. *Id.* at 22–23.

72. 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, 177 (2001) (discussing the proper level of patent protection for pharmaceuticals in developing countries).

from buying the cheaper generic versions of the drug as a result of the patent owner's exclusive rights to make and sell the drug.⁷³

Brazil is home to approximately one third of the total population of people infected with HIV/AIDS living in Latin America.⁷⁴ Started in 1997, Brazil's highly praised anti-AIDS program provides free treatment to approximately 180,000 HIV/AIDS patients and has been credited for keeping the HIV/AIDS epidemic in Latin America under control.⁷⁵ Brazil's provision of antiretroviral therapy is among the most comprehensive in the world and, according to the Joint United Nations Program on HIV/AIDS ("UNAIDS"), it has been yielding positive results.⁷⁶ Brazil's success in providing access to HIV/AIDS medication to its citizens has been attributed to "governmental commitment, the reduced cost of pharmaceuticals made possible by domestic manufacture of generic drugs, and negotiated price discounts for other drugs."⁷⁷

In furthering its campaign to provide affordable HIV/AIDS treatment, Brazil has used the threat of issuing a compulsory license as a means of negotiating lower prices with drug companies.⁷⁸ In 2001, Merck responded to Brazil's recent threat to issue a compulsory license by reducing the price of Stocrin, an HIV/AIDS medication.⁷⁹ In August of the same year, Swiss pharmaceutical company Roche also agreed to lower the price of its AIDS-fighting drug Viracept by forty percent, in response

73. *Id.* at 175–78.

74. UNAIDS EPIDEMIC UPDATE, *supra* note 64, at 48. In 2005, there was a total of 1.7 million people living with HIV in Latin America. *Id.* At the end of 2006, around 180,000 of the 210,000 people in need of ARVs in Brazil were receiving them. WHO PROGRESS REPORT, *supra* note 71, at 64.

75. BNA Report, *supra* note 1.

76. UNAIDS EPIDEMIC UPDATE, *supra* note 64, at 49. Mother-to-child transmission of HIV declined from 16% in 1997 to less than 4% in 2002. *Id.* Between 1996 and 2002, AIDS mortality rates decreased by 50%, and AIDS-related hospitalizations dropped by 80% during the same period. *Id.* UNAIDS has praised Brazil by stating that "Brazil's dual emphasis on prevention and treatment has helped to keep its HIV epidemic under control." *Id.*

77. Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 129 (2003). For example, between 1997 and 2001, the estimated annual cost of HIV therapy in Brazil has fallen from \$7858 per person to \$4137 per person. *Id.* This is at least two times lower than the cost of HIV therapy in the United States, which costs between \$10,000 and \$15,000 per patient per year. *Id.*

78. Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 209–10 (2002).

79. *Id.* at 209. In March 2001, Merck agreed to lower the prices of Indinavir and Efavirenz by 65% and 59%. In return, Brazil cancelled its plan to authorize generic production of the drugs. *See* Consumer Tech, *supra* note 11.

to Brazil's threat to issue a compulsory license.⁸⁰ Similarly, in 2003, Merck agreed to lower the price of ARV Kaletra after Brazil's threat to issue a compulsory license for the drug.⁸¹ This pattern of threats and negotiations clearly demonstrates that Brazil's threats to issue compulsory licenses for HIV/AIDS medications have resulted in lowering the costs of many essential drugs for the government's HIV/AIDS program.

B. The Recent Controversy: Brazil and Merck

Despite Brazil's previous success in negotiating with pharmaceutical companies, the cost of Brazil's HIV/AIDS program has almost doubled in the last several years,⁸² partially due to the increased demand for second-line HIV/AIDS medication.⁸³ At current prices, the annual cost of Merck's Efavirenz for the Brazilian government was \$42 million, at \$1.59 per pill.⁸⁴ Brazil's health ministry claimed that they could import a generic version of the drug from India at a price of \$0.45 per pill.⁸⁵ Since 2006, Brazil's Ministry of Health has attempted to negotiate with Merck for a price reduction.⁸⁶ Brazil stated that it wanted to pay the price for the drug that Merck currently offered to countries in similar income levels as

80. Bass, *supra* note 78, at 209. After unsuccessful negotiations over the price of the ARV Nelfinavir (sold under the brand name Viracept by Roche), Brazil's Health Minister announced that his country will issue a compulsory license for the local production of the generic version of the drug. *See* Consumer Tech, *supra* note 11. Nine days later, Roche and Brazil reached an agreement for a 40% reduction in the price of the drug in exchange for Brazil not issuing the compulsory license. *Id.*

81. *Id.*

82. BNA Report, *supra* note 1. The cost of the program has increased from \$247.5 million to \$445.5 million during the last several years. *Id.*

83. Medecines Sans Frontieres, *The Second-line AIDS Crisis: Condemned to Repeat?*, MSF ARTICLE, Apr. 13, 2007, http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=65D58C38-15C5-F00A25DE21CB571D3E0E&method=full_html [hereinafter MSF Article]. "While the needs for second-line regimens are likely to increase in the coming years, medicines used for second-line therapy are mostly unavailable or unaffordable in developing countries." *Id.*

84. BNA Report, *supra* note 1. According to the World Health Organization ("WHO"), Efavirenz is one the drugs used in the newly-recommended first-line ARV regimen for adults and adolescents. WHO, *SOURCES AND PRICES OF SELECTED MEDICINES AND DIAGNOSTICS FOR PEOPLE LIVING WITH HIV/AIDS* 5, WHO/EDM/PAR/2004.4 (2004), available at http://data.unaids.org/Publications/IRC-pub02/jc645-sources_prices_en.pdf. Currently, 38% of patients take the drug and it is estimated that by the end of 2007, 75,000 of the 200,000 patients currently on antiretroviral treatment in Brazil will be taking Efavirenz. Posting, *Brazilian Government Declares Efavirenz to be of Public Interest*, gabriela@abiaids.org.br, to EssentialDrugs.org (Apr. 26, 2007) [hereinafter Essential Drugs].

85. BNA Report, *supra* note 1.

86. Essential Drugs, *supra* note 84.

Brazil.⁸⁷ On April 25, 2007, Brazil took the first step in the compulsory licensing process by declaring Efavirenz in “the public interest.”⁸⁸ After the Health Ministry rejected Merck’s offer of \$1.10 per pill, the Brazilian government took the final step in its compulsory licensing process by issuing a license to import the generic version of the drug from India while paying Merck royalties of 1.5%.⁸⁹ The government claimed that the generic drug would permit an annual savings of \$30 million on their anti-AIDS program.⁹⁰ In justifying this unprecedented action, Brazil’s president stated that he was not willing to sacrifice the health of his country’s citizens for the sake of world trade.⁹¹

IV. ANALYZING BRAZIL’S RESPONSE

A. Brazil’s Actions are Valid Under the Compulsory Licensing Provision

If Merck challenges the legal validity of Brazil’s actions under the compulsory licensing provision, the United States may take the dispute in front of the WTO’s international panel, the Dispute Settlement Body (“DSB”), which is responsible for settling disputes between Member nations.⁹² In determining whether Brazil’s actions are valid under the com-

87. Press Release, Brazil Ministry of Health, Efavirenz: Questions About Compulsory Licensing (Apr. 25, 2007), <http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITE MID74BBB449C36442B9B92D6ACC1D9DFC21ENIE.htm> [hereinafter Brazil Health Web site—Efavirenz]. Brazil stated that the cost of the Merck’s Efavirenz is 136% higher in Brazil than in Thailand and that it would accept the same price offered to Thailand. *Id.*

88. Essential Drugs, *supra* note 83. Brazil’s compulsory licensing provision entails three steps: (1) declare in a decree that the product in question is “in the public interest”; (2) the government is required to negotiate with the company to see if a mutually acceptable price can be reached; (3) the government will issue another decree if the negotiations fail and it decides to issue a compulsory license. Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, to IP-Watch.org (May 4, 2007), available at <http://www.ip-watch.org/weblog/index.php?p=614&res=1280&print=0>.

89. BNA Report, *supra* note 1.

90. *Id.*

91. *Id.* “Between our trade and our health, we are going to take care of our health. It is not possible for someone to get rich from the misfortune of others.” *Id.*

92. WTO, UNDERSTANDING THE WTO—SETTLING DISPUTES 56 (2007), http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm#understanding_chapter (download Chapter 3: Settling Disputes for pdf version). Disputes arise under the TRIPS agreement when one country adopts a trade policy that another WTO Member believes to be violating the agreement. *Id.* at 55. The Dispute Settlement Body (“DSB”), composed of all WTO Members, is responsible for setting up panels to consider the case. *Id.* at 56. The decision of the panel is subject to review by a permanent appellate body. *Id.* Once a case has been decided, the losing “defendant” must conform its policy to the ruling of the panel. *Id.* at 58. If the losing party fails to conform to these rules, a suitable penalty, such as a sanction or tariff, may be imposed. *Id.* The DSB has never heard a case involving a

pulsory licensing provision of the TRIPS agreement, the DSB must first determine if Brazil has satisfied the conditions of the compulsory licensing provision which restrict its use.

The DSB will most likely find that Brazil's use of the compulsory licensing provision is valid for three main reasons. First, Brazil has sought prior negotiation with the patent holder Merck and thus satisfies the condition under article 31(b) requiring "reasonable" negotiation with the patent holder. Second, even if Brazil's negotiations with Merck are not considered reasonable, Brazil actions are valid under either the national emergency or the public non-commercial use exceptions of article 31(b), which waive the reasonable negotiating requirement. Finally, Brazil's use of the provision is valid because Brazil may import the generic Efavirenz from India under the waiver of article 31(f) provided by the August 30 Decision.

(i) Prior Reasonable Negotiation Requirement Under Article 31(b)

The compulsory licensing provision is ambiguous about many of the conditions and grounds for issuing a license, thus leaving the provision open to different interpretations. First, article 31(b) states that unless the license is granted for a national emergency, other circumstance of extreme urgency, or a public non-commercial use, the member must have previously attempted to negotiate with the patent owner under reasonable commercial terms and that such efforts have not been successful within a reasonable period of time.⁹³ However, what is considered "reasonable" under this provision is not defined and has been left to national laws.⁹⁴ For example, a reasonable period of time has been considered anywhere between 90 days and 6 months.⁹⁵ Although the United States may argue that Brazil has not attempted to negotiate for a reasonable period of time, this argument is not likely to be successful because prior to issuing the license, Brazil had negotiated with Merck for two years over the price of Efavirenz.⁹⁶

In arguing that Brazil did not negotiate under "reasonable commercial terms," the United States may point out that Brazil consistently refused Merck's offers which were based on fair terms.⁹⁷ However, Merck's of-

challenge to a country's use of the compulsory licensing provision. Consumer Tech, *supra* note 11.

93. See TRIPS Agreement, *supra* note 20, art. 31(b).

94. CORREA, *supra* note 25, at 320.

95. CARVALHO, *supra* note 41, at 234.

96. See UNDERSTANDING THE WTO: THE AGREEMENTS, *supra* note 4.

97. Gerhardsen, *supra* note 88. On a practical level, Merck has argued that the price of Efavirenz in Brazil is fair. Merck Statement, *supra* note 13. Merck bases its HIV pric-

fers were not fair in this instance because its pricing scheme disregarded extremely relevant factors, such as the extent of the country's population needing treatment and the actual number of patients currently being treated with the drug.⁹⁸ For example, the cost of Efavirenz is 136% higher in Brazil than in Thailand, a country of comparable income level.⁹⁹ In addition, approximately 75,000 people are taking Efavirenz in Brazil, while in Thailand only 17,000 people are taking the drug.¹⁰⁰ During negotiations, Brazil informed Merck that it would accept a price the same price offered to Thailand, namely \$0.65 per tablet.¹⁰¹ However, the lowest price Merck offered to Brazil was \$1.10 per tablet.¹⁰² Thus, Merck's reduced price offers were not consistent with the international pricing scheme for the drug and cannot be considered fair.

In response, the United States may argue that Brazil's repeated use of the compulsory licensing provision as a bargaining tool does not qualify as negotiating under reasonable commercial terms.¹⁰³ It will argue that by threatening to issue a compulsory license during negotiations with pharmaceutical companies, Brazil was not bargaining under reasonable commercial terms. Brazil may respond by arguing that the threat of issuing a compulsory license has provided a tactical advantage in prior negotiations and did not prevent successful agreements with pharmaceutical companies.¹⁰⁴ Thus, Brazil will argue that threatening to issue a compulsory license during negotiations qualifies as negotiating under reasonable commercial terms. It is unclear whether the DSB will consider the threat of using the provision as bargaining under reasonable commercial terms. However, the DSB will find that under the national emergency or the public non-commercial use exception of 31(b), the requirement to bargain under reasonable commercial terms has been waived.

ing policy on the comparable wealth and disease burden of the country. *Id.* Brazil is the world's twelfth largest economy and has a much lower rate of infection than many countries at its income level. *Id.* Thus Brazil has a greater capacity to pay for HIV/AIDS medicines than countries that are poorer or harder hit by the disease. *Id.*

98. Brazil Health Web site—Efavirenz, *supra* note 87.

99. *Id.*

100. *Id.*

101. *Id.*

102. BNA Report, *supra* note 1.

103. See Consumer Tech, *supra* note 11 (citing examples of Brazil's threats to issue a compulsory license that resulted in lower drug prices).

104. Consumer Tech, *supra* note 11. Until the current dispute with Merck, the pharmaceutical companies have reacted positively to Brazil's threats to issue a compulsory license by lowering prices and reaching an agreement with Brazil. *Id.*

(ii) The National Emergency and Public Non-Commercial Use Exceptions Under Article 31(b)

The requirement of reasonable prior negotiations with the patent holder under article 31(b)¹⁰⁵ is waived because Brazil's compulsory license falls under both the national emergency and public non-commercial use exceptions to article 31(b).

Brazil's compulsory license falls under the national emergency exception to article 31(b) and thus Brazil was not required to negotiate with Merck prior to issuing the license. Brazil's compulsory license was issued for an HIV/AIDS medication.¹⁰⁶ The WTO has explicitly stated that HIV/AIDS can qualify as a national emergency.¹⁰⁷ Thus, Brazil's use of the provision falls under the national emergency exception because Efavirenz will be used in the government's HIV/AIDS program.¹⁰⁸

The United States may argue that although the WTO has stated that AIDS "can" constitute a national emergency or other circumstance of extreme urgency, this does not necessarily mean that Brazil's AIDS epidemic actually *does* constitute such circumstances. In fact, the United States will point out that Brazil's rate of infection is much lower than in many countries, thus bolstering its argument that Brazil's AIDS epidemic does not qualify as a national emergency.¹⁰⁹ However, an important reason for Brazil's low rate of infection is the country's ability to obtain affordable medicine, either through negotiations with pharmaceutical companies or through actual use of the compulsory licensing provision.¹¹⁰ In addition, the WTO has avoided a clear declaration of what is considered a national emergency and has explicitly stated that each country must decide for itself the conditions of a national emergency.¹¹¹ This demonstrates that the DSB is unlikely to require that a country be

105. See TRIPS Agreement, *supra* note 20, art. 31(b).

106. See BNA Report, *supra* note 1.

107. See Doha Declaration, *supra* note 37, ¶ 5(c).

108. See BNA Report, *supra* note 1.

109. Ubiraja Regis Quintanilha Marques, Valesak Santos Guimaraes & Caitlin Sternberg, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 471 (2005). As a result of Brazil's extensive anti-AIDS program, only about 600,000 Brazilians are infected with the disease. *Id.* This is less than one percent of the adult population. *Id.*

110. Lazzarini, *supra* note 77, at 129. Brazil's success in providing access to AIDS medication to its citizens has been attributed to "governmental commitment, the reduced cost of pharmaceuticals made possible by domestic manufacture of generic drugs, and negotiated price discounts for other drugs." *Id.*

111. See *supra* note 52 and accompanying text.

“steeped in disease”¹¹² before it can invoke the national emergency exception under article 31(b). Thus, under the national emergency exception, Brazil was not required to engage in reasonable negotiations with Merck prior to issuing the license.

Furthermore, Brazil was not required to negotiate with Merck before issuing the license because Brazil’s compulsory license falls under the public non-commercial use exception to 31(b).¹¹³ Prior to issuing the license, Brazil’s government declared Efavirenz to be in the “public interest” in light of the need to ensure the viability of the government’s HIV/AIDS treatment program.¹¹⁴ Thus, the license was granted for a public non-commercial use because Efavirenz is part of the Brazilian government’s HIV/AIDS program.¹¹⁵ The United States will counter that Brazil’s use of the provision is not a public non-commercial use because the government is importing the generic drug from a private Indian manufacturer.¹¹⁶ However, the non-commercial nature of the use does not prevent the government from hiring a commercial contractor to actually exploit the patents on behalf of the government.¹¹⁷ Thus, Brazil’s actions are valid under the public non-commercial use exception in article 31(b).

(iii) Conditions of Compulsory Licensing Under Article 31(f) and the August 30 Decision

The most contentious aspect of the validity of Brazil’s actions under article 31 is Brazil’s use of the compulsory licensing provision to import generic Efavirenz from India.¹¹⁸ Although the August 30 Decision allows countries to import generic drugs by waiving article 31(f) of the compulsory licensing provision, the August 30 Decision requires that the importing country establish a lack of manufacturing capacity.¹¹⁹ The United States will argue that Brazil cannot establish a lack of manufacturing capacity because the country is itself a major producer of generic drugs.¹²⁰

112. Jennifer Bjornberg, *Brazil’s Recent Threat on Abbott’s Patent: Resolution or Retaliation?*, 27 NW. J. INT’L L. & BUS. 199, 218 (2006).

113. See CORREA, *supra* note 25, at 316 (describing the public non-commercial use exception in article 31).

114. See Essential Drugs, *supra* note 84.

115. See Essential Drugs, *supra* note 84.

116. BNA Report, *supra* note 1.

117. CORREA, *supra* note 25, at 317.

118. See BNA Report, *supra* note 1.

119. See TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET, *supra* note 32, at 6.

120. MARQUES ET. AL., *supra* note 109, at 473. Eight of the sixteen ARVs used in the anti-AIDS cocktails provided by the Brazilian government are manufactured in Brazil. *Id.* Compulsory licenses are not needed for these drugs because Brazil began to manufacture

However, the August 30 Decision does not require a country to demonstrate that it has no manufacturing capacity in the pharmaceutical sector.¹²¹ In fact, a lack of manufacturing capacity may also mean that a country has some manufacturing capacity in the pharmaceutical sector but that it is currently insufficient to meet its needs.¹²² Thus Brazil may argue that it has established a lack of manufacturing capacity to produce generic Efavirenz because its pharmaceutical laboratories are currently unable to produce a safe generic version of the drug. In order to ensure the quality, safety, and effectiveness of the generic drug, Brazil will only use generics produced from laboratories that are pre-qualified by the World Health Organization (“WHO”).¹²³ Currently, all the laboratories producing generic Efavirenz that are WHO pre-qualified are located in India.¹²⁴ Thus, Brazil currently lacks manufacturing capacity to produce generic Efavirenz because its laboratories are not WHO pre-qualified to produce the drug.

(iv) Brazil’s Compulsory License for Efavirenz is Valid Under Article 31

As this dispute demonstrates, there are many undefined and ambiguous terms in the compulsory licensing provision, which leave it open to different interpretations. So far, only a handful of countries have utilized the provision in the context of pharmaceuticals¹²⁵ and the DSB has yet to resolve a dispute resulting from the use of article 31 to import or produce generic HIV/AIDS drugs.¹²⁶ If the United States challenges Brazil’s use

these drugs before Brazil was forced to recognize patents for pharmaceutical drugs under the TRIPS agreement. *Id.*

121. See TRIPS AND PHARMACEUTICAL PATENTS: FACT SHEET, *supra* note 32, at 6.

122. *Id.*

123. Press Release, Brazil Ministry of Health, Treatment of AIDS: Brazil Issues Compulsory License for Efavirenz (May 4, 2007) <http://www.aids.gov.br/data/Pages/LUMISCEBD192AENIE.htm> (click on “More National Programme News,” go to page 3) [hereinafter Brazil Health Web site—Treatment of AIDS]. The WHO’s pre-qualification program lists manufacturers and suppliers whose HIV-related medicines have been found acceptable for procurement by U.N. agencies. WHO, PRE-QUALIFICATION PROGRAMME: ANNUAL REPORT 2 (2007), available at <http://healthtech.who.int/pq/default.htm> (click on Annual Report 2007 under quick-links on the right side).

124. Brazil Health Web site—Treatment of AIDS, *supra* note 123. See also WHO, PRE-QUALIFICATION PROGRAMME: ACCESS TO HIV/AIDS DRUGS AND DIAGNOSTICS OF ACCEPTABLE QUALITY 3–4 (2007), available at <http://healthtech.who.int/pq/> (click on pdf).

125. See *supra* note 58 and accompanying text.

126. WTO, Dispute Settlement: Index of Dispute Issues, http://www.wto.org/english/tra_top_e/dispu_e/dispu_subjects_index_e.htm#trips (last visited Nov. 2, 2007). There have

of the compulsory licensing provision, the DSB will most likely find that Brazil's recent actions are valid under article 31. Ultimately though, how this dispute is resolved in front of the DSB will create important precedent by defining many of the ambiguities in the compulsory licensing provision. The resolution of the DSB will be an important factor in determining if and how this provision will be used in the future.

B. Brazil's Actions Set Good Policy for the Future Use of the Compulsory Licensing Provision

In justifying his country's unprecedented use of the compulsory licensing provision, Brazil's president stated that he was not willing to sacrifice the health of his country's citizens for the sake of world trade.¹²⁷ This statement reflects the concern of many developing nations that strong intellectual property rights over pharmaceuticals prevents impoverished people from having access to life-saving medication. By allowing generic manufacturers to override the patent holder's rights, compulsory licensing provides a flexible and direct means for the rapid development of generics.¹²⁸ The introduction of generics creates competition in the pharmaceutical market and has been proven to reduce the cost of medicine.¹²⁹ The effect of the compulsory licensing provision to lower drug prices is demonstrated in Brazil. By using the compulsory licensing provision to import generic Efavirenz from India, the Brazilian government is saving \$30 million annually on their anti-AIDS program.¹³⁰ Thus, by lowering drug prices, compulsory licenses allow countries to provide greater access to medicines for their citizens.

However, the pharmaceutical industry's response to Brazil's issuance of a compulsory license has been extremely negative. Merck has stated that it is "profoundly disappointed" by the decision of the Brazilian government to issue a compulsory license for Efavirenz¹³¹ and considers the

only been two complaints filed with the DSB relating to pharmaceuticals. *Id.* Neither of these complaints involve the use of compulsory licenses. *Id.*

127. BNA Report, *supra* note 1. "Between our trade and our health, we are going to take care of our health. It is not possible for someone to get rich from the misfortune of others." *Id.*

128. Weissman, *supra* note 7, at 1116–20.

129. *Id.* "The empirical evidence in support of the price-reducing effects of the introduction of generics is overwhelming." *Id.* at 117. Empirical studies reveal that patents are a major factor in sustaining high drug prices and the introduction of generics lowers drug prices to the production costs. *Id.*

130. BNA Report, *supra* note 1.

131. Merck Statement, *supra* note 13. The company says that it had attempted to negotiate in good faith with Brazil and remains flexible and committed to reaching a mutually acceptable agreement with the Brazilian government. *Id.*

recent actions of Brazil to be a “major step backward.”¹³² Merck maintains that Brazil’s use of the compulsory licensing provision does not set good policy for two reasons. First, Merck argues that Brazil’s use of the provision sets bad precedent because it will encourage overuse of the provision, which will have a “chilling effect” on the R&D incentives of pharmaceutical companies. Second, Merck argues that Brazil’s use of the provision will discourage foreign investment and that it may deter pharmaceutical companies from introducing new life-saving drugs in Brazil.

Merck’s first argument is that by overriding the exclusive rights of the patent holder to produce and sell the drug, Brazil “sends a chilling signal” to pharmaceutical companies who develop life-saving drugs for diseases that afflict the developing world.¹³³ Research and development is a costly and risky process.¹³⁴ Pharmaceutical companies rely on patent protection in order to recoup a premium for the high research and development costs in creating a new drug.¹³⁵ By breaking patents where it is not absolutely necessary, developing countries may be discouraging pharmaceutical companies from creating new life-saving medications.

This argument is particularly relevant in the case of Brazil. Brazil is classified as an “upper-middle income country” and is the twelfth largest economy in the world.¹³⁶ In addition, Brazil has a very successful HIV/AIDS program and has been able to control the spread of the HIV/AIDS epidemic within its borders.¹³⁷ In this way, Brazil appears to

132. *Brazil Issues Compulsory License for AIDS Drug*, BRIDGES WEEKLY TRADE NEWS DIGEST, May 9, 2007, <http://www.ictsd.org/weekly/07-05-09/story4.htm>.

133. Merck Statement, *supra* note 13.

134. PhRMA Press Release, *supra* note 13. Last year alone, the U.S. pharmaceutical industry invested \$55 billion on research and development [“R&D”] of new medications. *Id.* Currently, there are seventy-seven medicines and vaccines being developed for HIV/AIDS. *Id.* See also Bruce Lehman & Michael Einhorn, *Intellectual Property and Compulsory Licensing: Pharmaceuticals and the Developing World* (on file with author). “The research process for new drugs is daunting.” *Id.* at 4. The development of new drugs averages 15 years. *Id.* There is a high risk of failure and “most efforts at innovation fail.” *Id.* at 5. The average new drug costs up to \$800 million to develop, while the generic version costs under two million. *Id.*

135. PhRMA press release, *supra* note 13. See also Lehman & Einhorn, *supra* note 134. Several studies have confirmed the correlation between patent protection and R&D. *Id.* at 5. In fact, one study concluded that 60 percent of drug inventions in a representative time period would not have been developed without patent protection. *Id.*

136. Central Intelligence Agency, *The World Factbook*, Rank Order—GDP, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html> (last visited May 30, 2008).

137. Central Intelligence Agency, *The World Factbook*, Rank Order—HIV/AIDS Adult Prevalence Rate, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2155rank.html> (last visited Nov. 10, 2007). The rate of adult HIV/AIDS infec-

be in a much less desperate situation than many countries who suffer not only from high rates of HIV/AIDS infection, but also from floundering economies and infrastructure. Because Brazil is a relatively wealthy nation and has been successful in controlling the HIV/AIDS epidemic, it may be argued that Brazil's use of the compulsory licensing provision is not appropriate because it is not necessary. The use of the compulsory licensing provision where it is not absolutely necessary may lead countries down a slippery slope to overuse the provision, thereby discouraging R&D by pharmaceutical companies. Thus, Brazil sets a negative example for how the compulsory licensing provision should be used by encouraging overuse of the provision and thereby disincentivising the R&D of new life-saving medications.

However, although strong patent protection may impede R&D by pharmaceutical companies, this claim has been exaggerated, especially in the context of developing countries. Pharmaceutical companies, driven by profits, invest most of their money in researching drugs for diseases that afflict developed nations.¹³⁸ For example, twenty-one percent of the global disease burden¹³⁹ comes from malaria, pneumonia, diarrhea, and tuberculosis.¹⁴⁰ However, these diseases received less than one percent of all public and private investment in health research.¹⁴¹ A recent report from the British Government's Commission on Intellectual Property

tion in Brazil in 2003 was 0.70%, compared with the rate in the United States of 0.60%.
Id.

138. Joseph Stiglitz, *Dying in the Name of Monopoly*, BUSINESS DAY, Mar. 9, 2007, available at <http://www.businessday.co.za/articles/topstories.aspx?ID=BD4A407148>. See also GLOBAL FORUM FOR HEALTH RESEARCH THE 10/90 REPORT ON HEALTH RESEARCH 2003–2004, at 122–23 (2004), http://www.globalforumhealth.org/Site/002_What%20we%20do/005_Publications/001_10%2090%20reports.php (click on chapter 5) [hereinafter THE 10/90 REPORT]. Data on the site shows that the most dangerous and widespread diseases receive the least percentage of total investment in health research. *Id.* The global disease burden combines death, morbidity, and disability in one figure to create an effective measuring tool for measuring conditions that are not on the priority list. Global Forum for Health Research, The 10/90 Gap: Themes—Burden of Disease, available at http://www.globalforumhealth.org/Site/003_The%2010%2090%20gap/003_Themes/01_Burden%20of%20disease.php [hereinafter Themes—Burden of Disease].

139. The global disease burden combines death, morbidity, and disability in one figure to create an effective measuring tool for measuring conditions that are not on the priority list. Global Forum for Health Research, The 10/90 Gap: Themes—Burden of Disease, available at http://www.globalforumhealth.org/Site/003_The%2010%2090%20gap/003_Themes/01_Burden%20of%20disease.php [hereinafter Themes—Burden of Disease].

140. THE 10/90 REPORT, *supra* note 138, at 122. These diseases have an overwhelming or exclusive incidence in poor countries. *Id.* at 123.

141. *Id.* at 122.

Rights found that “the IP system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market in the developed world.”¹⁴² This demonstrates that the patent protection provided in developing countries does not heavily contribute to the incentives of pharmaceutical companies for research and development because pharmaceutical companies are investing in drugs primarily for the benefit of developed countries.

Moreover, Brazil’s use of the compulsory licensing provision was appropriate because it is necessary for Brazil to use the compulsory licensing provision in order to maintain its successful HIV/AIDS program. The cost of Brazil’s HIV/AIDS program is rising, partially due to the high costs of second-line HIV/AIDS medication.¹⁴³ In addition, an important part of Brazil’s success in its HIV/AIDS program is due to Brazil’s ability to bargain for lower prices with pharmaceutical companies by threatening to issue a compulsory license.¹⁴⁴ By utilizing the compulsory licensing provision after repeated threats to do so, Brazil sends a clear message to pharmaceutical companies that it is serious about the health of its citizens.

Secondly, Merck argues that Brazil’s actions will have a negative impact on “Brazil’s reputation as an industrialized country” seeking to attract foreign investment.¹⁴⁵ This is because pharmaceutical companies may cease investing and introducing new drugs in countries where the compulsory licensing provision has been invoked and where the government of these countries does not provide sufficient protection of intellectual property rights. This argument is especially relevant in light of the recent dispute between Abbott Laboratories and Thailand. During the past year, Thailand issued compulsory licenses for the anti-retroviral drugs Efavirenz and Kaletra and for the heart disease medication Plavix.¹⁴⁶ The Thai government engaged in limited negotiations with pharmaceutical companies prior to issuing the licenses, claiming that prior negotiation with pharmaceutical companies is not an effective

142. COMMISSION ON INTELLECTUAL PROPERTY, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENTAL POLICY, EXECUTIVE SUMMARY 13 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPR_Exec_Sumfinal.pdf.

143. *See supra* notes 82–84 and accompanying text.

144. *See supra* notes 78–81 and accompanying text.

145. Merck Statement, *supra* note 13.

146. MINISTRY OF PUBLIC HEALTH AND NATIONAL HEALTH SECURITY OFFICE THAILAND, FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND Preface (2007), *available at* http://www.bilaterals.org/article.php3?id_article=7349 (link to pdf is in the middle of the page) [hereinafter Thailand White Paper].

means of getting a price reduction.¹⁴⁷ As a result of Thailand's decision to use the compulsory licensing provision, Abbott announced that it will not introduce new medicines into the country.¹⁴⁸ Abbott's reaction shocked the international community because Thailand's citizens will be deprived of several new essential drugs as a result of Abbott's withdrawal from the Thai market.¹⁴⁹

Although Abbott's reaction may not be justified, it is a potential hazard for a country that plans to use the compulsory licensing provision. However, Brazil's use of the compulsory licensing provision remains good policy because it is readily distinguished from the situation in Thailand. Unlike Thailand's use of the compulsory licensing provision, Brazil only used the provision one time, it engaged in long negotiations with Merck prior to issuing the license, and it used the provision to import generic HIV/AIDS drugs.¹⁵⁰

First, unlike Thailand, which issued three licenses within a three month period, Brazil has used the compulsory licensing provision only once in its entire history.¹⁵¹ Although Brazil has made repeated threats to use the provision in its negotiations with pharmaceutical companies, this is different than actual use of the provision because there remains a possibility of negotiating an agreement between the parties. This is demonstrated by the successful negotiations of the Brazilian government, which has been able to use the threat of compulsory licensing in order to negotiate for lower drug prices without resorting to actual use of the provision.¹⁵²

Second, Brazil's situation is different from Thailand because Brazil attempted to negotiate with Merck for two years prior to issuing the li-

147. *Id.* at 6.

148. On March 16, 2007, Abbott Laboratories announced that it would no longer introduce new medicines in Thailand. *Abbott Says it Will Not Introduce New Drugs in Thailand*, 21 World Intell. Prop. Rep. (BNA) No. 04 (Apr. 2007) [hereinafter BNA Report Thailand]. The company was responding to Thailand's recent decisions to issue compulsory licenses on "essential" medications. *Id.* Abbott's spokeswoman justified her company's actions by explaining that Thailand chose to break numerous patents on medicines, ignoring the patent system and as a result, Abbott elected to not introduce new medicines into the country. *Id.*

149. *Id.* The international non-profit organization Doctors Without Borders has called this decision "appalling" and "a major betrayal to patients." *Id.* Among the drugs that will not be introduced in Thailand as a result of Abbott's withdrawal from the Thai market is the heat-stable version of the vital second-line anti-retroviral Lopinavir. MSF Article, *supra* note 83. This anti-retroviral is needed in HIV/AIDS programs and has several advantages, most importantly the fact that it does not need to be refrigerated. *Id.*

150. *See supra* notes 82-90 and accompanying text.

151. Consumer Tech, *supra* note 11.

152. *Id.*

cense.¹⁵³ Although prior negotiations may not have been necessary under the national emergency or non-commercial use exceptions of the compulsory licensing provision,¹⁵⁴ Brazil's willingness to negotiate an agreement with Merck prior to issuing the license sends a positive signal to pharmaceutical companies by demonstrating that Brazil is serious about patent protection.

Finally, Brazil's case is distinguishable from Thailand because Brazil did not use the provision to import a controversial drug. Thailand's use of the provision to produce Plavix, a heart disease medication,¹⁵⁵ is contentious because it demonstrates that Thailand is willing to invoke the provision for any drug available on the market, even for drugs that are primarily sold to developed countries.¹⁵⁶ Moreover, this is the first time the provision has been used to produce a chronic disease medication and it is unclear if such drugs are an acceptable use of the compulsory licensing provision.¹⁵⁷ By contrast, Brazil used the compulsory licensing provision to produce generic HIV/AIDS drugs.¹⁵⁸ The use of the compulsory licensing provision for HIV/AIDS medication is not controversial because HIV/AIDS is explicitly listed in the provision under the national emergency exception¹⁵⁹ and the provision has been used several times before to produce generic HIV/AIDS drugs.¹⁶⁰

The differences between Brazil and Thailand's use of the compulsory licensing provision are further highlighted by Abbott's reaction to Brazil's compulsory license. In July of 2007, Abbott agreed to provide Brazil a 29.5% reduction on its HIV/AIDS drug Kaletra.¹⁶¹ The disparate reactions of the pharmaceutical industry and the major differences between the countries' use of the compulsory licensing provision demonstrates that, unlike Thailand, Brazil's use of the provision sets a positive example for how the compulsory licensing provision should be used in the future.

153. See *Essential Drugs*, *supra* note 84.

154. See TRIPS Agreement, *supra* note 20, art. 31(b).

155. BNA Report Thailand, *supra* note 148.

156. BNA Report Thailand, *supra* note 148. The pharmaceutical industry is concerned that Thailand's actions indicate that compulsory licensing will become a "routine occurrence in the operation of Thailand's public health system." *Id.*

157. For a discussion of the validity of Thailand's compulsory license for Plavix and its effect on international health and trade, see Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiological Transition*, 48 VA. J. INT'L L. 211 (2007).

158. BNA Report, *supra* note 1.

159. Doha Declaration, *supra* note 37, ¶ 5(c).

160. Consumer Tech, *supra* note 11.

161. *Government Abbott Reach Agreement to Reduce Price of AIDS Drug Kaletra*, 21 World Intell. Prop. Rep. (BNA) No. 08 (Aug. 2007).

Although Brazil's use of the compulsory licensing provision sets good policy, a country seeking to invoke the compulsory licensing provision must exercise caution. The situation in Thailand demonstrates that use of the compulsory licensing provision is risky. This is because pharmaceutical companies may stop introducing drugs into a developing country if they believe that the country is not respectful of patent protection on pharmaceuticals. Thus the future of compulsory licensing remains uncertain and the use of the provision must be evaluated according to the circumstances in each case.

CONCLUSION

In the context of pharmaceuticals, the compulsory licensing provision in the TRIPS agreement has most often been used to provide generic HIV/AIDS drugs for least developed countries.¹⁶² Brazil's recent use of compulsory licensing calls into question the scope and meaning of the provision by asking whether a large middle-income country like Brazil, with a relatively low rate of infection,¹⁶³ should be able to use the provision in order to import generic HIV/AIDS medication. The text of the compulsory licensing provision and the Doha Declaration support the legal validity of Brazil's actions. Likewise, in the context of HIV/AIDS, Brazil's actions create good policy for the future use of the provision by middle-income countries. However, as the recent dispute between Abbott and Thailand demonstrates, use of compulsory licensing is a risky endeavor and may not set good policy in every circumstance.

The goal of the TRIPS agreement is to balance the protection of intellectual property in order to incentivize future R&D while providing various exceptions, such as compulsory licensing, in order to reduce the short term costs of intellectual property protection. Although compulsory licensing provides a mechanism for increasing access to medicines in developing countries, this option is difficult and risky. Furthermore, in the context of pharmaceuticals, the protection of intellectual property raises an ethical dilemma. Questions of intellectual property in this context can be a life or death matter because residents of developing countries are dying of diseases such as AIDS because they cannot afford to buy essential medications.

There have been many proposed solutions that address the access to medicine gap between developed and developing countries.¹⁶⁴ One such

162. See *supra* notes 57–60 and accompanying text.

163. See *supra* notes 136–137 and accompanying text.

164. For example, the economist Joseph Steiglitz proposes a system of financial government prizes to complement the current patent system. Joseph E. Steiglitz, Editorial,

solution addresses the role of research universities, who have a responsibility to ensure that their research reaches the people who need it most.¹⁶⁵ Universities are a major contributor to pharmaceutical patent innovation and they own patent rights to key HIV/AIDS drugs that are on the market.¹⁶⁶ Universities can manage their pharmaceutical patents to ensure that the HIV/AIDS medications that are a product of university research are sold at affordable prices in developing countries.¹⁶⁷ This means that universities can bargain for specific licensing terms in their agreements with pharmaceutical companies that will ensure low-cost access to pharmaceuticals in the developing world.¹⁶⁸ This approach requires that stu-

Scrooge and Intellectual Property Rights, 333 BRIT. MED. J. 1279, 1279–80 (2006), available at <http://www.bmj.com/cgi/reprint/333/7582/1279>. The prizes will encourage research on neglected diseases that mostly afflict developing countries, such as malaria and tuberculosis. *Id.* This medical prize fund would give large rewards for cures or vaccines for diseases like malaria, that affect millions, and smaller rewards for drugs that are minor variations on existing ones. *Id.* The prizes would be funded by governments in developed countries. *Id.*

Another solution to the current international patent system is proposed by Jean Lanjouw, a senior fellow at the Brookings Institute, who argues that setting minimum standards of patent protection in all countries is unfair. Jean O. Lanjouw, *Opening Doors to Research: A New Global Patent Regime for Pharmaceuticals*, 21 BROOKINGS REV. 13–17 (2003). Lanjouw argues that patent rights in developing countries make drugs such as ARVs unaffordable and do not encourage research on diseases that primarily affect developing countries. *Id.* Lanjouw suggests that in order for a system of intellectual property to be fair, it will need to recognize the differences in the development level of countries. *Id.* One solution is to establish a system where patent protection in poor countries differs across diseases depending on the importance of those countries' markets as a potential source of research incentives. *Id.* Thus, patent protection would be minimal in the poorest countries and would increase gradually to cover more diseases, starting with diseases like malaria that are particularly prevalent in developing countries. *Id.*

165. Dave A. Chokshi & Rahul Rajkumar, *Leveraging University Research to Advance Global Health*, 298 J. AM. MED. ASS'N 1934, 1934 (2007).

166. *Id.* In 2002, research universities in the U.S. were estimated to have contributed \$19.6 billion to "the drug development pipeline." *Id.* University hold patents to one third of HIV drugs approved by the U.S. Food and Drug Administration between 1987 and 2007. *Id.*

167. *Id.* at 1935.

168. *Id.* at 1935. One such successful campaign took place at Yale University where a coalition of students and faculty requested that Yale, the patent holder to an important ARV, negotiate with Bristol-Meyers Squibb, the distributor of this ARV. Rahul Rajkumar, *The Role of Universities in Addressing the Access and Research Gaps*, Universities Allied for Essential Medicines National Conference 7–11 (Sept. 28, 2007), available at <http://www.essentialmedicine.org/wordpress/wpcontent/uploads/2007/10/uaemconference2007-day-1-role-of-universities.pdf>. Yale successfully worked with Bristol-Meyers Squibb to ensure that its patents do not prevent inexpensive HIV/AIDS therapy in developing countries. *Id.*

dents organize local, campus-based campaigns in order to pressure universities to include access provisions in their licensing agreements with pharmaceutical companies.¹⁶⁹ Through local activism, the students and faculty of research universities can have a major impact on the high price of medication in developing countries.

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169. *Id.* at 43.

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