NOTE

PHARMACEUTICAL PATENT PROTECTION AND TRIPS: THE COUNTRIES THAT CRIED WOLF AND WHY DEFINING "NATIONAL EMERGENCY" WILL SAVE THEM FROM THEMSELVES

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I. INTRODUCTION

The pharmaceutical industry is one of the most research-intensive industries in the entire global market.[1] Private pharmaceutical companies invest an estimated fifty billion dollars a year into research and development.[2] "Research and development" is a term of art used to describe the creation and testing of new molecular entities as well as modifications to existing molecular entities and the process whereby they become pharmaceutical products.[3] Pharmaceutical companies enter into research and development with the hope of developing new and innovative products.

The high costs associated with product development[4] necessitate the patent protection that governments afford to many pharmaceutical products.[5] Patents are issued for new, useful, and innovative products.[6] A patent provides the patent-holder with an

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1. *See* PHARM. RESEARCH & MFRS. ASS'N, THE FACTS ABOUT PHARMACEUTICAL MARKETING & PROMOTION 2 (2008) [hereinafter PHRMA FACTS], *available at* http://www.phrma.org/sites/default/files/159/marketing_and_promotion_facts_071108_final.pdf.

2. PHARM. RESEARCH & MFRS. ASS'N, WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? 8 (2005) [hereinafter PHRMA COST].

3. *See generally* CONG. BUDGET OFFICE, A CBO STUDY: RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

4. *See* John H. Barton, *TRIPS and the Global Pharmaceutical Market*, 23 HEALTH AFF. 146, 146 (2004).

5. The pharmaceutical industry also spends an estimated 12 billion dollars on marketing initiatives. *See* PHRMA FACTS, *supra* note 1, at 2. This number is often criticized, however, as an incorrect estimate of marketing expenditures. *See Big Pharma Spends More On Advertising Than Research and Development, Study Finds*, SCIENCE DAILY, Jan. 7, 2008, http://www.sciencedaily.com/releases/2008/01/080105140107.htm.

6. K. Balasubramaniam, *Patent Policies and Pharmaceutical Prices*, *in* TRIPS AND PHARMACEUTICAL INDUSTRY 15, 16 (Manish Ashiya ed., 2007).

exclusive right to exploit the patented product for commercial gain for a limited number of years.[7] Patents are issued in the pharmaceutical industry as an incentive to ensure that research and development remains a priority among pharmaceutical companies.[8]

It often costs very little for a pharmaceutical company to manufacture its own product.[9] The high prices associated with pharmaceuticals stem from the need for drug prices to cover the costs of research and development.[10] The rationale behind patent protection is that without an exclusive right to profit from its own innovations, no economically-minded company would spend money on research and development when it could simply wait for a competitor to develop a new product through research and development.[11] In such a situation, the company that did not bear the research and development costs of the product would be able to charge a more competitive price than the other company, which would have to recoup its expenses. This creates a race to the bottom whereby no company engages in significant research and development and the development of innovative pharmaceutical products is stagnated.[12]

For this reason, among others, the United States has long provided patent protection for innovation in the pharmaceutical industry.[13] It was not until late in the twentieth century, however, that a global arrangement for patent protection developed.[14] In 1994, the Agreement on Trade-Related Aspects of Intellectual

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7. *Id.*

8. *See* Ian F. Fergusson, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*, *in* TRIPS AND PHARMACEUTICAL INDUSTRY, *supra* note 6, at 27.

9. For an in-depth analysis of what goes into R&D, see CONG. BUDGET OFFICE, *supra* note 3, at 4.

10. *See id.*

11. *See* Del Jones, *Supreme Court Rules in Support of Patent Protection*, USA TODAY, May 28, 2002, http://www.usatoday.com/money/general/2002/05/29/patents.htm. As stated by Sean Suiter, a professor of patent law at Creighton University School of Law, "[o]ur economy likes competition, but to the extent that true innovators are unable to capitalize, they'll stop innovating." *Id.*

12. *See* E. Richard Gold et al., Debate, *Are Patents Impeding Medical Care and Innovation?*, PLoS MED., 3 (Jan. 2010), http://www.plosmedicine.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.1000208&representation=PDF.

13. *See A Brief History of the Patent Law of the United States*, LADAS & PARRY LLP, http://www.ladas.com/Patents/USPatentHistory.html (last visited Mar. 21, 2011) (explaining that the first federal patent law was the U.S. Patent Act of 1790).

14. DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 17 (2002) (describing how intellectual property became a subject of the 1986 GATT discussions).

Property Rights (TRIPS Agreement) was promulgated pursuant to World Trade Organization (WTO) negotiations.[15] The TRIPS Agreement establishes minimum standards of intellectual property protection and requires WTO member countries to comply with its provisions.[16] Article 27 of the TRIPS Agreement requires member countries to provide patent protection for foreign, as well as domestic, products and processes.[17]

A conflict has emerged in the public health community regarding the TRIPS Agreement provisions on patents. The TRIPS Agreement provides for greater patent protection, yet allows for compulsory licensing in circumstances of extreme urgency or situations characterized as national emergencies.[18] Compulsory licensing occurs when a country grants a license to use and exploit a patent without the prior approval of the patent-holder.[19] Although the TRIPS Agreement was entered into to provide greater protection for intellectual property, some countries have used the "national emergency" loophole to circumvent the TRIPS Agreement by declaring or threatening to declare a "national emergency or a situation of extreme urgency."[20] Faced with this threat, pharmaceutical companies have acquiesced to demands by certain countries that they receive patented pharmaceuticals at significantly discounted prices.[21]

Although the TRIPS Agreement is said to strike a balance between the protection of ideas and the preservation of public welfare,[22] the agreement undermines the purpose of patent protection by failing to limit the provisions of Article 31 to national emergencies only, and by failing to further define "national emergency." The lack of a concrete definition for the phrase "national

15. *Id.* at 7.

16. Hans-Friedrich Beseler, *Foreward* to PETER L. KOLKER, TRIPs AGREEMENT: PATENT PROTECTION 3, 4 (2000).

17. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

18. TRIPS also allows a country to issue a compulsory license if prior negotiations have failed. *See id.*

19. Manish Ashiya, *Introduction* to TRIPS AND PHARMACEUTICAL INDUSTRY, *supra* note 6, at 4.

20. *See* TRIPS Agreement, *supra* note 17, art. 31(b); *infra* Part II.D.

21. *See* Jillian Clare Cohen, *Brazil's Historical Approach to Intellectual Property Law: The Pharmaceutical Sector, in* TRIPS AND PHARMACEUTICAL INDUSTRY, *supra* note 6, at 72.

22. *See* TRIPS Agreement, *supra* note 17, art. 7 ("The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.").

emergency" allows nations to manipulate the system by issuing compulsory pharmaceutical licenses after declaring a "national emergency," despite the availability of alternative products and remedies. Additionally, the TRIPS Agreement fails to define "remuneration," which requires countries issuing compulsory licenses to compensate the patent-holders. Due to the absence of a definition of "remuneration" in the TRIPS Agreement, patent-holders have not been able to recoup costs expended in pursuit of new medications.[23]

This Note provides suggestions for determining what constitutes a "national emergency" under the TRIPS Agreement. The Note argues that a more concrete definition of the term "national emergency" will prevent developing countries from taking advantage of the TRIPS Agreement language, thus striking a more equitable balance between protection of the public welfare and protection of innovation.

In the discussion below, Part A provides further explanation of the role of research and development in the pharmaceutical industry, while Part B outlines the agreements in place prior to the TRIPS Agreement. Part C details the pertinent provisions of the TRIPS Agreement and the subsequent Doha Declaration, and Part D describes the policies of certain countries that have used loopholes in the TRIPS Agreement to circumvent patent protection. Part E provides examples of how other countries have defined "national emergency" and similar phrases. In the analysis section that follows, Part A puts forth a working definition of "national emergency." Part B provides examples of when the section may be appropriately utilized, and Part C addresses whether HIV/AIDS should be considered a "national emergency" under TRIPS. Part D suggests the use of an adjudicative body to monitor compliance with the standard, and Part E describes other methods of providing pharmaceuticals to countries in need, particularly through sections of the TRIPS Agreement not detailed in this Note.

II. Discussion

A. *An Overview of Research and Development in the Pharmaceutical Industry*

Pharmaceutical companies commonly reinvest a significant portion of their sales revenue into research and development.[24]

23. *See infra* Part III.F.

24. PhRMA Cost, *supra* note 2, at 3.

Among high technology industries, the pharmaceutical industry as a whole reinvests the greatest percentage of sales revenue into research and development.[25] Research and development is a term of art used to describe the start to finish process for development of a new drug.[26] The process for development of a tangible pharmaceutical drug is long and arduous, and begins with scientists researching various chemical compounds.[27] Only an estimated five out of every ten thousand chemical compounds will make it to subsequent clinical trials.[28] It takes an average of twelve to fifteen years to discover and develop a new medicine and, on average, the cost of discovery and development is approximately eight hundred million dollars.[29] Thus, research and development is incredibly costly and time-consuming.

Unfortunately, on average, only three out of every ten prescription medications available to the U.S. public generate revenues that meet or exceed average research and development costs.[30] On a cumulative cash flow basis, break-even is presently not reached until eighteen years after patent filing.[31] Additionally, there is a common misconception that the government funds a significant portion of research and development.[32] In 2004, the total operating budget for the National Institute of Health was almost twenty-eight billion dollars while non-government private pharmaceutical companies invested almost fifty billion dollars into research and development alone.[33] Due to this misconception, those not familiar with the pharmaceutical industry have failed to recognize the need for pharmaceutical companies to not only recoup money spent on research and development, but also the need for pharmaceutical companies to have profitable returns.

Due to the competitive nature of the manufacturing of pharmaceutical products, investors must see returns on their investments in order to acquiesce to further capital funding.[34] Additionally, because many pharmaceutical companies are openly traded on the

25. *Id.* at 2.
26. *See generally* CONG. BUDGET OFFICE, *supra* note 3.
27. *Id.* at 19.
28. *Id.* at 15.
29. *Id.* at 10.
30. *Id.* at 15.
31. MATTHEWS, *supra* note 14, at 175 n.4.
32. PHRMA COST, *supra* note 2, at 8.
33. *Id.*
34. *See* CONG. BUDGET OFFICE, *supra* note 3, at 9 ("[A]lternative sources of capital are more expensive because lenders and prospective shareholders require compensation (in the form of higher returns) for the additional risk they bear . . . .").

stock market,[35] a significant portion of their investment income can be generated by excitement caused by innovative products.[36] Furthermore, the pharmaceutical industry is subject to external factors, including pressures placed on it by the government, non-governmental organizations, and outside countries.[37] Thus, because the cost of development is so high and the likelihood that the newly developed medicine will be profitable is low, incentives other than the desire to help others must be great in order to encourage research and development in the pharmaceutical industry.

The pharmaceutical industry is responsible for a significant portion of the medications on the market today.[38] Without innovations from the private pharmaceutical industry, medication and health care would not be at the advanced stage that they are currently.[39] Thus, although the pharmaceutical industry has often been criticized for its big business attitude,[40] it is important to recognize that this attitude spurs new development and innovation. Development and innovation remain critical to the health and well being of the world at large, and absent a complete reformation of government dependability and developmental capabilities, the corporate nature of the pharmaceutical industry is simply a reality with which all nations must come to terms.

In order for a company to invest the amount of money required to produce a new medicine, the company needs to ensure that adequate safeguards will be in place to protect this investment. The most effective way for a company to profit from its efforts is by granting an exclusive right to manufacture and sell its product.[41] When a company maintains these exclusive rights, it ensures that for a period of time no one else will profit from its innovation, guaranteeing that all income generated from the product will go

35. For a list of pharmaceutical companies that are traded on the stock market, see *Companies in the Pharmaceuticals, Biotechnology, & Life Sciences Industry*, BLOOMBERG BUSINESSWEEK, http://investing.businessweek.com/research/sectorandindustry/industries/industrydetail.asp?code=3520 (last visited Mar. 21, 2011).

36. *See* Daniel M. Harrison, *Can Innovation Save the Economy?*, BIG MONEY (Oct. 13, 2009), http://www.thebigmoney.com/articles/judgments/2009/10/13/can-innovation-save-economy.

37. CONG. BUDGET OFFICE, *supra* note 3, at 1.

38. PHRMA COST, *supra* note 2, at 8.

39. *Id.*

40. *See* Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?*, 34 AM. J.L. & MED. 279, 280 ("The primary concern appears to be profit-driven . . . .").

41. *See* KOLKER, *supra* note 16, at 72. *But see generally* Gold et al., *supra* note 12.

towards recouping losses.[42] For these reasons, companies seek patent protection for their innovative products. Patent protection under the TRIPS Agreement is for a period of at least twenty years.[43]

Although patent protection has been available in developed countries for many years, there had been very little patent protection in lesser-developed countries until recently.[44] This turnaround occurred, in part, as a result of pharmaceutical companies pressuring their governments to seek patent protection in lesser-developed nations.[45] Pharmaceutical companies did so because they were losing profits due to drug counterfeiting in other nations.[46] This led to the enactment of the TRIPS Agreement in 1995,[47] which provides a framework for the protection of intellectual property rights in all countries that are members of the WTO.[48]

B. *A History of the Patent Law Prior to the TRIPS Agreement*

A variety of agreements and organizations existed at the same time, yet independently of one another, prior to the formation of the WTO and TRIPS. All of these organizations and agreements played a substantial role in bringing intellectual property rights to the forefront of global discussions. Although the agreements were entered separately from one another, together they formed the basis for intellectual property rights and protection.[49]

1. The General Agreement on Tariffs and Trade

The General Agreement on Tariffs and Trade (GATT) is the precursor to the TRIPS Agreement. In 1947, twenty-three states entered into the GATT, with the purpose of reducing tariffs in order to liberalize trade.[50] Over the next fifty years, the GATT underwent a series of modifications as the signatories held numerous rounds of negotiations, and eventually the GATT was

42. KOLKER, *supra* note 16, at 72.

43. MATTHEWS, *supra* note 14, at 61.

44. Naomi A. Bass, Note, *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, 191 (2002).

45. MATTHEWS, *supra* note 14, at 18.

46. *See id.* at 20.

47. *Id.* at 7.

48. *Id.*

49. *See* KOLKER, *supra* note 16, at 19–20.

50. *See* Douglas A. Irwin, *GATT Turns 60*, WALL ST. J., Apr. 9, 2007, http://online.wsj.com/article/SB117607482355263550.html.

expanded to cover issues beyond trade.[51] In 1986, ministers of the GATT member countries agreed to launch a round of negotiations with a carefully crafted set of issues to be explored and resolved.[52] The agenda extended beyond trade in products to trade in services, as well as intellectual property issues.[53] Negotiations took place over the next nine years, and on April 15, 1994, 123 governments signed a new trade agreement.[54] The agreement, known as the WTO Agreement for its establishment of the WTO, contained various provisions that were negotiated over the course of the Uruguay Round.[55]

Annexed to this agreement is the TRIPS Agreement, thirteen other Multilateral Agreements on Trade in Goods, and a General Agreement on Trade in Services.[56] There is also a provision regarding the settlement of disputes.[57]

2. World Intellectual Property Organization and U.S. Domestic Law

The World Intellectual Property Organization was established in 1967 as a United Nations agency to administer the Paris and Berne Conventions.[58] The Paris Convention for the Protection of Industrial Property of 1883 provided national treatment for foreign works under domestic laws for patents, trademarks, and a variety of other intellectual property.[59] The Berne Convention for the Protection of Literary and Artistic Works of 1886 provided protection for copyrights.[60] At present, there are 163 parties to the Berne Convention and 174 parties to the Paris Convention.[61] The conventions lack strong enforcement provisions, and signatories have been hesitant to carry out their obligations under the conventions.[62]

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51. *See* MATTHEWS, *supra* note 14, at 9–10.
52. *Id.* at 17.
53. *Id.*
54. *Id.* at 7.
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.* at 10.
59. *Id.*
60. *Id.*
61. *See* Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 102 Stat. 2853, 828 U.N.T.S. 221; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].
62. MATTHEWS, *supra* note 14, at 11.

At this time, the positions of the developing countries and the developed countries as relating to intellectual property rights were completely polarized. Traditionally, an argument promulgated by the countries against protection of intellectual property rights was that the acquisition of technology from developed countries would be prohibitively expensive for lesser-developed nations.[63] Additionally, developing countries viewed intellectual property as a public good, while developed countries viewed intellectual property as encompassing the same rights as physical property.[64] These arguments are still pertinent, and reflect the positions of the developing and developed countries advanced today.[65] Although countries met throughout the first half of the 1980s in an attempt to reform the Paris and Berne Conventions, negotiations failed and ultimately stalled. Facing domestic pressure, developed countries sought other means for enforcing their interests in intellectual property protection, like the GATT forum.[66]

In the United States, business entities played a significant role in pressuring the government to develop intellectual property protection.[67] The Trade and Tariff Act of 1974 created the U.S. President's Advisory Committee on Trade Policy and Negotiations (ACTPN).[68] The chief members of this group were high-level executives from industries that maintained heavy intellectual property rights, such as the pharmaceutical industry and the music industry.[69] Although the ACTPN and other groups recognized the success of the unilateral and bilateral measures taken the by the U.S. government, many of the organizations concluded that there were too many countries with inadequate intellectual property protection to take an individualized approach.[70] Accordingly, the ACTPN identified its long-term goal as bringing intellectual property rights within the scope of the GATT.[71] The creation of the ACTPN, along with pressure from the United States, led to the inclusion of intellectual property rights in the 1984 Uruguay

63. *See* Barton, *supra* note 4, at 148–49.

64. *See* Rosielyn Alviar Pulmano, Comment, *In Search of Compliance with TRIPS Against Counterfeiting in the Philippines: When is Enough Enough?*, 12 TRANSNAT'L LAW. 241, 252, 254–55 (1999).

65. *See* Bass, *supra* note 44, at 219.

66. *See* MATTHEWS, *supra* note 14, at 12.

67. *Id.* at 18.

68. *Id.*

69. *Id.*

70. *Id.* at 18–19.

71. *Id.* at 19.

Round GATT negotiation plan, and subsequent adoption of the TRIPS Agreement.[72]

The United States recognized the lack of enforcement provisions in the then-current intellectual property law and, facing domestic pressure, realized that the GATT forum would provide a method for enforcing intellectual property rights through the possibility of economic sanctions.[73] Accordingly, the TRIPS Agreement developed because the intellectual property issues arose in the right place at the right time.

C. *Understanding the TRIPS Agreement and the Doha Declaration*

1. Agreement on Trade-Related Aspects of Intellectual Property Rights

The TRIPS Agreement is particularly significant because, "for the first time in international law there was an obligation to provide minimum standards of intellectual property protection of a real and binding character."[74] Although the TRIPS Agreement deals with all aspects of intellectual property, for the purposes of this Note, the pertinent provisions address patent protection. Article 2.1 requires members to comply with Articles 1–12 and 19 of the Paris Convention.[75] Articles 1–5 of the Paris Convention cover the basic concepts and requirements for patent protection, such as national treatment of foreign patents, the rights of the patentholder, the requirement for filing a patent, and the term of the patent.[76] Article 19 of the Paris Convention recognizes the ability of signatories to enter into additional agreements with one another.[77]

Article 7 of the TRIPS Agreement, describing one of the basic purposes of intellectual property rights, provides the following:

> Protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[78]

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72. *Id.*
73. *Id.* at 15–16.
74. *Id.* at 46.
75. TRIPS Agreement, *supra* note 17, art. 2.
76. Paris Convention, *supra* note 61, arts. 1–5. Articles 6–12 address trademarks. *Id.* arts. 6–12.
77. *Id.* art. 19.
78. TRIPS Agreement, *supra* note 17, art. 7.

Section five of the TRIPS agreement is dedicated to a discussion of patent protection.[79] Article 27.1 sets out the basic requirements for patentability, stating as follows:

> Patents shall be available for any inventions, whether products or processes, in all field of technology, provided that they are new, involve an inventive step and are capable of industrial application . . . patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[80]

Article 27 also provides limits on what may be patented stating that, "[m]embers may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect the *ordre public* or morality, including to protect human . . . health . . . ."[81] Additionally, "[m]embers may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals . . . ."[82] Thus, Article 27 recognizes that certain innovative medical procedures may be excluded from patentability because of their value to the global community in saving lives.[83] Those who argue against patent protection point to this provision to demonstrate that the TRIPS Agreement does not permit patent protection to supersede any life saving devices, such as groundbreaking pharmaceutical products.[84] The counterargument to this statement is that those who drafted the TRIPS Agreement were aware of the value of innovative pharmaceuticals and that new medicines would likely arise that could better protect the public health, yet chose not to exclude these items from patentability under this provision.

Article 31 of the TRIPS Agreement addresses compulsory licensing and states that compulsory licenses may be issued on a case-by-case basis, but only after efforts have been made to obtain authorization from the patent-holder on reasonable commercial terms and conditions.[85] Article 31 states that "this requirement may be waived by a Member in the case of a *national emergency or other cir-*

79. *Id.* arts. 27–34.

80. *Id.* art. 27.

81. *Id.*

82. *Id.*

83. *See id.*

84. *See* Beata Guzik, *Botswana's Success in Balancing the Economics of HIV/AIDS with TRIPS Obligations and Human Rights*, 4 LOY. U. CHI. INT'L L. REV. 255, 262 (2007) ("Ambiguity in this provision led some to argue that HIV/AIDS drugs should not be subject to TRIPS because they are necessary to protect the public health.").

85. *See* Gold et al., *supra* note 12.

cumstances of extreme urgency or in cases of public non-commercial use."[86] The compulsory licenses must be non-exclusive, non-assignable, and predominately for domestic use.[87] Additionally, adequate remuneration must be paid to the patent-holder.[88] It is the failure of the TRIPS Agreement to provide for a definition of "national emergency" that is the subject of this Note.

2. The Doha Declaration

Subsequent to the passing of the TRIPS Agreement, public health advocates began to voice concerns regarding the effect of its provisions on access to medication in less developed countries with high incidents of HIV/AIDS, tuberculosis, malaria, and other infectious diseases.[89] As a result, at the Ministerial Conference in Doha, Qatar in 2001, an agreement expanding upon TRIPS was set forth, in what has become known as the Doha Declaration (Declaration).[90] The Declaration provides the following:

> 1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
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> . . . .
>
> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
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> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[91]

The Declaration continues:

> [W]e recognize that these flexibilities include:

86. TRIPS Agreement, *supra* note 17, art. 31(b) (emphasis added).

87. *Id.*

88. *Id.*

89. *See* Jamie Crook, Comment, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 BERKELEY J. INT'L L. 524, 531–33 (discussing positions and arguments of advocates of greater access to medicines).

90. *See* CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 19 (2002), *available at* http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf.

91. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, ¶¶ 1, 4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2001) [hereinafter Doha Declaration], *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

> a. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> b. 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.[92]

As a result of the Declaration, developing countries have taken advantage of the "national emergency" and compulsory licensing provisions, using the threat of compulsory licensing to strong-arm pharmaceutical companies into providing medications at a substantially reduced cost.[93] The states that have engaged in this behavior have failed to take into consideration the substantial harm that could occur by reduced investment in research and development.[94] These countries have engaged in a "right here right now" approach to the access of pharmaceutical treatments to the detriment of future progress of the fight against global epidemics.

D. *The Countries that Have Manipulated the System by "Crying Wolf"*

1. Brazil

It is estimated that 730,000 people in Brazil are infected with HIV/AIDS.[95] While this number may seem high, it represents only 0.6 percent of Brazil's population.[96] Notably, this percentage is identical to that of the United States, where 0.6 percent of the population is infected with HIV/AIDS.[97] In the United States, however, it is estimated that 1.2 million people are infected with HIV/AIDS.[98]

Brazil has been both lauded and criticized for its HIV/AIDS program.[99] While it is unquestionable that the program set forth by

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92. *Id.* ¶ 5.

93. *See infra* Part II.D.

94. *See infra* Part II.D.

95. *See Brazil – Statistics*, UNICEF, http://www.unicef.org/infobycountry/brazil_statistics.html#55 (last updated Mar. 2, 2010).

96. *See HIV/AIDS Among Adult Population, Ages 15–49, 2007/2008*, POPULATION REFERENCE BUREAU [hereinafter *HIV/AIDS Among Adult Population*], http://www.prb.org/Datafinder/Topic/Bar.aspx?sort=v&order=d&variable=80 (last visited Mar. 21, 2010).

97. *Id.*

98. *See Brazil – Statistics*, *supra* note 95.

99. *See* Jamie Feldman, Note, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT'L BUS. & L. 137, 154–55 (2009); Paul J. Flaer & Mustafa Z. Younis, *The Brazilian Experiment: HIV Drugs for All*, J. HEALTH CARE FIN., Winter 2009, at 90, 94 (2009) (the inter-

the Brazilian government has been effective in fighting the spread of HIV/AIDS within Brazil,[100] it must reform its program if it is to serve as a worldwide model for other countries. The Brazilian government has been successful at receiving low cost antiretroviral drugs from pharmaceutical companies because it has threatened to use the compulsory licensing and "national emergency" provisions of the TRIPS Agreement against the pharmaceutical companies in the event that they do not acquiesce to Brazil's demands for significantly discounted AIDS drugs.[101] Additionally, Brazil has threatened to suspend patents for HIV/AIDS drugs.[102]

In 1999, former Brazilian President Fernando Henrique Cardoso declared that compulsory licenses could be granted in cases of "national emergency" or public interest.[103] "National emergency" was expanded to mean "the imminent public danger, even if just in part of the national territory," and the president declared that matters related to the public health, among other things, were of public interest.[104] Additionally, Brazil implemented legislation to require that within three years of receiving a patent, the subject matter of the patent must be manufactured in Brazil.[105] The legislation also requires that if the subject matter of the patent is not produced in Brazil within this time frame and production is feasible, Brazilian companies can apply for permission to manufacture the patented product in Brazil.[106]

This legislation leaves pharmaceutical companies in a lose-lose situation. Since pharmaceutical companies spend far more money on research and development than on production,[107] refusing to provide the Brazilian government with pharmaceuticals will only lead to further losses for the pharmaceutical company, as they will not receive any revenue. Pharmaceutical companies, however, also

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national community found Brazil as an eager "poster child" in the universal access movement for HIV/AIDS drugs).

100. Ubirajara R.Q. Marques, Valeska S. Guimarães & Caitlin Sternberg, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 471–72 (2005).

101. Cohen, *supra* note 21, at 72.

102. Katia Cortes, *Brazil Deputies Suspend Patents on AIDS Drugs*, BLOOMBERG (June 1, 2005), http://www.bloomberg.com/apps/news?pid=10000086&sid=aqtnA4hCov2I&refer=latin_america.

103. Marques, Guimarães & Sternberg, *supra* note 100, at 473.

104. *Id.*

105. *Id.* at 474.

106. *Id.*

107. *See* PHRMA COST, *supra* note 2, at 2 ("Just as the cost of paper and ink does not determine the cost of a textbook and the cost of surgery has little to do with the price of a scalpel, the cost of a prescription medicine is more than the cost of its ingredients.").

do not wish to perpetuate the use, or the threat of use, of compulsory licensing by developing countries, as might happen if the pharmaceutical companies acquiesce when faced with these demands.

Notably, Brazil's actions correspond to a significant downturn in the amount of money invested into research and development in HIV/AIDS pharmaceuticals. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) notes that there has been a 30 percent decline in the number of antiretroviral drug companies in preclinical and clinical development since 1998, a period that corresponds with the "growing attacks on intellectual property rights linked to AIDS medicines."[108] Additionally, IFPMA noted that 65 percent of pharmaceuticals would not have been introduced, and 60 percent would not have been developed, if patent protection had not been available to the developing pharmaceutical company.[109] Thus, although Brazil's program has been effective in curbing the spread of HIV/AIDS, the continuation or expansion of similar programs could force pharmaceutical companies to change strategies, focusing their research and development initiatives on other health issues—perhaps those that cater to the wealthier countries or diseases that are not considered epidemics.

2. Rwanda and Canada

On July 17, 2007, Rwanda became the first country to inform the WTO of its intent to declare a "national emergency" in order to gain access to pharmaceuticals through compulsory licensing and parallel importing.[110] Rwanda entered into an agreement with Canada whereby Canada gave permission to its largest domestic pharmaceutical company to produce a generic version of a patented antiretroviral drug.[111] Neither Canada nor Rwanda sought permission from the patent-holder.[112]

Under one current interpretation of the TRIPS Agreement, a developing country without the adequate infrastructure to domestically produce pharmaceuticals may issue a compulsory license for a

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108. Daniel Pruzin, *Rewriting TRIPS Could Hurt Research, Pharmaceutical Industry Strongly Warns WTO*, WTO REPORTER, Sept. 20, 2001, http://www.cptech.org/ip/wto/bna0920 2001.html.

109. HARVEY E. BALE, TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development 5 (2000).

110. *See* Christina Cotter, Note, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT'L L. REV. 177, 185–86 (2008).

111. *See id.* at 185.

112. *See id.* at 185–86.

drug and then enter into an agreement with a developed country for generic production of this drug.[113] In this circumstance, the country actually producing the drug is the only country that must pay remuneration to the patent-holder.[114] Canada has taken active steps to amend its patent law to reflect this interpretation.[115] Additionally, Canada seeks to circumvent the TRIPS Agreement and patent laws by manufacturing and distributing generic drugs to developing nations through compulsory licenses issued by the developing nations. Although Canada is a developed nation and can afford to pay a significant portion of the retail value of patented pharmaceuticals, Canada will individually determine the value of the pharmaceutical product so that it may profit and provide a lower-cost product to developing countries.[116] Actions such as these undermine the purpose of the TRIPS Agreement, which is to protect innovation.

E. *Using Treaties and Statutes to Define the Phrase "National Emergency"*

The Doha Declaration declared 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."[117] Although it appears that the ministers of the WTO are determined to allow each member country to determine what constitutes a "national emergency" for itself, the ministers must define in specific terms what constitutes a "national emergency" with regard to the TRIPS Agreement in order to uphold the purpose of the agreement.

1. Interpreting the Phrase "National Emergency" According to Principles of International Law

As stated by the ministers of the WTO in the Doha Declaration, "each provision of the TRIPS Agreement shall be read in light of the object and purpose of the agreement as expressed, in particular in its objectives and principles."[118] Article 31 of the Vienna

113. *See id.* at 185.
114. *See id.*
115. *See id.*
116. *Id.* at 187–88.
117. Doha Declaration, *supra* note 91, ¶ 5.c.
118. *Id.*

Convention on the Law of Treaties (VCLT), supports such a reading, stating that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[119]

In March of 2000, the Dispute Settlement Board of the WTO issued a panel opinion regarding a dispute between Canada and the European Communities, and their respective states, addressing the issuance of compulsory licenses for parallel imports.[120] In its decision, the panel had the opportunity to consider the object and purpose of the TRIPS Agreement. The panel stated that "the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."[121] The panel thus held that the stated object and purpose of the TRIPS Agreement are in Articles 7 and 8 of the TRIPS Agreement.[122] Article 7, entitled Objective, states the following:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[123]

Article 8, entitled Principles, states the following:

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.[124]

It is clear from these provisions that the object and purpose of the TRIPS Agreement is to promote innovation through the granting

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119. Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter Vienna Convention].

120. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

121. *Id.* ¶ 7.26.

122. *See id.*

123. TRIPS Agreement, *supra* note 17, art. 7.

124. *Id.* art. 8.

of intellectual property rights, with due regard to the needs of the public at large and the provisions of the agreement.[125] These provisions, however, are of little aid in interpreting the phrase "national emergency." They state what is already known—that there are situations that will arise when patent protection may need to give way to the more pressing societal issues faced by a given country. The provisions are of little help in determining what those situations look like and when the "national emergency" provision should apply.

Article 32 of the VCLT, regarding Supplementary Means of Interpretation, states as follows:

> Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:
> (a) leaves the meaning ambiguous or obscure; or
> (b) leads to a result which is manifestly absurd or unreasonable.[126]

The phrase "national emergency" should be considered ambiguous or obscure due to the fact that a debate has arisen regarding the validity of issuances of compulsory licenses under the "national emergency" provision.[127] Furthermore, an interpretation of the phrase "national emergency" to include diseases that are long-term and incurable, in particular HIV/AIDS, is manifestly unreasonable because such an interpretation would allow a compulsory license to be issued in perpetuity.

While the serious and horrific nature of HIV/AIDS cannot be denied, an interpretation of the "national emergency" provision to include diseases that are long-term and incurable would derogate patent protection for pharmaceuticals that not only treat HIV/AIDS, but also other diseases, such as cardiovascular disease, which is the second leading cause of death in low-income countries as of 2004.[128] Like HIV/AIDS, cardiovascular disease is long-term and incurable, and greatly impacts low-income countries.[129] Addition-

125. *See id.* arts. 7–8.

126. Vienna Convention, *supra* note 119, art. 32.

127. *See generally* Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941 (2000).

128. *See* WORLD HEALTH ORG., FACT SHEET: THE TOP TEN CAUSES OF DEATH 1 (2008), *available at* http://www.who.int/entity/mediacentre/factsheets/fs310_2008.pdf. Note that the first leading cause of death was lower respiratory infections, while HIV/AIDS constituted the fourth leading cause of death. *Id.*

129. *See id.*

ally, like HIV/AIDS medications issued pursuant to the "national emergency" provision, medications for cardiovascular disease might extend life expectancy but would not cure the disease. Thus, by following the rationale of countries that have employed the "national emergency" provision, compulsory licenses for pharmaceutical products related to the prevention of cardiovascular disease may be issued pursuant to the "national emergency" provision because it is the leading cause of death in low income countries.[130]

Critics would likely argue that the difference between diseases like coronary heart disease and HIV/AIDS lies in the communicable nature of HIV/AIDS, and that, therefore, the number of those likely to die from HIV/AIDS will rapidly increase. While this differentiation is valid, communicability should not dictate whether a disease qualifies as a "national emergency." Use of the provision, as discussed below, should offer a tangible effect. Studies show that in 2003, 2 percent of sub-Saharan Africa received antiretroviral coverage, while in 2007, 30 percent of sub-Saharan Africa received antiretroviral coverage.[131] Nevertheless, between 2001 and 2007, the number of persons infected with HIV/AIDS grew from an estimated 20 million to 22 million.[132] While it is likely true that the antiretroviral medications have slowed the spread of HIV/AIDS, due to the expanding number of persons infected, it cannot be argued that the need for patented antiretroviral medications will end anytime in the near future. A definition of "national emergency" to include diseases that allow for compulsory licensing with no foreseeable end strikes against the object and purpose of TRIPS, which is to provide a *balance* between the protection of innovation and the public health to the extent that they differ.

2. Using Statutes to Define the Phrase "National Emergency"

The use of outside sources to determine the meaning of "national emergency" is appropriate in light of the VCLT because the phrase is ambiguous. As noted, the VCLT provides that supplementary means of interpretation are to be used when a phrase is ambiguous. Supplementary means include, but are not limited to,

130. *See id.* Cardiovascular disease is also the leading cause of death in high-income countries. *Id.*

131. *See Antiretroviral Coverage in Sub-Saharan Africa, 2003–2007*, WORLD HEALTH ORG., http://www.who.int/hiv/data/art_coverage/en/index.html (last visited Mar. 21, 2011).

132. *See* WORLD HEALTH ORG., *Annex: HIV and AIDS Estimates and Data, 2007 and 2001*, *in* 2008 REPORT ON THE GLOBAL HEALTH EPIDEMIC 214 (2008), *available at* http://data.unaids.org/pub/GlobalReport/2008/jc1510_2008_global_report_pp211_234_en.pdf.

treaties *in pari materia*, or a treaty whose subject matter is nearly identical; the preparatory work of a treaty; and the meaning of the term in common usage, unless otherwise indicated.[133] Black's Law Dictionary defines "national emergency" as "a state of national crisis; a situation demanding immediate and extraordinary national or federal action."[134] Canada's Emergencies Act defines both "national emergency" and "public welfare emergency."[135] The Emergencies Act defines "national emergency" as follows:

> For the purposes of this Act, a "national emergency" is an urgent and critical situation of a *temporary* nature that
> (*a*) seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it, or
> (*b*) seriously threatens the ability of the Government of Canada to preserve the sovereignty, security and territorial integrity of Canada
> and that cannot be effectively dealt with under any other law of Canada.[136]

In the 1964 Emergency Powers Act (amending the 1920 Emergency Powers Act), the United Kingdom speaks of a "state of emergency."[137] The act states that a state of emergency may be declared:

> If at any time it appears to [Her Majesty] that any action has been taken or is immediately threatened by any persons or body of persons of such a nature and on so extensive a scale as to be calculated, by interfering with the supply and distribution of food, water, fuel or light, or with the means of locomotion, to deprive the community, or any substantial portion of the community, of the essentials of life . . . .[138]

The United Kingdom has also adopted the Civil Contingencies Act of 2004, which provides a much more expansive definition of "emergency."[139] The act states the following:

> In this Part "emergency" means—
> (a) an event or situation which threatens serious damage to human welfare in a place in the United Kingdom,
> (b) an event or situation which threatens serious damage to the environment of a place in the United Kingdom, or

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133. *See generally* ULF LINDERFALK, ON THE INTERPRETATION OF TREATIES (2007).

134. BLACK'S LAW DICTIONARY 1122 (8th ed. 2004).

135. *See* Emergencies Act, R.S.C. 1985, c. 22 (4th Supp.) §§ 4–5 (Can.).

136. *Id.* §§ 5, 16, 27, 37.

137. *See* Emergency Powers Act, 1964, c. 38, § 1 (U.K.), *repealed by* Civil Contingencies Act, 2004, c. 36, § 32, sch. 3 (U.K.).

138. *Id.*

139. *See* Civil Contingencies Act § 1 (U.K.).

> (c) war, or terrorism, which threatens serious damage to the security of the United Kingdom.
> For the purposes of subsection (1)(a) an event or situation threatens damage to human welfare only if it involves, causes or may cause—
> (a) loss of human life,
> (b) human illness or injury,
> (c) homelessness,
> (d) damage to property,
> (e) disruption of a supply of money, food, water, energy or fuel,
> (f) disruption of a system of communication,
> (g) disruption of facilities for transport, or
> (h) disruption of services relating to health.[140]

III. ANALYSIS

A. *Defining "National Emergency" by Using Three Criteria*

The meaning of "national emergency" in these acts embodies, in a general sense, the concepts of temporality, scope, and impact. For the purposes of the TRIPS Agreement, the phrase "national emergency" should be specifically defined according to these terms, particularly because other mechanisms exist to aid developing countries in their accession to pharmaceuticals outside of the "national emergency" provision.[141]

Defining the phrase "national emergency" will not hinder the ability of developing countries to access pharmaceuticals. Instead, defining the phrase will prevent developing countries from forcing pharmaceutical companies to provide them with patented pharmaceuticals—below the necessary price through threat of compulsory license under the "national emergency" provision—to the detriment of research and development. In this sense, defining the phrase will provide for more equitable treatment between pharmaceutical companies and developing countries. Countries that truly face a "national emergency" will be able to use the provision, while countries that are seeking an easy out will be required to develop sound policy and infrastructure.

1. Temporality

Webster's defines the word "temporal" as "of or relating to time as opposed to eternity."[142] The phrase "national emergency" must place a limit on the duration of its use. In terms of the TRIPS

140. *Id.*
141. *See infra* Part III.E.
142. WEBSTER'S NEW COLLEGIATE DICTIONARY 1191 (1980).

Agreement, a "national emergency" should not be a continual state. Although it may be impossible to place an exact time limit on what may be deemed a "national emergency," it should not be permitted to exist in perpetuity. Canada's Emergencies Act provides that, "[a] declaration of a public welfare emergency expires at the end of ninety days unless the declaration is previously revoked or continued in accordance with this Act."[143] Similarly, the TRIPS Agreement should state that a "national emergency declared pursuant to this agreement shall expire at the end of ninety days unless previously revoked."[144] Additionally, the "national emergency" provision should provide for continuation of the declaration pursuant to the processes established by the agreement.[145]

Imposing a time limit on the "national emergency" provision is beneficial to both the people of the country where the "national emergency" is taking place, as well as the patent-holder. By placing a time limit on the duration of a "national emergency," a country will be required to act quickly to ensure that all necessary steps are taken, to the benefit of the people of that country.

Furthermore, a time limit on the "national emergency" will benefit the patent-holder as well. While previously a country could declare a "national emergency" for the sole purpose of accessing medication at a reduced price and could receive low cost medications in perpetuity, the expiration of the "national emergency" will serve as a barrier to this type of behavior. While it may have been worth the burden of dispute resolution when a country could receive reduced-cost medications for a multitude of years and an alternative manufacturer could manufacture for years, a ninety-day limit, for example, will make the license less attractive to manufacturers. Furthermore, it will likely be more cost effective for a country to engage in negotiations with a pharmaceutical company, rather than reap the benefits of a "national emergency" for ninety days and then be subject to costly dispute resolution.

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143. Emergencies Act, R.S.C. 1985, c. 22 (4th Supp.) § 7(2) (Can.).

144. Ninety days may not be the appropriate time frame. Further study should be undertaken to determine how long it takes a country to gain access to pharmaceutical products once a compulsory license has been issued.

145. As advocated below, the WTO should either expand the role of the Dispute Settlement Body to address these issues that are of an expedient nature, or establish a new body. Although this Note does not set out any particular procedural processes, the agreement should provide for the mechanisms whereby one can extend the declaration of a "national emergency."

2. Scope

A "national emergency" should exist only where the scope of the disaster places the nation in great peril and there is great concern about *imminent* death or harm to a significant portion of the nation. The definition of the phrase should make clear that declarations under the provision are to be issued only when the situation is such that the government cannot remedy the situation at hand through alternative means.

The exception should only be used where there is no less imposing means to achieve the end of the crisis that has created the "national emergency." Similarly, the exception should not be permitted where there are equal alternative measures. As the Canadian Emergencies Act provides, the situation must be one, "that cannot be effectively dealt with under any other law"[146] of that country. Such a situation may occur if there is a natural disaster—a hurricane or earthquake, for example—that has left a significant portion of the population without medicine and aid, or a sudden outbreak of a disease that is fast-spreading, or another unprecedented situation that significantly taxes the resources of the country.

Although a "national emergency" may be declared for other purposes, in terms of Article 31 of the TRIPS Agreement and compulsory licensing of pharmaceuticals, it should be considered sufficient that the lives, health, and safety of the countries' citizens are in danger to satisfy the scope prong. For situations such as the HIV/AIDS epidemic, countries like Swaziland should be able to satisfy this portion of the "national emergency" test, where 26.1 percent of the adult population is infected with HIV/AIDS.[147]

By requiring the scope of "national emergency" to be expansive, the provision ensures that the issuance of a compulsory license is the last resort. As previously stated, negotiation is an alternative that should be embraced by the WTO, as neither party should be able to force the hand of the other. Where a country is capable of negotiating with patent-holders because the circumstance is not one of exigency, it should abide by standards that are equitable.

3. Impact

Because the phrase "national emergency" connotes a need for expediency, the situation must not be one in which there is no

146. *See* Emergencies Act § 3.

147. *See HIV/AIDS Among Adult Population*, *supra* note 96.

immediately foreseeable solution. The issuance of compulsory licenses under the TRIPS Agreement must have an identifiable impact. The provision should only be invoked where the declaration of a "national emergency" under TRIPS will have an effect and serve to facilitate an immediate end to the "national emergency." In all other circumstances, where the issuance of a compulsory license will not have an immediate and identifiable effect, the government should use the other compulsory licensing provisions of Article 31, which require a country to negotiate with the patent-holder for a reasonable period of time.[148]

The requirement that the declaration of a "national emergency" for compulsory licensing purposes have an identifiable impact serves the greater purposes of the TRIPS Agreement, yet allows for consideration of the public health and public safety. Behind the compulsory licensing provisions is the recognition that there will be circumstances where the property rights of patent-holders may need to give way to protect the public. Thus, the impact requirement serves as a balance between the two. If an issuance of a compulsory license will not have an immediate and identifiable impact on the solution, then it should not be employed. A compulsory license should be considered the most extreme measure, as it deprives the patent-holder of all property rights.

B. *A Recent Crisis: Would it Pass Under the TRIPS Agreement?*

On December 9, 2008, Zimbabwe declared a "national emergency" due to an outbreak of cholera.[149] When the "national emergency" was declared, 560 had already died and over 12,000 were sickened.[150] As of February 17, 2009, more than 3600 people had died and more than 76,000 were sickened.[151] Cholera is easily treated through intake of fluids and antibiotics.[152] In such a situation, it would be appropriate for Zimbabwe to issue a compulsory license for the manufacture or import of the antibiotic that treats cholera, if such an antibiotic is patented.

The cholera outbreak would meet the standards for "national emergency" proposed by this Note. This declaration of a "national

148. *See* TRIPS Agreement, *supra* note 17, art. 31.

149. *Zimbabwe Cholera "An Emergency"*, BBC NEWS (Dec. 4, 2008), http://news.bbc.co.uk/2/hi/africa/7764200.stm.

150. *Id.*

151. Nkepile Mabuse, *Zimbabwe Cholera Epidemic Worsening*, CNN.COM (Feb. 17, 2009), http://www.cnn.com/2009/WORLD/africa/02/17/Zimbabwe.cholera.crisis/index.html.

152. *See* Arthur Schoenstadt, *Cure for Cholera*, EMEDTV (Oct. 15, 2006), http://diarrhea.emedtv.com/cholera/cure-for-cholera.html.

emergency" can easily satisfy the temporality requirement, because once antibiotics are obtained and distributed, a timeline for alleviation of the emergency can be readily established. Additionally, as indicated by the number of people that have already died or have been infected, the cholera outbreak is severe in scope. Mere numbers alone can serve to satisfy the scope prong. Lastly, the outbreak is a situation of urgency whereby the issuance of a compulsory license for antibiotics will have an immediate and identifiable effect once procured. The outbreak of cholera will not continue to spread if antibiotics are provided, but the outbreak will continue to spread if they are not. Thus, a declaration of a "national emergency" in this situation has an identifiable end, is of sufficient scope, and will have an identifiable impact.

A compulsory license of ninety days[153] would provide enough time for Zimbabwe to import the medication, if it does not have its own infrastructure. Furthermore, even if Zimbabwe was unable to distribute the medication in ninety days, it most certainly should be able to manufacture or import the amount that it considers to be necessary within that timeframe. If upon the expiration of ninety days, however, Zimbabwe was able to demonstrate a continuing need for the compulsory license pursuant to the procedures discussed below, it would be able to continue its use of the compulsory license to obtain access to pharmaceuticals.

Thus, the temporality, scope, and impact requirements of the proposed "national emergency" provision are not insuperable, but rather provide a barrier only to those countries that wish to undermine the intellectual property regime. Such a standard allows a country to assess whether the situation truly calls for the issuance of an immediate compulsory license. If the country adheres to the criteria, it is likely that settlement regarding remuneration will be achieved more quickly because the notions of fairness and equity can play a significant role. Without such standards, it is more likely that countries will engage in protracted discussions or litigation regarding whether the situation really called for a compulsory license or whether alternatives could have been pursued.

C. *Should HIV/AIDS Be Considered a "National Emergency?"*

Public health officials would likely argue that the HIV/AIDS pandemic that has swept across significant portions of South America and Africa should constitute a "national emergency" for

153. Once again, ninety days is an example used for the purposes of this Note.

compulsory licensing purposes. The actions taken by countries like Brazil, however, would counsel against declaring the HIV/AIDS virus a "national emergency." Declaring a "national emergency" should be the final resort for a nation steeped in a public health crisis, particularly where that country has not established adequate safeguards to protect itself. For example, in 2005, Brazil turned down a forty million dollar financial aid offer from the United States, because it required Brazil to outlaw commercialized prostitution.[154] Although Brazil has taken steps to ensure that its people are aware of the risks of prostitution and advocates safe sex through educational programs, the existence of a commercial sex industry in Brazil runs counter to the notion that it is taking every active step to curb the spread of HIV/AIDS. The highest method of transmission of HIV/AIDS in Brazil is through sexual intercourse.[155]

The "national emergency" provision is not suited for use where the situation involves a long-term and incurable disease. Furthermore, the provision is not well suited for situations where other modes of recourse exist. Those countries that have a significant HIV/AIDS infected population should use the alternative methods provided by the TRIPS Agreement, as detailed below, to obtain medication to stop the spread of the disease, as well as consider methods outside of the TRIPS Agreement, such as education awareness, free HIV/AIDS testing, or mandated male circumcision.[156]

D. *Implementing the Standard Through a WTO Adjudicative Body*

Although the WTO has already established a Dispute Settlement Body,[157] the WTO should either expand the scope of authority of

154. *See* Larry Rohter, *Prostitution Puts U.S. and Brazil at Odds on AIDS Policy*, N.Y. TIMES, July 24, 2005, http://www.nytimes.com/2005/07/24/international/americas/24brazil.html.

155. *See* USAID, HIV/AIDS PROFILE FOR BRAZIL – SEPTEMBER 2010, at 1 (2010), *available at* http://www.usaid.gov/our_work/global_health/aids/Countries/lac/brazil.pdf.

156. For example, companies such as Abbott and Boehringer Ingelheim provided free HIV/AIDS tests and medicines to pregnant women. *See* PHARM. RESEARCH & MFRS. ASS'N, GLOBAL PARTNERSHIPS 2 (2004) [hereinafter PHRMA GLOBAL]; *HIV/AIDS: Partners Funded by USAID*, USAID HEALTH, http://www.usaid.gov/our_work/global_health/aids/Partnerships/index.html (last updated Aug. 25, 2009) (listing global health initiatives). It is also important to note that circumcision reduces the risk of female to male transmission by 60 percent. *See* Jeremy Laurance, *Male Circumcision "Lowers Risk of Infection by 60%"*, INDEPENDENT, Aug. 9, 2006, http://www.independent.co.uk/life-style/health-and-families/health-news/male-circumcision-lowers-risk-of-hiv-infection-by-60-411113.html.

157. *See generally Dispute Settlement Gateway*, WTO, http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (last visited Mar. 21, 2011).

the Dispute Settlement Body or establish a tribunal to decide issues of an urgent nature that arise under the TRIPS Agreement. Such a tribunal should be able to make binding decisions in the event of a conflict regarding issues such as adequate remuneration or decide whether a country was correct in employing the "national emergency" provision.[158] If a state was required to go before an adjudicative body in the event of a disagreement, it would be less likely to use the threat of issuance of a compulsory license to achieve its goals. The state would not be able to strong-arm pharmaceutical companies into providing significantly below cost products or licenses because the tribunal would decide the issue of adequate remuneration.

Furthermore, the tribunal would be able to address whether sufficient evidence exists to extend the "national emergency" provision beyond the temporal requirement or whether sufficient evidence exists to revoke the issuance of the provision. The concept of a tribunal is appealing because it represents a compromise between two conflicting principles—the notion of intellectual property protection and that of protecting the public safety.

E. *Other Methods to Gain Access to Pharmaceuticals*

Under Article 31 of the TRIPS Agreement, a state may allow for the use of the subject matter of a patent without the prior permission of the patent-holder, provided that "prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."[159] Thus, developed and developing countries must first attempt to obtain the license from the patent-holder. If they are unable to do so, then they may issue a compulsory license. Negotiating with the patent-holder should always be the first step, yet the TRIPS Agreement recognizes that where a patent-holder is obstinate or unfair, recourse may be had to the compulsory license.

Additionally, states may issue a compulsory license if the product is to be used for public, non-commercial use[160]—that is, a government may issue a compulsory license if the product is to be used for the public good, and there is no commercial gain involved. For

158. The Dispute Settlement Body is considered an arbitration panel, and thus far, the opinions of the Dispute Settlement Body have been broad in nature. It has not decided relatively minor issues such as remuneration.

159. TRIPS Agreement, *supra* note 17, art. 31.

160. *Id.*

example, Thailand, which has a universal health care system that covers all but 4.5 percent of the general population,[161] used the public, non-commercial use provision of Article 31 to achieve access to pharmaceuticals.[162]

Furthermore, pharmaceutical companies themselves have become involved in significant initiatives to aid global health.[163] These initiatives are not limited to HIV/AIDS, but include a number of other diseases, such as malaria and tuberculosis.[164] The partnerships between pharmaceutical companies and countries in need are important because they allow pharmaceutical companies to determine how much each can donate without sacrificing any research and development initiatives.

The programs have been incredibly successful. For example, the pharmaceutical company Merck donated fifty million dollars to help Botswana improve its national response to HIV/AIDS.[165] Merck also donated antiretroviral medicines for more than 15,000 patients in Botswana's national ARV treatment program.[166] Botswana has the second-highest HIV/AIDS rate, with 23.9 percent of its adult population infected.[167] As stated by Botswana's former Minister of Health Lesego Motsumi, "[t]he Merck/Gates partnership has helped Botswana to fight back and stave off what would have been certain disaster. This unique partnership has served to focus the world's attention away from the question of whether it can be done to how it can be done."[168] Countries in need of pharmaceutical products should actively seek partnerships with pharmaceutical companies, as they benefit both the country and the pharmaceutical company.

F. *Final Gap Fillers: Other Problems in the TRIPS Agreement*

Despite the impact that providing a concrete definition for the "national emergency" provision may have, there are other loop-

161. *See* David Hughes and & Songkramchai Leethongdee, *Universal Coverage in the Land Of Smiles: Lessons from Thailand's 30 Baht Health Reforms*, 26 HEALTH AFF. 999, 1001 (2007).

162. *See* Robert S. Dailey, *Thailand's Compulsory Licensing of Pharmaceuticals Under TRIPS Stirs Controversy*, ORANGE BOOK BLOG (Feb. 22, 2007), http://www.orangebookblog.com/2007/02/thailands_compu.html.

163. *See generally* PHRMA GLOBAL, *supra* note 156.

164. *Id.* Tuberculosis and malaria were the eighth and ninth leading causes of death in lower- and middle-income countries in 2001. *See* Outterson, *supra* note 40, at 290 tbl.2.

165. PHRMA GLOBAL, *supra* note 156, at 2.

166. *Id.*

167. *HIV/AIDS Among Adult Population*, *supra* note 96.

168. PHRMA GLOBAL, *supra* note 156, at 15.

holes in the TRIPS Agreement that must be addressed if TRIPS is to fulfill its designated purpose. The TRIPS Agreement requires that countries issuing compulsory licenses compensate patent-holders.[169] Compensation must be reasonable.[170] This provision of TRIPS works in tandem with the compulsory licensing provisions, regardless of whether compulsory licensing occurs after failed negotiations, or pursuant to the "national emergency" provision. The TRIPS Agreement must contain a formula for determining adequate remuneration.

At present, countries that have used the "national emergency" provision have significantly devalued the price of pharmaceuticals. When determining the price of remuneration, countries have looked to manufacturing costs.[171] It is difficult to adequately determine the actual amount of money that has gone into producing a pharmaceutical, however, partly because a pharmaceutical is developed over the course of ten to fifteen years, and partly because a number of the large pharmaceutical companies have not opened their books to public record.[172] It has been stated, however, that when determining what constitutes adequate remuneration, countries have failed to take into account the extensive nature of research and development and the business model of pharmaceutical companies.[173] For example, Canada pays a remuneration fee at 4 percent of the retail price of a given pharmaceutical, while others have suggested paying as little as 1 percent of the retail price, which are likely equal to or less than the manufacturing costs.[174] A formula for remuneration that takes into account the costs of research and development is necessary.

Furthermore, the TRIPS Agreement leaves open what constitutes a "reasonable period of time" for the purposes of Article 31 negotiations to the discretion of the parties to the dispute.[175] The Dis-

169. TRIPS Agreement, *supra* note 17, art. 31.

170. *See id.*

171. *See* Scott Lucyk, *Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS*, 38 OTTAWA L. REV. 191, 194 (2006–07) ("[T]he system of compulsory licensing established under the Council's Decision is analysed [sic] in terms of the economics of generic drug manufacturing and the possible meaning of the system's requirement to pay patent owners adequate remuneration.").

172. Upon searching for the records of the pharmaceutical companies, I discovered that the books are not open to the public.

173. *See generally* Lucyk, *supra* note 171.

174. Jillian Clare Cohen et al., *TRIPS, the Doha Declaration and Increasing Access to Medicines: Policy Options for Ghana*, *in* TRIPS AND PHARMACEUTICAL INDUSTRY, supra note 6, at 95, 103.

175. TRIPS Agreement, *supra* note 17, art. 31.

pute Resolution Body should take an active role in terms of defining what constitutes a "reasonable period time." The Dispute Resolution Body should mandate a negotiation period, and review the negotiations to discourage hardball tactics.

IV. Conclusion

The purpose of the TRIPS Agreement is to provide protection for intellectual property rights and to encourage innovation. Although it is recognized that threats to the public health and safety may at times become so pressing that the need for access to medications will supersede patent protection, the TRIPS Agreement must be modified to provide more concrete and stronger language. The phrase "national emergency" must be given a definition that includes temporal, scope, and impact requirements.

The pharmaceutical industry has developed in such a way that innovation relies on the high price of pharmaceutical products. Although governments in developed countries contribute heavily to research and development, their contributions do not exceed or even match the investments made by private pharmaceutical companies. Absent a takeover of the pharmaceutical industry by governmental entities, low-cost pharmaceutical products are not feasible.

Furthermore, the interplay among research and development, innovation, market forces, and cost is so significant that it would be dangerous to attempt a restructuring of the pharmaceutical industry. The advocates of decreased patent protection for pharmaceutical products are taking a shortsighted approach, having failed to adequately consider the repercussions of undermining the exclusivity of rights that patent protection affords. In the absence of patent protection for medications that treat diseases that are considered public health disasters, pharmaceutical companies will likely have no choice but to stop pursuing medications for those diseases. As previously stated, the business model of the pharmaceutical industry requires outside investment, and outside investment depends on the profitability of the company. Unfortunately, it is unlikely that the goodwill of mankind will generate enough investment income.

Furthermore, the current state of the pharmaceutical industry works well. Private pharmaceutical companies occupy one sector of research and development, while governmental entities occupy

another.[176] If pharmaceutical companies choose to drop out of the market that seeks to aid public health disasters such as HIV/AIDS, governmental entities and non-profit organizations would be left to shoulder the research and development initiatives. Consequently, the time frame for finding a cure for such diseases would increase exponentially.

The conclusion that must be drawn from this scenario is that pharmaceutical companies and developing countries must work together to provide access to essential medicines. It is not in the interest of developing countries to alienate private pharmaceutical companies, nor is it in the interest of pharmaceutical companies to abandon the search for a cure to various medical crises. A course of action must be developed whereby pharmaceutical companies can provide access to medicines at a price that is suitable to both themselves and the developing countries. The developing countries must realize that they may have to pay more money than they would like to receive the medications, and the pharmaceutical companies must cut their profit margins. A joint initiative is the ideal method for achieving long-term success in the fight against pandemic diseases.

176. There is, of course, some overlap. The system, however, is set up in such a way that the government and the pharmaceutical companies complement each other.