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# PATENTING DILEMMA: DRUGS FOR PROFIT VERSUS DRUGS FOR HEALTH

Christopher K. Eppich\*

## I. INTRODUCTION

The use of anthrax by bioterrorists in attacks against the United States beginning in 2001 has resulted in a high demand for the leading antibiotic ciprofloxacin (Cipro).<sup>1</sup> The production of Cipro is limited to the manufacturing capabilities of the Bayer Corporation, its patent owner, until December 2003.<sup>2</sup> The capacity of this single company cannot meet the increased production demands for Cipro,<sup>3</sup> and thus shortages have resulted.<sup>4</sup> Consequently, one 500 mg tablet of this patented antibiotic may cost as much as \$4.67 to wholesale pharmacies, with even higher costs to patients.<sup>5</sup> In response to this short supply and high cost, United States Health and Human Services Secretary Tommy G. Thompson has threatened to override Bayer's patent rights to Cipro unless the company reduces prices and increases supply.<sup>6</sup>

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1. See James Love, *Talking Points on Cipro Patent Dispute* (Oct. 24, 2001), available at <http://www.cptech.org/ip/health/cl/cipro/talkingpoints.html> (last visited Jan. 15, 2002) [hereinafter Love, *Talking Points*]. Department of Health and Human Services Secretary Tommy Thompson stated, we need medication for 10 million persons at a recommended treatment of 120 tablets, or a total of 1.2 billion tablets. Bayer can produce two million tablets per day requiring 600 days to supply the order. See *id.*

2. See Al Engelberg's Memo to Senator Schumer Regarding Ciproflaxin (Oct. 13, 2001) (letter from Alfred B. Engelberg to Senator Schumer entitled *Increasing Access to Cipro: A Strategy for Rapid Creation of a Government Stockpile*), available at <http://lists.essential.org/pipermail/ip-health/2001-October/002105.html> (last visited Jan. 15, 2002) [hereinafter *Engleberg Letter*].

3. See *id.*

4. See *id.*

5. See Consumer Project on Technology, *Selected Prices for Ciproflaxin* (Oct. 25, 2001) (compilation of prices of Cipro for varying nations), available at [www.cptech.org/ip/health/cl/cipro/ciproprices.html](http://www.cptech.org/ip/health/cl/cipro/ciproprices.html) (last visited Jan. 15, 2002) [hereinafter *Cipro Prices*]. The price of one 500 mg tablet of Cipro available from Bayer ranges from \$1.83 to \$4.67 to the U.S. government and the U.S. wholesale drug industry respectively. See *id.*

6. See Denise Gellene, *Anthrax Cases Reshape Drug Price Debate*, L.A. TIMES, Nov.

This acute situation in the United States has renewed global attention on patent rights that legally create prescription drug monopolies. In and of itself, the invention and production of drugs used to treat disease creates a dilemma. On one hand, the profit opportunities motivate companies to extensively research and develop critical new pharmaceuticals. On the other hand, the public needs access to affordable medication in times of crisis.<sup>7</sup> Although patent protection is a necessary incentive to drive expensive research and development, health emergencies beyond the short-term need for Cipro in the United States, such as the spread of HIV in poor, developing nations,<sup>8</sup> require a reopening of this debate. The controversy rests largely upon the use of compulsory licensing<sup>9</sup> as a means of lowering pharmaceutical prices by removing patent rights and increasing drug availability in poor countries.<sup>10</sup> The World Trade Organization (WTO) met recently to solve the problem of making effective use of compulsory licensing under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, but could not find a solution.<sup>11</sup>

This comment examines the issues created by compulsory licensing and proposes a method to ensure successful use of compulsory licensing in developing countries. Part II offers an overview of the current health crisis<sup>12</sup> and reviews the provisions of the TRIPS Agreement related to compulsory licensing and patent law.<sup>13</sup> Part II also reviews attempts by the United States to regulate pharmaceutical patents abroad and the United States' emerging

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9, 2001, at Business 1. In response to these U.S. threats, Bayer agreed to lower its price of Cipro to the U.S. government to \$0.95 per tablet and to supply the necessary medication for 10 million persons. *See id.*

7. *See id.*

8. *See generally* Amir Attaran & Lee Gillespie, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886 (2001).

9. Compulsory licensing is the practice of issuing licenses to a country or third party of a government granted patent without the prior agreement of the rightful patent owner. Compulsory licenses are generally issued in times of public non-commercial use and in times of national emergency. *See infra* Part II.B.2.

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

11. *See* Declaration on the TRIPS Agreement and Public Health. (Nov. 14, 2001)(declaration from the Doha WTO Ministerial 2001), *available at* [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (last visited Aug. 14, 2002) [hereinafter *Doha*]. The Conference further called for a "solution to th[e] problem" of "making effective use of compulsory licensing" in WTO member countries with "insufficient or no manufacturing capabilities." *Id.* para. 6.

12. *See infra* Part II.A.

13. *See infra* Part II.B.

acceptance of compulsory licensing.<sup>14</sup> Part III reviews the recent Doha WTO Ministerial Conference and identifies the problems facing developing nations in the current inoperable system of international sales of patented pharmaceuticals.<sup>15</sup> Part IV examines the dilemma and discusses three possible methods of assisting developing nations in gaining access to life-saving drugs while paying adequate compensation to drug companies.<sup>16</sup> Part V proposes a solution calling for cooperation between developed nations, pharmaceutical companies, and developing nations to allow swift access to needed drugs worldwide.<sup>17</sup>

## II. BACKGROUND

### A. *An Overview of the Situation*

The United States has long advocated for pharmaceutical patent protection in international trade negotiations.<sup>18</sup> Even when developing nations resort to using compulsory licensing to force companies into cheaper agreements during times of medical crisis, the United States government uses threats of trade sanctions to pressure these nations into backing away from compulsory licensing.<sup>19</sup> However, even the United States itself has experienced the tug-of-war between protecting patent rights and ensuring public health, as exhibited by its threat to break patent protection to increase the supply of antibiotics following imminent danger from anthrax outbreaks in 2001 and 2002.<sup>20</sup>

#### 1. *Developing Economies: The AIDS Threat*

The AIDS epidemic is one of the most challenging public health problems globally.<sup>21</sup> More than forty million people worldwide are

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14. See *infra* Parts II.C-D.

15. See *infra* Part III.

16. See *infra* Parts IV.A-C.

17. See *infra* Part V.

18. See Reginald Dale, *Striking a Balance on Patent Rights*, INT'L HERALD TRIB., Oct. 30, 2001, at Finance 11 ("For years now, Washington has been the strongest defender of the patent rights of multinational companies, as developing countries have increasingly challenged them – most recently to procure cheaper medicines to combat AIDS.").

19. See Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 137 (2002).

20. See Dale, *supra* note 18 ("The United States – and Canada – started acting like developing nations.").

21. Bess-Carolina Dolmo, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137 (2001).

infected with the AIDS virus,<sup>22</sup> with the majority of those infected living in developing nations such as sub-Saharan Africa, South and Southeast Asia, and Latin America.<sup>23</sup> Sub-Saharan Africa is the most heavily impacted region, with 28.1 million people living with HIV and 3.4 million new infections occurring in 2001.<sup>24</sup>

The problem is staggering. In 2001, five million people contracted HIV worldwide, and three million died from AIDS.<sup>25</sup> Sub-Saharan Africa alone accounted for 68% of the five million new infections,<sup>26</sup> and reported an estimated 2.3 million deaths related to AIDS in 2001.<sup>27</sup> Presently, at least 8.4% of adults in sub-Saharan Africa are infected.<sup>28</sup> The morbidity rate continues to cripple developing nations and poses a real threat to the development of each nation's government, economy, and health care system.<sup>29</sup>

Newly patented antiretroviral therapies<sup>30</sup> have been shown to prolong life and reduce opportunistic infections, and may reduce HIV to a chronic infection.<sup>31</sup> Although these drugs present the possibility of lengthening the life span for millions of people,<sup>32</sup> high costs lower the availability in developing nations.<sup>33</sup> Patents on these medications drive up costs, making access difficult for the general public until generics

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22. See JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS (UNAIDS) & WORLD HEALTH ORG. (WHO), AIDS EPIDEMIC UPDATE 5 (2001), available at [http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001\\_en.pdf](http://www.unaids.org/worldaidsday/2001/Epiupdate2001/Epiupdate2001_en.pdf) (last visited Jan. 17, 2002) [hereinafter UNAIDS].

23. See *id.* at 7.

24. See *id.*

25. See *id.* at 5.

26. See *id.* at 7.

27. See *id.* at 20.

28. See UNAIDS, *supra* note 22, at 7.

29. See *id.* at 22.

30. Antiretroviral therapy is treatment concentrated on suppressing a retrovirus such as HIV. Retroviruses contain an enzyme called reverse transcriptase that transcribes the retrovirus' RNA into DNA. This new DNA integrates into the DNA of the host cell, expressing the virus.

31. See WORLD HEALTH ORGANIZATION, ANTIRETROVIRAL TREATMENTS FOR HIV/AIDS (1997), available at <http://www.who.int/inf-fs/en/fact163.htm> (last visited Jan. 17, 2002).

32. See Park, *supra* note 19, at 127-28. These treatments include a combination of the use of three types of drugs: antiretrovirals (ARVs) which act to decrease harm to the immune system and to prevent in vivo transmission, anti-infectives which act to prevent opportunistic infections, and palliative drugs which act to ease pain and suffering. See *id.*

33. Rachel Swarns, *AIDS Obstacles Overwhelm a Small South African Town*, N.Y. TIMES, Mar. 29, 2001, at A1. ARVs costs an average of \$12,000 in the United States. The average income of a person in the sub-Sahara is around \$500. Thus, even if pharmaceutical reduced the costs substantially, medical treatment is unaffordable for many sub-Saharan HIV/AIDS victims. See *id.*

can be manufactured at the expiration of the patent term.<sup>34</sup> Until that time, each poor nation faces the problem of medication in scant supply at high prices.<sup>35</sup>

## 2. *Developed Nations: The Anthrax Threat*

Developed nations encounter similar threats and arguments over patent rights and drug costs during a time when demand for medication is critical.<sup>36</sup> For example, on September 11, 2001, the possibility of bioterrorist attacks and the outbreak of an anthrax epidemic in the United States became a reality.<sup>37</sup> The United States Congress' Office of Technology Assessment projects that just 100 kg of the deadly spores could infect up to three million people with anthrax.<sup>38</sup> The Federation of American Scientists considers a "lethal dose of anthrax to be 10,000 spores," calculating that "80 percent of a population that inhaled such a dose would die."<sup>39</sup> Furthermore, "one millionth of a gram is invariably fatal within five days to a [sic] week after exposure."<sup>40</sup> Such an attack can easily be calculated to bear devastating results on any nation without the availability of an antibiotic.<sup>41</sup> However, with the use of an antibiotic, "the mortality rate [for cutaneous anthrax infection] falls to less than one percent."<sup>42</sup>

The antibiotic of choice for the treatment of anthrax is the Bayer Corporation's Cipro, after it became the only approved oral treatment of inhalation anthrax by the Food and Drug Administration and Centers for Disease Control and Prevention.<sup>43</sup> Following the September 11 terrorist attack and the ensuing anthrax scares, Americans besieged

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34. See Park, *supra* note 19, at 131 ("Unfortunately, the implications of patent protection mean developing countries will experience significantly higher drug prices."). See also *infra* Part II.B.1.

35. See Park, *supra* note 19, at 129.

36. Cf. Gellene, *supra* note 6 ("Now bioterrorism has given new meaning to what might be considered a health emergency.").

37. See Sharman Kobayashi, *Bayer-CIPRO: A Case For Overriding Patent Owner Rights?*, PATENT CAFÉ (Oct. 31, 2001), available at <http://www.patentcafe.com/ipfrontline/05-41.html> (last visited Jan 18, 2002).

38. See The Federation of American Scientists, *Biological Warfare Agents*, available at <http://www.fas.org/nuke/intro/bw/agent.htm#b02> (last visited Jan. 17, 2002).

39. *Id.*

40. *Id.*

41. See *id.*

42. *Id.*

43. See generally Bayer Corporation, *Infection Disease Specialist Dr. Paul Iannini Comments on Important Considerations for Taking Antibiotics for the Treatment of Anthrax* (Nov. 2, 2001), available at [http://www.ciprousa.com/news/press\\_releases\\_specialist.asp](http://www.ciprousa.com/news/press_releases_specialist.asp) (last visited Jan. 17, 2002).

pharmacies in demand of Cipro.<sup>44</sup> This led to massive shortages of the drug.<sup>45</sup> In addition, United States Health and Human Services Secretary Tommy G. Thompson ordered an emergency government stockpile sufficient to treat ten million Americans.<sup>46</sup> This order alone requires 1.2 billion tablets, as the recommended dosage per person is 120 tablets.<sup>47</sup> Bayer can manufacture just two million tablets per day, and thus a lag time of almost two years is required to fill the order.<sup>48</sup> Its patent protects Bayer as the sole producer of the drug,<sup>49</sup> and thus limits the supply of Cipro until at least December 2003.<sup>50</sup> The United States consequently faces a situation similar to that of developing nations in the sub-Sahara: medication has been created but is unavailable to those in need.<sup>51</sup>

### 3. *Prices and Patent Protection*

The cost of the antibiotics necessary to fight anthrax and other such potentially devastating diseases varies from nation to nation. For example, a 500 mg tablet of Cipro available in the United States costs \$4.67, while the same pill in New Zealand costs \$1.29, and \$2.10 in South Africa.<sup>52</sup> This disparity in price is caused in large part by the market control of pharmaceutical monopolies based on patent rights in each country.<sup>53</sup>

Patents operate to promote development of new products and processes in the market.<sup>54</sup> A pharmaceutical patent works to recoup expensive research and development costs in the financially demanding drug development industry.<sup>55</sup> A patent grants the owner a right to exclude others from practicing the technology the owner has

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44. See *Engelberg Letter*, *supra* note 2.

45. See *id.*

46. See *Love, Talking Points*, *supra* note 1.

47. See *id.*

48. See *id.*

49. See *Engelberg Letter*, *supra* note 2. Patent law creates a negative right in the patent owner to exclude others from making, using, or selling the patented product. See *infra* note 56 and accompanying text.

50. See *Engelberg Letter*, *supra* note 2.

51. See *Dale*, *supra* note 18.

52. See *Cipro Prices*, *supra* note 5.

53. See *Park*, *supra* note 19, at 128-29 ("Patent-protected antiretrovirals are exorbitantly priced, which makes them effectively inaccessible to those in need until their patents expire and generics can be produced.").

54. See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 59 (2d ed. 2001)[hereinafter CHISUM, PRINCIPLES]; see also U.S. CONST. art. I, § 8, cl. 8 ("To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.").

55. See *Park*, *supra* note 19, at 129.

developed.<sup>56</sup> But no uniform international patent system exists, so inventors are required to file patent applications in each country in which they seek protection.<sup>57</sup>

Some countries, such as Brazil and India, offer practically no patent protection for products.<sup>58</sup> India does not provide protection for processes, allowing any drug company to manufacture a product through any means.<sup>59</sup> Brazil, not granting protection for pharmaceuticals prior to accession to the TRIPS Agreement, allowed the manufacture of any drug, with international patents pre-dating its accession, inside its country.<sup>60</sup> Through manufacturing generic drugs, therefore, India and Brazil can offer pharmaceuticals at lower prices to its residents and to poorer neighboring countries.<sup>61</sup> Pharmaceutical companies face substantial losses in markets such as these.<sup>62</sup> Consequently, the United States and the European Union have directed their efforts toward an international agreement on intellectual property rights.<sup>63</sup>

## B. *The TRIPS Agreement*

### 1. *TRIPS on Intellectual Property*

The TRIPS Agreement<sup>64</sup> is the most comprehensive international agreement on intellectual property.<sup>65</sup> The World Trade Organization

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56. See CHISUM, PRINCIPLES, *supra* note 54, at 2; see also 35 U.S.C. § 154 (1994) (granting patent owners “the right to exclude others from making, using, offering for sale, or selling the invention”).

57. See 4 DONALD S. CHISUM, CHISUM ON PATENTS, § 14.02 (2001).

58. See Park, *supra* note 19, at 139-41.

59. See David K. Tomar, *A Look Into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT’L L.J. 579, 592 (1999). A “product,” or a “manufacture” as listed under U.S. Patent Law in 35 U.S.C. § 101, refers to articles of manufacture made “for use from raw or prepared materials.” *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931). For example, a single tablet of aspirin is an article or manufacture made from prepared materials, and hence, a product. A “process” refers to “a mode of treatment of certain materials to produce a given result. It is an act, or series of acts, performed upon the subject-matter to be transformed and reduced to a different state of thing.” *Cochrane v. Deener*, 94 U.S. 780, 788 (1876). For example, the chemical treatment employed in a series of steps to transform the materials into a tablet of aspirin is a process.

60. See JOHN R. THOMAS, CRS REPORT FOR CONGRESS: HIV/AIDS DRUGS, PATENTS AND THE TRIPS AGREEMENT: ISSUES AND OPTIONS (2001), available at <http://rxpolicy.com/studies/crs-aidspatentstrips-0701.pdf> (last visited July 10, 2002).

61. See Tomar, *supra* note 59, at 592.

62. See Park, *supra* note 19, at 129.

63. See *id.* at 130.

64. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, 33 I.L.M. 81 (1994) [hereinafter *TRIPS*].

65. See World Trade Org., *Overview: The TRIPS Agreement*, available at



(WTO) created the TRIPS Agreement in an attempt to establish an internationally uniform intellectual property rights standard<sup>66</sup> that formally links intellectual property laws with international trade.<sup>67</sup> The agreement sets out three main features: (1) a minimum standard of protection to be provided by each WTO member country for patents, copyrights, and trademarks; (2) domestic procedures for the enforcement of intellectual property rights; and (3) dispute settlement procedures.<sup>68</sup> In addition, the agreement allows member countries to use trade sanctions to enforce their intellectual property rights.<sup>69</sup> Unlike other treaties of its kind, the TRIPS Agreement directly regulates intellectual property protection as applied to WTO member countries.<sup>70</sup>

Under Article 27(1) of the TRIPS Agreement,<sup>71</sup> member countries must make patents, including pharmaceutical patents, available for inventions that are novel, involve an inventive step, and are capable of industrial application “whether [the inventions are] products or processes, in all fields of technology.”<sup>72</sup> The patent owner is granted “exclusive rights . . . to prevent third parties, not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing” the protected process or product.<sup>73</sup> The Agreement does not allow discrimination of protection for locally produced products over imported ones.<sup>74</sup> Patents under the TRIPS Agreement are valid for a term of twenty years from the filing date.<sup>75</sup>

The WTO created the TRIPS Agreement in part to persuade developing countries to establish their own intellectual property laws in

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[http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited Jan. 16, 2002) [hereinafter *TRIPS Overview*]. The TRIPS Agreement came into effect on January 1, 1995. *See id.*

66. *See* Vincent Chiapetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things*, 21 MICH. J. INT’L L. 333, 334 (2000).

67. *See* Robert J. Gutowski, *The Marriage of Intellectual Property and International Trade in the TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?*, 47 BUFF. L. REV. 713, 714-15 (1999).

68. *See* Chiapetta, *supra* note 66, at 342-46.

69. *See* Gutowski, *supra* note 67, at 714-15.

70. *See* John E. Giust, *Noncompliance with TRIPS by Developed and Developing Countries: Is TRIPS Working?*, 8 IND. INT’L & COMP. L. REV. 69, 71 (1997).

71. *See* TRIPS, *supra* note 64, at art. 27, para.1.

72. *Id.*

73. *Id.* at art. 28, paras. 1(a)-(b).

74. *See* TRIPS Overview, *supra* note 65. Thus, a member country may not issue patent protection for its own citizens’ inventions while not protecting the inventions from other countries. *See id.*

75. *See* TRIPS, *supra* note 64, at art. 33.

compliance with minimum standards.<sup>76</sup> However, as developing countries create patent protection for pharmaceuticals, drug prices inevitably increase.<sup>77</sup> Anticipating continuing need for developing countries to obtain pharmaceuticals at cheaper prices, the TRIPS Agreement includes several exceptions to alleviate the financial strain associated with patented drugs.<sup>78</sup>

## 2. *Exceptions in the Agreement*

The first noteworthy exception contained in the TRIPS Agreement is the public welfare guideline.<sup>79</sup> This exception allows WTO members to legislate any 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.”<sup>80</sup>

Secondly, as established January 1, 1994, Article 65 sets forth that all WTO member countries must comply with the provisions of the TRIPS Agreement within one year from signing the Agreement,<sup>81</sup> but also allows developing member countries to delay implementation of these provisions for up to an additional four years.<sup>82</sup> Article 65 further grants an additional five-year delay for technology not patentable in a member country at the time of the formation of the TRIPS Agreement.<sup>83</sup> Thus, a developing member country that signed the Agreement at its inception may have until January 1, 2005, to completely comply with the Agreement standards, including those pertaining to protecting pharmaceutical products and processes. Article 66 provides even greater accommodation to the poorest, least developed countries, allowing the country ten years from the date of application to comply with the provisions of the TRIPS Agreement in their entirety.<sup>84</sup> In a recent effort to lend further support to these least developed nations, the WTO amended Article 66, extending the deadline for complete compliance to January 1, 2016.<sup>85</sup>

The most significant and controversial exception found in the

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76. See Giust, *supra* note 70, at 70.

77. See Park, *supra* note 19, at 131.

78. See *id.*

79. See *TRIPS*, *supra* note 64, at art. 8.

80. *Id.* at art. 8, para. 1.

81. See *id.* at art. 65, para. 1.

82. See *id.*, para. 2.

83. See *id.*, para. 4.

84. See *id.* at art. 66, para. 2.

85. See *Doha*, *supra* note 11, at para. 7.

TRIPS Agreement is the allowance of compulsory licensing.<sup>86</sup> Compulsory licensing permits a government or government-appointed third party to use a patented product or process without a license for the product's use<sup>87</sup> with the patent owner entitled to reasonable compensation but not the ability to prevent the government or third party from using the product.<sup>88</sup> Furthermore, a third party authorized to use the patent cannot be sued for infringement.<sup>89</sup>

Compulsory licensing is subject to limitations. First, a member country may use compulsory licensing only in a time of "national emergency" or in cases of "public non-commercial use,"<sup>90</sup> in which case member countries must make an effort to obtain authorization from the patent holder prior to use.<sup>91</sup> Every authorization of compulsory licensing must be considered independently on its own merits.<sup>92</sup> Furthermore, compulsory licensing may be imposed only for domestic use,<sup>93</sup> and the patent owner must receive adequate compensation.<sup>94</sup> Finally, the license must be "terminated if and when the circumstances which led to [the license] cease to exist and are unlikely to recur."<sup>95</sup> The WTO further advises that although the provisions of the TRIPS Agreement permit these exceptions, each exception should be "read together with the related provisions of Article 27(1), which require that patent rights shall be enjoyable without discrimination as to the field of technology . . . whether

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86. See *TRIPS*, *supra* note 64, at art. 31. This exception encompassing compulsory licensing is enumerated in Article 31 of the TRIPS Agreement. See *id.*

87. See *id.*

88. See *id.* para. (h).

89. See *id.* at art. 31.

90. See *id.* para. (b). The definition of "public non-commercial use" varies from country to country. Generally, a "public non-commercial use" is the use of a patented technology with the primary purpose to serve the general public while not promoting the commercial success of a private company. Some countries interpret a public use to include any public interest, public welfare issue, government service or use, or even military use. See James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (Jan. 21, 2001), available at [www.cptech.org/ip/health/cl/recommendedstatepractice.html](http://www.cptech.org/ip/health/cl/recommendedstatepractice.html) (last visited Jan. 15, 2002) [hereinafter Love, *Models*].

91. See *TRIPS*, *supra* note 64, at art. 31, para. (b).

92. See *id.* para. (a). Thus, each act of compulsory licensing is subject to independent review. See *TRIPS Overview*, *supra* note 65.

93. See *TRIPS*, *supra* note 64, at art. 31, para. (f). Therefore, a nation issuing a compulsory license may only do so to use a patented invention for its own use and not to aid neighboring countries or to sell for profit to any other country. See *TRIPS Overview*, *supra* note 65.

94. See *TRIPS*, *supra* 64, at art. 31, para. (h).

95. *Id.* para. (g). Thus, at the end of any national emergency the use of the license must be terminated unless further approval is granted by the patent owner. See *TRIPS Overview*, *supra* note 65.

products are imported or locally produced.”<sup>96</sup> Hence, the TRIPS Agreement, while expressing the importance of a patent owner’s rights, defines exceptions to patent monopolies to allow a member country to obtain less costly medications through the use of specific compulsory licensing provisions.<sup>97</sup>

### C. *TRIPS and Beyond: United States Policy and Reaction Abroad*

The TRIPS Agreement provides that member countries may grant intellectual property protection beyond the minimum standard required by the TRIPS Agreement.<sup>98</sup> Member countries are also permitted to negotiate amongst themselves for greater protection.<sup>99</sup> The United States has thus attempted to negotiate changes in the patent laws of various nations that would preclude these nations from granting compulsory licenses on patented drugs.<sup>100</sup> Negotiation strategies of the United States often involve threats of trade sanctions or complex litigation through the WTO dispute resolution system.<sup>101</sup>

The United States’ effort to negotiate with other countries for patent rights is based primarily on the growth of the pharmaceutical industry in the United States.<sup>102</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) has reported that a new drug takes twelve to fifteen years to develop at a cost of \$500 million.<sup>103</sup> Although at great financial expense, research and development in the United States has yielded approximately 50% of all new commercial

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96. *TRIPS Overview*, *supra* note 65.

97. See Park, *supra* note 19, at 131 (“Compulsory licensing also assists countries in increasing access to cheaper drugs.”).

98. See *TRIPS*, *supra* note 64, at art. 1, para. 1 (“Members may implement in their domestic law more extensive protection than is required by this Agreement.”).

99. See Harrelson, *supra* note 10, at 188-189. TRIPS serves as a minimum standard for patent protection and as such any country can adopt greater protection for itself and negotiate with other member countries to do the same. See *id.*

100. See *id.* at 189. In these trade negotiations, the United States often uses threats of trade sanctions with countries not willing to legislate stricter patent protection. See *id.*; see also *infra* Parts II.C.1-3.

101. See Park, *supra* note 19, at 134.

102. See George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT’L L. & FOREIGN AFF. 283, 297-98 (1998). See also Park, *supra* note 19, at 129 (“Without the protection of patents, pharmaceutical companies risk losing millions of dollars as companies that did not have to undertake the costly research and development produce and sell the same drug at lower costs.”).

103. See The Pharmaceutical Research and Manufacturers of America (PhRMA), *A Monthly Report from America’s Pharmaceutical Companies* (Mar. 2001), available at <http://www.phrma.org/publications/documents/factsheets/2001-03-01.210.phtml> (last visited Jan. 17, 2002).

pharmaceuticals developed worldwide in the last twenty years.<sup>104</sup> Further, exportation accounts for approximately 40% of industry-wide sales of U.S. pharmaceuticals.<sup>105</sup>

Some foreign drug companies illegally copy and manufacture these drugs in an effort to reduce the cost of drugs by avoiding patent licensing fees.<sup>106</sup> As a result of these practices, pharmaceutical companies in the United States lose approximately \$5 billion annually.<sup>107</sup> According to the International Trade Commission, U.S. drug companies would be able to invest an estimated \$900 million into the development of new medicines with these lost revenues.<sup>108</sup> Thus, the United States, seeking to recoup the financial losses of the pharmaceutical industry and prevent further losses, gives great attention to the international effort to strengthen intellectual property protection in foreign trade policy.<sup>109</sup>

In a further attempt to persuade developing countries to strengthen their patent laws, the United States amended section 301 of the U.S. Trade Act of 1974<sup>110</sup> to allow trade sanctions against countries that manufacture, import, or export U.S. patented pharmaceuticals.<sup>111</sup> Under section 301, the United States Trade Representative (USTR)<sup>112</sup> may extend investigative efforts to uncover countries that offend intellectual property rights, based on allegations by citizen petitions<sup>113</sup> or on its own initiative.<sup>114</sup> The USTR identifies suspect countries and compiles a "watch list"<sup>115</sup> of those countries against which trade sanctions may be imposed if the countries fail to make necessary

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104. See The Pharmaceutical Research and Manufacturers of America (PhRMA), *U.S. is the World Leader in Drug Innovation* (Dec. 1999), available at [http://www.phrma.org/publications/backgrounders/world/12\\_global.phtml](http://www.phrma.org/publications/backgrounders/world/12_global.phtml) (last visited Jan. 17, 2002).

105. See Foster, *supra* note 102, at 297.

106. See *id.* at 296.

107. See *id.* at 297-98.

108. See *id.* at 298.

109. See *id.*

110. See 19 U.S.C. § 2411 (2001).

111. See Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT'L. L. & BUS. 379, 399 (2001). This amendment, enacted in 1988, is commonly referred to as "Special 301." See *id.*

112. The USTR is a cabinet member of the executive branch who develops and maintains U.S. international trade and investment policy and directs negotiations with other countries in these affairs. See Office of the United States Trade Representative, *About the USTR*, available at <http://www.ustr.gov/about-ustr/ustrrole.shtml> (last visited July 10, 2002).

113. See 19 U.S.C. § 2412(a) (2002).

114. See Rein, *supra* note 111, at 399.

115. See 19 U.S.C. § 2411(c) (2001).

changes in their patent laws.<sup>116</sup> For a developing nation seeking trade alliances to promote its own welfare, placement on such a list would have a “chilling effect” on its growth.<sup>117</sup> Thailand and South Africa are two nations that have responded to such action.

### 1. *South Africa*

The United States and South Africa have been involved in a dispute over the compulsory licensing of HIV treatments since South Africa passed the Medicines and Related Substances Amendment Act 101 in 1997.<sup>118</sup> In an effort to alleviate the spread of HIV by supplying affordable medicine to its citizens, South Africa enacted this legislation to permit the Minister of Health, at his discretion, to call for compulsory licensing of medication.<sup>119</sup> The new law allows the Minister to use compulsory licensing to import medication manufactured by a country other than South Africa.<sup>120</sup> The United States quickly used section 301 to threaten South Africa with trade sanctions and placed the country on the “watch list.”<sup>121</sup> The USTR based its retaliatory claims on the questionable compliance of the Act with the restrictive TRIPS Agreement with respect to compulsory licensing.<sup>122</sup>

The United States did not dispute that South Africa could have called upon the TRIPS Agreement to grant compulsory licensing to drug manufacturers in times of national emergency.<sup>123</sup> However, the United States alleged that the Act used illegal methods of compulsory licensing not in compliance with the standards outlined in the Agreement.<sup>124</sup> After much political pressure from other world trade leaders, the United States reevaluated its position and removed South Africa from the “watch list.”<sup>125</sup> However, the United States continues

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116. See Rein, *supra* note 111, at 399.

117. See *id.* at 400.

118. See Park, *supra* note 19, at 136. The Medicines and Related Substances Amendment Act 101 is also referred to as Article 15(C). See *id.*

119. See Rein, *supra* note 111, at 400.

120. See *id.* at 400-01. This effort is known as parallel licensing. The TRIPS Agreement does not prohibit this practice but it is disfavored by the United States as a further form of compulsory licensing. See *id.*

121. See Harrelson, *supra* note 10, at 185 (Placement on the “watch list” is a “precursor to trade sanctions.”).

122. See Rein, *supra* note 111, at 401 (“[T]he USTR placed South Africa on its ‘Watch List,’ implicating the [Article 15(C)] ‘ill-defined authority to issue compulsory licenses, authorize parallel imports and potentially otherwise abrogate patent rights.’”).

123. See *id.*

124. See *id.*

125. See Harrelson, *supra* note 10, at 185.

its surveillance of South Africa's use of compulsory licensing.<sup>126</sup>

## 2. Thailand

Thailand is another developing country in need of affordable HIV medication, with an estimated 700,000 people infected with HIV.<sup>127</sup> The HIV medication didanosine (ddI), developed and patented by Bristol-Myers-Squibb, costs \$1.25 per tablet and has a recommended daily dosage of four tablets.<sup>128</sup> Treatment costs of \$5.00 per day are affordable by less than 10% of Thais infected.<sup>129</sup> Unlike South Africa, Thailand has the ability to make generic ddI at reduced cost to the public.<sup>130</sup>

In 1999, the Thai government originally decided to issue a compulsory license but abandoned its plans after the United States threatened to place Thailand on the section 301 "watch list."<sup>131</sup> Thailand's developing economy depends on the United States as Thailand exports 25% of its goods to the United States.<sup>132</sup> The threat of trade sanctions would have a tremendous impact on Thailand.<sup>133</sup> Hence, patent-owning pharmaceutical companies have forced Thais to pay the often unaffordable price of non-generic drugs.<sup>134</sup> In January 2000, after political pressure from other trading nations, the United States lessened its pressure on Thailand and agreed to allow Thailand to produce generic ddI.<sup>135</sup> This agreement was contingent on Thailand's following the compulsory licensing protocols of the TRIPS Agreement, including paying adequate compensation to the rightful patent owner.<sup>136</sup>

## 3. India

The United States has applied similar pressure to India with respect to its extensive generic drug industry.<sup>137</sup> India is one of the leading producers of generic drugs in the world, and its prices remain

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126. *See id.*

127. *See* UNAIDS, *supra* note 22, at 19.

128. *See* Frank Ching, *Eye on Asia: Drug Patents vs. Human Rights*, FAR E. ECON. REV. (Feb. 17, 2000), available at 2000 WL-FEER 8518035 (cited in Harrelson, *supra* note 10, at 185-86.)

129. *See id.*

130. *See id.*

131. *See* Rein, *supra* note 111, at 402-3.

132. *See id.*

133. *See id.*

134. *See* Ching, *supra* note 128.

135. *See id.*

136. *See id.*

137. *See* Tomar, *supra* note 59, at 582-83.

among the lowest<sup>138</sup> because of its extremely low investment in research and development.<sup>139</sup> India's weak patent laws protect only the manufacturing process of the drug, not the product itself, allowing Indian companies to produce pharmaceuticals by a different process without paying any licensing fees or investing time and money in research.<sup>140</sup> These laws allow Indian companies simply to copy drugs, enabling them to produce drugs at a lower cost than their foreign competitors.<sup>141</sup> Consequently, the United States has placed India on its section 301 "watch list" until India agrees to strengthen its patent laws to provide adequate royalties to American pharmaceutical producers.<sup>142</sup>

#### D. *The United States' First Steps*

As an attempt to yield to the needs of global health crises, the United States has begun to decrease its opposition to compulsory licensing of pharmaceuticals when necessary to combat disease in a "national emergency."<sup>143</sup> On December 1, 1999, at the Seattle WTO Ministerial Conference, the United States announced it would permit trade policy to ensure that developing nations would have the necessary medication to fight national epidemics.<sup>144</sup> In May of 2000, President Bill Clinton prohibited all United States government agencies from acting as obstacles to supplying needed anti-AIDS drugs in South Africa.<sup>145</sup> This executive order effectively removed all United States opposition to the method of compulsory licensing as articulated in the TRIPS Agreement.<sup>146</sup> In fact, the United States now makes available \$1 billion in annual loans to help South Africa purchase patented pharmaceuticals to fight the AIDS crisis.<sup>147</sup>

Although the United States appears to have eased its pressure on the international pharmaceutical trade market, other countries are

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138. *See id.*

139. *See id.* at 582.

140. *See id.* at 583.

141. *See id.*

142. *See Park, supra* note 19, at 140 (The USTR placed India on the "watch list" "for its lack of protection for patented pharmaceutical drugs.").

143. *See Harrelson, supra* note 10, at 186 ("As evidenced in the change in position by the United States in its disputes with South Africa and Thailand, the United States' opposition to compulsory licensing is decreasing.").

144. *See Rein, supra* note 111, at 403.

145. *See Harrelson, supra* note 10, at 186. However, there is no identifiable support to substantiate President Clinton's plea. In addition, President Clinton was quick to declare that the order does not weaken the protection of intellectual property rights. *See id.*

146. *See Rein, supra* note 111, at 403.

147. *See Harrelson, supra* note 10, at 186.



skeptical about the United States' sincerity.<sup>148</sup> The U.S. policy remains uncertain because it has articulated no standards for compulsory licensing.<sup>149</sup> Therefore, when a developing nation issues a compulsory license, it must be willing to face challenges from the United States that resemble those under section 301.<sup>150</sup> The developing nation must balance on a "tightrope between pressing health needs, increasing pressures from domestic constituencies and the cost of challenging international pharmaceutical interests."<sup>151</sup>

AIDS activist groups argue that the \$1 billion U.S. government loan to Africa prioritizes patented drug profits over human health concerns.<sup>152</sup> Activists also contend that loan assistance is actually a method of increasing the reduced pharmaceutical prices that have resulted from the compulsory licensing because the loan simply enables developing nations to afford the patent owners' high royalty fees.<sup>153</sup> Further, activists argue that the use of compulsory licensing instead of loan programs would better permit developing countries to gain control over the availability of affordable drugs, thus ensuring low prices rather than relying on governmental funding to the patent owner.<sup>154</sup>

The current application of international intellectual property rights, treaties, and agreements governing the use of compulsory licensing creates the possibility that many people in developing nations will not be able to obtain life-saving pharmaceuticals. However, under less restrictive intellectual property regulations, American pharmaceutical companies might not be able to recover expensive research and development costs, making these companies less likely to invest in attempts to discover new medications. All of these factors point to the need for a better balance between allowing compulsory licensing of pharmaceuticals and providing patent owners sufficient royalties to continue research.

### III. IDENTIFICATION OF THE PROBLEM

The TRIPS Agreement became the most comprehensive international agreement on intellectual property,<sup>155</sup> creating uniform

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148. See Harrelson, *supra* note 10, at 186; see also Rein, *supra* note 111, at 403-4.

149. See Rein, *supra* note 111, at 403-04.

150. See Rein, *supra* note 111, at 404.

151. *Id.*

152. See *AIDS Groups Slam U.S. \$1 Billion for Africa*, Marketletter (Jul., 31, 2000), available at 2000 WL 7542853 (cited in Harrelson, *supra* note 10, at 186).

153. See *id.*

154. See Rein, *supra* note 111, at 403.

155. See *TRIPS Overview*, *supra* note 65.

intellectual property rights<sup>156</sup> while formally linking intellectual property laws with international trade.<sup>157</sup> The Doha WTO Ministerial Conference in November 2001 recognized the “gravity of the public health problems afflicting many developing and least-developed countries.”<sup>158</sup> It emphasized the importance of the TRIPS Agreement’s inclusion in any international solution aimed at helping developing nations gain access to patented pharmaceuticals.<sup>159</sup> The Conference further recognized the importance of intellectual property in the process of developing new pharmaceuticals and the effect of patent rights on the costs of drugs.<sup>160</sup> It reaffirmed the TRIPS Agreement as a means to support each WTO member’s need to protect public health and promote access to necessary medicine.<sup>161</sup> More importantly, the Conference reaffirmed each member’s right to use compulsory licensing to gain access to affordable medications in a time of national emergency.<sup>162</sup> At the same time, it recognized the difficulties that developing member countries face in making effective use of such compulsory licensing and called the Council for TRIPS to find a remedy.<sup>163</sup>

The United States’ long-standing opposition to the practice of compulsory licensing has become an impediment to developing nations’ abilities to obtain greatly needed pharmaceuticals.<sup>164</sup> The fervent efforts of the United States to recover research and development costs from international sales of U.S. patented pharmaceuticals have resulted in other nations being confronted with the threat of placement on the section 301 “watch list.”<sup>165</sup> Although the United States has shown signs of increasing compassion toward developing countries’ needs for affordable drugs, it remains steadfast in

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156. See Chiapetta, *supra* note 66, at 334.

157. See Gutowski, *supra* note 67, at 714-15.

158. *Doha*, *supra* note 11, at para. 1.

159. *See id.* (“We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights to be part of the . . . action to address these problems.”).

160. *See id.* para. 3 (“We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.”).

161. *See id.* para. 4 (“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”).

162. *See id.* paras. 5(b)-(c) (“[E]ach member has the right to grant compulsory licenses” and “the right to determine what constitutes a national emergency.”).

163. *See id.* para. 6. *See also Doha*, *supra* note 11 and accompanying text.

164. *See* Ed Silverman, *A Battered Bayer Opts Out of a Fight Over Its Cipro Patent*, STAR-LEDGER (Oct. 25, 2001), available at <http://www.nj.com/business/ledger/index.ssf?/business/ledger/14d2b51.html> (last visited Jan. 16, 2002). *See also* Dale, *supra* note 18 and accompanying text.

165. *See supra* Part II.C.

the requirement of guaranteeing payment of adequate compensation to patent owners.<sup>166</sup> As demonstrated in Thailand, adding compensation of royalty fees to the price of the generic drug may actually increase the price of the generic drug to a level nearly equivalent to that of the original brand-name patented drug.<sup>167</sup> If drug prices continue to remain high because of expensive royalty fees, developing nations, such as Thailand, will continue to be unable to access critical medication.<sup>168</sup> The dilemma remains: What remedy reduces costs of patented life-saving drugs through compulsory licensing while adequately compensating patent owners to encourage future development of critically needed pharmaceuticals?

#### IV. ANALYSIS

The WTO Conference at Doha issued a decree to the Council for TRIPS to find an effective means to support developing member countries, particularly those countries with little or no drug manufacturing capabilities, to implement effective compulsory licensing.<sup>169</sup> Although compulsory licensing by a WTO member country is permitted by the TRIPS Agreement, it contradicts some rights of the patent holder.<sup>170</sup> A patent grants the owner a right to exclude anyone from practicing the invention claimed in the patent.<sup>171</sup> The compulsory license provision partially removes this ability to exclude others.<sup>172</sup> Such a solution would require ensuring that rightful patent owners are adequately compensated as required by the TRIPS Agreement.<sup>173</sup> Therefore, careful examination of various solutions for developing nations is needed to evaluate the balance between the use of compulsory licensing to reduce the cost of medication against the guarantee of adequate compensation to patent owners.

##### A. *Establishing a Patent System for Developing Countries*

One solution is to use the provisions of the TRIPS Agreement that allow great discretion in member countries' methods of operation and administration of compulsory licensing under a national patent

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166. See Rein, *supra* note 111, at 403-4.

167. See *supra* Part II.C.2.

168. See Park, *supra* note 19, at 125.

169. See Doha, *supra* note 11, at para. 6.

170. See Harrelson, *supra* note 10, at 182.

171. See CHISUM, PRINCIPLES, *supra* note 54, at 59; see also *supra* note 56 and accompanying text.

172. See Harrelson, *supra* note 10, at 182.

173. See TRIPS, *supra* note 64, at art. 31, para. (h).

system.<sup>174</sup> But an individual national system that provides access to patented inventions and establishes a system of patent laws is given more weight in circumstances of licensing than are the specific TRIPS guidelines.<sup>175</sup> The TRIPS Agreement is administered only as a compliment to national systems to provide a minimum standard of effective intellectual property law.<sup>176</sup> However, under the TRIPS Agreement a member must issue patents on pharmaceuticals,<sup>177</sup> for example, because without an issued patent a member cannot issue a compulsory license and therefore cannot obtain medicines at reduced cost.<sup>178</sup> Thus, each member nation must maintain some minimal patent law system.

Unfortunately, patent law systems are expensive to employ and maintain, much like the process of litigation.<sup>179</sup> Most developing countries lack the financial resources necessary to establish a patent system, much less to enforce one.<sup>180</sup> James Love of Consumer Project on Technology developed the following solution that is designed to allow developing nations, with limited resources, to invest in intellectual property law systems without litigation.<sup>181</sup>

### 1. *Inexpensive Administrative Costs*

The model of patent systems for developing countries should be based on administrative processes.<sup>182</sup> Pharmaceutical companies routinely litigate intellectual property matters, and thus are skilled in taking advantage of gaps in the law at the expense of their competitors.<sup>183</sup> An administrative process can be used to regulate the system without this litigation.<sup>184</sup> Developing countries need to create intellectual property systems that are inexpensive to operate and not easily challenged by litigation of complex rules and regulations.<sup>185</sup>

An intellectual property system based on administrative processes

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174. See Love, *Models*, *supra* note 90, at para. 3.

175. See *id.*

176. See *id.* para. 4.

177. See *id.* para. 12.

178. See *id.*

179. See *id.* para. 8-9. The United States spends approximately \$1 billion annually maintaining the Patent and Trademark Office. Litigation expenses are also high with costs of an average patent litigation currently at \$2.4 million. See *id.*

180. See Love, *Models*, *supra* note 90, at para. 8-11.

181. See *id.* para. 14.

182. See *id.* para. 15.

183. See *id.*

184. See *id.*

185. See *id.*

is permitted under the TRIPS Agreement.<sup>186</sup> The TRIPS Agreement requires that the processes be “fair, transparent, and accountable.”<sup>187</sup> Thus, the developing nation must describe the basic processes involved in the administration of the laws.<sup>188</sup> The process must be centered on written regulations and decisions permitting uniform awareness of the law.<sup>189</sup> In addition, hearings must be available and an appeals process must include “independent review by a distinct higher authority.”<sup>190</sup> An appellate process ensures that the system correctly employs the use of compulsory licensing and is fair to all parties involved.<sup>191</sup>

An administrative process incorporating these principles would enable an appointed officer to make straightforward decisions based on known, written procedures and would also grant an independent person or board the ability to review and modify the officer’s decisions.<sup>192</sup> Although the process could also allow further appeals to the nation’s judiciary, the appellate review included in the administrative process would adequately serve most parties.<sup>193</sup> Hence, such a process would reduce litigation in the nation’s court system and decrease administrative costs of the nation’s patent system.

## 2. Government-Use Provision

The TRIPS Agreement permits governments great discretion in issuing compulsory licenses for public non-commercial uses.<sup>194</sup> This is known as a government-use provision. For example, following the TRIPS Agreement, the United States provides accessible requirements for the issuance of compulsory licenses for public non-commercial uses of patents.<sup>195</sup> However, it is imperative that government-use provisions

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186. See Love, *Models*, *supra* note 90, at para. 17. The TRIPS Agreement permits administrative practices on all Article 31 decisions, including interpreting rules and regulations, setting forth compensation, and conducting appellate procedures. See *id.*

187. *Id.* Thus, parties involved must be able to rely on written records and decisions to provide some type of standard. See *id.* See also *TRIPS*, *supra* note 64, at art. 41.

188. See Love, *Models*, *supra* note 90, at para. 17.

189. See *id.*

190. *Id.* para. 20. For example, the law could appoint an officer to make initial decisions and another independent committee to review and modify the initial decision. Likewise, appeals could be sent to the national court system for review as long as the standards of appeal are explicitly set forth. See *id.* para. 20. See also *TRIPS*, *supra* note 64, at art. 31, paras. (i)-(j).

191. See Love, *Models*, *supra* note 90, at para. 20.

192. See *id.*

193. See *id.*

194. See *id.* para. 23. For example, the United States allows any government official authorized to sign contracts to issue a compulsory license of a patent. Each agency may have additional guidelines, but, generally, the power granted is broad. See *id.* para. 18.

195. See *id.* para. 24.

are lawful and enforceable, without exceptions or loopholes, or in other words, they must be “strong laws.”<sup>196</sup>

The “strong law” models of Europe and the United States allow the government to license the patent for any public non-commercial purpose during a time of national emergency, without requiring negotiations with the patent owner for licensing.<sup>197</sup> Further, these models do not allow the patent owners to prohibit government use through injunctive relief,<sup>198</sup> but the government must notify the patent owner soon after using the patented technology.<sup>199</sup> If the compulsory license is intended to permit a non-government third party commercial use of a patent, authorization may require more restrictions to protect the patent owner.<sup>200</sup>

Following the TRIPS Agreement, even if the patent owner has not agreed to the use of the patent, he must be paid an adequate royalty as though he had approved the license.<sup>201</sup> Thus, the developing nation should provide the government broad power to utilize patents for public non-commercial use<sup>202</sup> to promote efficiency in the issuance of compulsory licenses.

### 3. *National Emergencies*

In addition to a provision authorizing the use of patents by the government for public non-commercial use, it is necessary that each nation’s patent system allow the issuance of compulsory licenses during times of widespread health crisis.<sup>203</sup> Article 31(b) of the TRIPS Agreement allows the same broad government discretion for times of crisis as for public non-commercial use.<sup>204</sup> By announcing a state of national emergency, however, the developing nation can authorize a third party to provide an adequate supply of medication without any negotiation with the patent owner.<sup>205</sup> The patent owner is entitled to a reasonable royalty, but the absence of negotiation saves time in getting the drug to market and likely increases the supply of the drug because

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196. See *id.* paras. 7, 15.

197. See Love, *Models*, *supra* note 90, at para. 15; see also TRIPS, *supra* note 64, at art. 31, para. (b).

198. See Love, *Models*, *supra* note 90, at para. 24.

199. See TRIPS, *supra* note 64, at art. 31, para. (b).

200. See Love, *Models*, *supra* note 90, at para. 19. For example, in Belgium a committee including consumer, labor, and small business interests are consulted prior to allowance of a compulsory license to a third party. See *id.*

201. See *id.* para. 24.

202. See *id.* para. 31.

203. See *id.* para. 15.

204. See *id.*

205. See *id.*

more generic drug manufacturers may compete in the market.<sup>206</sup> Thus, laws enacted to allow issue of compulsory licenses by the government in times of national emergency allow the persons affected by such emergencies rapid access to medication.

#### 4. *Patent Owner Compensation*

The developing nation's intellectual property law must include a "predictable system" for determining royalty compensation.<sup>207</sup> Article 31(h) of the TRIPS Agreement requires the rightful patent holder to be "paid adequate remuneration" for the unauthorized use of a patent.<sup>208</sup> A standard compensation guideline to determine royalties is the preferred method to provide patent owners with "predictability and transparency" in the law.<sup>209</sup> Such a system also allows for quick decision making by the administration, thus allowing the needed drugs to reach the market without unnecessary delay.<sup>210</sup> The royalty guidelines can be based on reasonable royalties known to the industry.<sup>211</sup> Royalty rates differ from country to country but are typically about 4% within the pharmaceutical industry.<sup>212</sup>

Furthermore, national patent law systems must require patent owners seeking royalties to provide the government information about the patented drug prior to receiving compensation.<sup>213</sup> The actual costs of research and development, along with data regarding the sales of the product since market introduction, should be part of the required disclosure.<sup>214</sup> Disclosure would permit public understanding of the economics of pharmaceutical research and development and provide a check on the pharmaceutical companies wishing to market products in

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206. See Love, *Models*, *supra* note 90, at para. 15.

207. See *id.* Such a "predictable" system would include a written, published, pre-determined royalty payment scale to be paid to any inventor seeking remuneration for the license used by the government under an issued compulsory license. See *id.*

208. See *id.* para. 36; see also TRIPS, *supra* note 64, at art. 31, para. (h).

209. See Love, *Models*, *supra* note 90, at para. 37.

210. See *id.*

211. See *id.* para. 39.

212. See *id.* The United States provides an average royalty rate to pharmaceutical companies of five percent. Japan has variable rates from two to four percent. Germany has rates from two to ten percent. However, developing nations should not be pressured into paying royalty rates similar to those of developed nations. A recent royalty schedule that was recommended to developing nations was a royalty of 3% to 5% for extremely useful pharmaceuticals or those expensive to research and develop, a royalty of 2% to 3% for newer pharmaceuticals and those with research funded in part by the governments, and a royalty of 1% or less for minor or older pharmaceuticals. See *id.* para. 40.

213. See *id.* para. 42.

214. See Love, *Models*, *supra* note 90, at para. 42.

the developing nation.<sup>215</sup> Such transparent, standard royalty guidelines would promote fast delivery of drugs to reach those in need.<sup>216</sup>

### 5. *Drug Exportation*

A nation's patent law system must also permit production of pharmaceuticals for exportation.<sup>217</sup> Article 31(k) of the TRIPS Agreement allows such exportation if the administration of a country finds that a single producer of a necessary therapeutic drug is dominating production while restricting access to the drug.<sup>218</sup> Therefore, Article 31(k) renounces the restriction of Article 31(f) that compulsory licensing may only be authorized for the member country's domestic use.<sup>219</sup> In addition, Article 30 of the TRIPS Agreement provides for production of medications for exportation to address public health needs in cases in which the export country gives patent protection and adequate compensation to the rightful patent owner.<sup>220</sup> A developing country could afford domestic manufacturing of at least some necessary drugs, and overproduction could permit some exportation as market share could reach beyond the country's own borders. Thus, by employing a more efficient, uninterrupted production system as opposed to an alternating, non-continuous system, lower operating costs would result.

### B. *Accessing U.S. Government-Funded Patents*

The United States government invests a large number of taxpayer dollars in research and development of health-promoting pharmaceuticals,<sup>221</sup> and this government-supported research yields many patentable products.<sup>222</sup> In 1995, the United States spent \$15.8 billion, approximately 44% of the nation's total expenditures for

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215. *See id.*

216. *See id.* para. 15.

217. *See id.*

218. *See id.*

219. *See TRIPS, supra* note 64, at art. 31, paras. (f), (k). *See also* James Love, *Implementing TRIPS Safeguards with Particular Attention to Administrative Models for Compulsory Licensing of Patents* (Aug. 21, 2001), available at <http://www.cptech.org/ip/health/cl/harare-aug2001.html> (last visited Jan. 8, 2002) ("Article 31(f) is waived when licenses are issued as a remedy to anticompetitive practices under Article 31(k).").

220. *See Love, Models, supra* note 90, at para. 15.

221. *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforceable Reasonable Pricing Requirement Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 *TUL. L. REV.* 631, 636 (2001).

222. *See id.*



health-related research and development, in drug development.<sup>223</sup> Some of these advanced the development of pharmaceuticals, including antibiotics used to treat the AIDS virus.<sup>224</sup> In the five year period between 1987 and 1991, over 50% of all pharmaceuticals and 71% of "significant drugs" were developed in the United States using government funding.<sup>225</sup> Federal funding from taxes implies that the public has both "moral and legal" claims on antibiotics that are "government-funded inventions."<sup>226</sup> James Love has proposed a solution taking into account U.S. taxpayer investment in patents.

The United States is granted patent rights for planned patents obtained from federally funded research under the Bayh-Dole Act of 1980.<sup>227</sup> The Act was developed to provide incentives for research and development of new inventions while increasing the competitiveness of U.S. industry as inventions are put into commercial use.<sup>228</sup> The Act then allows each business or non-profit organization the right to patent the inventions.<sup>229</sup>

The United States, however, retains an irrevocable license to the invention "on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States."<sup>230</sup> The United States also retains the right to license these patents to other governments "when necessary to fulfill health or safety needs."<sup>231</sup> Furthermore, the United States retains some royalties<sup>232</sup> and the right to intervene when the patent owner refuses to provide the patented

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223. See NAT'L INSTS. OF HEALTH, ESTIMATES OF NATIONAL SUPPORT FOR HEALTH R&D BY SOURCE OR PERFORMER: FISCAL YEARS 1986-1995, available at <http://grants.nih.gov/grants/award/trends96/pdfdocs/FEDTABLA.PDF> (last visited Jan. 17, 2002) (cited by Arno & Davis, *supra* note 221, at 636-37).

224. See Letter from Ralph Nader, James Love, Robert Weissman to Dr. Harold Varmus, Director of NIH, asking for NIH to give the World Health Organization, WHO, access to US government funded medical inventions, (Sept. 3, 1999), available at <http://www.cptech.org/ip/health/sa/varmus-sep99.html> (last visited Jan. 11, 2002) [hereinafter LOVE, VARMUS LETTER]. The United States funded the research for AIDS medication, including the patented drugs ddl, ddC, FddA, d4T, 3TC and others. See *id.*

225. See Arno & Davis, *supra* note 221, at 692 n.374.

226. See *id.* at 637.

227. See 35 U.S.C. § 200 (1994), cited in Arno & Davis, *supra* note 221, at 646. However, the Bayh-Dole Act is limited to only patents obtained from research leading to planned inventions. Hence, if inventions A, B, C, and D all stemmed from research with federally funded money but only A was planned by the government, the U.S. could claim rights to only invention A.

228. See *id.*

229. See 35 U.S.C. § 202(a) (1994), cited in Arno & Davis, *supra* note 221, at 646.

230. See 37 C.F.R. § 404.7(a)(2)(i) (2000).

231. See 37 C.F.R. § 404.7(a)(2)(ii) (2000).

232. See 37 C.F.R. § 401.5(g)(3) (2000), cited in Arno & Davis, *supra* note 221, at 647.

product at a reasonable price to the public.<sup>233</sup>

The rights of the United States under the Bayh-Dole Act have largely remained unused and represent a predominantly untapped resource to aid worldwide access to affordable medication.<sup>234</sup> Consumer advocates, including James Love, Ralph Nader, and Robert Weissman, have suggested that the United States agree to allow the World Health Organization (WHO) the right to use government-funded patents.<sup>235</sup> These advocates claim the United States could supply needed pharmaceuticals to developing nations pursuant to the rights of the United States under the Bayh-Dole Act.<sup>236</sup> Consumer advocates also submit that the WHO, with the use of government-funded patents, would be able to organize production of government-funded pharmaceuticals at a greatly reduced cost.<sup>237</sup> This would allow developing countries greater access to patented drugs without the necessity of a large economy.<sup>238</sup>

However, the Bayh-Dole Act was never intended to be used to promote competition between the government and individual patent owners.<sup>239</sup> It permits only non-commercial research use of the drug technology obtained from federal funding, not the use of the final product.<sup>240</sup> Furthermore, the National Institutes of Health (NIH) is restricted to licensing patent rights only in countries where the rightful patent owners also have patent protection.<sup>241</sup> Thus, these limitations of the Bayh-Dole Act and the licensing arrangements permitted by the NIH likely prohibit an assignment of patent rights to the WHO.<sup>242</sup>

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233. See 35 U.S.C. §§ 201(f), 203 (1994), cited in Arno & Davis, *supra* note 221, at 647 nn.87, 93.

234. See Arno & Davis, *supra* note 221, at 639-40. The benefits from the Bayh-Dole Act are adding up quickly. From 1993 to 1999, the royalties derived from inventions funded by the government were \$200 million, accounting for less than 1% of the NIH's investment. However, most of the research funded resulted in patents for large corporations allowing these companies to reap large profits from high drug prices. The Bayh-Dole Act permits the government to recoup its investment from these corporate profits. See *id.*

235. See LOVE, VARMUS LETTER, *supra* note 224.

236. See *id.*

237. See *id.*

238. See *id.*

239. See Letter from NIH Director, Dr. Harold Varmus to Ralph Nader, James Love, and Robert Weissman responding to their request calling on the NIH to provide the World Health Organization, WHO, access to US government funded medical inventions (1999), available at <http://www.cptech.org/ip/health/sa/varmusletteroct19.html> (last visited Jan 11, 2002).

240. See LOVE, VARMUS LETTER, *supra* note 224 ("It does not provide rights or access to a licensee's final product.").

241. See *id.* ("NIH can only license or otherwise grant rights to patents in countries where the agency or its grantees have sought and obtained patent protection.").

242. See Dolmo, *supra* note 21, at 161.

Even if the NIH cannot assign rights to a final product, consumer advocates believe that the United States and other developed nations could enforce their patent rights under the Bayh-Dole Act to control the rising prices of pharmaceuticals.<sup>243</sup> Although subject to procedures and limitations,<sup>244</sup> under the Act individual agencies can “march in”<sup>245</sup> to review the prices of drugs developed in part with federal funding and require patent owners to demonstrate the fairness of their prices.<sup>246</sup> Agencies review prices as part of the Act to prevent profits resulting from unreasonably high prices that gouge the public.<sup>247</sup> In theory, the government could regulate prices through their “march in” rights. Much dispute exists over the price control mechanism working in conjunction with the “march in” rights of the Act.<sup>248</sup> In addition, the pharmaceutical industry is “suspicious” of any United States “march in” provision that claims control over the production, marketing, or distribution of privately owned products in a free-trading economy.<sup>249</sup> The industry claims such control would devastate the efficiency and resiliency of the industry.<sup>250</sup>

The Act seeks to protect the public investment by ensuring fair and reasonable prices on government-funded inventions.<sup>251</sup> Consumer advocates argue that a solution is to use the Bayh-Dole Act to reduce pharmaceutical prices, thus making life-saving drugs accessible throughout the world by using price control mechanisms.<sup>252</sup>

### C. *Implementing Tiered Pricing*

A third solution posits a method for developing nations to gain medication at more affordable prices while providing compensation to the patent owners<sup>253</sup> through the use of a tiered pharmaceutical pricing system.<sup>254</sup> Under such a system, controlled by private enterprises, the

243. See Arno & Davis, *supra* note 221, at 632-34. The courts have interpreted the Act to allow patents to be “available to the public on reasonable terms” to mean the patents are available to the public at a reasonable price. See *id.* at 651.

244. See *id.* at 647-48.

245. See *id.* at 648, 653.

246. See *id.* at 653.

247. See *id.* at 663.

248. See *id.* at 681-82. There has been only one case on “march in” rights, but the opinion did not announce a clear standard as to the proper mechanism of the implementation of these rights (citing *John Hopkins Univ. v. CellPro*, 978 F. Supp. 184 (D. Del. 1997)). See *id.*

249. See Arno & Davis, *supra* note 221, at 660-61.

250. See *id.*

251. See *id.* at 684.

252. See *id.* at 692.

253. See Harrelson, *supra* note 10, at 195.

254. See *id.*

pharmaceutical companies would set the prices of a patented drug higher in developed, industrialized countries than in developing countries.<sup>255</sup>

This idea is not novel.<sup>256</sup> Pharmaceutical companies already set drug prices in each country based upon the amount of competition present in that country for the same medication.<sup>257</sup> For example, the anthrax medication Cipro sells for \$1.51 per tablet in Poland where a competing manufacturer produces a generic version for a lower price, while in the United States, where the patented drug has no competition, the cost per tablet is \$4.67.<sup>258</sup> This amounts to a price difference of over 300%. Likewise, the common AIDS medication AZT sells in Spain for 273% more than it does in Thailand simply because Spain does not have any competing manufacturers.<sup>259</sup>

Supporters of tiered pricing believe it can provide drugs to developing nations and simultaneously provide profits to patent owners, although the profits may not be as large as drug companies desire.<sup>260</sup> Pharmaceutical companies, however, are not so sure.<sup>261</sup> Economists have calculated that the average South African could not afford to pay even 10% of the cost of AIDS medication in the United States.<sup>262</sup> Thus, economists postulate that the profit made on drugs sold to developing nations would be insignificant.<sup>263</sup> Pharmaceutical companies would have to exercise tiered pricing with caution.

Pharmaceutical companies foresee the potential drawback of a practice known as parallel importing.<sup>264</sup> In a tiered-pricing system it would be possible in extreme circumstances<sup>265</sup> for a distributor to purchase the patented drug in a developing nation for a low price and then resell the drug in a developed nation for less than market price.<sup>266</sup>

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255. *See id.*

256. *See id.*

257. *See id.*

258. *See Cipro Prices, supra* note 5.

259. *See Harrelson, supra* note 10, at 195.

260. *See id.* at 196.

261. *See id.*

262. *See id.* at 195-96.

263. *See id.* at 196.

264. *See Harrelson, supra* note 10, at 196. Parallel importation is the practice in which countries or buyers search the world for low cost drugs and import them into its own nation rather than buying the same drugs domestically at a higher cost. This practice effectively lowers the cost of drugs and is viewed favorably by developing nations. *See Dolmo, supra* note 21, at 137-38.

265. An example of an extreme circumstance would be one requiring the distribution of AIDS medication in developing nations at a tenth of the cost of the drug in a developed nation such as the United States. *See Harrelson, supra* note 10, at 196.

266. *See Harrelson, supra* note 10, at 196.

This practice would serve to drive down prices in developed nations, thus diminishing the expected profits of pharmaceutical companies and thwarting the likelihood of pharmaceutical companies' initial implementation of a tiered-pricing system.<sup>267</sup> Companies would need to be prudent in determining appropriate circumstances to use tiered pricing.<sup>268</sup>

## V. PROPOSAL

This comment proposes cooperation among developing nations, developed nations, and large pharmaceutical companies to create a solution that effectively balances the use of compulsory licensing to reduce the cost of needed medication while simultaneously guaranteeing adequate compensation to the patent owners.

Part A consists of a minimal model of a patent law system to assist developing nations in taking advantage of compulsory licensing as allowed under the TRIPS Agreement. In order to guarantee both price reductions and compensation to patent owners, developed nations are encouraged to adopt price controls in their own nations for government-funded patents as stated in Part B. In addition, Part C recommends an emergency price regulation policy should the price reductions in Parts A and B prove insufficient.

### A. *Developing Nations*

Developing nations should enact or reform existing patent laws to provide a more effective system. Combining the following guidelines presented by James Love<sup>269</sup> with the TRIPS Agreement efficiently creates a simple patent law system.<sup>270</sup> A patent system should comprise five essential features: 1) authorize public, non-commercial use of patents; 2) allow the use of patents during national emergencies without prior negotiation of the patent owner; 3) establish a royalty guideline; 4) rely on administrative processes to ease the expense of the patent system while creating a strong law; and 5) permit production of patented drugs for exportation in times of public health crises.

### B. *Developed Nations*

Developed nations, like the United States, should more carefully enforce patent rights resulting from government-funded research

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267. *See id.*

268. *See id.*

269. *See supra* Part IV.A.

270. *See Love, Models, supra* note 90.

according to existing legislation.<sup>271</sup> Such enforcement should assign essential patent rights to the WHO, thus giving developing nations permission to manufacture select drugs royalty free. If the developed country is unwilling to commit to such an assignment of rights, the developed nation should at a minimum invoke control over the price of select drugs in their own market for the duration of times of emergency or public non-commercial use. Such price controls taken by developed nations will affect international markets, resulting in reduction of prices in developing countries. Too severe of a price reduction could have adverse effects, even causing the market to bottom out. If carefully monitored, however, pharmaceutical price controls could yield a moderate price reduction while permitting pharmaceutical companies to recover research costs.

### C. *Pharmaceutical Companies*

Pharmaceutical companies should implement a tiered-pricing system into the world drug market for use during times of national emergency.<sup>272</sup> An effective system would allow developing countries to receive drugs at a reduced cost, even as much as a small percentage of what developed nations pay, but still provide some royalty fee to the patent owner. Although apparently ineffective alone, a tiered pricing system enacted within a developing country's own patent system would further reduce the cost of drugs, even when compulsory licensing is employed. However, for proper implementation of tiered pricing, parallel importation must be prohibited and corresponding amendments to the TRIPS Agreement would be required to ensure careful implementation of tiered pricing during times of national emergency.

## VI. CONCLUSION

The limited supply and increasing cost of Cipro in the United States has renewed conflicting concerns over access to life-saving medication in developing countries and the cost of patented drugs.<sup>273</sup> This controversy focuses on the role of patent protection and the balance between legally created monopolies, which are necessary as an incentive for expensive research and development, against access to medicine at affordable prices.<sup>274</sup> Much of this debate rests on the use

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271. See *supra* Part IV.B.

272. See *supra* Part IV.C.

273. See Gellene, *supra* note 6.

274. See Attaran & Gillespie, *supra* note 8, at 1886.

of compulsory licensing as a means of lowering pharmaceutical prices and increasing drug availability in poorer countries.<sup>275</sup>

In answer to recent attempts to address the dilemma, this comment analyzes some of the problems created by compulsory licensing<sup>276</sup> and proposed a method to ensure successful use of compulsory licensing in developing countries.<sup>277</sup> Although the task requires deliberate efforts on the part of developing countries, this comment encourages cooperation among developing nations, resource-rich developed countries, and pharmaceutical companies to create a system of effective use of compulsory licensing while providing patent owners adequate compensation. The suggested model is a feasible means of balancing human health and patent-owner rights.

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275. See Harrelson, *supra* note 10, at 175.

276. See *supra* Part IV.

277. See *supra* Part V.