

AIDS, ANTHRAX, AND COMPULSORY LICENSING: HAS THE UNITED STATES LEARNED ANYTHING? A COMMENT ON RECENT DECISIONS ON THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS OF PHARMACEUTICAL PATENTS.

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I.	INTRODUCTION	185
II.	THE CREATION OF THE WORLD TRADE ORGANIZATION (WTO) AND THE TRIPS AGREEMENT	186
III.	PATENT BREAKING AND COMPULSORY LICENSING	190
IV.	COUNTRIES RESPOND TO TRIPS AND COMPULSORY LICENSING	192
V.	CHALLENGING THE CIPRO PATENT	198
VI.	UNITED STATES ANTHRAX SCARE FURTHER THREATENS BAYER AG	200
VII.	DOHA DECLARATION AND THE FUTURE	203
VIII.	CONCLUSION	208

I. INTRODUCTION

The concern over protection of Intellectual Property has been an issue for over 500 years. The basis behind the issue is to promote innovation by restricting competition, thus, guaranteeing the return of investments into research and development. This represents a very delicate balance between the corporations and individuals discovering these new ideas and the people that might benefit from them. The inventor is rewarded for his innovation with an exclusive right to sell the product and collect profits. This issue becomes increasingly sensitive when dealing with rights to patents of medicines held by corporations, but needed by millions of people with serious diseases. The cost of development of the drugs is high, but the demand is even higher, although the most needy of the people are typically not the ones that can afford them.

The United States, along with the other developed countries of the world, stands for strict protection of intellectual property rights. With the creation of

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the World Trade Organization, developing countries facing health crises, such as HIV/AIDS, were given a forum to express their concerns and needs for cheaper alternatives to the costly drugs produced by mostly American corporations. Although agreements were signed that provided options for these developing nations, trade pressure and legal threats by the United States and other developed nations prevented these options from being fully utilized.

Then came September 11th and the anthrax outbreaks, and suddenly it seemed as though the United States was singing a different tune. The United States warned that it would use the same options against Cipro manufacturer, Bayer AG, that it had prevented developing and least-developed countries from relying on to receive cheap AIDS drugs. The rest of the world was in an uproar over the United States' double standard and the full repercussions from this act have yet to be fully realized.

II. THE CREATION OF THE WORLD TRADE ORGANIZATION (WTO) AND THE TRIPS AGREEMENT

The Paris Convention, established in 1883, was the first important international treaty offering the protection of patents and other intellectual property.¹ It was based upon a national treatment principle in which the patent owner was only granted rights in the patent granting country.² As a result, an inventor who wanted to protect his invention in multiple countries had to file for patent protection in each country which he wanted protection.³ The main weakness of the Convention was that it did not require standardized patent laws among the participating countries and it offered no enforcement remedies in cases of infringement.⁴

Although the Paris Convention did go through several revisions, laws protecting intellectual property rights remained the same for nearly one hundred years. With the advent of many new technologies in the later parts of the twentieth century, public policy demanded greater intellectual property rights.⁵ The Uruguay Round, which represented seven and a half years of negotiations ending in 1994, is considered the largest series of trade negotiations that have

1. John A. Harrelson, IV, Note, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WID. L. SYMP. J. 175, 178 (2001).

2. *Id.* Belgium, Brazil, France, Ecuador, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain, Switzerland, Tunisia, and the United Kingdom approved the Convention in 1884 and the United States ratified it in 1887. *See id.*, *infra* note 24.

3. *Id.*

4. *Id.* at 179.

5. Rochelle Cooper Dreyfuss, Comment, *Coming of Age with TRIPS: A Comment on J.H. Reichman, The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 33 CASE W. RES. J. INT'L L. 179 (2001).

ever occurred.⁶ The first round of the negotiations occurred at a ministerial meeting of the General Agreements on Tariffs and Trade (GATT) members in Punta del Este, Uruguay.⁷ The importance of intellectual property rights to the United States' economy was just then being fully realized and the dominant countries were in agreement that more protection was better and that changes would always come in the direction of the intellectual property rights.⁸

The conclusion of the Uruguay Round negotiations culminated with the signing of the Marrakesh Agreement⁹ in April 1994.¹⁰ The Agreement established the World Trade Organization (WTO) and on January 1, 1995, it took effect.¹¹ One of the agreements, signed as part of the Marrakesh Agreement, was the Trade-Related Aspects of Intellectual Property Rights (TRIPs).¹² The 1995 agreement globalized trade rules, including setting up universal intellectual property rights.¹³ The TRIPs agreement is considered the most comprehensive and influential agreement on international intellectual property rights and it establishes the minimum standards on copyrights and related rights, including computer programs and databases, trademarks, geographical indications, industrial designs, patents, integrated circuits, and trade secrets.¹⁴ Every WTO member or country wishing to join the Organization was required to set up patent offices and legislate patent laws, protect copyrights, and fight piracy.¹⁵ Article 8(1) of TRIPs stated that members could adopt measures necessary to public health, provided that such measures were consistent with the other articles of the agreement.¹⁶ The treaty allowed that compulsory licenses be granted to countries, which then permitted the making, using, or selling of a design against the patent owner's wishes.¹⁷ Broad

6. *Trading into the Future: The Introduction to the WTO*, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited July 13, 2002). The Uruguay Round is a title used to encompass almost eight years of negotiations that occurred in Punta del Este, Montreal, Geneva, Brussels, Washington, Tokyo and, Marrakesh.

7. *Id.*

8. Dreyfuss, *supra* note 5.

9. *WTO: Marrakesh Agreement Establishing the World Trade Organization, Trade Compliance Center*, available at http://199.88.185.106/tcc/data/commerce_html/TCC_2/WTO_Marrakesh_Agreement.html (last visited June 27, 2002).

10. *Trading into the Future: The Introduction to the WTO*, *supra* note 6.

11. *Id.*

12. GATT Multilateral Trade Negotiations (the Uruguay Round): Agreement on the Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 (1994) [hereinafter TRIPs].

13. Carlyn Kolker, *Doing the Doha Shuffle – At a WTO Meeting, Nations Agreed to Break Pharmaceutical Patents During Emergencies. Or did They?*, THE AM. LAW., Feb. 2002.

14. Carlos M. Correa, *Life after the Agreement*, BUS. LINE, Mar. 11, 2002.

15. Kolker, *supra* note 13.

16. See TRIPs, *supra* note 13, at art. 8(1).

17. Kolker, *supra* note 13.

discretion was permitted by the agreement for determining when compulsory licenses would be afforded; it was up to the individual country to determine what situation required a compulsory license.¹⁸

The agreement created new conflicts within developing countries because the protection of intellectual property rights was not a part of the culture of many countries.¹⁹ One hundred seventeen nations signed the TRIPs agreement allowing intellectual property rights to be enforced by trade sanctions, despite this lack of tradition.²⁰ Although they had reservations about strengthening their intellectual property rights, many developing countries signed the TRIPs agreement because they were concerned about their own economic growth and participation in the WTO was essential for them to accomplish this.²¹

The TRIPs agreement took effect January 1, 1995, but under the agreement, WTO members had a transition period in which to comply with the obligations required by the agreement.²² Developed countries had until January 1, 1996 to comply, whereas developing countries had until January 1, 2000, and the least-developed countries had until January 1, 2006 to come into full compliance.²³ The goal of the agreement was the development of a framework for insuring the requirement of intellectual property protection was met, while allowing those countries facing a national health crisis to be able to provide adequate and cost effective treatments and medicines to combat the emergency.²⁴

The United States was reluctant to sign the agreement as it was against compulsory licensing, but did eventually sign.²⁵ Many countries already had compulsory licensing laws, but were reluctant to use them for fear of upsetting the intellectual property community.²⁶ The United States pharmaceutical industry lobbied against the TRIPs agreement, relying on the “slippery slope” argument, a legal fiction, believing that once one country was awarded a compulsory license, then all developing or least-developed countries would

18. *Id.*

19. Harrelson, *supra* note 1, at 176.

20. *Id.*

21. *Id.*

22. Committee Report, Scope of the Committee: *Intellectual Property as They Relate to International Trade Agreements such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the North American Free Trade Agreement (NAFTA), and the World Trade Organization (WTO)*, 2000 A.B.A. SEC. INTELL. PROP. L. REP. 263.

23. *Id.*

24. Markus Nolff, *Compulsory Patent Licensing in View of the WTO Ministerial Conference Declaration on the TRIPS Agreement and Public Health*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 133, 137 (2002).

25. Kolker, *supra* note 13.

26. *Id.*

request licensing.²⁷ There are two main responses to this argument: first, that the HIV/AIDS crisis is at epidemic proportions with millions dying from the disease and its complications; and second, that the pharmaceutical industry lobbied intensely to prevent the TRIPs agreement from incorporating the rules on compulsory licensing and lost the fight; the law was approved and actions are legal.²⁸

The result of the agreement is that compulsory licenses may be granted to countries to protect public health so long as the measures adopted are necessary to protect public health and are consistent with the provision of TRIPs.²⁹ The first provision, "necessary to protect public health," must be given effect before any adopted measures can be held to be consistent with the provisions of TRIPs.³⁰ Consistent with the provisions of TRIPs" means consistent with all of the other applicable provisions of the Agreement; anything that affects availability, maintenance, and revocation or forfeiture of patents must be in agreement with the other relevant TRIPs articles.³¹ Exceptions to the exclusive rights of a patent holder without authorization by the owner must be in agreement with TRIPs articles 30 and 31.³² A basis for a potential infringement cannot be public health, if it merely has an incidental effect on public health, for the concern is to prevent anti-competitive behavior and abuse of patent rights.³³

There must be a balance between the measure taken, namely exclusion of patent protection, and public health. The AIDS/HIV crisis was the perfect, albeit most controversial, case for the restriction of patent protection, especially the anti-retroviral AIDS drugs.³⁴ The concern for these drugs is that the regimen must be followed closely, eating food and drinking water at the correct times, and taking the drugs in the correct order and at the right times.³⁵ Refusing to do so could result in the generation of more resistant strands of the virus, which creates a serious problem in underdeveloped countries where citizens lack the proper amounts of food and water.³⁶ Some people even feel that it may be more

27. Frederick M. Abbott, *Discontinuities in the Intellectual Property Regime: The TRIPs – Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WID. L. SYMP. J. 71, 72 (2001).

28. *Id.*

29. See TRIPs, *supra* note 12, at art. 8(1).

30. Nolff, *supra* note 24, at 136.

31. *Id.*

32. See TRIPs, *supra* note 12, at art. 30, 31. Comparison of Article 30 of the TRIPs agreement to Article XX of the GATT Agreement suggest that measures taken under the TRIPs agreement using the public health theory cannot arbitrarily or unjustly discriminate against countries that have the same conditions or are a "disguised restriction on international trade." See Nolff, *supra* note 24, at 136.

33. Nolff, *supra* note 24, at 137.

34. *Id.*

35. *Id.* at 138.

36. *Id.*

cost effective to improve sanitary conditions, basic public health care, and raising public and government awareness.³⁷

One main weakness in the TRIPs agreement is an absence of adequate enforcement remedies in developing countries.³⁸ Most likely, the court used to resolve a dispute will be in a developed country, but the country in which the infringement took place would be a less developed country.³⁹ "Choice of law" rules in this area are underdeveloped themselves; jurisdictional issues may result in judgments that do not protect anyone's interests.⁴⁰ Countries that only have intellectual property laws because of their joining the WTO do not have a history of analysis of the law to allow the developed country to understand how its laws are intended to apply.⁴¹ Courts may even be inclined to harmonize the law between the developed and less developed countries, leading the court to apply precedents of the developed country to the less developed country.⁴²

III. PATENT BREAKING AND COMPULSORY LICENSING

According to Article 31 of the TRIPs agreement, compulsory licensing is the "use of subject matter without the authorization of the right holder."⁴³ Article 31 allows WTO members to use these patents, including use by governments or third parties authorized by a government. Subsection (b) mentions two uses: (i) "national emergency or other circumstances of extreme urgency;" and (ii) "public non-commercial use."⁴⁴ Public non-commercial use has been implicitly described as use by a government contractor, by or for the government, and is referred to as the "non-commercial use exception."⁴⁵ This exception is not one used for compulsory licensing of pharmaceuticals.

Each WTO member has the right to grant compulsory licenses and the freedom to determine the grounds upon which to grant them; the country must still meet the general and specific requirements applicable for granting of a

37. *Id.*; See Treatment Action Campaign and Others v. Minister of Health and Others, 2001 SACLR LEXIS 95 (2001). The President of South Africa, Thabo Mbeki, concluded that HIV was not the primary cause of AIDS and determined that the distribution of Nevirapine, a drug given to HIV infected pregnant women to prevent the passing of the virus to their child, was not necessary. In the case, the High Court of South Africa ordered the government to provide the drug to the HIV-positive mothers, which was being donated to South Africa free of charge by the manufacturer.

38. Dreyfuss, *supra* note 5.

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.*

43. See TRIPs, *supra* note 12, at art. 31.

44. *Id.*

45. Nolff, *supra* note 24, at 140.

compulsory license.⁴⁶ Subsection (b) of Article 31 requires that compulsory licensing can only be granted once “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions have not been successful within a reasonable period of time.”⁴⁷ This requirement can be waived in times of national emergency or other circumstances of extreme urgency. If the measure is needed in times necessary to public health, but not in an extreme emergency, then there must have been efforts to come to reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable amount of time.⁴⁸

Although the term “compulsory license” is not used in the TRIPs agreement, Article 31 of the agreement, when read in conjunction with Article 2(1) and Article 5.A.2 of the Paris Convention, is understood to mean that WTO members may grant compulsory licenses.⁴⁹ The provision created by the Paris Convention states that such measures should be taken to “prevent abuses which might result from the exercise of the exclusive rights conferred by the patent...”⁵⁰ Governments, including the United States, have interpreted this requirement liberally to allow the authorizing and granting of compulsory licenses in a wide variety of contexts.⁵¹

One of the arguments by developing countries against compulsory licensing is that the proceedings to be awarded a license are very costly and protracted, imposing substantial barriers that many countries seek to avoid.⁵² Even under administratively streamlined procedures, compulsory licenses are subject to pharmaceutical company opposition and can lead to trade pressure from the United States; these serve to deter humanitarian programs, which act merely to serve public health needs in distant countries.⁵³ Also, imposing fees for compulsory licenses on countries that do not even have patent laws means that a pharmaceutical company that does not have a patent in a certain country is going to benefit from its use.⁵⁴

There are arguments for compulsory licenses that favor developing countries. The argument says that sales of the drugs will increase, offsetting the lower pricing of the drugs, so long as a reasonable fee is granted and

46. *Id.*

47. *Id.*; See TRIPs art. 31(b).

48. *Id.* at 142.

49. Abott, *supra* note 27, at 74.

50. *Id.* See Paris Convention for the Protection of Industrial Property, 1967, article 5(A)(2).

51. *Id.*

52. *Pan-Africa; U.S. Post-Doha Conditions Can Kill*, AFRICA NEWS, Mar. 4, 2002 [hereinafter *Pan-Africa*].

53. *Id.*

54. *Id.*

pharmaceutical manufacturers will not be significantly harmed.⁵⁵ Developing countries only account for ten percent of pharmaceutical profits internationally, and Africa accounts for only 1.6 percent.⁵⁶ Therefore, compulsory licensing could result in the promotion of additional sales without impacting the ability of pharmaceutical companies to make profits to support research and development.⁵⁷

One alternative to compulsory licensing is parallel importing. With parallel importing, a country can search the global market for the best deal on a patented product, as frequently, a drug manufacturer will sell a product at a drastically different price depending on location.⁵⁸ A distributor in a higher priced location can obtain drugs from a country with lower prices and then compete with the manufacturer in the higher priced market.⁵⁹ By parallel importing, a country can use free market forces to obtain the best price, thus, preventing the need for domestic manufacturing capabilities, currently a TRIPS requirement.⁶⁰

The mere threat of the generic production of patented drugs is often all that is needed to achieve discounted prices. Developed countries use compulsory licensing laws, which are complex and rarely used, as bargaining power for national governments against the drug producers.⁶¹ Developing countries can also use generic manufacturers as a negotiating tactic to reduce the price of brand-name drugs.⁶² Also, developing countries have contracted with pharmaceutical companies to build their own domestic production facilities to achieve technology transfer and increase their own technical capacity.⁶³

IV. COUNTRIES RESPOND TO TRIPS AND COMPULSORY LICENSING

Tens of millions of Africans have HIV/AIDS, but only 10,000 to 15,000 can afford medicines at their full price, even when treatment is partially subsidized by private medical plans.⁶⁴ On June 12, 2001, Kenya passed a law making it only the second country in Africa to legalize generic versions of patented drugs against HIV/AIDS, just after President Moi declared the disease a national disaster.⁶⁵ Parliament passed the Industrial Property Bill of 2001,

55. Harrelson, *supra* note 1, at 191.

56. *Id.*

57. *Id.*

58. *Id.*, at 192.

59. *Id.*

60. Harrelson, *supra* note 1, at 192.

61. Michael A. Gollin, *Practice Focus*, LEGAL TIMES, Nov. 5, 2001, at 31.

62. *Id.*

63. *Id.*

64. *Pan-Africa*, *supra* note 52.

65. *Kenya; Nairobi can manufacture, import HIV/Aids drugs*, AFRICA NEWS, Nov. 26, 2001.

allowing both parallel importing and production of generic anti-retroviral drugs; Kenya is a WTO member and this created much discord with the Organization.⁶⁶ The Public Health Administer said that the anti-retroviral (ARV) drugs needed by patients could not be imported and distributed free of charge due to the extremely high prices.⁶⁷ The purpose of the Bill was to replace a previous bill, and to allow Kenya to comply with the TRIPs agreement.⁶⁸ Kenya is a member of the Paris Convention for the Protection of Intellectual Property and a member of the WTO, and according to the Kenya government, the new bill fully addressed the requirements under the agreement.⁶⁹

South Africa passed the Medicines and Related Substances Control Act of 1997, which permitted the government power to override patents.⁷⁰ Thirty-nine drug companies filed a lawsuit against the government claiming that the new law was unconstitutional.⁷¹ In the litigation against the South African government, the pharmaceutical industry argued that the legislation authorizing the Health Minister to allow parallel importation of generic drugs was too broadly drafted and would allow the Minister to take action beyond that of parallel importation.⁷² To succeed at such a claim, the pharmaceutical industry would have to persuade the South African courts that the TRIPs agreement directly affects South African law, essentially saying that the industry can rely on the terms of the TRIPs agreement as the legislation in the national courts.⁷³ The European Court of Justice previously ruled that TRIPs did not directly affect the law of the European Union and the United States Congress expressly precluded it from having a direct effect on the law of the United States.⁷⁴ The South African constitution had undergone several recent revisions that have affected the way that international treaties influence the national law.⁷⁵ South African Parliament approved the Uruguay Round Agreements of 1995 and did not stipulate specifically that the agreements would have direct effect.⁷⁶ The lawsuit was settled when all thirty-nine drug manufacturers agreed to sell the drugs at significantly reduced prices.⁷⁷

South African and Brazilian officials met to discuss the purchase of generic ARV drugs by South Africa from Brazil at a price more than fifty percent less

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. Kevin Gopal, *Tectonic Shift*, PHARM. EXEC., Apr. 1, 2001 [hereinafter *Tectonic Shift*].

71. *Id.*

72. Abbott, *supra* note 27, at 82.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. Gollin, *supra* note 61.

than the brand name equivalent.⁷⁸ The South African government acknowledged that it might be infringing on patent rights, but it felt that the patent holder's rights should not outweigh the people's access to life saving medicines; the government felt that this was inline with the governmental and international public policy.⁷⁹ The medicines imported from Brazil have patents in South Africa, but the government felt that there is a constitutional right to life and dignity and that providing these drugs to its citizens falls within this right.⁸⁰ The country's concern is that since the drug companies hold monopolies on the drugs, the prices are too high.⁸¹ In response to this, the Medicine Control Council of South Africa immediately approved the use of these generics for the treatment of HIV/AIDS.⁸²

In the late 1990's, Brazil had a problem providing government subsidized access to affordable AIDS drugs and the government responded by passing laws authorizing the domestic production of generic versions of the American drugs.⁸³ United States trade representatives stated, "the United States would use its strength and international laws to modify the situation."⁸⁴ The United States approves the use of compulsory licensing in impoverished countries such as Senegal and Uganda, but in situations such as Brazil, which is considered a middle-income country, the United States believes that Brazil has an adequate gross domestic product and industrial support to afford the brand-name pharmaceuticals.⁸⁵

In 1996, Brazil passed legislation that guaranteed that all AIDS patients would receive state-of-the-art treatment, provided for by the government.⁸⁶ In 1994, the World Bank estimated that by the year 2000, there would be 1.2 million people affected with AIDS; there were only 530,000.⁸⁷ Brazil's use of generic versions of HIV/AIDS drugs, coupled with a national program of education on the disease, directly contributed to this.⁸⁸

A second law passed in 1996 in Brazil declared that any product commercialized before May 14, 1997, would remain unpatented in the country,

78. *South Africa: Cosatu Statement on the Importation of Generic Antiretrovirals From Brazil*, AFRICA NEWS, Jan. 29, 2002.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. Mike Godwin, *Prescription Panic: How the Anthrax Scare Challenged Drug Patents*, REASON FOUND., Feb. 1, 2002.

84. *Id.*

85. *Id.*

86. *Success Story*, PHARM. EXECUTIVE, Mar. 1, 2001 [hereinafter *Success Story*].

87. *Id.*

88. *Id.*

of which most of the first generation anti-retroviral drugs lie.⁸⁹ The prices of the brand-name drugs with Brazilian equivalents have dropped almost eighty percent, whereas drugs without Brazilian generic equivalents have only dropped nine percent.⁹⁰ In 2000, the Brazilian government spent 444 million dollars on AIDS drugs for its citizens, but saved 422 million dollars between 1997-1999 because of the decline of hospitalizations resulting from AIDS-related illnesses.⁹¹

Brazil has even announced that it would be spending considerably more money on research into an AIDS vaccine than it has ever before and plans to work with the nations of Africa to accomplish this.⁹² After receiving international acclaim for its anti-AIDS/HIV programs, Brazil's new victories come from its contentions that drug patents can be waived in cases of public health emergencies.⁹³ In Brazil, it is the government institutes that conduct all the research into the AIDS/HIV programs.⁹⁴ The Far-Manguinhos Institute produces seven of the fifteen medicines now used in the anti-retroviral cocktail offered in Brazil, which has led to many new innovations, and three other drugs are currently being developed.⁹⁵ Brazil's stand is that if the molecules are found to be effective against resistant viruses, the patent will be public and drug industries of any country would be free to produce them.⁹⁶ The institute's situation puts itself in a unique bargaining position for the reduction in price of pharmaceuticals for Brazilian law provides for the granting of compulsory licenses of generic versions of drugs in cases of public health emergencies.⁹⁷ According to the WTO and the TRIPs agreement, compulsory licenses are only permitted in countries that have the production ability, and the Far-Manguinhos Institute provides Brazil with this ability.⁹⁸ The Health Minister of Brazil threatened to ignore several patents and this resulted in a forty to seventy percent reduction in price of two of the anti-AIDS drugs; a third is a new target.⁹⁹

89. *Id.*

90. *Id.*

91. *Success Story, supra* note 86.

92. Mario Osava, *2001-2002: Brazil's Successful Anti-AIDS Efforts Set to Expand*, INTER PRESS SERVICE, Dec. 26, 2001.

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.* Ninety-five percent of the 16,500,800 patents granted in the United States between 1977 and 1996 were awarded to only ten different industrialized countries, while during this period, developing countries only accounted for two percent of the patents. *Correa, supra* note 14.

97. Osava, *supra* note 92.

98. *Id.*

99. *Id.* Brazil also provides education to other countries on how to produce their own versions of the drugs. Angola now has a production facility that was partly funded by Brazil. Brazil is also intensifying

The government now plans on concentrating on the areas that are especially impoverished, like the north and northeast sections of the country.¹⁰⁰ Of the nearly 600,000 Brazilians infected with HIV/AIDS, most of them are not even aware that they have contracted the virus.¹⁰¹ Brazil recognizes the importance of early detection and plans on continuing to produce the cheap generic versions of the ARV combinations of drugs free of charge to its citizens, a cost that does not overstress the national budget.¹⁰²

In June 2001, China completed negotiations with the United States for its accession into the WTO, which would grant China permanent normal trade relation status.¹⁰³ China will be expected to continually comply with its WTO obligations and this will be monitored by United States trade representatives.¹⁰⁴ China is considered a priority foreign country, since it does not maintain proper intellectual property protection, and could have sanctions imposed against it for failing to meet specific standards, of specific importance is compliance with the TRIPs agreement.¹⁰⁵ Before 1985, China awarded no patent protection, as the government awarded inventors of "useful" inventions with a certificate and a cash award; China then became the owner.¹⁰⁶ With the threat of added trade duties on all Chinese imports, China agreed to improve its system of protecting intellectual property, passing laws that were approved on August 25, 2000, and effective on July 1, 2001.¹⁰⁷

China still has changes that it needs to make to come into full compliance with TRIPs. Currently, China does not permit patents on inventions that are prohibited by its country's laws.¹⁰⁸ Additionally, China needs to amend its laws to include the condition that compulsory licenses will be predominately for the domestic market and that adequate remuneration will be provided to the patent

cooperation with China and India, two countries that do not recognize patents and produce generic medicines and chemical substances at low costs. *Id.*

100. *Id.*

101. *Id.*

102. Osava, *supra* note 92.

103. Thomas T. Moga, *China Changes Patent Law to Comply with TRIPS*, NAT'L L. J. (2001).

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.* In 1993, consistent with article 27(1) of the TRIPs agreement, China agreed to the protection of patenting of chemical and pharmaceutical products, as well as food, beverages, and flavorings. The amendments also extended the period of protection from 15 to 20 years, complying with article 33 of TRIPs. They provided for offering for sale as an exclusive right of the patent holder, hence complying with Article 28 of the TRIPs agreement. Also amended was the section of their law that limited the situations where compulsory licenses could be granted, bringing it into compliance with Article 31 of the TRIPs agreement. China also amended its law to provide for injunctive relief against infringement and shifted the burden of proof to the defendant to prove that an infringement did not occur, complying with article 34(1) of TRIPs. *Id.*; See generally TRIPs, *supra* note 12.

108. Moga, *supra* note 103. This expressly violates article 27(2) of TRIPs.

holder in the case a compulsory license is issued.¹⁰⁹ Article 41(1) of TRIPs requires a system of enforcement and remedies in the case of an infringement of a patent, and to conform to these requirements, China must increase criminal penalties and reduce the threshold for minimum damages.¹¹⁰ Considering that China's patent laws are less than twenty years old, the country has shown commitment to compliance with the TRIPs agreement and the desire to be a responsible member of the WTO.¹¹¹

India, through its Indian Patent Act of 1970, abolished all product patents and only recognizes process patents for pharmaceutical purposes.¹¹² Indian manufacturers have an advantage because their manufacturing costs are forty-five percent lower than those in the United States, and the result is that sixty percent of the generics sold in the United States are imports.¹¹³ Additionally, in India, the government has control over maximum pricing of the drugs.¹¹⁴

The United Kingdom, Canada and European Union members all have existing well-developed national patent laws giving maximum protection to their governments.¹¹⁵ The TRIPs provisions are not as far reaching as the existing laws in these developed countries.¹¹⁶ British law is governed by the Patent Act of 1977, which provides for United Kingdom government exemption from the exclusive rights held by patent owners and thus, need not apply for compulsory licenses.¹¹⁷ A patent holder could have its patent invalidated by the Crown.¹¹⁸ The United Kingdom provides tax incentives to companies researching medicines and vaccines for diseases of poverty that could total fifty percent relief in certain situations.¹¹⁹ Under Canadian law,¹²⁰ the government may impose a compulsory license on the patent holder and have generic manufacturers produce the drug, but adequate remuneration must be paid to the patent holder to account for the economic loss.¹²¹

109. *Id.* This would bring China into compliance with article 31(f) and (h).

110. *Id.*

111. *Id.*

112. Bernard D'Mello, *Transnational Pharmaceutical Corporations and Neo-Liberal Business Ethics in India*, 36 J. OF BUS. ETHICS 165 (2002).

113. *Id.*

114. *Id.* Additionally, India, Egypt and Pakistan are not required to adopt the medicine provisions of the TRIPs agreement until 2005. *Medicines: Commission Seeks to Square Poor Country Circle*, EUR. REP., June 15, 2002.

115. Scott Farnsworth, *Opinion: Scott Farnsworth*, THE LAWYER, Apr. 8, 2002 at 17.

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. Patent Act, § 19(4) (1985) (Can.).

121. Shashank Upadhye, *After Cipro Battle, Patent-Busting is Still Live Issue. Attempts at Generic Versions Compulsory Licensing Issues State Infringement?*, 24 NAT'L L.J. (2002).

The United States, home to most of the research-based pharmaceutical companies, has tried to influence countries to adopt patent laws that exceed the minimum provisions of TRIPs and totally exclude compulsory licensing.¹²² Because the United States' economy is increasingly moving away from basic manufacturing into high-technology industries, intellectual property protection has become much more of a concern.¹²³ The United States has labored to discourage foreign governments from breaking pharmaceutical patents and buying unauthorized generics from such countries as China and India, recognized as the two major exporters of unauthorized generic drugs.¹²⁴ As a deterrent, the United States has trade barriers and other various forms of political pressure on non-compliant governments.¹²⁵ Critics state that the United States argument that the TRIPs agreement allows it to prevent developing countries from addressing national health emergencies through the use of parallel importing and compulsory licensing by the imposition of trade sanctions, undermines the political foundations of the WTO itself.¹²⁶ They claim that such steps poison the environment in which negotiations are undertaken, agreements are carried out, and disputes are settled.¹²⁷

A current House bill¹²⁸ will permit generic companies to force a compulsory license from brand-name companies. Under the Affordable Prescription Drug Act, the brand-name drug manufacturer would be forced to license a generic equivalent.¹²⁹ The generic drug company would be required to pay a reasonable royalty to the brand-name company and civil penalties would result from failure to do so.¹³⁰

V. CHALLENGING THE CIPRO PATENT

Bayer AG, a German corporation, owns the 4,670,444 patent (the 444 patent) on the main ingredient of Ciprofloxacin Hydrochloride (Cipro) until 2003, and the 5,286,754 patent (the 754 patent) covering the pharmaceutical formulation of the main ingredient until 2011.¹³¹ In 1997, Bayer settled a patent infringement case in which Barr Labs alleged that Bayer's patents were no

122. Harrelson, *supra* note 1, at 176.

123. *Id.*

124. Godwin, *supra* note 83.

125. *Id.*

126. Abbot, *supra* note 27, at 85.

127. *Id.*

128. House Report HR 1708.

129. Upadhye, *supra* note 121.

130. *Id.*

131. *Id.*

longer valid over prior art.¹³² Part of the settlement included Bayer paying Barr fifty million dollars a year not to produce a generic equivalent to Cipro.¹³³ Bayer instituted a reexamination of the patent and the United States Patent and Trademark Office (PTO) maintained the validity of the patent.¹³⁴ Other generic companies sued under the same theory, but the District Court of New Jersey ruled in favor of Bayer and dismissed the invalidity actions.¹³⁵ Many other generic manufacturers have filed for certification of each patent once the originals expire.¹³⁶

Cipro was the first drug approved by the Food and Drug Administration (FDA) for treatment of anthrax infections, but the last case of anthrax infection occurred in the 1970's.¹³⁷ Cipro's major anthrax testing occurred more than ten years ago by the United States Army biowarfare researchers on rhesus monkeys.¹³⁸ The Persian Gulf War proved beneficial to Bayer, as Cipro was rushed through the FDA approval amongst fears that Saddam Hussein might use anthrax as a biological weapon.¹³⁹ This quick approval was due to Cipro's advantages over other antibiotics.¹⁴⁰ It is not a part of the same family of drugs as penicillin or tetracycline, which means that it would remain an effective antidote against strains of anthrax resistant to penicillin or tetracycline.¹⁴¹ Cipro is the best selling antibiotic in the world and has been since 1991, and in 1999 Bayer's gross sales of Cipro totaled 1.04 billion dollars.¹⁴²

132. *Id.* See *In Re Ciprofloxacin HydroChloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001). Barr first applied for a generic version of Cipro in 1991 and received tentative approval for the generic version in 1995. But by 1997, Barr, along with two other companies, Rugby and Hoechst-Marion Roussel, had come to an agreement whereby Bayer would pay the companies over \$200 million in exchange for the company's promise not to produce generic versions of Cipro. *Consumer Group Challenges Cipro Pact*, 9 No. 6 ANDREWS ANTITRUST LITIG. REP. 9 (2001).

133. *Id.* It was a consumer advocacy group that sued to dislodge the agreement between Bayer and other drug manufacturers that prohibited any generic versions of Cipro to be made. The Prescription Access Litigation project is a group of more than sixty organizations from over twenty-nine states that challenged the agreement. Unlike other challenges in the court at that time, the suit was only seeking injunctive relief, whereas the others were seeking monetary damages. Nick Dutton, *The Price You Pay for Their Patent Protection*, GLASS AGE, Jan. 31, 2002.

134. Upadhye, *supra* note 121.

135. See *Bayer AG v. Schein Pharmaceutical, Inc.*, 129 F.Supp.2d 705 (NJ 2001); *Meyers v. Bayer AG*, 143 F.Supp.2d 1044 (E.D. Wisc 2001).

136. Upadhye, *supra* note 121.

137. Godwin, *supra* note 83.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

142. *Consumer Group Challenges Cipro Pact*, 9 No. 6 ANDREWS ANTITRUST LITIG. REP. 9 (2001).

The United States Code¹⁴³ holds that the government has the authority to infringe on patents.¹⁴⁴ Under this section, the government need not negotiate the patent's use with the owner.¹⁴⁵ The government, or its agents, would have to pay some compensation to the owner, and the government's use cannot be enjoined.¹⁴⁶ The royalty the government has used is based on an eminent domain theory of recovery and is measured by what the patentee has lost rather than what the government has gained.¹⁴⁷

VI. UNITED STATES ANTHRAX SCARE FURTHER THREATENS BAYER AG

Tommy Thompson was the United States Secretary of Health and Human Services at the time of the recent anthrax scare and as such, he was responsible for the health of every American. When problems arise he has the power to require immunizations and quarantines and order the distribution of medicine.¹⁴⁸ Traditionally, the courts defer to the judgment of the Secretary.¹⁴⁹ He also controls governmental spending in areas of scientific research, as well as having the duty to pass on information discovered by the government to the pharmaceutical companies.¹⁵⁰ Above it all, his main objective is to protect the lives of American citizens.¹⁵¹

Following the anthrax scares that occurred in October 2001, and in response to concerns over an inadequate supply of Cipro doses, Thompson's first statement was that the government lacked the statutory authority to grant itself a compulsory license for the generic production of Cipro.¹⁵² It was James Love and Ralph Nader that co-authored a public letter to the Secretary declaring that Title 28, Section 1498, of the United States Code was more than sufficient

143. See 28 U.S.C. § 1498 (2002).

144. See also *Crater Corp. v. Lucent Tech.*, 255 F.3d 1361 (Cir. 2001). Where it was held that 14 U.S.C. § 1498 provides for such authority.

145. Godwin, *supra* note 83.

146. *Id.* The government has even required compulsory licensing for the military on such things as satellite technology and night-vision glasses, using public interest as the main argument. Harrelson, *supra* note 1.

147. *Id.* This is refuted by the pharmaceutical industry as the correct reading of the law. The Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) believes that section refers to "eminent domain" compensation, and that the United States has a greater obligation under the WTO and the TRIPs agreement to work with the drug manufacturer first. *Id.*

148. Matt Fleischer-Black, *The Cipro Dilemma---In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?*, AM. LAW., Jan. 2002.

149. See *Bowen v. Mi. Acad. of Family Physicians*, 476 U.S. 667 (1986); *Furlong v. Shalala*, 238 F.3d 227 (2nd Cir. 2001); *Diagnostic Cardioline Monitoring of N.Y., Inc., v. Shalala*, No. 99-CV-5686 (JS), 2000 U.S. Dist. LEXIS 13443, at 1 (E.D.N.Y. 2000).

150. Fleischer-Black, *supra* note 148.

151. *Id.*

152. Godwin, *supra* note 83.

law to permit the production of generic drugs.¹⁵³ In 1918, a law was passed that gave the government the ability to guarantee that its shipbuilding orders would not be hindered by patent litigation.¹⁵⁴ This law was the authority for Senator Charles Schumer's suggestion that Secretary Thompson allow other drug manufacturers to produce Cipro during the anthrax crisis.¹⁵⁵ Schumer said that the generic versions of Cipro would both reduce the reliance on a sole supplier and could significantly reduce costs.¹⁵⁶ At first, Thompson was concerned about the delicate balance between patent protection and the concern for adequate Cipro supply.¹⁵⁷ He made a statement with regard to this balance, knowing that a month later the WTO would be having a meeting to discuss whether nations have the right to disregard patents to address public health concerns.¹⁵⁸

But there is another law that controls FDA decisions concerning generic drugs, which would prevent the government from buying generic Cipro because it had not first passed final FDA approval.¹⁵⁹ Under the 1984 Hatch-Waxman Act, companies cannot produce generic versions of drugs for thirty months if the patent is not expired and the patent holder opposes the production of generic versions of its drug.¹⁶⁰ These conflicting laws created a very difficult position for Secretary Thompson to be in.¹⁶¹

It was on October 18, 2001, that the Canadian Minister of Health signed a contract with other pharmaceutical manufacturers for the production of Cipro.¹⁶² His reasoning was for the sufficiency of Canada's stockpile and Bayer's ability to provide an adequate supply.¹⁶³ Canada's position was that if Bayer could not produce, then Health Canada, the national health care system, would be forced to use its supply of generic equivalents.¹⁶⁴ The next day,

153. *Id.*; See also 28 U.S.C. § 1498 (2002).

154. Fleischer-Black, *supra* note 148. See The Act of June 25, 1910, c. 423, 36 Stat. 851, as amended by The Act of July 1, 1918, c. 114, 40 Stat. 704. See also *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbing Co.*, 246 U.S. 28 (1918).

155. *Id.* Simply put, the law said that the federal government could take license for itself, so long as the patent holder was provided with adequate compensation. *Id.*

156. Lawrence B. Ebert, *Where Have You Gone, Richard K. Lyon?*, INTELLPROP TODAY, Dec. 2001.

157. Fleischer-Black, *supra* note 148.

158. *Id.*

159. *Id.*

160. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

161. Fleischer-Black, *supra* note 148.

162. *Id.*

163. *Id.*

164. Ebert, *supra* note 156. Canada's Health Minister commissioned a generic manufacturer to produce a million doses of Cipro even as Bayer assured that it could supply Canada's needs. Upadhye, *supra* note 121. As well, there had been no anthrax outbreaks in Canada. *Id.* It was questionable whether Canada's action was "necessary to protect public health," as required under Article 8(1) of the TRIPs agreement. *Id.* It seemed that the Health Canada official who ordered the generic Cipro did not get prior approval from the

Thompson started threatening Bayer by saying that he would have laws changed so that he could break the Cipro patent.¹⁶⁵ Soon after, Canada brokered a deal with Bayer to purchase Cipro at a significantly reduced price; this allowed Thompson to do the same, effectively saving the country eighty-two million dollars, as well as preventing certain future litigation.¹⁶⁶ Thompson later stated at a Congressional hearing that the issue was price and not the supply.¹⁶⁷

The pharmaceutical industry believed that even if Bayer was unable to meet the demand for Cipro at that time, the best decision was to still contract with Bayer.¹⁶⁸ Bayer could then meet the new demand by licensing the Cipro to other manufacturers, allowing Bayer to maintain its long-term value.¹⁶⁹ Bayer could set the prices of the private transactions and still meet the demands of the government during a public health crisis.¹⁷⁰

Politicians and the media were greatly concerned over the possibility of "busting" Bayer's patent on Cipro so that an alleged shortage of the drug could be supplied.¹⁷¹ In a traditional drug patent-busting lawsuit, a generic drug company will file with the FDA an abbreviated new drug application (ANDA) on the drug, claiming that its generic version is basically the same as the brand-name drug.¹⁷² This could have been a possibility for breaking the Cipro patent.¹⁷³ Normally, if the generic version is the same, then the ANDA will be approved and a generic equivalent will enter the market.¹⁷⁴ The most common type of application is a Paragraph IV ANDA certification, which says that the applicant seeks immediate permanent approval because either the generic will not infringe, or the patent is invalid.¹⁷⁵ Under United States law,¹⁷⁶ a brand-

Patent Commissioner of the Ministry of Industry. *Id.* Godwin, *supra* note 83. Additionally, no national emergency had been declared. Godwin, *supra* note 83. It was an Indian company that offered to sell the generic Cipro at one-twentieth the cost. Gollin, *supra* note 77.

165. Fleischer-Black, *supra* note 148.

166. *Id.*

167. Ebert, *supra* note 156.

168. Godwin, *supra* note 83.

169. *Id.*

170. *Id.*

171. Upadhye, *supra* note 121.

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.* There are also Paragraph I, II, and III ANDA certifications. Paragraph I certification said that the drug had not been patented. Paragraph II certification meant that the patent had expired. Paragraph III certification meant that the date on which the generic equivalent will go on the market will be after the date which the patent will expire. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, available at <http://www.oblon.com/Pub/seeker.php3?hatchwax.html> (last visited on July 15, 2002).

176. See 35 U.S.C.S. § 271(e)(2)(A)(B).

name drug manufacturer can sue a generic drug company that files a Paragraph IV ANDA certification.¹⁷⁷

The Bayer chief executive stated that Bayer would not give Cipro away to the United States because if it had done so, then it would have to give it away to all the other countries sharing the United States ideals, because they would be threatened as well.¹⁷⁸ Seven other antibiotics were offered for free from their manufacturers, including Bristol-Meyers Squibb's Tequin and Johnson & Johnson's Levaquin, which are in the same family as Cipro, but have yet to be approved for use against anthrax.¹⁷⁹ The two companies stated that they each would donate 100 million tablets to the United States if they could receive automatic approval for use against anthrax.¹⁸⁰

When Secretary Thompson threatened to override the Cipro patent, he claimed that this was in compliance with the TRIPs agreement.¹⁸¹ If the United States government had used Article 31 of the TRIPs agreement to grant compulsory licenses for the eighteen cases of anthrax, then poorer countries would use that decision to extort compulsory licenses of the AIDS cocktail drugs to treat the millions of cases of AIDS.¹⁸² The economy of drug licensing would be disrupted, as research and development profits are returned to the companies through sales in developed countries.¹⁸³ The developed countries help to offset lower prices in poorer countries, but profits are lost when compulsory licenses are used as a threat by developed countries seeking to reduce the prices of drugs to generic levels.¹⁸⁴

VII. DOHA DECLARATION AND THE FUTURE

On November 14, 2001, the WTO members met in Doha, Qatar for a ministerial conference to discuss specifically international intellectual property rights under the TRIPs agreement. The Ministerial Declaration reaffirmed that each WTO member has the right to determine what constitutes a national emergency or other extreme urgency, as required under the TRIPs agreement before a compulsory license can be granted.¹⁸⁵ Paragraph 1 of the Declaration

177. Upadhye, *supra* note 121.

178. *Bayer's Reasons for not Giving Cipro Away; USA Slammed for "Double Standards,"* MARKETLETTER, Nov. 12, 2001 [hereinafter *Bayer's reasons*]. Bayer did donate eight million Cipro tablets to the front-line workers involved in the anthrax crisis.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Bayer's reasons, supra* note 178.

183. *Id.*

184. *Id.*

185. See Ministerial Conference, Nov. 14, 2001, MINISTERIAL DECLARATION [hereinafter Ministerial Declaration].

specifically lists AIDS/HIV, tuberculosis and malaria.¹⁸⁶ Although the Declaration does not define a public health crisis, the examples provided help to narrow the scope. Paragraph 4 states that the TRIPs agreement does not and should not prevent members from taking measures to protect public health.¹⁸⁷ Paragraph 5(b) states that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.¹⁸⁸ This provides a presumption of validity to a WTO member determining that a national health emergency exists.¹⁸⁹ Additionally, this represents a shift of “balance of rights and obligations” away from the patent owner.¹⁹⁰ Under threat of compulsory licensing, a patent holder will be persuaded easier by a WTO member to conclude a licensing agreement.¹⁹¹

Both health activists and the pharmaceutical industry see the Declaration as a victory.¹⁹² The Declaration drew on drafts provided by two opposite sides of the issue: one from developed nations, and the other from sixty developing nations.¹⁹³ The first side recognized that intellectual property protection is important for the development of new medicines.¹⁹⁴ The second side relied more on the TRIPs agreement’s effect on drug prices, saying that it should not prevent members from taking measures to protect public health.¹⁹⁵ The final version stated that compulsory licensing need not be restricted to pandemics, as the United States-led draft suggested.¹⁹⁶ The compromise reached recognized the problem that countries having little or no manufacturing ability would not be able to make effective use of compulsory licensing.¹⁹⁷ Activists and

186. *Id.* at ¶ 1.

187. *Id.* at ¶ 4.

188. *Id.* at ¶ 5(b).

189. Nolff, *supra* note 24, at 144.

190. *Id.*, at 145.

191. *Id.*

192. Kevin Gopal, *New Accord: A WTO Declaration on the TRIPs Agreement Affirms Countries’ Right to Protect Public Health Through Access to Medicines for All*, PHARM EXEC., Jan. 1, 2002 [hereinafter *New Accord*].

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. Dubey Muchkund, *Implications of Doha for India – II*, THE HINDU, Dec. 25, 2001. India played a major role in creating a degree of unity and cohesion between the developing countries and had wanted to include in the declaration a provision allowing parallel importation of drugs from other developing countries, but this was not accepted. *Id.*; India’s National Working Group on Patents felt that the Declaration had not diluted the TRIPs agreement in favor of the least-developed countries in any way. Currently, most of India’s 22,000 drug companies are small local pharmaceutical manufacturers, and TRIPs compliance will force between 50-75 percent of them out of business by the year 2015. It is estimated that by 2025, only 200-250 will remain. *Indian Pharma’s Mixed Views on Doha Declaration on TRIPs and Public Health*, MARKETLETTER, Dec. 10, 2001.

developing nations said that the Declaration clarified the interpretations of the ambivalent agreement.¹⁹⁸

Within the context of the Ministerial Declaration, in order to grant a compulsory license in times of public health emergencies, it is required that the license is necessary to protect public health and address a public health crisis, authorization of the license must be considered on its individual merits, and the right holder must be notified.¹⁹⁹ The scope and duration must be limited to the purpose for which it was authorized, and must be liable to be terminated if and when the circumstances, which led to it, cease to exist and are unlikely to recur.²⁰⁰ Underdeveloped countries and private sector advocates see the new declaration as a way out of the AIDS crisis and other health emergencies, but they still realize that it is a battle of lives versus money.²⁰¹

The Ministers did oppose a proposal recommended by the developing countries that countries without manufacturing ability could import medicines made under compulsory licenses in another country.²⁰² This creates the situation where many developing countries cannot make use of compulsory licenses.²⁰³ They do not have manufacturing ability, which is a requirement for granting a compulsory license.²⁰⁴ It is estimated that only ten of the one hundred thirty developing members of the WTO can use compulsory licenses to manufacture their own drugs.²⁰⁵ Article 31(f) of the TRIPs agreement imposes the requirement that production under compulsory licenses must be predominately for the domestic market.²⁰⁶ One of the options proposed to deal with the developing countries with little or no domestic manufacturing ability is to remove the requirement completely from Article 31(f), but this was not done.²⁰⁷ Another option was to interpret Article 30 of the agreement to mean that products made under compulsory licenses can be exported to developing countries facing public health problems that lack the domestic production capacity.²⁰⁸

The World Health Organization (WHO) and the Commission of European Communities welcomed the Doha Declaration and the pro-public health

198. *New Accord*, *supra* note 192.

199. Nolff, *supra* note 24, at 143.

200. *Id.* at 141.

201. Kolker, *supra* note 13.

202. *New Accord*, *supra* note 192.

203. *Campaigners Urge Action on Poor Countries' Access to Cheaper Drugs*, AGENCE FRANCE PRESSE, Mar. 28, 2002.

204. *Id.*

205. *Id.*

206. *TRIPS Meeting Examines Drug Licensing Hitches*, BUS. LINE, Mar. 14, 2002; *See also* TRIPs article 31(f).

207. *Id.*

208. *Id.*; *See also* TRIPs article 30.

approach it had.²⁰⁹ The WHO and the European Commission (EU) have agreed to work closely with the WTO and the World Intellectual Property Organization (WIPO) on technical assistance to developing countries implementing the TRIPs agreement, believing that global cooperation is required so that generic manufacturers can provide the lowest prices on a sustainable basis to the poorest countries.²¹⁰ The European Commission is proposing an exception to the TRIPs agreement that allows WTO members to export generic drugs produced under compulsory licenses to developing countries without quantitative limits, so that countries without production capability can rely on other countries for its supply.²¹¹ The European Union even proposed an option amending the TRIPs agreement to include for the export of medicines to poorer countries.²¹² The EU is also proposing a global tiered pricing system for certain pharmaceutical products in the poorest countries.²¹³ Tiered pricing is used in some countries, but the push is to use it for all developing countries.²¹⁴

The TRIPs agreement was not altered or amended, but the Declaration merely acted as a suggestion for how to interpret the agreement.²¹⁵ Medicines are treated as any other commodity, but the declaration says that since they save lives, their patents should have different standards applied.²¹⁶ Drug companies rely on the fact that the agreement was not amended and, therefore, the agreement still stands as it did before.²¹⁷ Drug companies do hold the upper hand because they can stop the research into new drugs when they lose confidence on the payoffs.²¹⁸

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) pointed out that the Declaration was political rather than a legal or binding instrument, but did agree that the final version reflected the balanced interest to encourage innovation in drug therapies and vaccines, while seeking to promote improved access to medicines.²¹⁹ The European Federation of Pharmaceutical Industries and Associations (EFPIA) said that it welcomed the Declaration's confirmation that the TRIPs agreement was flexible enough to

209. *Commission and WHO Join Forces to Tackle Health Threats*, RAPID, June 6, 2002.

210. *Id.*

211. *Id.*

212. *Id.*

213. *Tectonic Shift*, *supra* note 70.

214. *Id.*

215. Kolker, *supra* note 13.

216. *Id.*

217. *Id.*

218. *Id.*

219. *Pharma Industry View's WTO's "Political" Doha Declaration on TRIPS*, MARKETLETTER, Nov. 26, 2001 [hereinafter *Pharma industry*].

take account of public health concerns and that intellectual property protection is vital for the development of new medicines.²²⁰

The United States position opposing an easing of TRIPs had been undermined by Washington's threat, just before the meeting, to break Bayer's patent on Cipro, unless the drug company lowered the price.²²¹ The international community felt that this represented a double standard by the United States.²²² The United States had previously received criticism for calling on the WTO to rule that Brazil's legal requirement that patent holders must produce patented products in the country, rather than have them imported, was in violation of WTO.²²³ Brazil was in fact, given much credit for brokering the Declaration and this gave Brazil more assurance to confront the abusive pricing of brand-name drugs.²²⁴

The United States is also trying to limit the countries that could benefit from the production-for-export exception.²²⁵ The United States wishes to limit the applicability of the rule to small market countries for fear that small rich countries will benefit.²²⁶ This will affect many small African countries that are considered small market because they have small populations and have a low number of people that can afford the drugs.²²⁷ In reference to AIDS and other diseases of poverty, the production-for-export exception may be the only way to get these countries affordable medicines, for they do not have their own production capacity.²²⁸ The United States is also trying to exclude the larger developing and middle-income countries because they are considered an area of future growth for the patent pharmaceutical industry.²²⁹ By limiting the conditions, which would warrant a compulsory license to only "serious" health conditions, the other much needed medicines, such as expensive antibiotics and diabetes medicines, are excluded.²³⁰ The main concern over the exception in the United States is that the "production-for-export" medicines will find their way back into the United States and be sold on the American market.²³¹

220. *Id.*

221. *Id.*

222. *Id.*

223. *Id.*

224. *Pharma Industry, supra* note 219.

225. *Pan-Africa, supra* note 52.

226. *Id.*

227. *Id.*

228. *Id.* Some even believe that the exception would even benefit the United States and EU countries in cases of orphan diseases. These diseases have small incidence and require orphan drugs at exorbitant prices. Additionally, this could be used for bioterrorism or epidemic outbreaks in developed countries to import the drugs needed. *Id.*

229. *Id.*

230. *Pan-Africa, supra* note 52.

231. *Id.*

It is important to provide access to affordable medicines both through the public and private sectors.²³² First, existing workplace clinics of larger employers provide considerable capacity to the private sector through benefits to employees.²³³ Since ARV medicines have not been reduced in price in the private sector, employers are refusing to supply them to employees.²³⁴ Second, medical aid plans that extend to both the private and public sectors have benefit limits that make it impossible to pay for ARV medicines unless they have been heavily discounted.²³⁵ Third, non-governmental organizations (NGO) and mission hospitals, which are included in the private sector, have in place the ability to deliver high quality treatment and care, but only if the drugs are made more affordable.²³⁶

The shift of balance of rights and obligations, created by the Declaration, away from the patent owner has already resulted in more favorable agreement for purchases of pharmaceuticals by governments than might have been possible.²³⁷ Possibly the biggest impact of the Ministerial Declaration is that the threat of a compulsory license will make it easier for a WTO member to persuade a patent holder to concede a licensing agreement.²³⁸

VIII. CONCLUSION

The need for affordable drugs in developing countries due to the AIDS crisis has further defined the contrast between these countries and the developed nations such as the United States. Although the United States does have an AIDS problem, it does not see the same high percentage of infections as do the lower income less-developed countries. Developing countries that do have high infectious rates may see this as a lack of compassion by the United States for the crises affecting their countries.

The United States, through a concern for returned investments of large corporations, may have lost sight into what the founding fathers based the country on: the protection of life, liberty, and the pursuit of happiness. AIDS in America is still seen mostly as a disease among homosexuals and, therefore, the government may be more concerned with profits rather than human lives, but the countries in Africa and South America do not have the same ideals. They are using whatever means they have to get free medicines to the millions of their citizens afflicted with a disease that will surely end their life and any

232. *Id.*

233. *Id.*

234. *Id.*

235. *Pan-Africa*, *supra* note 52.

236. *Id.*

237. Nolff, *supra* note 24, at 145.

238. *Id.*

chance at happiness. The irony found behind the anthrax attacks and the United States' reaction to them is that Americans now have a fear that they never had before; whereas developing countries facing the AIDS crises may have more hope for the future than ever before.