

COMMENTS

The Influence of Disease on the Evolution of U.S. Patent Law and Policy Towards Foreign Patent Laws in the Late Twentieth to Early Twenty-First Century

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I.	INTRODUCTION	227
II.	THE EVOLUTION OF PATENT LAW.....	229
A.	<i>The Spotlight Is Directed Towards Pharmaceutical Patents.....</i>	230
B.	<i>South Africa's Medicines and Related Substances Control Act of 1997: The First Strike Against Pharmaceutical Patents and the Resulting International Lawsuit for Protection of Pharmaceutical Patents.....</i>	234
C.	<i>The September 11, 2001 Terrorist Attack and the October 2001 Anthrax Attacks: The Foundation Is Unknowingly Laid for Change in U.S. Patent Policy and the U.S. View Towards International Patent Law.....</i>	239
D.	<i>The First Step Towards Change: The Doha Declaration.....</i>	242
III.	THE FUTURE OF PATENT LAW IN THE UNITED STATES WITH THE MID-2004 AMENDMENT TO TRIPS.....	244
IV.	CONCLUSION: WHAT'S NEXT?	247
V.	RECENT UPDATES	247

I. INTRODUCTION

In 1883, patents were officially protected by an international treaty at the Paris Convention.¹ There have been numerous changes to patent law since then as events have shaped our world such as industrialization, the discovery of Penicillin, and the landing on Mars in January 2004, to

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1. 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, 178 (2001).

name just a few. Patent law is one-third of a trinity that encompasses intellectual property law. Trademark and copyright are property rights like patent law, and were also protected by the Paris Convention.² Patent law is distinguished from the trinity because unlike trademarks or copyrights, patents can be a matter of life and death. Life-saving drugs are patented by the companies that create them. Patented pharmaceuticals can save a life, and a life can be lost if the patented pharmaceutical is not used. As Lynn Woods succinctly stated, patent law can be described as “the Price of Life.”³ Thus, patent law has a history and a future distinct from trademark and copyright law. Patent law’s future will be a matter of life and death for many people around the world, especially in countries ravaged by the AIDS epidemic.

The United States does not face an AIDS epidemic of such immense proportion as Africa. But what if the United States did face such an epidemic, or even just the threat of an epidemic? What if there were a biological terrorist attack? What if the mere economic and political unrest in another country due to an epidemic or public health emergency could harm the United States indirectly through trade relations? Would the United States have different patent laws as a result? Some of these questions have been answered as recently as August 2003, when United States President Bush announced the United States’ new stance on low-cost drugs to poor countries, while other questions still wait to be answered. Patent law is waiting, dormant if you will, while the United States decides its new patent law and policy regarding foreign patent laws, based on the events of the past ten years that can no longer be ignored.

The purpose of this Comment is not to answer all of the above questions, but to raise more questions by examining how the United States has behaved thus far towards domestic and foreign patent law in the wake of the AIDS epidemic in the 1990s, the biological terrorist attacks in 2001, and the international trade agreements since 1995 and as recently as 2004. Hopefully, we can finish answering the lingering questions. The biggest question of all is whether patent law and policy will survive as we know it, where invention and innovation are awarded above all else, while people die without needed medication. The only answer that I see to that question is illustrated by a recent trend towards finding our humanity. In the face of epidemics and national catastrophes, our sense of humanity is stronger than our desire for money. Or

2. *See id.*

3. Lynn Woods, *Government AIDS Effects Target Drug Makers, Pharmaceuticals Act to Stop Backlash Against Their IP Rights*, BUS. WITHOUT BORDERS, Aug. 18, 2000, at col. 1.

maybe, the evolution of U.S. patent law and policy is being driven by the simple and innate fear for our own lives. No longer does the strict patent policy of using exclusivity as the means for innovation lead the pharmaceutical industry. Perhaps now, fear is the new driving force for change and evolution in patent law and policy. Regardless of the motivation for change, this Comment will examine the evolution of patent law and policy in the United States since 1995 in order to help determine the future trend in the United States and how the United States will relate to other countries.

II. THE EVOLUTION OF PATENT LAW

Article 1, Section 8, Clause 8 of the United States Constitution states that the purpose of Intellectual Property law is “[t]o promote the Progress of . . . useful Arts.”⁴ The reason for patent law in the United States is two-fold. First, a person who develops an invention should be rewarded for the effort and retain a property right in the creation.⁵ Subsequently, this reward and property right promotes innovation,⁶ encouraging private funding of research and development of new drugs.⁷ Second, society should benefit from the invention. Thus, the inventor will publicly disclose his invention to society so that society can improve on the invention in exchange for the reward.⁸

Other countries either do not base their patent law on the above principles or do not have a formal patent law system at all.⁹ Many developing countries have not formalized an intellectual property law system that encourages or even provides *any* patent protection. Developing countries, unlike the United States, do not conduct a lot of scientific or technological research, and thus there are very few people requesting patent protection.¹⁰ Also, most countries’ laws state that the country merely has to protect foreign drug companies to the same degree

4. U.S. CONST. art. I, § 8, cl. 8.

5. Harrelson, *supra* note 1, at 187.

6. Andrew Beckerman-Rodau, *Patent Law—Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 14 (2002).

7. *Id.* at 22.

8. Harrelson, *supra* note 1, at 187.

9. Thomas F. Mullin, *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*, 9 ILSA J. INT’L & COMP. L. 185, 188 (2002).

10. Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT’L TRADE L.J. 57, 60 (2002).

that they would protect their own local drug companies.¹¹ Due to the discrepancy between U.S. patent law and the patent law of the rest of the world (like developing countries), the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) took effect on January 1, 1995,¹² in order to create some sort of world agreement. Since many developing countries did not have any patent law, developing countries were given until 2006 to add to or significantly change their patent laws to fully conform to TRIPS.¹³

A. The Spotlight Is Directed Towards Pharmaceutical Patents

The TRIPS agreement is meant to normalize international intellectual property law, including patent laws relating to pharmaceuticals.¹⁴ Fundamentally, TRIPS requires all members, which originally included 117 countries,¹⁵ to grant patents for pharmaceutical drugs.¹⁶ TRIPS not only harmonized patent law, but also connected patent law with international trade.¹⁷ Intellectual property activists wanted an agreement, like TRIPS, because they viewed intellectual property protection outside the United States as a hindrance to the success of U.S. international trade.¹⁸ The United States was not the only beneficiary to the TRIPS agreement, nor was the United States the only supporter. Although developing countries lacked the fertile economic climate of developed countries, developing countries also wanted to protect their countries' technologies.¹⁹ Therefore, at the time of conception, TRIPS was viewed by many as a good compromise and a beginning for the formation of an international intellectual property system that would satisfy everyone.

Adhering TRIPS member countries must follow the guidelines of TRIPS so as to maintain the compromise that was negotiated, but TRIPS

11. Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 *FORDHAM L. REV.* 1133, 1145 (2002).

12. Robert Weissman, *AIDS Drugs for Africa*, 20 *MULTINATIONAL MONITOR* 9, Sept. 1999, at <http://multinationalmonitor.org/mm1999/99sept/aids.html>.

13. John S. James, *WTO Accepts Rules Limiting Medicine Exports to Poor Countries*, *AIDS TREATMENT NEWS*, Sept. 12, 2003, at 2, available at <http://www.aids.org/atn/a-394-01.html>.

14. Susan K. Sell, *Proceedings of the 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance? TRIPS and the Access to Medicines Campaign*, 20 *WIS. INT'L L.J.* 481, 481 (2002).

15. Harrelson, *supra* note 1, at 175.

16. *Id.*

17. *Id.* at 179.

18. Sell, *supra* note 14, at 481.

19. Ansari, *supra* note 10, at 60.

does not directly determine the patent law of the European Union or the United States.²⁰ In fact, TRIPS only establishes uniform *minimum* standards of protection that the members must implement.²¹ The minimum standards were outlined in TRIPS so that developing countries could begin to follow the patent law system of more developed countries, like the United States.²² The United States arguably has the strictest intellectual property law of all the members of TRIPS, so it would be very difficult for countries with no patent law to suddenly create a strict-U.S. patent law system in their own country.

TRIPS is a more “open” document than first perceived. Underlying the TRIPS provisions is the idea that members should have flexibility in their implementation of TRIPS provisions.²³ Thus, TRIPS contains guidelines for patent protection, but once the member countries have implemented the minimum standards as stated in the TRIPS guidelines, the members may format their patent system to fit their country’s public health and economic needs.²⁴ Some of the minimum standards of intellectual property protection include the rights of the patent owner to prevent unauthorized people from using, making, or selling their patented invention. There is also a twenty-year patent protection minimum.²⁵ Due to the lack of stricter provisions other than the two mentioned above, a member country can interpret and implement TRIPS liberally when considering their own public health and economic needs or emergencies.²⁶ Not surprisingly, there has been a ferocious debate about the TRIPS agreement before and after its 1995 implementation mainly because of differing views as to how strict protection laws should be.

There are two sides of the debate over the TRIPS agreement, even though the TRIPS agreement reflects compromise by both sides of the debate.²⁷ One side believes that the minimum standards for patent

20. Mullin, *supra* note 9, at 193.

21. J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT’L LAW. 345, 351 (1995).

22. *Id.*

23. Arnaldo Lacayo, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 304 (2002).

24. Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1311 (2002).

25. Lacayo, *supra* note 23, at 301.

26. Christopher K. Eppich, *Patenting Dilemma: Drugs for Profit Versus Drugs for Health*, 43 SANTA CLARA L. REV. 289, 297 (2002).

27. Reichman, *supra* note 21, at 351.

protection stated in the TRIPS agreement are insufficient, while the other side views the TRIPS rules as too “strict, U.S.–style.”²⁸ The U.S. pharmaceutical industry is arguably the harshest critic to TRIPS and has ardently encouraged all member countries to follow the “strict, U.S.–style” patent rules. The U.S. pharmaceutical industry objected to TRIPS because of the climate of the U.S. economy.

The U.S. economy is not surprisingly extroverted and trade between other countries is vastly important to its vitality. In particular, forty percent of the income of the U.S. pharmaceutical industry comes from exporting its pharmaceuticals.²⁹ The U.S. companies are most likely to export to countries that are members of TRIPS since there are 117 member countries. Consequently, the U.S. companies want their buyers to conform to TRIPS. The U.S. pharmaceutical industry continues to put significant pressure on TRIPS members to adhere to and expand the TRIPS provisions because intellectual property has been a rapidly growing field since TRIPS was implemented in 1995.³⁰ The greatest concern of the U.S. pharmaceutical industry is that countries to which they export will only implement the *minimum* standards stated in TRIPS, or perhaps will not even implement the minimum standards if the country can argue that there is an emergency or public health need. Thus, the pharmaceutical industry has been the leader in trying to stop practices like compulsory licensing in TRIPS member countries that the industry thinks are below the minimum standards that the U.S. government would support.

Compulsory licensing is one practice that TRIPS members have tried to use many times. Compulsory licensing allows a government to force a patent holder to grant licenses to local makers of the drug, who ultimately sell the drug at much lower prices.³¹ The U.S. government views compulsory licensing as an exceptional practice that should not be the norm.³² The concern of the U.S. government and the U.S. pharmaceutical industry is that, if one country is allowed to use compulsory licensing, then other countries will want to as well. The result would be a

28. Weissman, *supra* note 12.

29. Harrelson, *supra* note 1, at 183.

30. Mullin, *supra* note 9, at 198.

31. Kara M. Bombach, *Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement*, 19 B.U. INT'L L.J. 273, 276 (2001).

32. See Murthy, *supra* note 24, at 1308 (noting the limited number of compulsory licensing provisions in the United States).

“slippery slope,”³³ since all countries would want their local manufacturers to make the drug at a cost ninety percent cheaper than importing from patent holder manufacturers (who are primarily U.S. companies).³⁴ The TRIPS agreement regulates the use of compulsory licensing by member countries.³⁵ Normally, if a country wants to use compulsory licensing, then it must explain why and try to obtain the permission of the patent owner; however, if a country claims that there is a national emergency, the above process can be waived.³⁶ Thus, the U.S. pharmaceutical industry argues that there will no longer be incentive for U.S. companies to invest in research and create new drugs.³⁷ The benefit that the inventor receives for his work and the economic sacrifice he made to create the drug will not be rewarded as it should under a proper intellectual property law system. Thus, the industry asks: who will want to compete with a company that has nothing to show for its success?³⁸ Competition that drives new innovations could be lost!

Although the U.S. pharmaceutical industry has strong arguments, the counter-arguments against many of the strict rules that the U.S. government and U.S. pharmaceutical industry have imposed have been voiced equally, albeit not as forcefully due to the lack of U.S. government support and the funding that wealthy companies have. One argument made against the U.S. pharmaceutical industry’s push for stricter patent law and stricter enforcement of the TRIPS provisions is that the reward given for research and funding is not meant to exceed reasonable monetary boundaries.³⁹ Also, there are existing limits to patentability such as novelty, subject matter, and nonobviousness that have prevented material from being patented. Yet these limits have not prevented or hindered companies’ relentless pursuit to find the next valuable drug.⁴⁰ Another argument by the opposition is that TRIPS standards are only beneficial to countries and companies with a large income.⁴¹ Developing countries that are TRIPS members are quick to point out that although the United States might have viewed the TRIPS provisions as inadequate, many countries felt that the TRIPS provisions were “out of their reach.”⁴²

33. Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 72 (2001).

34. Bombach, *supra* note 31, at 276-77.

35. Harrelson, *supra* note 1, at 181.

36. *Id.*

37. Bombach, *supra* note 31, at 282.

38. Beckerman-Rodau, *supra* note 6, at 20.

39. Bombach, *supra* note 31, at 283.

40. *Id.* at 284.

41. Ansari, *supra* note 10, at 60.

42. *Id.*

These countries continued to feel the pressure to conform to TRIPS and also to conform to the “strict, U.S.-style” patent rules that were *not* expressly stated in TRIPS.

The fierceness of the debate over TRIPS continued to progress for many years after 1995 because of an interesting provision of the TRIPS agreement. Article 27(1) of TRIPS permits member countries to negotiate amongst themselves for stricter patent laws and thus grant greater patent protection between their countries.⁴³ Perhaps without this provision, the events following the TRIPS implementation in 1995 would not have occurred. The United States may not have continued to be as relentless as it was in its pursuit to change the patent laws that member countries implemented had that provision of TRIPS not existed. The first stand against the United States’ relentless pursuit to have stricter, U.S.-style patent law in all TRIPS member countries occurred not more than two years after TRIPS was in effect. The first stand was made by a country that could no longer be bullied by the United States to conform to strict U.S.-style patent law, as will be discussed shortly.

In conclusion, the formation of TRIPS in 1994 and its implementation in 1995 had little to no impact on U.S. patent evolution. The U.S. patent system was unchanged at this time. Instead the United States deliberately tried to change world patent law and policy to fit its own law. The formation of TRIPS is merely the starting point in the U.S. evolution to watch and see how U.S. patent law and policy towards foreign patent law evolve. The extreme position of the United States at this time will help to show the sometimes dramatic change to U.S. patent law and policy that occurred after 1995. Perhaps due to the United States’ stubbornness and forcefulness in trying to make other countries’ patent law resemble U.S. patent law, the United States in fact set the stage for evolution by its very own actions. By pushing and bullying other countries, someone would eventually push back and instead cause change in *U.S.* patent law. The first change occurred in 1997.

B. South Africa’s Medicines and Related Substances Control Act of 1997: The First Strike Against Pharmaceutical Patents and the Resulting International Lawsuit for Protection of Pharmaceutical Patents

While TRIPS was negotiated and implemented, scientists in the United States and abroad were working feverishly trying to find a cure

43. Eppich, *supra* note 26, at 299.

for AIDS, referred to as the “Modern Black Death.”⁴⁴ Millions of men, women, and children worldwide were already infected with AIDS and the numbers were increasing daily. Once the United States acknowledged that AIDS was not a disease that solely affected the homosexual community in the 1980s, governments and international organizations started to recognize the importance and gravity of the disease. Pharmaceutical companies and national health organizations also began to recognize the importance and began to look for a cure, if there was one. In 1995, scientists first demonstrated that a “cocktail” of drugs known as “highly active anti-retroviral therapy” could slow the progress of the debilitating disease.⁴⁵ This was a historic breakthrough in the fight against AIDS. It was a breakthrough, however, that only the truly wealthy or lucky could afford. The average cost for the drugs per year was \$16,000.⁴⁶ Many people in the United States were able to benefit from this “cocktail” therapy, but the countries that were being decimated by the disease, particularly sub-Saharan Africa where at least twenty-five million people were infected,⁴⁷ could not afford the drugs. As one author pointed out, the humanitarian framework of U.S. foreign policy towards infectious diseases in the twentieth century persisted *until* the AIDS epidemic was recognized.⁴⁸ The AIDS epidemic and the South Africa Medicines and Related Substances Control Act amendment in reaction to the AIDS epidemic were the turning point for the evolution of patent law and policy in the United States.

In 1997, South Africa was one of the countries hardest hit by AIDS and thus passed the Medicines and Related Substances Control Act Amendment,⁴⁹ affectionately known as “the Bill.”⁵⁰ The amendment allowed the government to do what was necessary to ensure that more infected citizens could get AIDS drugs,⁵¹ including the “cocktail” therapy as stated in the Preamble of the Bill, “to provide for measures for the supply of more affordable medicines in certain circumstances.”⁵² No one was quite sure what exactly the health minister of South Africa would be able to do or not do in relation to compulsory licensing, parallel imports,

44. David P. Fidler, *Racism or Realpolitik? U.S. Foreign Policy and the HIV/AIDS Catastrophe in Sub-Saharan Africa*, 7 J. GENDER RACE & JUST. 97, 100 (2003).

45. Zita Lazzarini, *Access to HIV Drugs: Are We Changing the Two World Paradigm?*, 17 CONN. J. INT'L L. 281, 283-84 (2002).

46. *Id.* at 284.

47. Abbott, *supra* note 33, at 71.

48. Fidler, *supra* note 44, at 107.

49. Mullin, *supra* note 9, at 192-93.

50. Bombach, *supra* note 31, at 274.

51. Ferreira, *supra* note 11, at 1148-49.

52. Bombach, *supra* note 31, at 276.

or abrogating patent rights when the Bill was passed.⁵³ Reactions to the Bill were nothing short of a full-fledged temper tantrum by pharmaceutical companies in the United States and abroad.

Forty multinational pharmaceutical companies and the South African Pharmaceutical Manufacturers Association sued the government of South Africa in order to stop the implementation of the amendment because the companies did not want to have to grant a license to a country that would market a generic version of a patented drug for nearly a tenth of its original price.⁵⁴ What could possibly have been their reason for suing a government that was merely trying to help stop the AIDS epidemic as best they could? The companies argued that the amendment violated TRIPS, an agreement to which South Africa was a member.⁵⁵ The companies also argued that the TRIPS agreement directly affected South African law.⁵⁶ The companies objected to practices like compulsory licensing and parallel importing, that the South Africa Medicines Act amendment appeared to permit, because both practices limited the control that the pharmaceutical companies would have over the drugs they created,⁵⁷ thereby reducing their profit margin.

Although the pharmaceutical companies made effective and forceful arguments, protestors to the lawsuit and supporters of South Africa's amendment had their own arguments. South Africa only intended the law to allow generic substitution during this time of "national emergency," as South Africa interpreted TRIPS to permit.⁵⁸ Also, South Africa vehemently argued that it is the government's duty to protect the health of its citizens,⁵⁹ and this amendment was merely furthering that goal by not allowing drug companies to charge whatever they want for drugs nor to bully a market that represents a small percentage of the total market for the pharmaceutical companies' drugs.⁶⁰

However strong South Africa's arguments may have been, the forty pharmaceutical companies not only had vast amounts of money to continue the lawsuit, but they also had the active support of the U.S. government. The U.S. government attempted to conform South Africa

53. See generally Simon Barber, *Stars & Stripes—SA Between a Rock and a Hard Place on TRIPS Arrangement*, BUS. DAY (S. Afr.) Aug. 18, 1999, at 2, available at 1999 WL 21400088 (discussing the South African health minister's ill-defined authority).

54. Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 30 (2000).

55. Bombach, *supra* note 31, at 274.

56. Mullin, *supra* note 9, at 193.

57. Weissman, *supra* note 12.

58. Ferreira, *supra* note 11, at 1150.

59. *Id.* at 1150-51.

60. Weissman, *supra* note 12.

patent law to the more strict U.S.-style provisions that were not necessarily articulated in TRIPS itself, but that were supported by the U.S. government.⁶¹ The U.S. government never articulated what specific provisions of TRIPS the South Africa Medicines Act amendment violated, but nevertheless insisted that TRIPS was potentially being violated,⁶² since companies' intellectual property rights must not be infringed and a company must be able to charge what it needs to pay for the cost of research.⁶³ The U.S. government is the watchdog to ensure that patent rights of its citizens are not infringed.⁶⁴ It is not surprising that the U.S. government did not think that it needed to explain what TRIPS provisions were violated because TRIPS was viewed as an "untidy compromise" and lacking in the stricter provisions that the United States favors in its patent law system.⁶⁵ The methods the U.S. government used against South Africa to make South Africa repeal their amendment have been characterized as nothing short of "bullying."⁶⁶ A February 1999 report from the United States Department of State con-firmed that all relevant agencies of the U.S. government were involved in an "assiduous, concerted campaign" to modify the amendment.⁶⁷ The U.S. government even put South Africa on the Special 301 Watch List in May of 1998.⁶⁸ This was perhaps the most significant thing that the U.S. government did. The U.S. government was not just supporting pharma-ceutical companies in a lawsuit, but was now going so far as to threaten South Africa with trade sanctions if it did not comply with the demands of the pharmaceutical companies and U.S. government to not implement the amendment.⁶⁹

Just as quickly as the South African amendment and the subsequent lawsuit erupted onto the international scene with such fervor, the dispute ended. In September 1999, the U.S. government stated that it would stop pressuring South Africa and permit it to get the AIDS drugs it needed by any means necessary.⁷⁰ Later, in April 2001, the pharmaceutical companies settled with South Africa and withdrew their lawsuits.⁷¹ Why the

61. Ferreira, *supra* note 11, at 1152-53.

62. *Id.* at 1152.

63. Weissman, *supra* note 12.

64. *See generally* Ferreira, *supra* note 11, at 1152-53 (discussing the United States' initial opposition).

65. Barber, *supra* note 53, at 2.

66. Weissman, *supra* note 12.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. Ferreira, *supra* note 11, at 1156.

sudden change by the U.S. government and later the pharmaceutical companies when many legal analysts believed that the drug companies had a strong case?⁷² United States Vice President Al Gore might have stated it best, “We tend to think of a threat to security in terms of war and peace. Yet no one can doubt that the havoc wreaked and the toll exacted by HIV [and] AIDS do threaten our security.”⁷³ Thus, without the support of the powerful U.S. government, pharmaceutical companies were now alone to support their patent rights.⁷⁴ Some commentators felt that the U.S. government did not bring about the change in U.S. policy towards South Africa, but rather that the AIDS activists who were relentless in their pursuit to educate the United States and the world about the AIDS epidemic changed it.⁷⁵ Pharmaceutical companies could no longer stand on their legal arguments concerning patent law rights and TRIPS when a developing country was trying to save millions of lives by using more affordable AIDS drugs.⁷⁶ Nor could the U.S. government ignore the threat that the AIDS epidemic in Africa posed to U.S. trade.⁷⁷ The U.S. government backed down from bullying South Africa, but there was still no official stance by the U.S. government towards Africa and its AIDS epidemic.

On May 10, 2000, the Clinton Administration issued Executive Order No. 13,155, 65 Fed. Reg. 30521,⁷⁸ and that signified the new U.S. government stance towards foreign nations. United States President Clinton’s executive order was an official stance by the President of the United States to allow sub-Saharan African countries to use necessary strategies, like compulsory licensing, to fight the AIDS epidemic. Thus, South Africa was influential in the first visible change in U.S. patent policy.

The U.S. patent laws themselves did not change, but the policy surrounding the U.S. patent laws began to change. Policy is what shapes the words of law, including patent law. The U.S. government acquiesced to South Africa’s health emergency and the necessity to use compulsory

72. Stephen Ward, *Pharmaceutical Rights Under Threat, Drug Patents: International Agreements Allowing Access to Patented Medicines Have Faced Their First Test*, FIN. TIMES (London), June 11, 2001, available at 2001 WL 25827926.

73. Betsy Pisik, *Gore Calls AIDS a Security Threat Will Seek \$150 Million for African Programs*, WASH. TIMES, Jan. 1, 2000, at A1, available at 2000 WL 4145832.

74. Ward, *supra* note 72.

75. Weissman, *supra* note 12.

76. Sarah Boseley, *Struggle for Cheap Medicines: AIDS Drugs War Between the Big Firms and the Poor Countries*, THE GUARDIAN (London), Nov. 27, 1999, at 15.

77. Barton Gellman, *A Conflict of Health and Profit; Gore at Center of Trade Policy Reversal on AIDS Drugs to S. Africa*, WASH. POST, May 21, 2000, at A1.

78. Sell, *supra* note 14, at 508-09.

licensing and parallel importation, which are practices disliked by the strict U.S. patent law system. The U.S. patent policy awakened to a new sense of duty. The U.S. government's duty regarding patent law was no longer to support the pharmaceutical companies through exclusive rights to control the drugs they create and the high prices they could charge. Perhaps this stage of the evolution of U.S. patent law signifies a change in the duty of the government; the duty to protect has shifted from those who *make* patented products to those who *need* them.

C. The September 11, 2001 Terrorist Attack and the October 2001 Anthrax Attacks: The Foundation Is Unknowingly Laid for Change in U.S. Patent Policy and the U.S. View Towards International Patent Law

September 11th was an event that most Americans never expected and will never forget. It took away our sense of security, but most importantly it took thousands of lives. The attacks changed the United States socially, economically, politically, and perhaps even biologically. September 11th changed our lives in more ways than we can recognize at first glance, and U.S. patent law was not immune to its effects either. After September 11th, it seemed as though terrorists were surrounding the United States threatening another day of catastrophe or threatening attacks in new ways that most of us were not expecting. The October 2001 anthrax "attacks" were one way that directly and irrevocably changed U.S. patent law and the United States' understanding of foreign patent law relating to similar biological threats.

After the September 11th attacks, the United States reported numerous anthrax attacks, most notably at the Capitol building in Washington, D.C.⁷⁹ Suddenly, the United States faced a new kind of attack: a biological entity that could only be fought by containment and medication. The government was quick to act. Containment was reached by evacuating and decontaminating buildings, and isolating individuals suspected of infection. During containment, there was massive public fear of the possibility of anthrax infection. The public demanded anthrax medication. The public demand and fear of anthrax was not helped by the shortage of anthrax drugs. Bayer AG Corporation held the patent for the popular anthrax drug, Cipro.⁸⁰ Generic versions of Cipro would not be permitted under U.S. patent law for a number of

79. Lacayo, *supra* note 23, at 313.

80. Murthy, *supra* note 24, at 1315.

years, even though five or six other companies were already qualified to sell generic versions of Cipro.⁸¹

As a result of the public outcry for anthrax drugs, the U.S. government bullied Bayer AG Corporation. The U.S. government told Bayer that it would have to lower its price for medication or the government would issue a compulsory license for Cipro.⁸² Basically, the U.S. government was going to “override” a patent (i.e., sidestep and appropriate the right to a private patent),⁸³ but ultimately the U.S. government effectively overturned its stance of strict patent protection (as illustrated during the South Africa Medicines Act Amendment issue).⁸⁴

The U.S. government has the ability and the sanctioned right to appropriate patent rights under certain situations, like war.⁸⁵ Also, other government agencies, like the National Institute of Health, have included means to appropriate patent rights in their practice.⁸⁶ Although the U.S. government has the sanctioned power to appropriate patents in certain situations, when a patent owner is not adequately compensated, suits in the United States Court of Federal Claims are possible under 28 U.S.C. § 1498.⁸⁷ “Just compensation” is still an extremely important debate that has not been resolved yet.⁸⁸ Thus, in the wake of the 2001 anthrax attacks, the U.S. government was threatening years of hard-lined patent protection due to one “minor” disease attack that only infected twenty-two people and killed five,⁸⁹ as compared to the millions infected with and millions more killed by AIDS.

Not surprisingly, countries criticized the United States and called the United States a hypocrite.⁹⁰ Why shouldn't Africa and other countries criticize the United States when the United States had fought relentlessly for years against countries using compulsory licenses because it was perceived as a violation of TRIPS?⁹¹ Under 28 U.S.C. § 1498, the U.S.

81. Donald G. McNeil, *A Nation Challenged: The Drug Rush for Cipro, and the Global Ripples*, N.Y. TIMES, Oct. 17, 2001, at A1.

82. Murthy, *supra* note 24, at 1315.

83. Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 127 (2002).

84. Mullin, *supra* note 9, at 186; *see also* discussion *infra* Part II.B.

85. Cahoy, *supra* note 83, at 135-36.

86. *Id.* at 135.

87. *Id.* at 140.

88. *Id.* at 151.

89. David P. Fidler, *Bioterrorism, Public Health, and International Law*, 3 CHI. J. INT'L L. 7, 21 (2002).

90. *See* Gardiner Harris, *Questions of Security: Bayer Is Accused of Profiteering on Cipro*, WALL ST. J., Oct. 26, 2001, at A6 (discussing past U.S. efforts to preclude patent seizures by poor nations coping with the AIDS pandemic in Africa).

91. Murthy, *supra* note 24, at 1315.

government has the power to issue a compulsory license,⁹² but the government did not want to use that power *until* the anthrax attacks. Most likely, the U.S. government recognized that, if it used compulsory licenses, then other countries would want to as well. Thus, the question still remains, if the United States can use compulsory licensing when only twenty-two people are infected with a virus, then shouldn't countries with millions infected with a virus like AIDS also be able to use compulsory licensing?⁹³

In a moment of *déjà-vu*, as quickly as the Cipro patent crisis began, it ended when Bayer agreed to triple its production of Cipro⁹⁴ and lower its price of the drug.⁹⁵ A spokesman for the Pharmaceutical Research and Manufacturers of America replied to Bayer's acquiescence, "[i]t means making some compromises."⁹⁶ It would appear again that just before the U.S. government would have to make a critical choice that would affect its patent law and policy towards foreign patent laws as was seen during the South Africa Medicines Act Amendment issue, the United States was given a stay of execution and did not have to publicly change its patent policy. Perhaps like Bayer, the United States has learned that compromises may need to be made. However, unlike the South Africa AIDS crisis, where the United States through Clinton's Executive Order publicly and officially recognized Africa's need to protect its public health, the United States learned during the anthrax crisis that compromises must be made very quickly when *U.S.* public health in particular is affected. The United States also learned during this evolutionary stage that compromises must be made without delay, between strictly holding patents against a threat to U.S. public health and the pharmaceutical companies' rights to a profit.

At this stage of the legal development, the United States was standing on a precipice of change and, although no public change to U.S. patent law and policy was stated by government officials, the evolution of patent law was continuing forward. Unlike the South Africa Medicines Act Amendment issue, the United States was the principal cause of its own change in patent law and policy this time. There was a quick decision that the United States had to make and the choices were these: "the U.S. will respect the patent right, even if it means en-

92. 28 U.S.C. § 1498 (2000).

93. Murthy, *supra* note 24, at 1315.

94. Tom Cohen, *Canada Agrees to Buy Cipro from Bayer*, AP ONLINE, Oct. 23, 2001, available at 2001 WL 29336130.

95. Cahoy, *supra* note 83, at 127.

96. Harris, *supra* note 90, at A6.

dangering public health,”⁹⁷ or the United States could bend the patent laws until they are effectively broken when there is a U.S. public health crisis. Although the U.S. government did not have to “override” Bayer’s patent, the U.S. government most likely would have, thereby favoring public health and the lives of its citizens over protecting patent rights and the profits of pharmaceutical companies.⁹⁸ The United States was starting to understand the arguments of the African countries, which had been fighting for the health of their citizens. By recognizing those arguments, U.S. patent law and policy continued evolving.

D. The First Step Towards Change: The Doha Declaration

Preceding the anthrax attacks, the U.S. political arena had already taken charge in changing patent law and policy in the United States, and the United States had progressed in its evolution from a strict policy stance to a more understanding world leader. Although the United States did not have to officially change its patent law or policy during the anthrax attacks in 2001, as already noted, the United States would most likely have overridden Bayer’s patent for Cipro.⁹⁹ Thus, U.S. patent law and policy towards foreign patent laws would have changed, and the next stage of the evolution would have been very visible. A visible and official change in U.S. policy did occur, however, in November of 2001 in Doha, Qatar, where members of TRIPS met to discuss ambiguous terms in TRIPS, such as “compulsory licensing” and “national emergency,”¹⁰⁰ and to discuss countries’ access to essential drugs through tools like compulsory licenses that had not been clearly defined in TRIPS.¹⁰¹ As always, members of TRIPS would be negotiating and compromising.¹⁰²

The meeting in Doha, Qatar, in November of 2001 occurred while the South Africa Medicines Act amendment case and the anthrax crises were still taking place.¹⁰³ Those events helped to shape the Doha Declaration. This would be the first step by the United States to agree,

97. Wendy Lim, *Towards Developing a Natural Law Jurisprudence in the U.S. Patent System*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 559, 605-06 (2003) (quoting Matt Fleischer-Black, *The Cipro Dilemma*, AM. LAW., Jan. 8, 2002, <http://www.law.com>).

98. James Thuo Gathii, *Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-Terrorism: An Analysis of In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 13 ALB. L.J. SCI. & TECH. 651, 657-58 (2003).

99. See discussion *infra* Part II.B.

100. Murthy, *supra* note 24, at 1320.

101. *Id.* at 1322.

102. See Helene Cooper & Geoff Winestock, *WTO Envoys Agree to Ease Access to Key Drugs*, WALL ST. J., Nov. 13, 2001, at A17 (discussing participation by 142 countries in the WTO).

103. Murthy, *supra* note 24, at 1315-16.

officially and publicly, to a change in not only world patent laws and policy, but also in *U.S.* patent law and policy by agreeing to the Doha Declaration. The Declaration did clarify the meaning of terms in TRIPS like “national emergency” and “epidemic.” It also reaffirmed and emphasized that TRIPS is an agreement meant to reasonably protect intellectual property¹⁰⁴ and is not meant to prevent members from protecting the public health of their citizens.¹⁰⁵

Similar to TRIPS, the Doha Declaration was not accepted automatically and without argument. Although more recently the United States was less strict concerning patent policy and more understanding of epidemics abroad and in the United States, the United States still wanted to maintain the policy of promoting intellectual property protection. The arguments by the pharmaceutical companies were the same as before.¹⁰⁶ The arguments were also the same by the countries needing a more lenient and understanding patent policy in TRIPS.¹⁰⁷ Although the arguments were the same for and against a stricter or more lenient patent policy in TRIPS, events such as U.S. acquiescence to South Africa’s Medicines Act amendment, President Clinton’s Executive Order, and the 2001 anthrax attacks, changed the climate surrounding the arguments. Thus, the Doha Declaration as adopted on November 14, 2001, was practically a mirror-image of what the developing countries wanted.¹⁰⁸ Not only would countries be able to help their citizens obtain drugs for major pandemics like AIDS, but they would also be able to break patents for diseases like cancer, diabetes, and even asthma.¹⁰⁹ The Declaration did not answer all questions and solve all problems, but it was a major first step toward change in the U.S. patent policy. The Declaration states, “we agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”¹¹⁰ Therefore, by agreeing to this international Declaration, the United States was also agreeing to change its own patent policy.

In conclusion, the Doha Declaration helped to clarify the TRIPS agreement, which began evolutionary changes to U.S. patent law and

104. *Id.* at 1331.

105. See generally Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT’L L.J. 101, 104 (2003) (discussing how developing countries could not avail themselves of the flexibility in TRIPS because of pressure from interested groups).

106. See discussion *infra* Part II.B.

107. *Id.*

108. Ansari, *supra* note 10, at 63.

109. Helene Cooper & Geoff Winestock, *Tough Talkers: Poor Nations Win Gains in Global Trade Deal as U.S. Compromises*, WALL ST. J., Nov. 15, 2001, at A1.

110. Sell, *supra* note 14, at 516.

policy in 1995. This stage of the evolution of U.S. patent law is subtle. The United States is still internally torn between strict and lenient patent protection and understanding patent protection in the face of public health crises. This stage of the evolution merely solidifies what the evolutionary stage was during the Cipro incident. The United States could not stand by its historically strict stance on supporting patents above everything else when faced with public health crises. Thus, now the patent owner (most notably a U.S. pharmaceutical company) will more likely acquiesce to a licensing agreement and be persuaded by the legitimate and now possible threat of compulsory licensing by member countries.¹¹¹ Since the United States agreed to the Doha Declaration, the evolution of U.S. patent policy towards foreign patent laws will reflect the U.S. ability to be more easily persuaded to bend its patent protection when faced with a member country threatening compulsory licensing. The United States has officially and visibly agreed to put public health above patent rights,¹¹² unlike during the South Africa Medicines Act amendment and the Cipro incident.

III. THE FUTURE OF PATENT LAW IN THE UNITED STATES WITH THE MID-2004 AMENDMENT TO TRIPS

Since the Doha Declaration, the climate in the United States has changed dramatically. One author noted how the decreasing economy after the 2001 terrorist attacks and the anthrax incidents alone “tested” the U.S. patent system.¹¹³ The U.S. war in Iraq has also continued to test the U.S. patent system. The evolutionary stage, as seen in the Doha declaration, where the United States was open to all types of less strict rules is over. The United States has found a more level medium of agreement as to what it is willing to support. On August 30, 2003, the United States was a member of negotiations of the World Trade Organization that adopted new rules concerning patented drugs.¹¹⁴ A permanent amendment to TRIPS is due sometime in 2004 to reflect the WTO organization agreement.

The United States and the developing countries were participants in the recent 2003 negotiations and both parties agreed to make AIDS drugs and other medications more available to poor countries.¹¹⁵ However

111. Mullin, *supra* note 9, at 204.

112. Fidler, *supra* note 44, at 112.

113. Sridhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 168 (2003).

114. James, *supra* note 13.

115. *Id.*

noble the United States and the pharmaceutical companies (who were not surprisingly major players in this negotiation) might appear, the agreement reached by the WTO is more expansive in the rights given to the United States than was agreed to in Doha a few years back. In fact, the Doha Declaration was supposed to be implemented through the August 30, 2003, agreement,¹¹⁶ but that is not what occurred. The United States was given the freedom to do whatever necessary when there is a biological attack or epidemic.¹¹⁷ Developing countries, however, were not given this unlimited freedom. Although it seems that the United States was the ultimate beneficiary, developing countries still benefited from the agreement.

The WTO compromise contained a condition that would allow countries to override patents provided that the rules were “used in good faith to protect public health . . . not to be an instrument to pursue industrial or commercial policy objectives.”¹¹⁸ This is an impressive concession by the United States and pharmaceutical industry that had earlier, during the Doha negotiations, proposed a very strict list of diseases that generic drugs could be exported to treat.¹¹⁹ There is no longer a ban on exports of generic drugs for any disease except those listed.¹²⁰ The argument for the strict list, which included diseases like AIDS and malaria, is that pharmaceutical companies had spent billions of dollars creating those drugs.¹²¹ Under the August 2003 WTO agreement, countries are now able to import generic drugs and not just issue compulsory licenses when necessary.¹²² Under the Doha Declaration, developing countries could not import drugs from countries like India because of the international patent laws, but now they can.¹²³ Thus, developing countries have gained a lot of freedom in fighting epidemics like AIDS and are also able to improve general public health.

There is both support and criticism for the August 2003 WTO agreement that will not be solidified in TRIPS until 2004. The critics are from abroad *and* the United States, while the supporters are from the

116. *Id.*

117. *Id.*

118. *WTO Votes to Bypass Patents on Medicines; Cheap Generics Go to Poor Nations*, WASH. POST, Aug. 31, 2003, at A16.

119. James, *supra* note 13.

120. *Id.*

121. *Editorial—No to Pill Piracy*, WINNIPEG FREE PRESS, Sept. 30, 2003, at A14, available at 2003 WL 64395872.

122. Gustavo Gonzalez, *Trade-Americas: FTAA Talks a Matter of Life and Death, MDs Say*, INTER PRESS SERV., Nov. 19, 2003, available at 2003 WL 66986511.

123. Eric Pfanner, *Obstacles to Drugs Are Being Eased AIDS: The Global Challenge*, INT'L HERALD TRIB., Dec. 1, 2003, at 10.

United States *and* abroad. The critics are concerned that the final TRIPS amendment will include too many obstacles for developing countries in their fight against AIDS and other epidemics,¹²⁴ while the supporters are concerned with public health. Both support and criticism are important since the final amendment will not be solidified until mid-2004. Thus, a strong voice in support or in opposition could change what the final amendment to TRIPS will look like in 2004.

In February 2004, the August 30, 2003, proposed amendment to TRIPS was used for the first time, even though an official amendment to TRIPS has not yet been created.¹²⁵ Malaysia issued a compulsory license to import generic AIDS drugs from India in February 2004.¹²⁶ As the Indian Pharmaceuticals Alliance secretary general DG Shah said, "It could provide an interesting test case to assess whether the August 30 decision is workable or needs modification."¹²⁷ There were requirements attached to the permit such as limited use to two government hospitals in Malaysia for two years only, and a rate of compensation to the patent holders of the drug to be determined at a later date.¹²⁸ Thus, this appears to be a very limited use that is highly regulated by restrictions, but the outcome of this recent test has not been released yet.

The United States, in this final stage of evolution, has truly developed its ultimate character. The United States is no longer the iron fist it was during the South Africa Medicines Act Amendment dispute, or the hypocrite during the anthrax debate, or the easy-going understanding follower during the Doha negotiations. The patent law and policy of the United States is now a balance of drug access, profit, and public health. This present stage in the evolution of patent law and policy in the United States is signified by equilibrium and balance. The U.S. patent system is not a follower, or a leader, or a passive or aggressive player, but rather a mixture designed to meet the present U.S. and world needs for patented drugs, while also ensuring the continuing U.S. history of patent law to encourage innovation and invention. The current domestic patent laws and the U.S. policy towards foreign patent laws will still be criticized, but in this stage of the evolution the United States has successfully met its

124. James, *supra* note 13.

125. KG Narendranath, *Cipla First Company to Gain from Doha Pact's Compulsory License Norm*, ECON. TIMES, Feb. 26, 2004, available at 2004 WL 60727474.

126. *Id.*

127. Our Bureau New Delhi, *Cipla Gets Malaysian Nod for AIDS Drugs: In a Trailblazing Move, Malaysia Has Issued a Compulsory License...*, BUS. STANDARD, Feb. 26, 2004, at 10, available at 2004 WL 55445906.

128. *Id.*

needs and the world's needs in a commendable balance for the time being.

IV. CONCLUSION: WHAT'S NEXT?

The history of the U.S. policy towards foreign patent laws, the events that shaped that policy and its domestic patent laws, and the recent events of August 2003 and 2004, describe in themselves the evolution of patent law. So, are our questions answered? Will patent law survive as we know it? The answer is, I do not know. None of us will know yet. Patent law is evolving as we speak. With the amendment to TRIPS due sometime in 2004, we do not know how the international agreement will change U.S. policy towards foreign and domestic patent laws, if at all.

International patent law from its humble beginning at the Paris Convention in 1883 has changed radically, but never has it evolved as quickly as it has in the past 10 years. We have seen the transition from the strict hard-nosed U.S. policy on upholding patent law to the understanding United States that recognized that public health and humanity are more important than profit and industry. Who knows what events will take place in the next year, let alone the next ten years, that will change U.S. patent law and policy towards foreign patent laws. Another terrorist attack? A new epidemic? We will just have to wait and see.

V. RECENT UPDATES

On January 18, 2005, WTO officials announced that they would not make any permanent amendments to the trade rules of TRIPS by March of 2005.¹²⁹ The amendments the WTO members discussed would allow poor and developing countries to import pharmaceutical drugs at a reduced rate.¹³⁰ The reasons given for the failure to make permanent amendments are that various members of the WTO are unable to agree on the wording of the changes.¹³¹

Developing countries have experienced some success in getting Western pharmaceutical companies to lower their prices or issue voluntary licenses by using the TRIPS compulsory licensing provisions as leverage in negotiations.¹³² This success has only been enjoyed,

129. European Information Service, *Medicines: Hopes of WTO Deal in March on Patent Rule Fading*, EUR. REP., Jan. 19, 2005, available at 2005 WL 64583876.

130. *Id.*

131. *Id.*

132. *Id.*

however, by the few countries with some pharmaceutical production capability such as Brazil, India, and Indonesia.¹³³ Moreover, there is concern among the parties working on the amendment that even those countries will not be able to keep importing cheaper drugs nor make generic versions themselves once their temporary exemptions from TRIPS expire.¹³⁴

133. *Id.*

134. *Id.*