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Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism"

Grace K. Avedissian

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GLOBAL IMPLICATIONS OF A POTENTIAL U.S. POLICY SHIFT TOWARD COMPULSORY LICENSING OF MEDICAL INVENTIONS IN A NEW ERA OF “SUPER-TERRORISM”

GRACE K. AVEDISSIAN*

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INTRODUCTION

After witnessing the effects of a large-scale chemical attack in Japan in 1995,¹ the international community's attention turned to the realities of the new era of "super-terrorism."² On March 20, 1995, a

1. See SUPER TERRORISM: BIOLOGICAL, CHEMICAL, AND NUCLEAR x (Yonah Alexander & Milton Hoenig eds., 2001) [hereinafter SUPER TERRORISM] (stating that the Tokyo incident's greatest significance was its demonstration of the potential use of chemical weapons against states by non-state organizations).

2. See *id.* at ix-x (defining super-terrorism as the use of weapons of mass destruction, i.e., biological, chemical, and nuclear weapons). This Comment focuses on biological and chemical weapons because they are more accessible than

religious cult released Sarin,³ a lethal nerve gas, in a crowded Tokyo subway train during the morning rush hour.⁴ This form of terrorism resulted in twelve casualties and over five thousand injuries, but experts recognize that a slightly greater concentration of Sarin would have led to a much higher casualty rate.⁵ The Tokyo subway incident exposed both the vulnerability of nations to such acts of terrorism, and the enormity of the danger that such acts pose.⁶ It also

nuclear weapons, and therefore more likely to be used. See Joseph F. Pilat, *The Bioterrorism Threat: Technological and Political Considerations*, in SUPER TERRORISM, *supra* note 1, at 66. Today, many terrorist organizations prefer superterrorism to traditional methods of terrorism, such as explosives. See *Gilmore Commission First Annual Report, Reasons and Rationales Behind Potential CBRN Terrorism*, in SUPER TERRORISM, *supra* note 1, at 12, 15 [hereinafter *Gilmore*]. Biological and chemical weapons are relatively easy to disperse, and therefore cause mass casualties. See *id.* at 14-15. For example, releasing 1,000 kilograms of the nerve gas Sarin in open air would kill approximately 10,000 people. See *id.* Terrorists may also use biological or chemical weapons as an effective means of sabotaging a nation's economy, creating a sense of fear among its citizens, and initiating a loss of public confidence. See JEFFREY D. SIMON, *TERRORISTS AND THE POTENTIAL USE OF BIOLOGICAL WEAPONS: A DISCUSSION OF POSSIBILITIES* 8-9 (1989). For example, in 1988, the Chilean economy suffered immensely when traces of cyanide were found in Chilean grapes, compelling the United States to recall all Chilean fruit for several weeks. See *id.* More recently, the 2001 anthrax attacks in the United States caused several federal government buildings to shut down for several days or weeks, and severely disrupted the U.S. Postal Service. See Avram Goldstein & Michael Powell, *Anthrax in Five More D.C. Buildings; Officials Troubled by Infection of N.J. Woman Who Doesn't Work in a Mailroom*, WASH. POST, Oct. 30, 2001, at A1 (reporting the discovery of anthrax spores in mailroom facilities of government buildings); see also Ellen Nakashima, *Postmaster Asks Senate for Bailout of \$5 Billion; Congress Reluctant to Cover Losses*, WASH. POST, Nov. 9, 2001 (reporting that the anthrax-related sanitation of mailroom facilities and vaccination of postal employees will cost billions of dollars).

3. See *Gilmore*, *supra* note 2, at x, 15 (describing Sarin as "highly toxic, volatile, and relatively easy to manufacture").

4. See SUPER TERRORISM, *supra* note 1, at x (recounting the Tokyo subway incident).

5. See *id.* (discussing the consequences of a chemical assault on an unsuspecting civilian population); see also Biological and Chemical Weapons Research Act, S. 1764, 107th Cong. (2001) § 2(2)(A) (relating the events and consequences of the Tokyo attack).

6. See SUPER TERRORISM, *supra* note 1, at x (indicating that chemical terrorism results in high fatality rates and injuries). Experts say that the agents or chemicals most likely to be used as weapons are smallpox, anthrax, botulism, and plague. See World Health Organization, *Frequently Asked Questions Regarding*

galvanized some nations to increase their efforts at taking preventive and responsive countermeasures in the event of a chemical or biological attack within their borders.⁷

The United States, a world leader in science and technology, has the greatest capacity to finance the research and development necessary for producing vaccines and drugs that counter chemical and biological agents.⁸ Since 1995, the United States has devised medical counterterrorism initiatives.⁹ These efforts increased recently¹⁰ following the terrorist attacks of September 11, 2001,¹¹ and

the Deliberate Use of Biological Agents and Chemicals as Weapons, at <http://www.who.int/emc/questions.htm> (last visited Sept. 5, 2002). Smallpox poses the most serious global bioterrorism threat due to its high transmissibility and fatality rates. See Center for Civilian Biodefense Strategies, *Smallpox Fact Sheet*, at <http://www.hopkins-biodefense.org/pages/agents/agentsmallpox.html> (last visited Sept. 5, 2002).

7. See *Presidential Decision Directive No. 39, U.S. Policy on Counterterrorism* (demonstrating renewed U.S. efforts and strategies to combat terrorism after the chemical attack in the Tokyo subway), at <http://www.fas.org/irp/offdocs/pdd39.htm> (last visited Sept. 5, 2002). Another mobilizing factor included the discovery, in 1995, of new documents revealing that Iraq had a more enhanced biological weapons system than initially suspected. See Donald A. Henderson, *Bioterrorism: Our Front Line Response Evaluating U.S. Public Health and Medical Readiness*, in *SUPER TERRORISM*, *supra* note 1, at 106. Moreover, in the 1990s, the international community realized the scope and capacity of Russia's biological weapons program after senior Russian officials defected. See *id.*

8. See Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 *BROOK. J. INT'L L.* 363, 372 (2000) (comparing the research and development ("R&D") expenditure of the developed world—slightly over two percent of GDP—to the R&D expenditure of the United States—two and eight tenths percent of its GDP); see also Office of Global Health Affairs, U.S. Department of Health and Human Services, *Global Health Core Messages* [hereinafter *Global Health Core Messages*] (stating that the U.S. Department of Health and Human Services is a "recognized leader in health research") at <http://www.globalhealth.gov/quotes.shtml> (last visited Sept. 5, 2002).

9. See National Defense Authorization Act for Fiscal Year 1997, Pub. L. No. 104-201, §§ 1411-1415, 110 Stat. 2422 (1996) (describing the development and coordination of an emergency response program for public health emergencies involving biological or chemical weapons).

10. See Robert Stevens, Thomas Morris, Jr., Joseph Curseen, Kathy Nguyen, Otilie Lundgren, and Lisa J. Raines Biological and Chemical Weapons Research Act, S. 1764, 107th Cong. (2001) (providing incentives to pharmaceutical companies to increase the research and development of drugs that prevent and treat

the subsequent bioterrorist activities.¹² The dissemination of anthrax¹³ spores through the U.S. mail system demonstrated the ease and effectiveness of utilizing biological agents as lethal weapons.¹⁴ In response to bioterrorism, the U.S. government is encouraging the pharmaceutical industry to invent and improve medical products that combat biological warfare.¹⁵

The United States has been the target of bioterrorism since September 11, 2001,¹⁶ but terrorists have targeted many other

illnesses resulting from biological or chemical attacks); *see also* Bioterrorism Preparedness Act of 2001, S. 1765, 107th Cong. sec. 404 (2001) (proposing to accelerate research and development of medical countermeasures to super-terrorism).

11. *See* Serge Schmemmann, *U.S. Attacked; President Vows to Exact Punishment for 'Evil'*, N.Y. TIMES, Sept. 12, 2001, at A1 (describing the sequence of events on September 11, 2001, resulting from the hijacking of U.S. airplanes and their ensuing crashes into the World Trade Center towers in New York City and the Pentagon in Washington, D.C.).

12. *See* Michael Powell & Ceci Connolly, *Experts Warn Bioterrorism Could Expand; N.Y. Hospital Worker Dies of Anthrax*, WASH. POST, Nov. 1, 2001, at A1 (reporting on the increase of fatalities from exposure to anthrax spores throughout the United States and the fear of expansion of bioterrorism).

13. *See* World Health Organization, *Anthrax Fact Sheet No. 264*, (describing anthrax as a bacterium agent that humans can acquire from contaminated food, through airborne spores, or through cutaneous contact with spores) at <http://www.who.int/inf-fs/en/fact264.html> (last visited Sept. 5, 2002); *see also* Gilmore, *supra* note 2, at 14 (indicating that the use of anthrax as a biological weapon can be costly because turning the spores into a powder form requires expensive equipment); *see also* Joshua Lederberg, *The Diversity of Bio Weapons*, in SUPER TERRORISM, *supra* note 1, at 18 (stating that anthrax is more lethal when the spores are disseminated by aerosols (i.e., aerosol cans, crop dusters) and are inhaled by humans).

14. *See* David Brown, *Canadian Study Shows Anthrax's Easy Spread: One Letter Could Cause Many Deaths*, WASH. POST, Dec. 12, 2001, at A27 (discussing the results of a study which showed that small particles of anthrax spores—three to ten microns in diameter—could become airborne and spread within ten minutes after opening a letter, and a high dosage could be lethal).

15. *See* S. 1764, secs. 6, 8-9 (granting federal tax incentives, two-year patent term extensions for inventions that counter biological and chemical agents, exclusive licensing of certain patented products, and protection against liability with respect to products that combat biological or chemical terrorism).

16. *See* Powell & Connolly, *supra* note 12, at A1 (reporting on one of a series of anthrax-related fatalities in the United States since the beginning of a wave of bioterrorism after September 11, 2001).

countries in the past.¹⁷ If a developing country is the target of such an attack, however, it would not likely have the financial resources to purchase therapeutic drugs at full price.¹⁸ Such a case would raise important legal issues regarding intellectual property rights. Under the U.S. Patent Act,¹⁹ pharmaceutical companies have certain exclusive rights with regard to their patents.²⁰ The companies are neither required to sell therapeutic drugs at a discount, nor to license drug patents to a third party who can manufacture and sell the drugs at more affordable prices.²¹

This Comment analyzes the impact on global counterterrorism efforts if Congress amends U.S. patent law to permit compulsory licensing of patents for health-related inventions. Part I briefly outlines the historical debate between developed and developing countries with respect to patent rights, and discusses U.S. policy on patent rights and compulsory licensing.²² This section also discusses the challenges confronting the U.S. government regarding its policy on patent protection in the wake of the recent bioterrorist attacks on the nation, and examines pending U.S. legislation regarding

17. See *supra* notes 2, 4, 5 and accompanying text (describing the use of biological agents to poison Chilean grapes in 1988, and the chemical attack incident in Japan in 1995); see also SIMON, *supra* note 2, at 9 (describing an attempt by Palestinian extremists to sabotage the Israeli economy by injecting mercury into Israeli oranges in 1978).

18. Cf. James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 734 (2001) (discussing the inability of millions of HIV/AIDS patients in developing countries, particularly in Sub-Saharan Africa, to afford HIV/AIDS treatment drugs).

19. 35 U.S.C. §§ 1-376 (2001).

20. See *id.* § 271(a) (providing that any unauthorized fabrication, use, sale, or importation into the United States of any patented invention during its patent term constitutes patent infringement); see also ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 14 (1999) (explaining that U.S. patent law grants a patent owner the exclusive right to make, use, sell, offer to sell, or import a patented invention for a twenty-year period).

21. See generally 35 U.S.C. §§ 1-376 (lacking any provision that would compel a patent holder to license a patent to a private third party).

22. See discussion *infra* Parts I.A, I.B (comparing developing and developed countries' perspectives on the issue of compulsory licensing and the balancing of social and commercial interests in the TRIPS Agreement).

compulsory licensing.²³ Part II assesses the problems under the compulsory licensing framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), a multilateral accord on intellectual property rights,²⁴ and it analyzes the provisions of pending U.S. compulsory licensing bills.²⁵ This section also evaluates the potential impact of U.S. compulsory licensing legislation on the global availability of health-related products that counter biological and chemical agents, as well as the potential impact on medical research and development.²⁶ Finally, Part III of this Comment argues that combating super-terrorism will require global cooperation, which can only be achieved through increased flexibility in U.S. policy on patent rights.²⁷ Specifically, this Comment recommends that the World Trade Organization ("WTO") promote public health over commercial interests, and that the U.S. Congress amend U.S. patent law to incorporate compulsory licensing provisions.²⁸

I. BACKGROUND

A. THE GLOBAL DEBATE ON COMPULSORY LICENSING

In the past decade, developed and developing countries have hotly debated the highly contentious issue of compulsory licensing.²⁹ Compulsory licensing is generally defined as the granting of a license by a government to a third party to use a patent without the

23. See discussion *infra* Parts I.C, I.D (discussing the U.S. predicament arising from the threat of bioterrorism and the U.S. compulsory licensing bills).

24. See discussion *infra* Part II.A.

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

26. See discussion *infra* Part II.C.

27. See discussion *infra* Part III (demonstrating the need for global cooperation and response preparedness to combat super-terrorism).

28. See discussion *infra* Parts III.A, III.D.

29. See Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2464 (1995) (presenting the differing views of developed and developing countries on the issue of international intellectual property rights).

authorization of the patent holder.³⁰ The patentee receives royalty fees in return for issuance of the license.³¹ In the pharmaceutical context, compulsory licensing enables a government to license patented drugs to generic manufacturers without the patent holder's consent.³² The goal of compulsory licensing for prescription drugs is to increase the supply of the drugs, and thereby reduce their prices through increased market competition by generic drug companies.³³ Global access to generic drugs through compulsory licensing is particularly vital in the wake of recent bioterrorist attacks in the United States in October 2001.³⁴

1. Perspective of Developed Countries

Many developed countries and the brand-name pharmaceutical industry oppose compulsory licensing because a weak intellectual property regime in foreign countries undermines patent holders' rights and reduces amounts spent on research and development ("R&D").³⁵ Opponents of compulsory licensing contend that drug research is costly and time-consuming, and that a high degree of economic risk is associated with the process.³⁶ Pharmaceutical

30. See Bess-Carolina Dolmo, Note, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South Africa Example*, 7 BUFF. HUM. RTS. L. REV. 137, 138 (2001) (explaining the concept of compulsory licensing).

31. See *id.* (stating that under a compulsory licensing scheme, the patent holder is entitled to reasonable compensation for an amount pre-determined by the government granting the license).

32. See *id.* (defining compulsory licensing as the process of "[allowing] regular licensure grants to a third party that will manufacture a drug still under patent").

33. See *id.* at 142 (indicating that compulsory licensing is beneficial for increasing market competition and thereby reducing prices of pharmaceuticals).

34. See *supra* notes 11-16 and accompanying text (describing the medical and political repercussions of the recent anthrax attacks in the United States).

35. See Carroll, *supra* note 29, at 2469; see also Consumer Project on Technology, *Compulsory Licensing of Essential Medical Technologies* (explaining that the United States and the European Union, as a result of heavy lobbying by large pharmaceutical companies, have increased trade pressures against compulsory licensing of drugs) at <http://lists.essential.org/1999/info-policy-notes/msg00010.html> (last visited Sept. 5, 2002).

36. See Pharmaceutical Research and Manufacturers of America, *Why Do Medicines Cost So Much?* [hereinafter *Why Do Medicines Cost So Much?*]

companies rely on sales revenues to recoup their losses from past R&D efforts and apply them toward continuing R&D.³⁷ According to the pharmaceutical industry, only a small number of highly successful products generate the majority of the industry's profits.³⁸ Therefore, strong patent protection for these products is crucial for financing future R&D.³⁹

Opponents of compulsory licensing also argue that the absence of a strong intellectual property rights regime discourages investments in pharmaceutical firms, and thereby deters R&D.⁴⁰ According to this theory, investors infuse capital in companies in anticipation of a sufficient rate of return on their investments.⁴¹ Patent law provides the economic incentive to invest in drug research by ensuring that pharmaceutical patent holders have exclusive patent rights for twenty years from the date of filing an application, which gives them a market advantage during that time period.⁴² However, if investors

(claiming that marketing one successful drug costs pharmaceutical companies approximately \$500 million, that only five out of 5,000 compounds that are discovered by the pharmaceutical industry are sufficiently effective for human testing, and that only one out of 5,000 is marketable for patient use) at <http://www.phrma.org/publications/publications/brochure/questions/whycostmuch.phtml> (last visited Mar. 6, 2002).

37. See Singham, *supra* note 8, at 373-74 (noting that pharmaceutical companies in the United States generally invest between sixteen percent and twenty and eight tenths percent of their sales revenue in research and development).

38. See *id.* (citing a study that reveals that ten percent of marketable drugs generate fifty-five percent of the pharmaceutical industry's profits).

39. See *id.* at 373 (arguing that patent protection is more essential for the pharmaceutical industry than other industries due to the higher costs and risks associated with pharmaceutical research); see also Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 304 (1994) (attributing the financial growth of the pharmaceutical industry to exclusivity provided by patent law).

40. See Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 357-58 (1993) (alleging that compulsory licensing has the negative effect of reducing the financial security and attractiveness of investing in pharmaceutical companies).

41. See Carroll, *supra* note 29, at 2469 (supporting the theory that a strong patent regime promotes investment by assuring investors sufficient returns from successful products).

42. See 35 U.S.C. § 154(a)(2) (specifying the duration of a patent term); see also Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the*

perceive that compulsory licensing will increase competition and lower industry profits, they would likely refrain from investing in the R&D of innovative pharmaceutical products.⁴³ This, in turn, would have a negative impact on global health care.⁴⁴

Finally, critics conclude that compulsory licensing is detrimental to the social and economic welfare of developing nations with weak patent protection systems.⁴⁵ They claim that developed countries are reluctant to export products and technologies to such countries, for which technological and industrial advancement is an essential component of national prosperity.⁴⁶ For corroboration of this theory, analysts cite to studies that reveal a strong correlation between the infusion of new technology into the domestic market of a country and economic and social progress.⁴⁷

In summary, developed countries advance the following arguments against compulsory licensing: (1) strong patent protection

WTO Doha Ministerial Conference 4 (Sept. 2001) (unpublished paper, on file with Quaker United Nations Office - Geneva) (analyzing the benefits of a strong intellectual property regime) *at* <http://hostings.diplomacy.edu/quaker/new/doc/OP7%20Abbott1.pdf> (last visited Sept. 5, 2002).

43. *See* Carroll, *supra* note 29, at 2469 (recognizing the economic reality of market incentives and profit maximization goals).

44. *See* Singham, *supra* note 8, at 374 (correlating weak patent protection with a reduction in research for life saving drugs, due to a hampering of the pharmaceutical industry's ability to recover high research costs).

45. *See id.* at 375 (linking strong intellectual property protection to economic prosperity through increased foreign direct investment). *But see* Abbott, *supra* note 42, at 8 (challenging the notion that strong patent protection encourages a higher level of direct foreign investment in developing countries).

46. *See* Carroll, *supra* note 29, at 2469 (attributing foreign investment in developing countries to the degree of investment security provided by their patent regime); *see also* Singham, *supra* note 8, at 375 (linking strong intellectual property protection to greater technological development and economic growth). For example, Mexico and South Korea, which have strong patent systems, have the greatest technological development among developing countries. *See id.* at 378.

47. *See* Singham, *supra* note 8, at 375-76 (recognizing a relationship between technological advancement and economic and social prosperity). Studies of American economic growth have related high economic output to increased research and technology. *See id.* Also, commentators argue that weak patent protection depletes a country's intellectual resources by reducing incentives to innovate, which drives local scientists and engineers from developing countries to countries with stronger patent systems. *See id.* at 378-79.

stimulates future innovations of medical products;⁴⁸ (2) patents encourage capital investment in pharmaceutical companies;⁴⁹ and (3) strong patent regimes attract direct foreign investment, thereby benefiting developing nations in the long term.⁵⁰ WTO Members from developed countries exert economic and political pressure on developing Members to limit their use of compulsory licensing.⁵¹ They allege that the developing countries that are the primary sources for low-cost generics (i.e., Brazil and India) engage in compulsory licensing to promote commercial rather than public health interests.⁵²

48. See *supra* notes 35-39 and accompanying text (discussing the argument that weak patent protection jeopardizes the pharmaceutical industry's ability to engage in future R&D).

49. See *supra* notes 40-44 and accompanying text (posing the argument that a weak intellectual property regime reduces investment in pharmaceutical enterprises and thereby reduces research and development of essential pharmaceutical products).

50. See *supra* notes 45-46 and accompanying text (presenting the argument that a strong intellectual property regime increases the influx of foreign investments and innovative technologies, which lead to economic and social development).

51. See, e.g., Julie S. Park, Note, *Pharmaceutical Patents in the Global Arena: Thailand's Struggle Between Progress and Protectionism*, 13 B.C. THIRD WORLD L.J. 121, 142-45 (1993) (discussing the United States' use of trade sanctions to compel Thailand to incorporate more aggressive patent protection in its patent law); see also Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 954 (2000) (stating that the United States threatened to impose trade sanctions on South Africa in response to the South African government's enactment of a compulsory licensing law).

52. See Joseph Kahn, *Trade Talks Hinge on Finesse of U.S.*, N.Y. TIMES, Nov. 10, 2001, at A6 (reporting that United States Trade Representative ("USTR") Zoellick is trying to limit the use of the Brazilian and Indian generic pharmaceutical markets by offering patent exemptions to least developed African countries facing public health pandemics); see also Letter from James Love, Director of Consumer Project on Technology, to USTR Zoellick regarding WTO Patent discussions [hereinafter Letter to USTR Zoellick] (criticizing the United States' continuous attempt to discredit the position held by Brazil and India on compulsory licensing), at <http://lists.essential.org/pipermail/ip-health/2001-November/002379.html> (last visited Sept. 5, 2002).

2. *Perspective of Developing Countries*

Many developing countries⁵³ have enacted compulsory licensing provisions in their patent law.⁵⁴ They use compulsory licensing to provide their citizens greater access to essential pharmaceutical products.⁵⁵ Many health and humanitarian organizations assert that citizens of developing countries lack access to critical life-saving or life-enhancing prescription drugs because they cannot afford expensive brand-name pharmaceuticals.⁵⁶ Governments of developing countries claim that the pharmaceutical industry exploits their impoverished citizens, who are dependent on foreign pharmaceutical companies to provide essential medicines.⁵⁷ They

53. See, e.g. Gathii, *supra* note 18, at 734, 766 (identifying South Africa, Thailand, and Brazil as three ardent proponents of compulsory licensing of essential medicines).

54. See, e.g., Republic of South Africa, *Medicines and Related Substances Control Amendment Act No. 90 of 1997*, sec. 15(c) ("SAMMDRA 15(c)") (authorizing South African public health officials to issue a compulsory license to protect public health), available at <http://www.polity.org.za/legislation/1997/act90.pdf> (last visited Sept. 5, 2002); Thai Patent Act, B.E. 2522 (1992) (containing compulsory licensing provisions); see also Brazilian Patent Act, Law No. 9279, of May 14, 1996 (establishing that in cases of emergency or public interest, the Federal Executive Authorities can officially grant a temporary, non-exclusive compulsory license).

55. See *infra* notes 97-98 and accompanying text (discussing South Africa's need for a compulsory licensing law to broaden access to essential drugs that treat HIV/AIDS patients); see also Park, *supra* note 51, at 130-31 (describing Thailand's compulsory licensing provisions, which allow compulsory licenses of patented products that are unreasonably expensive or cannot sufficiently satisfy domestic public demand).

56. See, e.g., Médecins Sans Frontières, *The Campaign, The Basic Pillars* (claiming that "[t]he patenting of medicines confers a market monopoly to pharmaceutical companies who often charge the same high price world-wide. The result is that people in the developing world cannot afford the medicines that could extend, improve, or save their lives"), at <http://www.accessmed-msf.org/campaign/pillars.shtml> (last visited Sept. 5, 2002); see also World Health Organization, *Expert Committee on Essential Drugs* (stating that "[e]ssential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford"), at <http://www.who.int/medicines/organization/par/edl/infedlmain.shtml> (last visited Sept. 5, 2002).

57. See Julian-Arnold, *supra* note 40, at 357 (suggesting that developing countries prefer weaker patent systems to limit the rights of pharmaceutical

contend that the long-term benefits of a strong intellectual property regime would not alleviate their present public health crises.⁵⁸ These governments recognize the need to invoke national policies that would alleviate the present human suffering in their countries.⁵⁹

In response to assertions that compulsory licensing impedes future R&D and investments in pharmaceutical companies, proponents argue that compulsory licensing laws limit the generic production of patented drugs to the local domestic market of the country granting the compulsory license.⁶⁰ Therefore, drug companies could recover their expenses through successful marketing in other countries.⁶¹ Also, the issuance of a compulsory license is contingent on the existence of certain conditions.⁶² Thus, only certain patented inventions would be subject to compulsory licensing, and the patent holder would receive reasonable compensation for the license.⁶³

companies that exploit the local populations by charging high prices for essential products).

58. See Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 72 (2001) (supporting the notion that the monumental task of addressing and alleviating the HIV/AIDS epidemic in developing countries preempts any long-term intellectual property concerns).

59. See, e.g., Gathii, *supra* note 18, at 734 (writing that in 1997, Brazil realized the enormity of its HIV/AIDS crisis and instituted a policy of free, universal access to AIDS drugs, which reduced the rate of AIDS-related deaths in Brazil by half between 1996 and 1999).

60. See Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) *reprinted in* INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY 588 (Michael Leaffer ed., 1999) [hereinafter TRIPS Agreement] (providing that a compulsory licensee predominately supply the domestic market of the host country).

61. See Dolmo, *supra* note 30, at 161 (arguing that developing countries are a small source of revenue for the pharmaceutical industry, since they comprise only about ten percent of international sales).

62. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31 (setting conditions under which a WTO Member can grant compulsory licenses); see also Dolmo, *supra* note 30, at 137, 141 (explaining that South Africa issued compulsory licenses to abate a public health crisis).

63. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(h). Article 31(h) provides that: "The right holder shall be paid adequate remuneration [for the

Developing countries also justify the use of compulsory licenses as a legitimate means of developing and fostering a local generic pharmaceutical industry.⁶⁴ Among the benefits that may arise from a domestic industry is domestic economic growth, which in turn would strengthen the global economy.⁶⁵ Also, a domestic industry may provide medications at prices that are compatible with the average local income.⁶⁶ Finally, a local generic drug industry would enable a developing country to retain its intellectual capital (e.g., scientists, engineers, and pharmacists) by increasing employment opportunities for professionals in their home country.⁶⁷

In general, proponents of compulsory licensing espouse a policy that public health concerns are paramount to commercial profits, and should be addressed immediately.⁶⁸ Compulsory licensing laws must provide a delicate balance between maintaining the rights of patent owners in foreign countries and providing governments with the necessary equipment to address the health and safety of their citizens

unauthorized use of a patent by the government or by third parties authorized by the government], taking into account the economic value of the authorization." *Id.*

64. *See* Julian-Arnold, *supra* note 40, at 353-54 (recognizing that the development of local pharmaceutical industries in developing countries can have beneficial consequences for the developing world).

65. *See id.* (associating the development of an enterprising pharmaceutical industry with national economic growth).

66. *See id.* (stating that pharmaceutical industries in developing nations can produce medications at lower costs than pharmaceutical companies in industrialized countries, due to lower labor costs in developing nations).

67. *See id.* (implying that a country's ability to retain its professional labor force heightens its prospects for new technological inventions).

68. *See, e.g.,* Press Release, The Kenya Coalition for Access to Essential Medicines, Doha Puts Life Before Profit (Sept. 5, 2002) (advocating for international recognition that public health interests prevail over commercial profits), *available at* <http://lists.essential.org/pipermail/ip-health/2001-November/002420.html> (last visited Sept. 5, 2002); *see also* Press Release, Joint Statement: Médicines Sans Frontières, OXFAM, Third World Network, Consumer Project on Technology, Consumers International, Health Action International and The Network, *Green Light to Put Public Health First at WTO Ministerial Conference in Doha* (Nov. 15, 2001) [hereinafter Joint Statement] (interpreting the Doha Declaration as "a clear political statement that public health concerns must override commercial interests"), *available at* <http://www.oxfam.org.uk.whatnew/press/doha2.html> (last visited Sept. 5, 2002).

under exigent circumstances.⁶⁹ This balance of two fundamental rights is the basic principle of various international treaties on intellectual property rights.⁷⁰

3. *The TRIPS Compromise*

The TRIPS Agreement,⁷¹ negotiated at the Uruguay Round of the General Agreement of Tariffs and Trade, establishes the minimum international standards of intellectual property protection.⁷² The TRIPS Agreement attempts to strike a delicate balance between the short-term objective of providing access to existing medicines and the long-term objective of developing new medicines through incentives for future R&D.⁷³ In the area of patents, Article 31 of the TRIPS Agreement permits WTO Members to grant compulsory patent licenses under limited circumstances⁷⁴ and upon satisfying certain conditions.⁷⁵ Notably, many analysts argue that the language

69. See Gathii, *supra* note 18, at 748-50 (exploring the invariable tension between social and commercial interests within the intellectual property context, and concluding that the TRIPS Agreement is based on a balance between the two objectives).

70. See, e.g., World Trade Organization, *Fact Sheet: TRIPS and Pharmaceutical Patents; Philosophy: TRIPS attempts to strike a balance* [hereinafter WTO Fact Sheet] (claiming that the TRIPS Agreement balances long-term incentives for research and development of new products with short-term needs for access to existing products), at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm (last visited Sept. 5, 2002).

71. See generally TRIPS Agreement, *supra* note 60 (establishing an international legal framework for intellectual property rights).

72. See *id.* Part II, sec. 5, art. 31 (setting out the framework for national laws on compulsory licensing).

73. See WTO Fact Sheet, *supra* note 70 (explaining that the underlying goals of the TRIPS Agreement are equally important).

74. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(b) (limiting the use of compulsory licensing under the TRIPS Agreement to circumstances of national emergency, antitrust violations, and public non-commercial use); see also Singham, *supra* note 8, at 401 (arguing that the WTO recognized the dangers of compulsory licensing and therefore restricted its use by WTO Members for limited circumstances).

75. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(b) (detailing the procedural criteria under the TRIPS Agreement for implementing compulsory licensing laws). Article 31 lists the following pre-conditions to granting a

of Article 31 of the TRIPS Agreement is too ambiguous in its current form.⁷⁶ They assert that the WTO should clarify various terms and provisions therein to prevent developed countries, including the United States, from using the ambiguity of the TRIPS accord to thwart the use of compulsory licensing by developing countries.⁷⁷

B. U.S. POSITION ON COMPULSORY LICENSING

Over the years, U.S. policy on compulsory licensing has been inconsistent.⁷⁸ Historically, the United States aggressively opposed the use of compulsory licensing by foreign countries with respect to patented pharmaceutical inventions.⁷⁹ The United States Trade Representative ("USTR") has used, or threatened to use, trade sanctions⁸⁰ against countries that enact laws permitting compulsory

compulsory license: (a) each case must be considered on its merits; (b) the licensee must first attempt to seek authorization from the patent holder on reasonable commercial terms and within a reasonable time frame; (c) the scope and duration of the license must be limited to its authorized purpose; (d) the license cannot be exclusive; (e) the license cannot be assigned; (f) the licensee must predominately supply the domestic market of the country granting the license; (g) the license must terminate once an authoritative body determines that the circumstances giving rise to the compulsory licensing have ceased to exist and will not reoccur; (h) the patent holder must be adequately compensated; (i) decisions regarding the issuance of a license and royalty fees must be subject to judicial review; (j) provisions (b) and (f) shall not apply in cases arising from anti-competitive practices. *See id.* art. 31(a)-(k); *see also* Abbott, *supra* note 58, at 73-75 (analyzing Article 31 provisions of the TRIPS Agreement).

76. *See* Ford, *supra* note 51, at 960-62 (examining the ambiguity of the terminology in Article 31).

77. *See* Abbott, *supra* note 42, at 80 (alleging that the U.S. government is exerting economic pressure on developing countries to impede them from enacting and implementing national laws that would enable them to take advantage of the flexibility of the TRIPS Agreement).

78. *See infra* notes 99, 102-108 and accompanying text (analyzing the progression of U.S. trade policy relating to intellectual property rights).

79. *See* Ford, *supra* note 51, at 953-54 (listing various U.S. objections to the use of compulsory licensing).

80. *See* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 § 1303 (codified as amended in scattered sections of 19 U.S.C. (1988)) (authorizing the USTR to investigate intellectual property right violations by trading partners and to impose sanctions against countries that do not take action to strengthen their intellectual property rights regimes).

licensing.⁸¹ Many commentators argue that this traditional U.S. posture of defending patents over public health is incompatible with the goals of the TRIPS Agreement.⁸² The U.S. government only recently adopted a more lenient trade policy towards developing countries with an HIV/AIDS epidemic.⁸³ Ironically, the federal government has frequently exercised its own authority to use or issue patents without patent holders' permission.⁸⁴

The U.S. Patent Act does not contain a general compulsory licensing section.⁸⁵ Certain statutory provisions, however, authorize compulsory licensing for preventing air pollution,⁸⁶ public health purposes,⁸⁷ government use,⁸⁸ atomic energy,⁸⁹ aerospace,⁹⁰ and

81. See, e.g., Gathii, *supra* note 18, at 768 (discussing the retaliatory measures implemented against South Africa by the USTR in response to a South African compulsory licensing law); see also, e.g., Rafael V. Baca, *Compulsory Patent Licensing in Mexico in the 1990s: The Aftermath of NAFTA and the 1991 Industrial Property Law*, 8 TRANSNAT'L LAW. 33, 42 (1995) (writing that in May 1989, the USTR placed Mexico on a "Priority Watch List" pursuant to Special 301 sanctions of the U.S. Trade Act).

82. See Abbott, *supra* note 58, at 72, 75 (alleging that the United States has attempted to use the TRIPS Agreement in bad faith to oppose compulsory licensing laws, even though the TRIPS Agreement expressly authorizes the use of compulsory licenses to address public health emergencies); see also Letter to USTR Zoellick, *supra* note 52 (urging the U.S. government to adopt a pro-public health interpretation of the TRIPS Agreement).

83. See *infra* notes 102-104, 108 and accompanying text (discussing the U.S. government's acceptance of compulsory licensing laws enacted in South Africa and Thailand to address the public health crisis associated with the HIV/AIDS pandemic).

84. See *infra* notes 86-92 and accompanying text (highlighting statutory provisions under which the U.S. government can use compulsory licensing).

85. See *supra* note 21 and accompanying text (noting the absence of a general compulsory licensing provision in the U.S. Patent Act).

86. See Clean Air Act of 1988, 42 U.S.C. § 7608 (2001) (requiring mandatory licensing of patents by the government to ensure compliance with the requirements of the Clean Air Act).

87. See March-in Rights, 35 U.S.C. § 203(1)(b) (2001) (allowing the government to license patents for inventions funded by the government and invented by a small business or nonprofit organization in circumstances where the patent holder could not reasonably satisfy public health or safety needs).

88. See 28 U.S.C. § 1498(a) (2001) (entitling patent holders the right to sue and claim compensation for the federal government's unauthorized use of a patent, or

national security.⁹¹ In addition, the U.S. government can issue compulsory licenses under the antitrust laws to remedy anti-competitive practices.⁹² Notwithstanding these provisions that reserve the right to issue compulsory licenses, the United States generally promotes strong patent protection rights in the United States and abroad.⁹³

The U.S. alliance with the brand-name pharmaceutical industry generated many political disputes with foreign nations, particularly developing countries.⁹⁴ In 1997, the conflicting interests of the

the government's licensing of a patent to third parties acting by or for the government).

89. See Atomic Energy Act of 1988, 42 U.S.C. § 2183 (2001) (permitting the government to use or license a patent in connection with the production of nuclear materials or atomic energy, if doing so would advance the public interest).

90. See *id.* § 2457 (2001) (granting patent rights for innovations related to the national space program to the government rather than the inventor, i.e., government employee or contractor).

91. See 35 U.S.C. § 181 (2001) (granting government agencies the authority to withhold patents for inventions that may endanger national security).

92. See Antitrust Procedures and Penalties Act, 15 U.S.C. §§ 16(b)-(h) (2001) (describing the procedural requirements for obtaining consent judgments in antitrust proceedings); see also, e.g., *United States v. 3D Systems Corp. & DTM Corp.*, No. CIV.1:01CV01237(GK), 2001 WL 964343, at *3-4 (D.D.C. Aug. 16, 2001) (ordering 3D Systems Corp. to license 178 of its patents in the United States, Canada, and Mexico, to a third party). The U.S. Department of Justice initiated the suit against 3D Systems Corp. to prevent a prospective acquisition of DTM Corp. by 3D Systems Corp., which would give the merged company a monopoly on rapid prototyping technologies in the U.S. market. See James Love & Michael Palmedo, *Examples of Compulsory Licensing of Intellectual Property in the United States*, ch. 3 (discussing various U.S. antitrust cases in which the courts implemented compulsory licensing as a remedy to anti-competitive practices), at <http://www.cptech.org/ip/health/cl/us-at.html> (last visited Sept. 5, 2002).

93. See Abbott, *supra* note 42, at 71 (observing that the United States has pressured developing WTO Members to accelerate their adoption of patent protection laws for pharmaceuticals); see also Christopher Scott Harrison, Comment, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L L. & COM. REG. 457, 495, 498 (2001) (suggesting that strong foreign intellectual property regimes allow U.S. pharmaceutical companies to recover their exorbitant R&D costs and allow the United States to maintain its competitiveness in the global market).

94. See *infra* notes 99, 106 and accompanying text (showing that the United States has taken combative measures against countries that have instituted compulsory licensing laws, such as South Africa and Brazil).

United States and the developing world concerning patent rights attracted international attention when the South African Parliament passed compulsory licensing legislation⁹⁵ to reduce the cost of pharmaceuticals.⁹⁶ The South African government resorted to this legislation as the only practical means of addressing its growing HIV/AIDS epidemic.⁹⁷ By instituting a compulsory licensing law, the government intended to reduce AIDS-related deaths by broadening access to affordable generic drugs.⁹⁸ The United States responded by threatening the South African government with sanctions and exerting economic pressure on the country.⁹⁹ It is likely that the U.S. reaction stemmed partially from a fear that submission to South Africa's intellectual property policy would set a precedent for other countries to implement similar policies.¹⁰⁰ The pharmaceutical

95. See SAMMDRA 15(c), *supra* note 54 (authorizing the South African Health Minister to issue compulsory licenses for patented pharmaceutical drugs to protect public health).

96. See Dolmo, *supra* note 30, at 138, 143 (relaying the political ramifications of and controversy arising from the enactment of SAMMDRA 15(c)).

97. See Ford, *supra* note 51, at 954 (presenting the public interest motivations for implementing SAMMDRA 15(c)); see also Dolmo, *supra* note 30, at 139 (assessing the magnitude of the AIDS-related public health crises in South Africa and other third-world countries). In 1990, the life span of South Africans was fifty-nine years; by 2010, it is expected to be less than forty years. See *id.*

98. See Dolmo, *supra* note 30, at 140 (estimating that HIV/AIDS drugs cost \$12,000 a year in many African countries); see also Gathii, *supra* note 18, at 734 (showing that Brazil's compulsory licensing law of 1997 produced five generic AIDS drugs, causing AIDS-related deaths to drop by about half between 1996 and 1999 and the incidence of HIV infections to drop by sixty to eighty percent).

99. See Consumer Project on Technology, *Time-Line of Disputes over Compulsory Licensing and Parallel Importation in South Africa* (showing that the USTR placed South Africa on its Special 301 Watch List on May 1, 1998), at <http://www.cptech.org/ip/health/sa/sa-timeline.txt> (last visited Sept. 5, 2002). On February 23, 1998, the Pharmaceutical Research and Manufacturers of America ("PhRMA") had asked the USTR to designate South Africa as a Priority Foreign country under the Special 301 Review. See *id.* PhRMA was quoted as saying, "South Africa has become a 'test case' for those who oppose the U.S. government's long-standing commitment to improve the terms of protection for all forms of American intellectual property, including pharmaceutical patents." *Id.*

100. See Abbott, *supra* note 58, at 72 (stating that the pharmaceutical industry advances the slippery-slope argument that the United States' leniency towards South Africa and Thailand will eventually result in an obligation to permit compulsory licensing in any country that alleges the necessity for such a law). The countervailing view is that, first, the devastating nature of the current HIV/AIDS

industry fueled the U.S. opposition by filing a lawsuit against the South African government to challenge the law in the South African courts.¹⁰¹

The United States contested South Africa's compulsory licensing law for two years before capitulating to public and interest group pressure.¹⁰² By 1999, the U.S. government unexpectedly changed its combative attitude.¹⁰³ The policy shift came as a result of public and political recognition of the gravity of South Africa's public health crisis.¹⁰⁴ In fact, Vice President Al Gore announced to the U.N. Security Council in spring 2000 that the United States would pledge \$150 million toward addressing the HIV/AIDS epidemic in South Africa.¹⁰⁵

epidemic outweighs any long-term patent infringement concerns, and, second, compulsory licensing for public health emergencies is legal and consistent with the TRIPS Agreement. *See id.*

101. *See* The Pharmaceutical Manufacturers' Association of South Africa, et. al. v. President of the Republic of South Africa, No. 4183/98 (Transvaal Provincial Division) (notice of motion filed on Feb. 18, 1998) (alleging that the South African government violated the domestic patent law by enacting SAMMDRA 15(c)), at <http://www.cptech.org/ip/health/sa/pharmasuit.html> (last visited Sept. 5, 2002); *see also* Dolmo, *supra* note 30, at 138, 143, 151 (describing the strong opposition to SAMMDRA 15(c) by the United States and the pharmaceutical industry and noting that forty major pharmaceutical companies filed suit against South Africa).

102. *See* Dolmo, *supra* note 30, at 143-44 (maintaining that lobbying efforts by public health and consumer rights advocates pressured the U.S. administration to change its position in favor of addressing global public health issues); *see also* Gathii, *supra* note 18, at 768 (determining that world-wide protests motivated then-Vice President Al Gore, who initially opposed SAMMDRA 15(c), to form a commission and act as co-chair in negotiating a resolution with South Africa).

103. *See* Ford, *supra* note 51, at 955 (reporting that the United States and South Africa engaged in bilateral negotiations to address South Africa's need for access to affordable HIV/AIDS drugs). The United States acknowledged the special nature of the HIV/AIDS epidemic and agreed to stop applying trade pressures on South Africa, but the United States did not actually acknowledge the legality of compulsory licensing. *Id.* at 955-56.

104. *See* Dolmo, *supra* note 30, at 139-40, 143-44 (attributing the U.S. government's change in attitude toward SAMMDRA 15(c) to public and interest group pressures, as well as to the alarming statistics on HIV/AIDS infections and AIDS-related deaths in sub-Saharan Africa).

105. *See id.* at 152 (showing that the United States is willing to assist in alleviating a global public health crisis by providing financial assistance and withdrawing its opposition to South Africa's compulsory licensing law).

Generally, the current U.S. position on compulsory licensing still favors the interests of the pharmaceutical industry.¹⁰⁶ As the pivotal South African situation suggests,¹⁰⁷ however, the United States may withhold trade sanctions against countries implementing compulsory licensing laws for public health emergencies.¹⁰⁸ In light of this recent shift in U.S. policy and the series of bioterrorism attacks in the United States since September 11, 2001,¹⁰⁹ the United States should

106. *See id.* at 151-52 (emphasizing the inconsistency in U.S. trade policy towards other countries that have enacted compulsory licensing laws). For example, the United States still opposes compulsory licensing laws in Brazil. *See Gathii, supra* note 18, at 735-36. In January 2001, the United States requested that a WTO panel examine Brazil's compulsory licensing law to determine if it conforms to the TRIPS Agreement. *Id.*

107. *See supra* notes 99-105 and accompanying text (showing an evolution of U.S. policy regarding South Africa's HIV/AIDS epidemic and compulsory licensing measures implemented to alleviate the public health crisis).

108. The Office of the USTR is willing to make concessions to other countries as well, in the context of the AIDS crisis. In a letter to Thailand, the USTR Office wrote:

We recognize and support the Government of Thailand's goal of extending effective health care to all its citizens - including people living with AIDS. This is a goal we fully endorse and believe can be achieved while providing appropriate protections for intellectual property We encourage Thai officials to explore all options for extending access to effective treatments, including ongoing direct dialogue with pharmaceutical manufacturers. But the final choice is one for Thailand to make. If the Thai government determines that issuing a compulsory license is required to address its health care crisis, the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Letter from Joseph S. Papovich, Assistant U.S. Trade Representative for Services, Investment and Intellectual Property, to Mr. Paisan Tan-Ud, Chairman of PHA Network of Thailand (Jan. 27, 2000), *available at* <http://www.cptech.org/ip/health/c/thailand/ustrletterjan27.html> (last visited Sept. 5, 2002); *see also* Exec. Order No. 13,155, Access to HIV/AIDS Pharmaceuticals and Medical Technologies, 65 Fed. Reg. 30,521 (May 10, 2000) (exempting sub-Saharan African countries from trade sanctions if any such country promulgates a law that broadens access to HIV/AIDS drugs or medical devices and is consistent with the TRIPS Agreement).

109. *See supra* notes 12-14 and accompanying text (providing an account of recent bioterrorist activities in the United States and the lethal consequences of bioterrorism).

implement its own compulsory licensing laws as a means of facilitating global preparation for super-terrorist activities.¹¹⁰

C. THE CURRENT U.S. DILEMMA ON COMPULSORY LICENSING ARISING FROM THE THREAT OF BIOTERRORISM

At the outbreak of the anthrax attacks in 2001, the Bush Administration faced the dilemma of whether to issue a compulsory license of the antibiotic ciprofloxacin ("Cipro"),¹¹¹ a standard treatment for individuals exposed to anthrax.¹¹² Naturally, public health officials wanted to insure the protection of the American public by stockpiling an adequate supply of Cipro in the event of additional bioterrorist attacks.¹¹³ The U.S. government could have achieved this goal by exercising its eminent domain authority under 28 U.S.C. § 1498 to issue a compulsory license.¹¹⁴ Issuing such a

110. See discussion *infra* Part III.D (advocating the enactment of the compulsory licensing bills currently pending in Congress to alleviate health needs that may not be met by patent holders).

111. See Letter from Consumer Project on Technology to Tommy G. Thompson, Secretary of Health and Human Services [hereinafter CPT's Letter to Secretary Thompson] (noting that only one pharmaceutical firm, Bayer, markets ciprofloxacin in the United States), at <http://www.cptech.org/ip/health/cl/cipro/nadethom10182001.html> (last visited Sept. 5, 2002); see also Consumer Project on Technology, *Talking Points on Cipro Patent Dispute* [hereinafter CPT's Talking Points on Cipro] (highlighting that at least five generic companies, which have received FDA approval for the quality of their ciprofloxacin, could manufacture the drug), at <http://www.cptech.org/ip/health/cl/cipro/talkingpoints.html> (last visited Sept. 5, 2002).

112. See Russell Mokhiber & Robert Weissman, *The Cipro Rip-Off and the Public Health*, ZNet Daily Commentaries (discussing the government's conflict of interest between protecting the public health and promoting corporate profiteering), at <http://www.zmag.org/sustainers/content/2001-12/02mokhiber-weissman.cfm> (last visited Sept. 5, 2002).

113. See CPT's *Talking Points on Cipro*, *supra* note 111 (reporting that Secretary of Health and Human Services Tommy Thompson sought an emergency reserve of 1.2 billion pills to adequately treat ten million American citizens, but that Bayer could only produce two million pills per day).

114. See 28 U.S.C. § 1498(a) (allowing the federal government to invoke its eminent domain power to use or license a patent without the authorization of the patent owner).

license for Cipro, however, would have undermined the U.S. position at the WTO conference¹¹⁵ in Doha, Qatar in November 2001.¹¹⁶

The Doha agenda included central issues concerning the compulsory licensing of drugs, and the importation of drugs under a compulsory license when countries have insufficient domestic manufacturing capabilities.¹¹⁷ Public health officials feared that if they granted a compulsory license for Cipro, the United States could not legitimately oppose the compulsory licensing laws of other countries at the WTO conference, as it had done in the past.¹¹⁸ Therefore, rather than compromise the U.S. position during the Doha conference, officials chose to negotiate an agreement with Bayer Corporation, the manufacturer of Cipro, for the bulk purchase of Cipro at a discounted rate.¹¹⁹

The Cipro situation illustrates how the United States may find itself in a precarious political position in the wake of other potential

115. See World Trade Organization, *The Fourth WTO Ministerial Conference* (noting that the Fourth WTO Ministerial Conference took place from November 9-14, 2001 in Doha, Qatar), at http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (last visited Sept. 5, 2002).

116. See Mokhiber & Weissman, *supra* note 112 (proposing that the U.S. administration's reluctance to authorize the generic production of Cipro stemmed from the recognition that it would jeopardize its negotiating position in the impending Doha WTO meeting); see also *CPT's Talking Points on Cipro*, *supra* note 111 (suggesting that the Bush Administration was "cutting corners on public health" to protect its position against compulsory licensing of drugs during the Doha WTO conference).

117. See World Trade Organization, *supra* note 115 (discussing the agenda of the Doha Ministerial Conference).

118. See *CPT's Talking Points on Cipro*, *supra* note 111 (anticipating that the United States, Canada, and the European Community would oppose the African countries at the Doha WTO conference on the central issues of compulsory licensing of drugs and the importation of drugs under a compulsory license by countries that do not have an adequate capacity for the domestic production of the drugs).

119. See Press Release, U.S. Department of Health and Human Services, HHS, Bayer Agree to Cipro Purchase (Oct. 24, 2001) (reporting that under the terms of the HHS-Bayer agreement, the federal government will purchase the first order of 100 million pills at 95 cents per tablet, rather than the previous charge of \$1.77 per tablet), available at <http://www.hhs.gov/news/press/2001pres/20011024.html> (last visited Sept. 5, 2002).

bioterrorist attacks.¹²⁰ The outcome of the Cipro patent dispute suggests that the Bush Administration is reluctant to change its anti-compulsory licensing policy, even when such a policy threatens to jeopardize American lives.¹²¹ The daunting prospect of high casualties, however, would likely compel the government to use compulsory licensing in the event of a large-scale biological or chemical attack in the United States, or in a foreign country that could not afford life-saving antibiotics.¹²² For instance, in 1999, the U.S. government succumbed to public and political pressure and reversed its policy against the compulsory licensing law implemented by the South African government in order to combat its HIV/AIDS epidemic.¹²³ Similarly, the U.S. government will be subject to high public criticism and political pressure if it does not re-evaluate its position so as to utilize compulsory licensing in the wake of a public health emergency caused by super-terrorism.¹²⁴

120. See Mokhiber & Weissman, *supra* note 112 (asserting that the U.S. government is acting hypocritically by contemplating the use of compulsory licensing to stockpile supplies of Cipro while simultaneously trying to limit the ability of poor countries to use compulsory licensing to address their public health crises).

121. See *id.* (accusing the Bush Administration of colluding with the pharmaceutical industry to protect patent monopolies instead of protecting public health); see also Elisabeth Bumiller, *The Nation*; *Public Health or Public Relations*, N.Y. TIMES, Oct. 21, 2001, sec. 4, at 4 (questioning the Bush Administration's decision to prioritize Bayer's patent right on Cipro over consumer concerns of inadequate access to Cipro).

122. See Dolmo, *supra* note 30, at 143-44 (describing the United States' attitudinal change towards South Africa's compulsory licensing law once U.S. officials became aware of the alarming fatality statistics in South Africa associated with HIV/AIDS infections).

123. See *id.* (stating that public health and consumer rights advocates alerted U.S. officials about the dire nature of the public health crisis in South Africa and lobbied successfully to initiate a U.S. policy shift).

124. See Press Release, U.S. Congressman Charles Schumer, Schumer: New Cipro Source Could Dramatically Increase Supply (Oct. 16, 2001) (reporting that Senator Schumer sent a letter to Secretary Thompson of the Department of Health and Human Services, writing that, "[B]ayer can only produce so much Cipro, and we should not put our best response to anthrax in the hands of just one manufacturer . . . If we make arrangements to purchase it from multiple generic drug manufacturers, we'll have it if we need it"), available at http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/PR00728.html (last visited Sept. 5, 2002); see also Mark Weisbrot, *Protecting Pharmaceutical Companies from the Threat of Bio-Terrorism*, ZNet (observing

D. PROPOSED U.S. COMPULSORY LICENSING LEGISLATION

On May 3, 2001, Representative Sherrod Brown (D-Ohio) introduced a bill entitled the Affordable Prescription Drugs and Medical Inventions Act ("House Bill 1708").¹²⁵ If enacted, House Bill 1708 would confer to the Secretary of Health and Human Services ("HHS") and the Federal Trade Commission ("FTC") the authority to grant compulsory licenses of patented prescription drugs and health care devices under certain circumstances,¹²⁶ without the authorization of the patent holders.¹²⁷ The bill requires that generic companies pay reasonable royalties to a patent holder in exchange for a license.¹²⁸

Following the acts of terrorism against the United States on September 11, 2001, and the subsequent anthrax attacks, Representative Brown also sponsored the Public Health Emergency Medicines Act ("House Bill 3235") on November 6, 2001.¹²⁹ House

that pressure from Senator Charles Schumer and consumer advocate groups caused the Secretary of Health and Human Services to threaten to purchase generic drugs if Bayer did not cut its price for Cipro), at <http://www.zmag.org/weispharm.htm> (last visited Sept. 5, 2002).

125. H.R. 1708, 107th Cong. (2001), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR01708:@@L&summ2=m&> (last visited Sept. 5, 2002). House Bill 1708 was referred to the House Committee on the Judiciary and to the Committee on Energy and Commerce. *See id.* Each committee then referred the bill to subcommittees—Subcommittee on Courts, the Internet, and Intellectual Property and Subcommittee on Health—neither of which has taken any further action as of the date of this Comment. *Id.*

126. *See* H.R. 1708, sec. 2(a)(b) (listing five conditions under which compulsory licensing is permissible).

127. *See id.* (granting the discretion to issue compulsory licenses to HHS and the FTC); *see also* Allan Z. Litovsky, *The Law of Unintended Consequences: How Will The Affordable Prescription Drugs and Medical Inventions Act Affect American Health Care?*, 13 No. 5 HEALTH LAW. 20, 21-22 (2001) (emphasizing the significance of amending U.S. patent law to allow compulsory licensing).

128. *See* H.R. 1708, sec. 2(a)(d) (listing a number of factors for the Secretary of HHS and the FTC to consider in determining a reasonable compensation for the patent holder for use of the patent).

129. H.R. 3235, 107th Cong. (2001), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR03235:@@L&summ2=m&> (last visited Sept. 5, 2002). House Bill 3235 was referred to the Committee on the Judiciary, which referred the bill to the Subcommittee on Courts, the Internet, and Intellectual Property. *Id.*

Bill 3235 authorizes the Secretary of HHS to grant compulsory licenses of patented health care products¹³⁰ in the event of a public health emergency.¹³¹ The premise of these two compulsory licensing bills is that introducing more generic competition in the pharmaceutical market would reduce the cost of prescription drugs in the United States and ease monopolistic control of the pharmaceutical industry.¹³² Supporters of the bills believe that even the mere threat of compulsory licensing would likely encourage pharmaceutical companies to provide affordable drugs to U.S. citizens.¹³³

II. ANALYSIS

A. ANALYSIS OF THE COMPULSORY LICENSING FRAMEWORK OF THE TRIPS AGREEMENT

The TRIPS Agreement allows for compulsory licensing under Article 31, but limits its use for antitrust violations, governmental use, and extremely urgent circumstances, including national emergencies.¹³⁴ Article 31, entitled "Other Use Without

The subcommittee has not taken any further action as of the date of this Comment. *See id.*

130. *See* H.R. 3235, sec. 2(a)(e) (defining "health care product" as any drug or device, any biological product, or any technology or process as applied to health or health care).

131. *See id.* (limiting the export of health care products in emergency situations to those countries that provide an adequate system of protection for patent owners' rights).

132. *See* The Affordable Prescription Drugs Act, Statement of Congressman Sherrod Brown, Ranking Member, Commerce Health and Environmental Subcommittee [hereinafter Statement of Congressman Brown] (explaining the importance of implementing market forces to induce pharmaceutical companies to reduce prescription drug costs), at <http://www.house.gov/sherrodbrown/afpda.htm> (last visited Sept. 5, 2002).

133. *See id.* (suggesting that drug companies would voluntarily lower their prices in order to avoid compulsory licensing under the proposed bills).

134. *See* TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(b) (carving out exceptions to the general requirement that the licensee attempt to obtain a voluntary license from the patent holder on reasonable terms and conditions before applying for a compulsory license); *see also id.* Part I, art. 8, para. 2 (providing exceptions to patent enforcement to prevent the abuse of patent rights and

Authorization of the Right Holder,”¹³⁵ does not expressly refer to the term compulsory licensing.¹³⁶ Rather, the permissibility of compulsory licensing is implied when Article 31 is read in conjunction with Article 2(1) of the TRIPS Agreement and Article 5(A)(2) of the Paris Convention of 1967.¹³⁷ Article 2(1) of the TRIPS Agreement states that WTO Members must comply with specific articles of the Paris Convention, including Article 5.¹³⁸ Article 5(A)(2) of the Paris Convention expressly permits the use of compulsory licensing by governmental authorities in order to prevent patent abuses by patent holders.¹³⁹ Therefore, Article 31 of the

unreasonable trade restraints); *see also id.* Part II, sec. 8, art. 40, paras. 1-2 (allowing WTO Members to enact legislation that controls the licensing of patents to prevent anti-competitive practices by patent holders and licensees).

135. *See id.*, Part II, sec. 5, art. 31. Article 31 reads: “Where the law of a Member allows for *other use* of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected . . .” *Id.* (emphasis added); *see also id.*, art. 31, n. 7 (defining the term “other use” in Article 31 as “use other than that allowed under Article 30”); World Trade Organization, *Fact Sheet: TRIPS and Pharmaceutical Patents; Obligations and exceptions* (explaining that “other use” includes compulsory licensing and use by governments for their own purposes), at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Sept. 5, 2002); Abbott, *supra* note 42, at 15 n.34 (noting that footnote 7 to Article 31 indicates that Members may not invoke both Articles 30 and 31 in connection with the same practice).

136. *See Ford, supra* note 51, at 958 (noting that the phrase compulsory licensing does not appear in the text of the TRIPS Agreement).

137. *See id.* (determining that the language of Article 31 implies compulsory licensing); *see also* Abbott, *supra* note 58, at 73-74 (concluding that Article 31 of the TRIPS Agreement expressly allows compulsory licensing, since Article 2 of the TRIPS accord states that the Paris Convention of 1967 applies to Parts I, III, and IV of the TRIPS Agreement); *see also* Paris Convention for the Protection of Industrial Property, July 14, 1967, *reprinted in* INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY 17 (Michael Leaffer ed., 1999) [hereinafter Paris Convention] (establishing a multilateral agreement for intellectual property rights and obligations).

138. *See* TRIPS Agreement, *supra* note 60, Part I, art. 2, paras. 1-2 (emphasizing that the provisions of the TRIPS Agreement do not discredit the existing obligations under other international treaties, particularly the Paris Convention). This article of the TRIPS Agreement also mandates compliance with Articles 1-12 and 19 of the Paris Convention. *Id.*

139. *See* Paris Convention, *supra* note 137, at 24 (stating in Article 5, sec. A(2) that “[e]ach country of the Union shall have the right to take legislative measures

TRIPS Agreement is a key provision for many WTO Members that need expeditious access to affordable prescription drugs.¹⁴⁰

1. *Legal Obstacle to Compulsory Licensing Created by Article 31(f)*

Article 31 of the TRIPS Agreement sets forth conditions under which WTO Members may grant compulsory licenses.¹⁴¹ Article 31(f) of the Agreement is one of the most controversial provisions of the treaty.¹⁴² Subparagraph (f) provides that a compulsory license “[s]hall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”¹⁴³ Subparagraph (k) provides that “[m]embers are not obliged to apply the conditions set forth in [subparagraph (f)] where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”¹⁴⁴ The express text of the provision limits a government’s use of compulsory licensing to predominantly supply its domestic market, except when necessary to remedy anti-competitive practices.¹⁴⁵

providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”); *see also* Julian-Arnold, *supra* note 32, at 352 (analyzing compulsory licensing provisions under the Paris Convention).

140. *See* TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(b) (allowing other uses of patents without authorization of the right holder, which may be interpreted as allowing compulsory licensing). *But see* Ford, *supra* note 51, at 963-67 (discussing the ambiguity of the language in Article 31 and the potential for disparate interpretation of the ambiguous terms).

141. *See supra* note 75 and accompanying text (listing pre-conditions to granting a compulsory license); *see also* Abbott, *supra* note 58, at 73-75 (analyzing Article 31 provisions of the TRIPS Agreement).

142. *See* Letter to USTR Zoellick, *supra* note 52 (indicating that public health coalitions argue for a liberal interpretation of subparagraph (f), while the United States and the European Community support a more restrictive view).

143. TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(f).

144. *Id.* art. 31(k).

145. *See* Carlos Correa, *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*, SOUTH CENTRE PUBLICATIONS, ch. X, sec. 2 (2000) (concluding that a compulsory licensee can export a licensed product when the export is not the primary transaction of the licensee with regard to the product, or when the patent holder is engaging in monopolistic practices), at http://www.southcentre.org/publications/publichealth/publichealth-12.htm#P1449_146569 (last visited Sept. 5, 2002); *see also* Consumer Project on

From the perspective of WTO Members from developing countries, the restriction under Article 31(f) on compulsory licensing for exports presents a barrier to essential medicines.¹⁴⁶ The provision stipulates that a compulsory license must be used “predominantly” (i.e., more than half) for the supply of the domestic market of the government issuing the license.¹⁴⁷ On its express terms, subparagraph (f) does not prohibit a WTO Member from authorizing a compulsory license to import medicines, but it places a significant constraint on the exporters.¹⁴⁸ By requiring foreign compulsory licensees to supply a predominant part of their production to their domestic market, subparagraph (f) limits the licensee’s ability to export medicines to a country with public health needs.¹⁴⁹ This limitation creates a problem

Technology, Comments Presented at the WHO/WTO Joint Secretariat Workshop on Differential Pricing and Financing of Essential Drugs (delivered in Høsbjør, Norway on Apr. 11, 2001) [hereinafter CPT’s Comments Presented at the WHO/WTO Joint Secretariat Workshop] (commenting that the United States extensively uses the Article 31(k) exception of the TRIPS Agreement by granting compulsory licenses to remedy anti-competitive conduct, irrespective of the market restrictions imposed by Article 31(f)), available at <http://www.cptech.org/ip/health/econ/jamie-hosbjor.html> (last visited Sept. 5, 2002).

146. See Letter to USTR Zoellick, *supra* note 52 (analyzing the harmful consequences of restricting compulsory licensing to domestic manufacturers, and arguing that the American and European public do not support their government’s trade policies, which limit access to affordable medicines for developing countries).

147. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31(f). The relevant text reads: “Any such use shall be authorized *predominantly* for the supply of the domestic market of the Member authorizing such use.” *Id.* (emphasis added). However, this limitation may not apply in cases where a government grants a compulsory license to remedy anti-competitive practices. See *id.* art. 31(k) (granting discretion to member nations as to the application of the export limitation under Section (f)); see also Correa, *supra* note 145, at sec. 2 (interpreting Article 31(f) to mean that exports “should probably not constitute the main activity of the licensee with regard to the licensed product”).

148. See Consumer Project on Technology, *Exports of Medicines under TRIPS* [hereinafter *Exports of Medicines under TRIPS*] (recognizing that although imports of medicines under a compulsory license are permitted under the TRIPS framework, importers will have difficulty finding an export source based on the express language of Article 31(f)), at <http://lists.essential.org/pipermail/ip-health/2001-November/002425.html> (last visited Sept. 5, 2002).

149. See Frederick M. Abbott, Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health 26 (Feb. 2002) (unpublished paper, on file with Quaker United Nations Office -

for developing countries that either completely lack or have an insufficient capacity for manufacturing pharmaceuticals.¹⁵⁰ Under the existing TRIPS Agreement rules, poor countries can procure medicines from other developing or least developed countries that do not currently have patent protection for pharmaceutical products.¹⁵¹ However, this option will be unavailable once the suppliers become

Geneva) (stating that “Article 31(f) creates difficulties on the supply and demand side of the generic drug pipeline” because generic suppliers are precluded from exporting under a compulsory license, while importers are unable to satisfy the public demand for pharmaceuticals due to industrial constraints and the export limitation of Article 31(f)).

150. See World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Fourth Ministerial Conference in Doha, Qatar, para. 6 (adopted Nov. 14, 2001) [hereinafter Doha Declaration] (acknowledging that developing countries with inadequate manufacturing capacities may have problems in implementing compulsory licensing under the TRIPS Agreement), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Sept. 5, 2002). However, instead of addressing the serious problem that Article 31(f) poses, the WTO referred the issue to the TRIPS Council to find a solution and report back before the end of 2002. See *id.* Paragraph 6 of the Doha Declaration reads:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Id.; see also World Trade Organization, Ministerial Declaration, Fourth Ministerial Conference in Doha, Qatar, paras. 38-41 (adopted Nov. 14, 2001) (recognizing the need to provide funding to developing countries to improve their technological capacity), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (last visited Sept. 5, 2002).

151. See *Exports of Medicines under TRIPS*, *supra* note 148 (appreciating the present availability of medicines that are not under patent (“off-patent medicines”), but warning that developing countries will have difficulty in finding exporters in the future once the TRIPS Agreement becomes effective for all WTO developing Members); see also Abbott, *supra* note 42, at 3 (acknowledging the permissibility of importing off-patent medicines from Brazil, China, and India, since the existing TRIPS Agreement does not mandate an export or import restriction). Brazil amended its patent law in 1996 to authorize patent protection for pharmaceuticals as of the effective date of the amendments, but did not authorize retroactive protection for non-patented products already on the market. *Id.* at 3 n.2. Also, although India does not currently provide patent protection for pharmaceuticals, the Parliament is debating an amendment to the patent law that would mandate protection. *Id.* at 3 n.3.

TRIPS-compliant in 2005 or 2006, requiring them to protect the legitimate rights of patent holders.¹⁵²

A restrictive interpretation of Article 31(f) creates a paradox.¹⁵³ The poor nations that are most in need of medicines are prevented from using compulsory licensing, while rich nations with developed industrial and technological capacities benefit from the compulsory licensing provisions of the TRIPS Agreement.¹⁵⁴ These unintended consequences suggest that Article 31(f) should be construed more liberally so as to allow WTO Members to grant compulsory licenses to foreign generic manufacturers, who can produce and export health products back to the country that issued the license.¹⁵⁵

2. *The Article 30 Approach to Authorizing Exports of Medicines Under a Compulsory License*

Article 30 of the TRIPS Agreement, a patent exception clause, could also be interpreted broadly so as to circumvent the export problems that arise under Article 31(f).¹⁵⁶ Article 30 expressly provides exceptions to exclusive patent rights with three conditions: (1) the exception must be limited; (2) it must not unreasonably

152. See Abbott, *supra* note 42, at 3 (noting that in recognition of the social and economic adjustments that countries must undergo to comply with the TRIPS Agreement, the WTO granted a transition period for some member countries to become TRIPS compliant, that is. developing Members have until January 1, 2005, and least developed Members have until January 1, 2006, to comply).

153. See *id.* at 15 (discussing the implementation problems that result from a constrictive reading of Article 31(f)).

154. See *id.* (reasoning that Article 31(f) impedes developing countries from implementing compulsory licensing because they lack the capacities and the domestic markets for local manufacturing); see also Letter to USTR Zoellick, *supra* note 52 (noting that a country's level of technological advancement affects its ability to use compulsory licensing under the provisions of Section 31(f)).

155. See Ministerial Declaration, *supra* note 150, at paras.17-19 (reaffirming the need for a flexible interpretation of TRIPS to allow governments to protect public health over patent rights); see also Letter to USTR Zoellick, *supra* note 52 (recommending that the United States support an expansive reading of Article 31(f) so that developing countries can overcome a serious impediment to compulsory licensing caused by underdeveloped industrial capacities).

156. See *Exports of Medicines under TRIPS*, *supra* note 148 (recommending that developing countries adopt the Article 30 approach and "take their chances on a WTO dispute panel").

conflict with the normal use of the patent; and (3) the legitimate interests of the patent holder must be protected, while also taking into account the legitimate interests of third parties.¹⁵⁷ The language of Article 30 implies that a WTO Member may export patented pharmaceuticals to a foreign market in cases where the importing country does not provide patent protection,¹⁵⁸ or where the importing country grants a compulsory license.¹⁵⁹ Applying the “limited exception” in Article 30 to the export of medicines would be most consistent with the WTO Ministerial declaration (“Doha Declaration”) drafted at the recent Doha conference.¹⁶⁰ The Doha Declaration states that WTO Members should implement the TRIPS Agreement in a manner supporting public health and promoting access to medicines for all.¹⁶¹ Thus, a liberal interpretation of Article

157. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 30. Article 30 reads:

[WTO] Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

See also Abbott, *supra* note 149, at 35-36 (interpreting the express terminology of Article 30). “Limited exceptions” means that the WTO may interpret Article 30 in a manner allowing deviations from the exclusive patent rights conferred by Article 28 of the TRIPS Agreement, but such deviations must be within certain boundaries. See *id.* at 35. “Provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent” means that deviations from the enforcement of patent rights should not operate inequitably in the ordinary use of patents. See *id.* “[A]nd do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties” means that deviations should not inequitably affect the patent holder’s expected rights, while also taking into consideration the effect on third parties. See *id.* at 36.

158. See *Exports of Medicines under TRIPS*, *supra* note 148 (identifying India as an export source that does not currently provide patent protection for pharmaceutical products, but will be obligated to comply with TRIPS in 2006).

159. See Abbott, *supra* note 42, at 14-15 (reasoning that as long as the three criteria of Article 30 are satisfied, the clause allows an exception for the issuance of a compulsory license to export products, an action that Article 31(f) fails to expressly permit).

160. See *id.* at 15 (suggesting that unmet public health and nutrition needs can satisfy the “limited” nature of the Article 30 exception to patent rights).

161. See generally Doha Declaration, *supra* note 150 (recognizing the need to render an interpretation of the TRIPS Agreement that promotes public health). Paragraph 4 of the Doha Declaration reads: “[W]e affirm that the [TRIPS]

30 would permit a country to use compulsory licensing for exporting medicines for public health purposes, where the legitimate interests of the patent owner are protected in the export market.¹⁶² This is the approach that U.S. House Representatives invoked in House Bill 3235, the compulsory licensing bill discussed *supra* that is currently pending in Congress.¹⁶³

B. ANALYSIS OF PENDING U.S. COMPULSORY LICENSING BILLS

The compulsory licensing bills that are presently in congressional committees are consistent with the compulsory licensing provisions of the TRIPS Agreement.¹⁶⁴ House Bills 1708 and 3235 satisfy the conditions for compulsory licensing set forth in Article 31 of the TRIPS accord.¹⁶⁵ Also, House Bill 3235 adopts a liberal construction of Article 30 of the TRIPS agreement, which allows the U.S. government to issue compulsory licenses with more expansive

Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." *Id.*

162. See Letter to USTR Zoellick, *supra* note 52 (urging the U.S. government to support an interpretation of Article 30 that would complement the approach taken in House Bill 3235, which proposes to permit exports of medicines for public health emergencies); see also Abbott, *supra* note 149, at 55 (analyzing the significance of the Doha Declaration with regards to eliminating legal barriers to compulsory licensing). Paragraph 6 of the Doha Declaration indicates that when a WTO Member cannot address its public health needs by issuing a compulsory license due to an insufficient manufacturing capacity, that insufficiency can serve as a basis for authorizing another WTO Member to export the necessary drugs to its co-Member by invoking an Article 30 limited exception to exclusive patent rights. See *id.*; see also Doha Declaration, *supra* note 150, para. 6.

163. See H.R. 3235, sec. 2(a)(c) (authorizing the Secretary of HHS to grant compulsory licenses for export of patented health care products in the event of public health emergencies).

164. See *infra* notes 165-166 and accompanying text (demonstrating that the proposed U.S. compulsory licensing bills comply with international law).

165. See generally H.R. 1708; H.R. 3235 (noting that House Bills 1708 and 3235 do not contain any provisions that would violate any of the conditions for compulsory licensing in Article 31 or any other TRIPS provisions). See also H.R. 1708 sec. 2(a)(e); H.R. 3235 sec. 2 (a)(d) (requiring that any regulations adopted implement the purposes of the legislation in compliance with the TRIPS Agreement).

authority than the existing patent regime offers.¹⁶⁶ The incorporation of these bills into U.S. patent law would signify U.S. support for a WTO interpretation of the TRIPS Agreement that protects public health and promotes access to medicines for all nations.¹⁶⁷

1. Compulsory Licensing Framework of House Bill 1708

House Bill 1708 establishes guidelines under which the Secretary of HHS and the FTC could grant a compulsory license for health-related products.¹⁶⁸ The language of House Bill 1708 gives the Secretary and the FTC broad discretion in evaluating the criteria for the issuance of unauthorized patent licenses.¹⁶⁹ First, it requires a determination that the patent holder (or its contractor, licensee, or assignee) has neither taken, nor is expected to take “effective steps” within a “reasonable time” to apply the patented invention in a “field of use.”¹⁷⁰ However, the bill does not define what constitutes “reasonable time,” “effective steps,” and “field of use,” deferring to the Secretary and the FTC to define the terms.¹⁷¹ The second condition requires a determination that the patent holder (or any of its contractors, licensees, or assignees) is unable to provide medicines or other health care products “adequately” to alleviate public health or safety emergencies.¹⁷² The bill, however, does not specify what constitutes adequacy for satisfying health and safety

166. See *infra* notes 189-194 and accompanying text (developing the argument that although Article 30 has not yet been implemented by WTO Members to allow an export exception for compulsory licensing—which is expressly authorized in House Bill 3235—it may be so interpreted).

167. See Letter to USTR Zoellick, *supra* note 52 (indicating that if the United States adopts a policy approach similar to the export exception invoked in House Bill 3235, it would allow developing countries to take advantage of the flexibility of the TRIPS Agreement).

168. See H.R. 1708, sec. 2(a)(b) (enumerating five conditions under which government officials may issue compulsory licenses).

169. See Litovsky, *supra* note 127, at 20 (emphasizing that the bill would grant unprecedented powers to the Secretary of HHS and the FTC to grant compulsory licenses for health care products).

170. H.R. 1708, sec. 2(a)(b)(1).

171. See Litovsky, *supra* note 127, at 20 (arguing that the language in the bill is too ambiguous, thereby giving too much discretion to public health authorities).

172. H.R. 1708, sec. 2(a)(b)(2).

needs.¹⁷³ The Secretary and the FTC have discretion in determining this adequacy requirement.¹⁷⁴

The third condition for compulsory licensing under House Bill 1708 is a determination that the patent holder employs anti-competitive practices.¹⁷⁵ Although the bill contains examples of monopolistic practices—e.g., excessive pricing and unreasonable licensing terms for a patented invention relating to health care—it does not provide clear criteria for evaluating the reasonableness of the patent holder's practices to determine the presence of anti-competitive behavior.¹⁷⁶ Under the fourth condition, the Secretary of HHS or the FTC must determine that the patent obstructs future innovations that involve an "important technical advance."¹⁷⁷ Once again, the Secretary and the FTC have considerable latitude in determining what constitutes an "important technical advance" and deciding whether such technological progress warrants the limitation of patent rights.¹⁷⁸ Finally, the Secretary or the FTC can issue a compulsory license if they determine that the patent is both necessary for continuing research that promotes public health and is licensed on unreasonable terms and conditions.¹⁷⁹ The bill gives the authorities discretion to evaluate the reasonableness of patent license terms and conditions.¹⁸⁰

The broad language of House Bill 1708 allows a flexible interpretation of the conditions for compulsory licensing for health-

173. See Litovsky, *supra* note 127, at 20 (contemplating whether the cost of a pharmaceutical product would factor into the adequacy analysis).

174. See *id.* (criticizing the broad authority the bill grants to the Secretary of HHS and the FTC in determining whether to issue compulsory licenses).

175. H.R. 1708, sec. 2(a)(b)(3).

176. See *id.* (providing two examples of anti-competitive practices that would justify compulsory licensing).

177. H.R. 1708, sec. 2(a)(b)(4).

178. See Litovsky, *supra* note 127, at 20 (highlighting that the bill fails to specify the criteria for determining what constitutes an "important technological advance," and falls short of stating who would make the determination).

179. H.R. 1708, sec. 2(a)(b)(5).

180. See Litovsky, *supra* note 127, at 20-21 (criticizing the lack of substantive guidelines for evaluating the public health interest and the "reasonableness" of the license terms and conditions).

related products in the United States.¹⁸¹ If Congress enacts House Bill 1708, compulsory licensing may become a useful administrative tool for deterring pharmaceutical companies from inflating drug prices.¹⁸² Controlling the prices of pharmaceutical products is more important than ever in the aftermath of September 11, 2001, given the increase in demand for the production and worldwide availability of counterterrorism health products.¹⁸³

2. *Compulsory Licensing Framework of House Bill 3235*

House Bill 3235 provides a narrower scope for the use of compulsory licensing than House Bill 1708, but may have far greater global consequences.¹⁸⁴ House Bill 1708 grants officials the authority to issue compulsory licenses when a patent holder satisfies one of five conditions.¹⁸⁵ By contrast, section 2(a)(a) of House Bill 3235 limits the use of compulsory licensing by the government to national public health emergencies.¹⁸⁶ The Secretary of HHS, the sole decision-making authority, still has flexibility in determining what circumstances constitute a public health emergency.¹⁸⁷ In addition,

181. *See id.* at 20 (commenting that the broad language of the bill grants a high degree of discretion to the Secretary of HHS and the FTC).

182. *See* Statement of Congressman Brown, *supra* note 132 (promoting the bill as the best weapon against the brand-name pharmaceutical industry's exploitation of patented drugs).

183. *See, e.g.*, Press Release, *supra* note 124 (calling on HHS to purchase cheaper versions of Cipro in bulk quantities rather than Bayer's more expensive version in order to calm the public and meet its needs).

184. *See* Consumer Project on Technology, *CPTech Comments on H.R. 3235 the "Public Health Emergency Medicines Act"* [hereinafter *CPT's Comments on H.R. 3235*] (discussing the importance of a provision that would allow exports of medicines in foreign public health emergency situations arising from biological or chemical terrorism), at <http://lists.essential.org/pipermail/ip-health/2001-November/002358.html> (last visited Sept. 5, 2002).

185. *See supra* notes 168-180 (discussing the five circumstances in which compulsory licensing may be granted under House Bill 1708)

186. H.R. 3235, sec. 2(a)(a).

187. *See id.* (lacking a definition for "public health emergency"); *see also* Joint Statement, *supra* note 68 (noting that although Article 31(b) of the TRIPS Agreement authorizes the use of compulsory licensing by WTO Members to address an emergency situation, it fails to define what constitutes an emergency situation, thereby allowing the individual countries to make the determination).

section 2(a)(c) of House Bill 3235 gives the Secretary the authority to permit the use of compulsory licenses for exporting medicines to a country experiencing a public health emergency.¹⁸⁸ In conformity with Article 30 of the TRIPS Agreement, the provision only allows exports from countries that protect the legitimate interests of the patent owner.¹⁸⁹

Nonetheless, House Bill 3235 may actually provide more expansive authority than the TRIPS Agreement for allowing the government to authorize the non-voluntary use of a patent for a foreign market.¹⁹⁰ The current TRIPS framework does not explicitly authorize the export of medicines that are manufactured pursuant to a compulsory license.¹⁹¹ However, as discussed earlier, a liberal interpretation of Article 30 of the TRIPS Agreement, which allows limited exceptions to patent rights enforcement, could permit exports of medicines if the export market protects the legitimate interests of the patent holder.¹⁹² This is the approach proposed in House Bill 3235.¹⁹³ Thus, the bill expressly allows the U.S. government to use compulsory licensing to export drugs to foreign countries under requisite circumstances, while the permissibility of such an act is still ambiguous under the TRIPS Agreement.¹⁹⁴ The approach taken by

188. H.R. 3235, sec. 2(a)(c).

189. *See* H.R. 3235, sec. 2(a)(c)-(a)(d) (expressing conformity with the provisions of the TRIPS Agreement).

190. *See* Letter to USTR Zoellick, *supra* note 52 (indicating that Article 30 could authorize exports of medicines, like House Bill 3235, but developing countries have not utilized it as of yet due to opposition from the United States and the European Union).

191. *See* TRIPS Agreement, *supra* note 60, Part II, sec. 5, arts. 30-31 (lacking an express provision that permits exports of medicines).

192. *See* Abbott, *supra* note 42, at 15-16 (concluding that an Article 30 "limited exception" may apply to compulsory licensing for exports).

193. *See* H.R. 3235, sec. 2(a)(c) (permitting the export of health care products in public health emergencies, pursuant to the unauthorized use of a patent, where the legitimate interests of the patent owner are protected in the export market); *see also* Letter to USTR Zoellick, *supra* note 52 (advocating the approach taken by the bill in authorizing the use of compulsory licensing for the export of medicines).

194. *See* Letter to USTR Zoellick, *supra* note 52 (comparing House Bill 3235 to the TRIPS Agreement and submitting that the language of TRIPS Article 30 could and should be construed to conform to the export provision of the U.S. bill).

House Bill 3235 could save thousands of lives in the event of a large-scale international incident of biological or chemical terrorism.¹⁹⁵

C. IMPLICATIONS OF A U.S. COMPULSORY LICENSING LAW ON
GLOBAL COUNTERTERRORISM EFFORTS

House Bills 1708 and 3235 primarily address the high cost of prescription drugs in the United States.¹⁹⁶ However, if Congress enacts the bills into law, compulsory licensing arrangements for prescription drugs in the United States would also increase global access to therapeutic drugs to treat victims of biological or chemical terrorism.¹⁹⁷

1. *Impact on Worldwide Availability of Pharmaceutical Products to
Combat Super-Terrorism*

House Bills 1708 and 3235 would facilitate access to counter-terrorism drugs for foreign nations that are victimized by biological or chemical warfare in two ways.¹⁹⁸ First, House Bill 3235 would allow compulsory licensees to export therapeutic drugs immediately to foreign countries following a biological or chemical attack.¹⁹⁹

195. See *id.* (suggesting that House Bill 3235 could be used to rush life-saving medicines to countries with inadequate access to health related products in case of an act of biological terrorism in that country).

196. See Statement of Congressman Brown, *supra* note 132 (attributing the inflation in employee health plan premiums and the curtailment of Medicare coverage to an excessive increase in prescription drug costs in the United States since 1993). Brown also notes that the primary incentive for introducing compulsory licensing bills in Congress is to reduce the cost of prescription medications for U.S. citizens. *Id.*

197. See CPT's Letter to Secretary Thompson, *supra* note 111 (urging the Bush Administration to provide a legal framework for acquiring critical medicines immediately).

198. See CPT's Comments on H.R. 3235, *supra* note 184 (determining that House Bill 3235 would facilitate the use of compulsory licensing by addressing two controversial issues—the amount of remuneration due to a patent holder and the ability to export products pursuant to a compulsory license).

199. See *infra* notes 204-25 and accompanying text (discussing the global benefits of allowing one country to use compulsory licensing to export health related products to another country).

Second, both House Bills 3235 and 1708 provide a compensation framework that would expedite the compulsory licensing process.²⁰⁰

The export provision of House Bill 3235 is necessary to facilitate foreign access to therapeutic drugs that pharmaceutical companies patent in the United States.²⁰¹ Most developing countries do not have the factories to produce vaccines or antibiotics that would alleviate the suffering and reduce the casualties from biological or chemical warfare.²⁰² Following the bioterrorism attacks in the United States in October 2001, many governments focused on methods of improving the response to such future events in their own countries.²⁰³ However, in terms of preparation for responding to super-terrorism, the United States is in the best position to provide public health disaster relief in case of an international incident.²⁰⁴ Without House Bill 3235, it is unclear how much time would pass before the U.S. government would render aid to a foreign country facing a public health crisis from super-terrorism.²⁰⁵ For example, it took years of pressure by

200. See discussion *infra* Part II.C.2 (showing the need for legislation that would address the concerns of U.S. officials regarding the compensation process for compulsory licensing under the current law).

201. See Joint Letter from Consumer Project on Technology, Essential Action, Médicines Sans Frontières, Oxfam International, Health GAP Coalition, and the Third World Network to the World Trade Organization's TRIPS Council [hereinafter Joint Letter to the TRIPS Council] (arguing that exports of patented medicines are essential for protecting public health and promoting universal access to medicines), available at <http://www.cptech.org/ip/health/art30exports.html> (last visited Sept. 5, 2002).

202. See Letter to USTR Zoellick, *supra* note 52 (noting that local manufacturers in most developing countries do not have the factories or technological capacity to produce pharmaceutical products).

203. See Pan American Health Organization ("PAHO"), Conclusions of the Advisory Meeting on Bioterrorism (reporting that the bioterrorism incidents in the United States precipitated a PAHO conference to discuss preparation for responding to bioterrorism), at <http://www.paho.org/english/PED/antiterrorism.htm> (last visited Sept. 5, 2002).

204. See *supra* notes 9-10 and accompanying text (showing that the United States began to prepare for bioterrorism and chemical terrorism in 1995 following the Tokyo subway chemical attack, and increased its efforts and resources for responding after the bioterrorist attacks in the United States in 2001).

205. See, e.g., Dolmo, *supra* note 30, at 142-43 (stating that the U.S. government and the pharmaceutical industry did not cooperate with the South African government's efforts to address its HIV/AIDS epidemic for two years and only agreed to negotiate after feeling public and political pressure); see also, e.g.,

interest groups to convince the U.S. authorities to permit the use of compulsory licenses for alleviating the HIV/AIDS pandemic, even while thousands of infected people worldwide were dying of AIDS.²⁰⁶ House Bill 3235 provides an implementation mechanism that would expedite the process of providing humanitarian assistance to poor countries experiencing health emergencies.²⁰⁷ Clearly, the Secretary of HHS may still be reluctant to issue compulsory licenses due to pressure from the pharmaceutical industry.²⁰⁸ However, the media, the public, public health interest groups, and some politicians would also likely exert pressure on the Secretary, compelling him to exercise his authority under House Bill 3235.²⁰⁹

Furthermore, the passage of House Bill 3235 would serve the best interests of American citizens living abroad in a country targeted for super-terrorism.²¹⁰ If a foreign country has an inadequate supply of medicines, American lives could depend on the availability of drugs exported from the United States.²¹¹ The U.S. government has an

Mokhiber & Weissman, *supra* note 112 (alleging that the U.S. government allied itself with the pharmaceutical industry to protect patent rights rather than public health, even when American lives were at risk during the Cipro patent dispute).

206. See Gathii, *supra* note 18, at 733 (reporting that, by 1999, at least fifteen million Africans had died of AIDS, even though AIDS can be treated with a combination of drugs).

207. See CPT's *Comments on H.R. 3235*, *supra* note 184 (proposing that the provision for exports of medicines in House Bill 3235 would allow the United States to rush medicines to a foreign country during a public health emergency generated by an act of biological warfare).

208. See Dolmo, *supra* note 30, at 143 (discussing the pharmaceutical industry's powerful influence on U.S. trade policies with respect to patent rights).

209. See *id.* at 143-44 (noting that public pressure, together with successful lobbying efforts by public health and consumer rights interest groups, influenced U.S. officials to change the trade policy regarding the use of compulsory licensing for HIV/AIDS drugs).

210. See Letter to USTR Zoellick, *supra* note 52 (contending that House Bill 3235 could save the lives of many Americans living in developing countries with inadequate access to pharmaceutical drugs).

211. See *id.* (reasoning that under House Bill 3235, the Secretary of HHS could authorize generic manufacturers in the United States to produce and export patented medicines to countries in which American lives may be at risk in a public health crisis).

obligation to aid American citizens living on foreign soil.²¹² However, without the export provision of House Bill 3235, the U.S. government does not have an adequate legislative vehicle to ensure that Americans in foreign countries receive supplies of antibiotics for treatment against exposure to biological or chemical agents.²¹³

The United States also needs the proposed compulsory licensing bills to provide clarity as to the remuneration entitlements of patent holders who do not authorize the government's licensing of their patents.²¹⁴ Presently, the United States may issue compulsory licenses for patents to address public health concerns under its eminent domain authority in 28 U.S.C. § 1498.²¹⁵ However, section 1498 is an inadequate provision for compulsory licensing because it does not provide a legal framework for determining the royalty fees to which patent holders are entitled for the use of their patents.²¹⁶ The

212. See Madeleine K. Albright, *Countering Terrorism Abroad*, in SUPER TERRORISM, *supra* note 1, at 113 (stating that the United States must provide the best security possible to U.S. citizens living all around the world, even to diplomatic personnel, who according to international law are legally under the protection of their host countries).

213. See CPT's Comments on H.R. 3235, *supra* note 184 (implying that the export of patented medicines is discouraged under the current U.S. patent regime).

214. See *infra* notes 215-20 and accompanying text (discussing the problems under current U.S. law regarding compensation for the issuance of a compulsory license law and the need to address them in order to increase access to essential medicines in case of a public health emergency).

215. See 28 U.S.C. § 1498(a) (1994) (permitting the federal government to use or license a patent without the authorization of the patent owner); see also Memorandum from Al Engelberg, former U.S. Justice Department attorney, to Senator Charles Schumer (explaining, with reference to Cipro, that the government may assert the same defenses to the patent infringement allegation that are available to a private party, i.e., the patent is invalid, not infringed, or unenforceable), at <http://lists.essential.org/pipermail/ip-health/2001-October/002105.html> (last visited Sept. 5, 2002).

216. See Press Release, U.S. Congressman Sherrod Brown, GOP Bioterrorism Plan Neglects Key Points (Nov. 15, 2001) [hereinafter GOP Bioterrorism Plan] (commenting that the Bush Administration would not invoke its eminent domain authority to override Bayer's patent for Cipro because the amount of compensation to be decided later by a judge may be too high, and contending that House Bill 3235 has an administrative compensation process that would eliminate that element of uncertainty), available at <http://www.house.gov/sherrodbrown/bioterror1115.html> (last visited Sept. 5, 2002).

statute allows patent owners to sue the government for compensation for patent infringement, but only after the government issues a compulsory license.²¹⁷ Consequently, since the amount of compensation is unclear at the outset, a judicial holding could subject the government to high compensatory liability.²¹⁸ The unpredictability of this compensation process under 28 U.S.C. § 1498 deters the use of compulsory licensing.²¹⁹ House Bills 1708 and 3235 would mitigate this problem by providing clear criteria for an administrative determination of reasonable compensation at the time of the licensing.²²⁰

Under the remuneration provisions of the bills, public officials would determine a “reasonable” remuneration for use of a patent based on numerous factors.²²¹ Among the factors to consider are the risks and costs associated with the R&D of the product, the degree of

217. See 28 U.S.C. § 1498(a) (granting a patent owner the right to sue the government for the non-voluntary use of its patent and receive compensation in an amount determined by a judge). *But see* *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1282-83 (Fed. Cir. 1988) (holding that 28 U.S.C. § 1498(a) prevents a patent holder from enjoining a compulsory licensee from selling the patented product to the federal government and from suing the licensee for patent infringement).

218. See *GOP Bioterrorism Plan*, *supra* note 216 (stating that Secretary Thompson of HHS argued against invoking 28 U.S.C. § 1498 to override Bayer’s patent on Cipro because the amount of damages for which the government would be liable could be too excessive).

219. See *CPT’s Comments on H.R. 3235*, *supra* note 184 (fearing that the uncertainty surrounding the compensation issue for compulsory licensing under 28 U.S.C. § 1498 influenced the U.S. government’s reluctance to use compulsory licensing to obtain an adequate stockpile of Cipro).

220. See H.R. 1708, sec. 2(a)(d) (2001) (providing a list of considerations for the Secretary of HHS and the FTC to evaluate the “reasonableness of . . . the remuneration” to be paid to a patent owner for the authorized use of its patent); *see also* H.R. 3235, sec. 2(a)(b) (2001) (granting the Secretary of HHS the right to determine “reasonable remuneration for use of the patent”); *see also* *CPT’s Comments on H.R. 3235*, *supra* note 184 (stating that “HR 3235 is needed to introduce more predictability and certainty in the compensation process, so that public health officials can act fast and confidently, to address a crisis as it happens”).

221. See H.R. 1708, sec. 2(a)(d) (listing six factors to consider in determining remuneration for the compulsory licensing of a patent); *see also* H.R. 3235, sec. 2(a)(b) (enumerating nine factors that the Secretary of HHS may take into account when determining a reasonable compensation amount to a patent holder for the unauthorized use of its patent).

importance of the invention to public health, the degree to which the government funded the research and development of the invention, and the public health benefits arising from increased access to the product.²²² In stark contrast, the amount of damages under the current compensation system of 28 U.S.C. § 1498 may be based on the financial loss of the patent owner resulting from the compulsory license.²²³ Under this formula, the government could end up paying the same amount as it would have originally paid for the brand-name drug before issuing the compulsory license, and additionally, it would incur legal expenses from the litigation.²²⁴ This result would defeat the purpose of the compulsory license, which is to increase the availability of essential drugs at a reasonable cost.²²⁵

2. *Impact on R&D of Pharmaceutical Products that Combat Super-Terrorism*

Compulsory licensing legislation in the United States would not hinder the pharmaceutical industry's ability to develop new medicines that counter biological or chemical agents.²²⁶ The

222. H.R. 1708, sec. 2(a)(d); H.R. 3235, sec. 2(a)(b); *see also* Mokhiber & Weissman, *supra* note 112 (discussing the compensation criteria of House Bill 3235).

223. *See* Correa, *supra* note 145, sec. 3.1 (explaining that remuneration under 28 U.S.C. § 1498 may be based on the amount of loss incurred by the patent owner, not the amount gained by the licensee); *see also, e.g.,* Leeson Corp. v. U.S., 599 F.2d 958, 969 (Ct. Cl. 1979) (holding that in an eminent domain case, the proper measure of damages is "what the owner has lost, not what the taker has gained").

224. *See* Todd Zwillich, *Bill Would Allow Emergency Bypass of Drug Patents*, REUTERS, Nov. 8, 2001 (reporting that supporters of House Bill 3235 claim that under the current system, a potential suit for patent infringement against the government could be very costly to the government), *available at* <http://lists.essential.org/pipermail/ip-helath/2001-November/002366.html> (last visited Sept. 5, 2002).

225. *See id.* (indicating that the compensation process of 28 U.S.C. § 1498 frustrates the purpose of compulsory licenses).

226. *See* Dolmo, *supra* note 30, at 160-61 (presenting the microeconomic theory that compulsory licensing will increase drug sales when prices decrease, and therefore compulsory licensing does not harm sales revenue to the extent that drug industries contend); *see also* Statement of Congressman Brown, *supra* note 132 (noting that drug companies whose patents are under compulsory licenses would still reap the financial rewards of marketing their products first, and would be entitled to royalties from generic producers); Médecins Sans Frontières, MSF

pharmaceutical industry and other opponents of compulsory licensing allege that revenue from drug sales is necessary to maintain investments and recoup R&D costs.²²⁷ The occasional use of compulsory licensing by the government, however, would not likely dissuade investors from participating in a highly lucrative industry.²²⁸ Even if private investments in the industry decrease slightly, it would not drastically affect R&D financing.²²⁹ Pharmaceutical companies finance less than half of the R&D for new products.²³⁰ The majority of R&D funding comes from American tax dollars, private foundations, and state and local governments.²³¹ Also, the companies receive generous tax breaks on their portion of the R&D expenditure.²³² Moreover, the government offers drug companies

Response to 'Boys from Brazil' (asserting that "[w]ith Africa accounting for only one percent of drug sales, it is ludicrous to suggest that the use of generics in Africa diminishes the economic incentive for multinationals to conduct research"), at <http://www.msf.org/content/page.cfm?articleid=826FCC89-E1EC-4E25-99DE3E9BB3FAC3D7> (last visited Sept. 5, 2002).

227. See Carroll, *supra* note 29, at 2469 (discussing developed countries' argument that investors would consider the pharmaceutical industry a risky investment because compulsory licensing would preclude drug companies from recovering their R&D expenditures).

228. See Statement of Congressman Brown, *supra* note 132 (highlighting the fact that profits in the pharmaceutical industry are at least five percent higher than profits in any other industry and will increase by sixteen to eighteen percent over the next four years); see also U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS 104 (1993) (finding that, throughout the 1980s, the net returns on pharmaceutical R&D well exceeded the cost of capital investments, including the time and risks incurred by investors), *available at* http://www.wws.princeton.edu/~ota/disk1/1993/9336_n.html (last visited Feb. 28, 2002).

229. See Statement of Congressman Brown, *supra* note 132 (indicating that compulsory licensing would not impair R&D capabilities of drug companies because a large proportion of R&D is subsidized through non-industry funding).

230. See *id.* (presenting data that show drug companies contribute less than half of the overall pharmaceutical R&D expenditures in the United States).

231. See *id.* (stating that taxpayers fund forty-two percent of pharmaceutical R&D, while other non-pharmaceutical sources generate eleven percent of R&D financing).

232. See PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" ii [hereinafter RX R&D MYTHS] (highlighting that in addition to obtaining federal funding, pharmaceutical companies receive tax advantages for conducting research and developing new drugs), *available at*

additional financial incentives for testing the safety of drugs for children.²³³

The enactment of House Bill 1708 would ensure that drug prices accurately reflect the costs incurred by drug companies for R&D.²³⁴ Section 3 of the bill requires pharmaceutical companies to provide the Secretary of HHS with annual disclosure of their audited financial information relating to the pricing of their drugs.²³⁵ The Secretary evaluates the pricing schemes based on the reported cost of R&D for a specific drug, as well as overall R&D activities.²³⁶ This financial reporting system is the best challenge to the industry's persistent claim that compulsory licensing inhibits R&D of future medical inventions.²³⁷

http://www.citizen.org/publications/print_release.cfm?ID=7065 (last visited Sept. 5, 2002).

233. *See id.* (noting that as a result of the "pediatric exclusivity" incentive for testing the effects of drugs on children, the drug industry generates an additional \$600 million in profits per year, while incurring costs of less than \$100 million a year).

234. *See* H.R. 1708, sec. 3(a) (mandating that drug companies submit annual financial reports to the Secretary of HHS). The Secretary may penalize any drug company that fails to meet the reporting requirement by assessing a maximum fine of \$25,000 for each day that passes the reporting deadline, but only after the Secretary provides a written notice of delinquency and gives the company an opportunity to request a judicial hearing. *See id.* sec. 3(b)(1) - (2); *see also* Statement of Congressman Brown, *supra* note 132 (urging that it is time to hold the pharmaceutical companies accountable for their drug pricing and purported expenses).

235. *See* H.R. 1708 sec. 3(a) (requiring a financial report from drug companies disclosing costs associated with the research and development of a new drug and costs allocated to all research and development activities of the company).

236. *See* Statement of Congressman Brown, *supra* note 132 (expressing the importance of a reporting system that would allow authorities to ascertain the true costs incurred by the pharmaceutical industry).

237. *Compare* Press Release, Pharmaceutical Research and Manufacturers of America, Health Care Advocates to Fight Efforts by Generic Industry to Jeopardize the Progress in Medical Research (Feb. 25, 2002) (claiming that any attempt to weaken the patent protections under the current law will harm research efforts for new drugs), *available at* <http://www.phrma.org/press/newsreleases//2002-02-25.347.phtml> (last visited Sept. 5, 2002) *with* Statement of Congressman Brown, *supra* note 132 (challenging the pharmaceutical industry's assertion that drug companies could not produce new drugs if the government institutes compulsory licensing laws).

Given the ongoing tension between the pharmaceutical industry and developed countries on one side, and developing countries on the other side, the following section suggests ways in which the WTO and the United States can alleviate some of the problems associated with the compulsory licensing debate.²³⁸ The international community must take immediate steps to address this issue before the use of biological and chemical agents becomes a prevalent means of global terrorism.²³⁹

III. RECOMMENDATIONS

Compulsory licensing is an essential legal and legislative tool in the fight against global super-terrorism.²⁴⁰ The U.S. opposition to compulsory licensing permits pharmaceutical companies to profit from bioterrorism,²⁴¹ and poses an unacceptable health risk to populations exposed to biological or chemical agents.²⁴² In light of the effects of globalization, the United States and other developed countries cannot afford to ignore global health concerns.²⁴³ A large-scale super-terrorist attack on any country would result in

238. See discussion *infra* Part III (proposing various proactive approaches that the WTO and the United States should adopt to facilitate the use of compulsory licensing).

239. See *id.* (urging prompt action by the WTO and the United States in establishing clear guidelines and new policies regarding compulsory licensing for national public health emergencies).

240. See CPT's *Comments on H.R. 3235*, *supra* note 184 (indicating that it would be unconscionable for the United States to fail to aid developing nations suffering from biological or chemical attacks).

241. See CPT's Letter to Secretary Thompson, *supra* note 111 (warning that the U.S. government has an obligation to prevent pharmaceutical companies from exploiting the state of panic and urgency resulting from bioterrorist attacks); see, e.g., Keith Bradsher, *A Nation Challenged: The Treatment; Bayer Halves Price for Cipro, But Rivals Offer Drugs Free*, N.Y. TIMES, Oct. 26, 2001, at A1 available at WL 29615551 (suggesting that Bayer stands to make large profits from the sale of Cipro even after negotiating a price reduction with public health officials).

242. See CPT's Letter to Secretary Thompson, *supra* note 111 (purporting that the government's policy on compulsory licensing is endangering the lives of U.S. citizens); see also, Mokhiber & Weissman, *supra* note 112 (advocating the prioritization of public health concerns over corporate profiteering).

243. See *Global Health Core Messages*, *supra* note 8 (submitting that the United States' best interests are served through global good health).

devastating human loss and would create regional or global panic, with rippling effects on the global economy.²⁴⁴ Accordingly, the WTO must add breadth to the compulsory licensing provisions of the TRIPS Agreement.²⁴⁵ Also, the U.S. government must facilitate the use of compulsory licensing by addressing concerns regarding remuneration to patent holders and the effects of compulsory licensing on research and development.²⁴⁶ This policy shift would recognize the need to assist the developing world during health emergencies, particularly those arising from the acts of super-terrorism.²⁴⁷

A. THE WTO MUST RECOGNIZE ITS MEMBERS' RIGHT TO OBTAIN COMPULSORY LICENSED PRODUCTS FROM FOREIGN MARKETS

In the event of a biological or chemical disaster, developing countries that lack the capacity to manufacture essential drugs must be able to exercise their legitimate right to use compulsory licensing without the fear of economic or legal reprisal from developed countries.²⁴⁸ The WTO must acknowledge this right by adopting an interpretation of the TRIPS Agreement that protects public health.²⁴⁹

244. See SIMON, *supra* note 2, at 8-9 (writing that terrorists use biological and chemical agents to create public fear and panic, and sabotage the economy); see also *Global Health Core Messages*, *supra* note 8 (stating that "[h]ealth is vital to social and economic development and to global political stability").

245. See discussion *infra* Part III.A (recommending that the WTO recognize its Members' right to obtain compulsory licensed products from foreign markets).

246. See discussion *infra* Parts III.B and III.C (recommending that the United States take actions in support of compulsory licensing).

247. See Letter to USTR Zoellick, *supra* note 52 (urging the United States to adopt a pro-public health position that would allow developing countries to meet their citizens' health needs).

248. See Joint Statement, *supra* note 68 (interpreting the Doha Declaration as a political victory for developing countries that were apprehensive about legal repercussions of using compulsory licensing, because it declares that the TRIPS Agreement can and should be interpreted and implemented in a manner to protect public health).

249. See Doha Declaration, *supra* note 150, para. 6 (recognizing the problems in Article 31(f) of the TRIPS Agreement, but deferring on an interpretation of the TRIPS Agreement as to the issue of where countries with insufficient or no manufacturing capacity for pharmaceuticals will obtain medicines under a compulsory license); see also CPT's Comments Presented at the WHO/WTO Joint Secretariat Workshop, *supra* note 145 (stating that, "We have to begin to think

In the Doha Declaration, the WTO Ministers instructed the TRIPS Council to find a solution to the problem arising from the inadequate manufacturing capacity of some developing nations.²⁵⁰ As an integral part of the solution, the Council must allow countries to either (1) grant a compulsory license to a generic drug manufacturer in a foreign market under Article 31(f) of the TRIPS Agreement,²⁵¹ or (2) import medicines that are the product of a compulsory license issued by the exporting country—as permitted under House Bill 3235.²⁵² A contrary interpretation would simply defeat the fundamental purpose and premise of compulsory licensing under the TRIPS Agreement, that is, increasing global access to life-saving drugs.²⁵³ Without a proper implementation mechanism for compulsory licensing, the TRIPS Agreement offers empty benefits to poor countries in dire need of affordable drugs.²⁵⁴

Although the WTO could permit Members to issue compulsory licenses under either Article 30 or Article 31(f) of the TRIPS Agreement, it is more feasible to employ Article 31(f).²⁵⁵ Since

about pro-active globalization initiatives to address the needs to the public, including the poor, rather than the needs of firms that are global”).

250. See Doha Declaration, *supra* note 150, para. 6 (requiring the TRIPS Council to find a solution before the end of 2002).

251. See Letter to USTR Zoellick, *supra* note 52 (imploring the United States and the WTO to interpret Article 31(f) of the TRIPS Agreement in a manner that would allow a WTO Member country to grant a compulsory license to foreign manufacturers).

252. See Joint Letter to the TRIPS Council, *supra* note 201 (urging the WTO to adopt an interpretation of Article 30 that would permit WTO Members to export drugs to countries that lack capacities for local manufacturing of pharmaceutical products).

253. See Abbott, *supra* note 42, at 16 (recognizing a frustration of purpose of allowing compulsory licensing under Article 31 of the TRIPS Agreement if poor countries cannot address public interests because they lack the technological capacities to manufacture pharmaceutical products).

254. See Letter to USTR Zoellick, *supra* note 52 (highlighting that flaws in the text of Article 31(f) of the TRIPS Agreement preclude most developing countries from implementing compulsory licensing laws).

255. See WTO, TRIPS Council Secretariat, *Communication from the United States Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/340 (Mar. 14, 2002) [hereinafter *U.S. Communication to the TRIPS Council*] (indicating that the United States would not concede to employing Article 30 as a possible solution for addressing the difficulty that poor

Article 31 is the technical provision that authorizes compulsory licensing, it contains various terms and conditions that grant some protection to patent holders.²⁵⁶ For instance, under Article 31, a compulsory license expires when the circumstances requiring it cease to exist, and the licensee must pay the patent holder “adequate remuneration” for the license.²⁵⁷ On the other hand, Article 30 does not offer such specific protections to patentees.²⁵⁸ Consequently, developed countries are more likely to oppose the use of this provision as the basis for permitting compulsory licensing for exports.²⁵⁹ These countries, however, may be more receptive to a broad interpretation of Article 31(f), whereby a WTO Member can export medicines under a compulsory license to a Member that lacks or has an insufficient manufacturing capacity for pharmaceuticals.²⁶⁰

The enactment of House Bill 3235 would be significant for the development of a WTO resolution regarding the scope of compulsory licensing under the TRIPS Agreement.²⁶¹ In the past, the U.S. government acted strategically to prevent the WTO from adopting a flexible interpretation of the TRIPS Agreement by exerting economic and political pressure on developing countries.²⁶²

countries have in using the compulsory licensing provisions of the TRIPS Agreement).

256. See TRIPS Agreement, *supra* note 60, Part II, sec. 5, art. 31 (providing twelve conditions under which WTO Members can issue a compulsory license).

257. See *id.* art. 31(g)-(h) (taking into consideration the interests of patent owners).

258. See *id.* art. 30 (stating in general terms that the limited exception to patent rights must not “unreasonably conflict with a normal exploitation of the patent and [must not] unreasonably prejudice the legitimate interests of the patent owner”).

259. See U.S. Communication to the TRIPS Council, *supra* note 255 (rejecting the proposal that Article 30 could be interpreted to allow exceptions to patent rights for export of medicines because doing so would “seriously prejudice the rights and obligations of Members under the TRIPS Agreement”).

260. See *id.* (exploring the potential of Article 31(f) as the legal basis for allowing Members to issue compulsory licenses).

261. See Abbott, *supra* note 42, at 3-4 (discussing the influential role of the United States in TRIPS negotiations); see also, e.g., Carroll, *supra* note 29, at 2440 (examining the influence of U.S. patent law on international developments in the biotech industry).

262. See Abbott, *supra* note 42, at 12 (stating that despite the United States’ public endorsement of the need to address global public health issues, trade representatives continue to exert political and economic pressures on developing

It is time for the United States to reverse its policy.²⁶³ In light of the recent anthrax attacks in the United States and the potential for greater harm from biological or chemical warfare, the United States must acknowledge the importance of global cooperation and worldwide access to counterterrorism antibiotics.²⁶⁴ Congress should pass House Bill 3235 to clearly indicate the United States' support for allowing exports of medicines to address public health crises in developing countries.²⁶⁵

B. THE UNITED STATES MUST FACILITATE THE REMUNERATION PROCESS OF COMPULSORY LICENSING UNDER U.S. LAW

The recent controversy over the potential compulsory licensing of the Cipro patent demonstrates that Congress must amend U.S. patent law to incorporate compulsory licensing provisions.²⁶⁶ The Cipro

countries that advocate for a liberal interpretation of the TRIPS Agreement); *see also* Letter to USTR Zoellick, *supra* note 52 (criticizing the U.S. government's strategy of proposing language at TRIPS conferences that appears to benefit the poorer countries, but which would actually restrict protections for public interests and advance the interests of pharmaceutical companies).

263. *See* Letter to USTR Zoellick, *supra* note 52 (accusing the U.S. government of harming foreign relations and its own standing in the international community through its abuse of power with regard to intellectual property issues).

264. *See* International Centre for Trade and Sustainable Development, *Draft Declaration on TRIPS and Health Highlights Divisions in the WTO*, BRIDGES WKLY. TRADE NEWS DIG., Oct. 30, 2001 (quoting Justin Forsyth, Oxfam GB Policy Director as saying, "We had hoped that the issue of access to the patented anti-Anthrax drug, Cipro, would make rich country governments more sensitive to the needs in developing countries . . . But the latest reports from the WTO in Geneva indicate that the US has not budged an inch"), *available at* <http://www.ictsd.org/weekly/01-10-30/story2.htm> (last visited Sept. 19, 2002); *see also*, International Centre for Trade and Sustainable Development, *Anthrax Scare Draws New Focus on IPRs and Access to Medicines*, BRIDGES WKLY. TRADE NEWS DIG., Oct. 23, 2001 [hereinafter *Anthrax Scare*] (quoting Paulo Teixeira, Director of the Brazilian government's AIDS program as saying, "The anthrax outbreak is very distressing but I hope it will make [the United States and Canada] reflect more about our position that compulsory licensing is an entirely legitimate instrument if there is a problem of access to a crucial drug"), *available at* <http://www.ictsd.org/weekly/01-10-23/story2.htm> (last visited Sept. 19, 2002).

265. *See* *Anthrax Scare*, *supra* note 264 (urging the USTR to take the lead in changing trade policy to reflect public interest rather than the interests of large pharmaceutical companies and lobbyists).

266. *See* GOP Bioterrorism Plan, *supra* note 216 (stating that the anthrax attacks and the subsequent dispute over the Cipro patent demonstrates the need for a

dispute indicates that the uncertainty over amounts of compensation to be paid to patent holders may be a factor in the U.S. government's reluctance to use compulsory licensing.²⁶⁷ As long as government officials are uncomfortable with allowing courts to determine the government's liability for issuing compulsory licenses under 28 U.S.C. § 1498, they will continue to choose the conservative approach of avoiding the use of compulsory licensing to eliminate the risk of liability.²⁶⁸

Congress should enact House Bills 1708 and 3235 to address the concerns regarding compensation for the non-voluntary use of a patent.²⁶⁹ The administrative compensation process proposed in the bills should mitigate the fear of exposing the government to future litigation and liability upon the issuance of compulsory licenses.²⁷⁰ The factors enumerated in the bills for determining compensation to

statutory basis for compulsory licensing other than eminent domain authority to effectively address the threat of bioterrorism).

267. See *Other Anthrax Drugs*, N.Y. TIMES, Oct. 28, 2001 (publishing a letter from Bernard A. Schwetz, the Acting Principal Deputy Commissioner of the Food and Drug Administration, in which he defends the Bush Administration's decision to not exercise its eminent domain authority to override the Cipro patent because "if the government overrode the patent, Bayer could bill the Treasury for lost revenues"); see also *CPT's Comments on H.R. 3235*, *supra* note 184, paras. 2-3 (asserting that Secretary Thompson's reluctance to obtain essential antibiotics through compulsory licensing, simply because damage payments for patent infringement could be expensive, will subject the public to higher health risks).

268. See *CPT's Comments on H.R. 3235*, *supra* note 184, para. 3 (fearing that "[b]ureaucrats will cut corners with the public health" due to concerns about unpredictable liability costs).

269. See *GOP Bioterrorism Plan*, *supra* note 216 (arguing that House Bills 1708 and 3235 would prevent extensive litigation and unnecessary costs that could otherwise arise under 28 U.S.C. § 1498).

270. Regarding the Bush Administration's plan to address bioterrorism, Congressman Brown stated in his address to Secretary Tommy Thompson of HHS and Director Jeffrey Koplan of the Centers of Disease Control and Prevention:

The spread of anthrax has already taken a significant toll on the nation's sense of security. Unencumbered access to drugs is an essential element in our response to bioterrorism. Establishing the statutory and regulatory framework now to secure generic drugs on an expedited and affordable basis simply makes sense. Taking that step now will help ensure that the priority of doing what's best for the public is not subsumed by cost concerns, red tape, or legal haggling. I'd like to work with you to ensure you have this [sic] compulsory licensing tool available to you before another 'Cipro situation' arises.

Id.

patentees are fairly comprehensive and should generate reasonable royalty fees.²⁷¹ The remuneration provisions, however, should also include such considerations as the domestic market share for the licensed product, general royalty rates in the pharmaceutical sector, and royalty rates that licensees would pay for a voluntary license of the product.²⁷² This administrative procedure will allow public officials to act more promptly and decisively in issuing compulsory licenses, which would be particularly important in the aftermath of a biological or chemical attack.²⁷³ It would permit the government to immediately increase the production and distribution of generic drugs in times of national and international public health disasters.²⁷⁴

C. THE U.S. GOVERNMENT SHOULD AGGRESSIVELY ADDRESS PURPORTED R&D CONCERNS THAT IMPEDE COMPULSORY LICENSING

The most practical challenge to the pharmaceutical industry's claim that compulsory licensing impedes R&D is to implement a system by which officials can scrutinize the R&D records of pharmaceutical companies.²⁷⁵ At present, the government does not

271. See H.R. 1708, sec. (2)(a)(d) (listing such factors as the costs of R&D, the importance of the product to public health, the amount of public funding received for R&D, the need for providing incentives for new inventions, public interest considerations, and public health benefits from increased access to the product); see also H.R. 3235 sec. 2(a)(b) (listing the same five factors as H.R. 1708 and including additional factors, such as the benefits of increased availability of the product to working families and retired persons, and the need to remedy anti-competitive behavior).

272. See Correa, *supra* note 145, ch. X, sec. 3.1 (discussing various methods used by U.S. federal courts for determining "reasonable" royalty rates).

273. See GOP Bioterrorism Plan, *supra* note 216 (noting that the rapid availability of therapeutic drugs is essential to saving thousands of lives in the event of a release of a biological agent like anthrax).

274. See CPT's *Comments on H.R. 3235*, *supra* note 184 (emphasizing that legislation providing more predictability in the compensation process of compulsory licensing would facilitate the government's ability to address both domestic and foreign public health emergencies as they arise).

275. See Statement of Congressman Brown, *supra* note 132 (arguing that a requirement that pharmaceutical companies provide audited, detailed information regarding their expenses is a necessary component of challenging the industry's threat that drug companies will cease to produce new drugs if legislators compel price reductions for marketed drugs); see also RX R&D MYTHS, *supra* note 232, at

attempt to verify or explore the industry's claim that drug prices merely reflect the high risks and costs associated with R&D.²⁷⁶ The pharmaceutical industry has refused for years to disclose its R&D records to congressional investigators and independent auditors.²⁷⁷ Nevertheless, the drug companies still receive substantial governmental subsidies, generous tax incentives, and other financial incentives to engage in R&D of new pharmaceutical products.²⁷⁸ Section 3 of House Bill 1708 would be an effective legal tool for exposing the true costs incurred by the drug companies, since it requires both the Secretary of HHS and Congress to review the financial reports submitted by the companies.²⁷⁹ The financial reporting requirements of the bill are also useful to the authorities in determining whether a patent holder is engaging in monopolistic

23-24 (advocating for the disclosure to Congress of R&D costs by the drug industry).

276. See *Why Do Medicines Cost So Much?*, *supra* note 36 (alleging that R&D costs for each new drug brought to the market total on average \$500 million). But see RX R&D MYTHS, *supra* note 232, at ii (exposing the falsehoods of the industry's claims by scrutinizing government studies, companies' financial filings with the U.S. Securities and Exchange Commission, and other documents obtained through the Freedom of Information Act). In the 1990s, the actual after-tax R&D costs for each new drug ranged from \$57 million to \$71 million, not \$500 million. *Id.* Also, pharmaceutical R&D is not as risky as the industry claims, given the fact that only twenty-two percent of the new drugs on the market over the past two decades were actually innovative rather than mere replicas of existing drugs. *Id.*

277. See RX R&D MYTHS, *supra* note 232, at ii (noting that the pharmaceutical industry won a nine-year legal battle to limit the ability of congressional investigators from the General Accounting Office to review the industry's R&D records). Although Congress has the authority to subpoena the industry's R&D records, it has never invoked that authority. *Id.* Congress' failure to act may be attributed to the fact that the pharmaceutical industry makes generous financial contributions to political campaigns. *Id.* For example, in 1999-2000, the pharmaceutical industry spent \$262 million on federal lobbying, campaign contributions, and "issue" advertisements for candidates. *Id.*

278. See Statement of Congressman Brown, *supra* note 132 (criticizing the fact that prescription drug prices are soaring, even though the drug industry receives tax breaks, and is well-funded by taxpayers, private foundations, state and local governments, and other non-industry sources); see also RX R&D MYTHS, *supra* note 232, at ii (recognizing that the federal government provides various financial incentives to drug companies in connection with their R&D activities, and arguing that R&D risks and costs are significantly reduced by taxpayer-funded research).

279. See H.R. 1708, sec. 3(a) (mandating that drug companies submit annual audited financial reports related to drug pricing to the Secretary of HHS, who would provide a copy of the reports to Congress).

practices (i.e., excessive pricing) and whether compulsory licensing is a proper remedial course of action.²⁸⁰

Some commentators argue that drug companies still rely heavily on revenue from products they have already placed on the market in order to cover their half of the R&D budget.²⁸¹ The industry, however, could clearly compensate for lower sales revenues by curtailing certain expenditures.²⁸² Drug companies allocate exorbitant sums of money for inordinate expenses, such as generous employee compensation packages, marketing, and advertising.²⁸³ The ability to incur expenses of such magnitude casts doubt on the assertion that pharmaceutical companies cannot afford lost revenues because it would reduce their R&D capacities.²⁸⁴ House Bill 1708 should serve as a mechanism to regulate private drug companies by subjecting their financial reports to scrutiny by the Secretary of HHS and

280. See *id.* sec. 2(b)(3) (providing that anti-competitive conduct by a patent holder could subject the patent of products at issue to compulsory licensing); see also Statement of Congressman Brown, *supra* note 132 (accusing the drug industry of price-gouging).

281. See Litovsky, *supra* note 127, at 22 (arguing that despite government funding, drug companies need to raise sufficient revenue from drug sales to cover total R&D costs). Commentators reason that the introduction of lower-priced products in the marketplace through compulsory licensing would lead to fewer sales for patent holders and lower profits for investors. *Id.* Commentators argue that reduced earnings would have adverse consequences on R&D financing by the patent holding drug companies. *Id.*

282. See, e.g., RX R&D MYTHS, *supra* note 232, at 20 (attributing an increase in drug prices to increased advertising since 1997). But cf. Fisch, *supra* note 39, at 311 (arguing that cutting back on pharmaceutical drug advertisements would harm patient care because the advertisements inform patients about a potential treatment and encourage them to contact a physician).

283. See Statement of Congressman Brown, *supra* note 132 (illustrating that drug companies allocate excessive amounts of money to non-essential expenses). For example, in 2000, Bristol-Myers Squibb dispensed \$1.2 million for the CEO's salary, \$1.9 million for his bonuses, and \$30.4 million in stock options. *Id.* Furthermore, pharmaceutical companies spent \$8.3 billion in 2000 for marketing and advertising. *Id.*

284. Compare Litovsky, *supra* note 127, at 22 (alleging that increasing competition in the generic drug market will discourage private investments and will significantly reduce the R&D budgets of brand-name drug companies) with Statement of Congressman Brown, *supra* note 132 (arguing that brand-name drug companies must account for all their expenditures if they continue to maintain that high drug prices are necessary to cover their R&D expenditures).

Congress.²⁸⁵ Consequently, drug company executives may adopt a more conservative fiscal policy with regard to their expenses.²⁸⁶ Such curtailed expenditures, coupled with the availability of public funding for R&D, would limit the effect of compulsory licensing on the total R&D budget for future pharmaceutical innovations.²⁸⁷

D. COMPULSORY LICENSING LEGISLATION IS NEEDED TO FACILITATE GLOBAL PREPAREDNESS FOR SUPER-TERRORISM

The U.S. Congress should pass compulsory licensing legislation in order to demonstrate a willingness to provide humanitarian aid and international cooperation during a foreign public health crisis.²⁸⁸ Although the world has not yet witnessed a major bioterrorism or chemical terrorism incident, super-terrorism is a global threat and warrants global preparation.²⁸⁹ National security is clearly a priority for the Bush Administration, which has initiated domestic

285. See H.R. 1708, sec. 3(a) (requiring pharmaceutical companies to submit annual financial reports on drug costs and sales to the Secretary of HHS).

286. See Statement of Congressman Brown, *supra* note 132 (supporting the notion that drug companies should account for their expenses).

287. Cf. RX R&D MYTHS, *supra* note 232, at 20 (contrasting the expenditures on marketing and administrative costs—thirty percent of revenue, by Fortune 500 drug companies in 2000—with the expenditure on research and development—twelve percent of revenue).

288. See Albright, *supra* note 212, at 110 (acknowledging that the United States must assist foreign nations that are victimized or threatened by terror, and stating that “[i]t is not enough for Americans to be concerned only about attacks against Americans”).

289. See Pan American Health Organization (“PAHO”), *Latin America, Caribbean Urged to Plan for Bioterrorism* (reporting that experts on bioterrorism and emergency response who met at a PAHO conference after the bioterrorist attacks in the United States urged Latin American and Caribbean countries to prepare to respond to bioterrorism), at <http://www.paho.org/English/DPI/pr011026.htm> (last visited Sept. 5, 2002). At a meeting of Health ministers from the Americas at PAHO, U.S. Secretary of HHS Thompson stated:

Given the evolving opportunities and the reality of an uncertain future, we must work together if we really want to make a difference Although each country has a responsibility to meet the health needs of its people, there are few issues countries working alone can fully resolve. The need to build partnerships and alliances has never been more compelling.

Id.

preparedness programs to prevent and respond to bioterrorism and chemical terrorism.²⁹⁰ However, it is insufficient for the United States to adopt an isolationist attitude towards health.²⁹¹ Superterrorism requires global preparedness because it has significant international repercussions.²⁹² A healthy population is a vital aspect of any country's economic welfare, since the loss of human capital reduces the country's labor and intellectual workforce.²⁹³ Also, the economic shortfall resulting from an emerging public health crisis in developing countries has detrimental effects on international trade and global markets.²⁹⁴

290. See Press Release, U.S. Department of Health and Human Services, Secretary Thompson Testifies on HHS Readiness and Role of Vaccine Research and Development (Oct. 23, 2001) (noting that following the anthrax attacks in October 2001, the Bush Administration requested \$1.2 billion for production of vaccines and antibiotics and \$643 million for expansion of the National Pharmaceutical Stockpile), *available at* <http://www.hhs.gov/news/press/2001pres/20011023.html> (last visited Sept. 5, 2002).

291. See *Global Health Core Messages*, *supra* note 8 (acknowledging that American health and economic prosperity is "inextricably linked" to the health of the world population and the prosperity of its trading partners); see also PAHO, *supra* note 289 (reporting that experts on bioterrorism and emergency response at the PAHO conference noted that "[g]iven the global economy, an outbreak anywhere in the world may be considered a threat to virtually all nations").

292. See American Medical Association, *AMA Urges Global Ban of Biological Weapon Development* (warning that exposure to a communicable biological agent anywhere in the world would have global health repercussions due to globalization and the ease and frequency of travel), *at* <http://www.ama-assn.org/ama/pub/article/2403-5338.html> (last visited Sept. 5, 2002); see also Symposium, *Bioterrorism: Homeland Defense Symposium: The Next Steps*, Threat Panel (Feb. 8, 2000) (analyzing the destabilizing effects of agriculture bioterrorism (i.e., animal and crop disease from exposure to biological agents) on global public health, political and social welfare, and the economy), *available at* <http://www.rand.org/nsrd/bioterr/chalk.htm> (last visited Sept. 5, 2002).

293. See *Global Health Core Messages*, *supra* note 8 (noting that there is a critical link between healthy individual growth and the development of intellectual capital of a nation, and that intellectual capital is a universal currency).

294. See *id.* (stating that "[h]ealthy populations and healthy economies are vital for a healthy world economy and strong markets").

Compulsory licensing is an important component of global preparedness.²⁹⁵ If a developing country falls prey to super-terrorism, it would need medical assistance to treat its infected population with antibiotics.²⁹⁶ The international community, and especially the United States—the largest source for pharmaceutical products—has a moral and ethical obligation to provide affordable therapeutic drugs to developing countries that do not have the resources to combat super-terrorism.²⁹⁷ The failure to act when thousands of lives are at risk is unacceptable.²⁹⁸ Consequently, the export provision of House Bill 3235 is particularly crucial in light of the potential for alarmingly high mortality rates from biological or chemical terrorism.²⁹⁹

CONCLUSION

The increased threat of bioterrorism since September 11, 2001, refocused the attention of the international community on the need to address problems in the compulsory licensing provisions of the TRIPS Agreement.³⁰⁰ In this new era of super-terrorism, compulsory

295. See GOP Bioterrorism Plan, *supra* note 216 (declaring that the U.S. government should have compulsory licensing legislation before the occurrence of another bioterrorism incident).

296. See Abbott, *supra* note 42, at 12-13 (explaining that for poor countries with inadequate local manufacturing capacities, the only means of gaining access to essential drugs is through importation).

297. See Letter to USTR Zoellick, *supra* note 52 (indicating that the U.S. government should provide humanitarian aid to a foreign nation facing a public health emergency).

298. See Gilmore, *supra* note 2, at 15 (finding that the release of 1,000 kilograms of the nerve gas Sarin in open air would kill approximately 10,000 people); see also Federation of American Scientists, *Biological Warfare Agents* (reporting that one hundred kilograms of anthrax “released from a low-flying aircraft over a large city on a clear, clam night, could kill one to three million people”), at <http://www.fas.org/nuke/intro/bw/agent.htm> (last visited Sept. 5, 2002).

299. See H.R. 3235, sec. 2(a)(c) (establishing an administrative authority with power to issue a compulsory license for exportation of generic medicines to a country with urgent public health needs).

300. See *Anthrax Scare*, *supra* note 264 (observing that Canada’s decision to issue a compulsory license for Cipro and the United States’ consideration of purchasing generic versions of the antibiotic rekindled debates on the issues of compulsory licensing and access to essential medicines).

licensing is an essential legal mechanism for saving thousands of lives.³⁰¹ It is imperative that the WTO and the TRIPS Council continue to interpret the TRIPS Agreement in a way that supports the protection of public health and implements the Doha Declaration in good faith.³⁰² Also, the United States must cease its abuse of economic power to influence the TRIPS negotiations.³⁰³ It is time for the United States to recognize that a change in its patent protection policy is necessary to mitigate the threat of biological or chemical terrorism on public health. The adoption of compulsory licensing legislation in the United States would be a monumental step toward facilitating access to life-saving medicines in a time of national or foreign public health crisis resulting from super-terrorism.³⁰⁴

301. See GOP Bioterrorism Plan, *supra* note 216 (indicating that compulsory licensing is an essential counterterrorism tool).

302. See Doha Declaration, *supra* note 150, para. 4 (containing a promise and an obligation to interpret and implement the TRIPS Agreement in a manner supporting the right to protect public health and promote universal access to medicines).

303. See Abbott, *supra* note 42, at 12 (stating that the U.S. representative to the TRIPS Council continues to exert pressures against a flexible interpretation of the TRIPS Agreement, while the USTR continues to threaten developing countries with trade sanctions).

304. See discussion *supra* Part III.D (demonstrating that the United States must adopt a more lenient posture on the issue of compulsory licensing to show its support for international cooperation in the fight against super-terrorism).