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THE LIFE-SAVING MEDICINES EXPORT ACT: WHY THE PROPOSED U.S. COMPULSORY LICENSING SCHEME WILL FAIL TO EXPORT ANY MEDICINES OR SAVE ANY LIVES

INTRODUCTION

In the twenty-six years that have passed since doctors observed the first cases of AIDS, no region of the world has escaped the wrath of the AIDS pandemic.¹ Fortunately, the HIV incidence rate² reached its highest levels in the late 1990s, and has since stabilized.³ Nevertheless, an estimated 38.6 million people around the world were afflicted with HIV in 2005, including approximately 4.1 million new HIV infections and 2.8 million AIDS deaths.⁴ Although there is no cure for HIV/AIDS, antiretroviral drug treatment slows the progression of the virus. As a result, antiretroviral drug treatment has decreased the number of HIV/AIDS-related illnesses and deaths globally.⁵ However, access to

1. See Joint United Nations Programme on HIV/AIDS [UNAIDS], *2006 Report on the Global AIDS Epidemic*, 1 (May 30, 2006), available at http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp. At the Special Session of the United Nations (“UN”) General Assembly on AIDS in 2001, 189 nations acknowledged the high priority of the AIDS epidemic by signing the historic Declaration of Commitment on HIV/AIDS. The Declaration established steps to encourage the UN’s Millennium Development Goal to stop and begin to reverse the AIDS epidemic by 2015. See generally G.A. Res. 55/2, para. 19, UN Doc. A/RES/55/2 (Sept. 18, 2000). To monitor progress, the Declaration required assessment of the epidemic at the end of 2003, 2005, and 2010. See *id.* The 2006 Report on the Global AIDS Epidemic provides “the most comprehensive set of data on the country response to the AIDS epidemic ever compiled.” UNAIDS, *2006 Report on the Global AIDS Epidemic: Executive Summary*, 3 (May 30, 2006), available at http://data.unaids.org/pub/GlobalReport/2006/2006_GR-ExecutiveSummary_en.pdf. One hundred and twenty-six countries, with active participation by civil society groups, submitted information for the report. See *id.*

2. The “HIV incidence rate” is the number of people newly infected with HIV in a given year compared to the number of previously uninfected people. See UNAIDS, *2006 Report on the Global AIDS Epidemic*, *supra* note 1, at 8.

3. See *id.*

4. See *id.*

5. See *id.* at 150. At the International AIDS Conference XI in 1996, studies were presented to show that antiretroviral treatment was effective in preventing AIDS-related illness and death. In the years following the conference, the number of AIDS-related deaths dropped significantly in high-income developed countries, while the number of deaths in low- and middle-income countries continued to skyrocket. See *id.*

antiretroviral drugs is limited in sub-Saharan Africa, where HIV/AIDS plagues citizens more than in any other area of the world.⁶ In recent years, there has been international activism demanding a universal human right to access life-saving treatment.⁷ As a result, access to antiretroviral drugs has increased in sub-Saharan Africa.⁸ In 2005, more than five times as many people used antiretroviral drugs in low- and middle-income countries compared to those who used the drugs in 2001.⁹ Nevertheless, in sub-Saharan Africa, still only about one in six (seventeen percent) of the 4.7 million people needing antiretroviral drug treatment now receive it.¹⁰

There is no panacea that will resolve the problem of access to essential medicines in impoverished countries.¹¹ These countries often lack adequate health care systems and sufficient numbers of doctors or other health care workers to prescribe and distribute the drugs.¹² In addition, government regulations often hinder access to essential medicines, through taxes on essential medicines or regulatory red tape.¹³ Notwithstanding these infrastructure problems, poverty—and the resulting inability to afford essential medicines—is arguably the most significant barrier to access.¹⁴ Even though access to essential medicines would face many

6. *See id.* at 15. In 2005, almost sixty-four percent of all people suffering from HIV (24.5 million people), and almost nine out of ten children under the age of fifteen suffering from HIV (2.0 million children) live in sub-Saharan Africa. In the same region, there were approximately 2.7 million new HIV infections, and approximately 2.0 million AIDS deaths. *See id.* For country-specific HIV/AIDS data in sub-Saharan Africa, *see id.* at 15–23.

7. *See id.* at 150.

8. *See id.* at 152–53. On World AIDS Day 2003, the World Health Organization (“WHO”) introduced the ambitious “3 by 5 Initiative,” which sought to provide three million people in developing countries with antiretroviral drugs by 2005. WHO, About the 3 by 5 Initiative, <http://www.who.int/3by5/about/initiative/en> (last visited Oct. 9, 2007). Although the 3 by 5 Initiative didn’t meet its goal, it spurred global action to increase access to HIV/AIDS treatment. *See* UNAIDS, *2006 Report on the Global AIDS Epidemic*, *supra* note 1, at 150.

9. *See id.* at 151. Antiretroviral drug use increased from approximately two hundred and forty thousand people in 2001 to approximately 1.3 million people in 2005. *See id.*

10. *See id.* at 15. Furthermore, progress throughout sub-Saharan Africa has not been uniform. While at least fifty percent of those needing antiretroviral treatment in Botswana and Namibia in 2005 received it, access in many other countries is as low as ten percent. *See id.* at 152. One-quarter of antiretroviral drug use in sub-Saharan Africa can be found in South Africa. *See id.* at 15.

11. *See* WHO Comm’n on Macroeconomics & Health [CMH], *Macroeconomics and Health: Investing in Health for Economic Development* 86 (Dec. 20, 2001).

12. *See id.*

13. *See id.*

14. *See id.*

obstacles even in the absence of pharmaceutical patents, patents affect prices, and remain a significant hurdle to access to medicines.¹⁵ Protection of intellectual property rights (“IPR”) permits a patent holder to charge high prices for patented brand-name medicines and grants a monopoly on the protected drug during the life of the patent.¹⁶

In April 2006, the World Health Organization (“WHO”) Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH”) published its report to illustrate how an emphasis on protecting IPR may affect issues of public health.¹⁷ The Commission concluded that “innovation [is] pointless in the absence of favourable conditions for poor people in developing countries to access existing, as well as new products. . . . Intellectual property rights are important, but as a means not an end.”¹⁸ On one side of the debate, high prices of patented drugs are justified because they are necessary to fund a pharmaceutical company’s research

15. See generally DONALD G. RICHARDS, *INTELLECTUAL PROPERTY RIGHTS AND GLOBAL CAPITALISM: THE POLITICAL ECONOMY OF THE TRIPS AGREEMENT* 53 (2004) (“IPRs are exclusive rights granted to the creators of knowledge-based commodities to market their creations. This grant is deemed necessary in order for the creators to engage in creative activity and production.”).

16. See David B. Resnik & Kenneth A. De Ville, *Bioterrorism and Patent Rights: “Compulsory Licensure” and the Case of Cipro*, 2 AM. J. BIOETHICS 29, 34 (2002). IPR advocates argue that a right to one’s ideas can be based on traditional property laws. Because knowledge and innovation are forms of “property,” there are libertarian justifications for patent law, which argue that a person should have a right to both the tangible and intangible products of one’s labor. See *id.*

Philosopher John Locke argues that, based on natural law principles, non-human resources are gifts from God, to which all of humankind enjoys a common property right. See RICHARDS, *supra* note 15, at 27–31. According to Locke, a person creates a private property right to these resources by using labor to increase the value of the property, as long as the person leaves enough of the resource for others. See *id.* (citing JOHN LOCKE, *TWO TREATISES OF GOVERNMENT* (Cambridge Univ. Press 1963) (1698)). It is argued that Locke’s concern with common property rights does not mean that knowledge and ideas are also gifts from God to be shared by humankind. See Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 315 (1988). Instead, because ideas are inexhaustible, and one person’s use of an idea does not deplete the common property, people are free to take and protect their ideas as private property under Locke’s labor theory of property. See *id.*

17. See WHO CIPIH, *Public Health: Innovation and Intellectual Property Rights* (Apr. 2006), available at <http://www.who.int/intellectualproperty/report/en/>. In May, the World Health Assembly and World Trade Organization (“WTO”) member states agreed to set up CIPIH to assess the relationship between the fields of intellectual property rights, innovation, and public health. The Commission was given the task of collecting data from different sources and recommending appropriate funding and incentives for the creation of new pharmaceutical products to fight diseases affecting developing countries. See *id.*

18. *Id.* at ix–x.

and development ("R&D"). Each successful medical innovation that results in millions of dollars in profits must pay for the millions of dollars lost during the countless failed R&D efforts.¹⁹ Nevertheless, these patents, and the high costs of the patented drugs they protect, are not justified to the extent that they deprive those who cannot afford life-saving medication.²⁰

This Note does not attempt to resolve all of the barriers preventing access to essential medicines.²¹ Instead, this Note focuses solely on the responsibility of the United States, as a developed country with immense

19. See PhRMA, Key Industry Facts/About PhRMA, http://www.phrma.org/key_industry_facts_about_phrma/ (last visited Oct. 9, 2007). Pharmaceutical Research and Manufacturers of America ("PhRMA"), discussing the findings of the Tufts Center for the Study of Drug Development, reports that development of a new drug is estimated to cost a pharmaceutical company \$802 million, and takes an average of ten to fifteen years to get the drug from the laboratory to the pharmacy shelf. A pharmaceutical company recovers its R&D costs mainly from commercially successful products. PhRMA reports that out of 5,000 to 10,000 screened compounds, only 250 compounds succeed to reach preclinical testing, five pass preclinical testing to reach human clinical trials, and only one compound is eventually approved by the Food and Drug Administration. *See id.*

Consequently, proponents of pharmaceutical patents argue that the patents are necessary to allow temporary market exclusivity. Market exclusivity would permit these pharmaceutical companies to recoup their economic costs, profit from their inventions, and would incentivize future innovations.

20. Among these reasons are those founded in international law and principles of moral obligation. First, the right to health is emphasized in customary international law. *See* Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT'L L.J. 325, 336 (2003) (citing International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3). Article 12 of the International Covenant on Economic, Social, and Cultural Rights ("ICESCR") acknowledges "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." *Id.* In addition, the Economic, Social, and Cultural Rights Committee recognized that a state's minimum obligation pursuant to the ICESCR is to provide access to essential medicines. *See id.* at 337. Moreover, the right to enjoy the scientific progress in medicine derives from Article 15 of the ICESCR, which "recognize[s] the right of everyone . . . [t]o enjoy the benefits of scientific progress and its applications" applies to medications. *Id.* at 344.

Second, the obligation to developing countries is also supported by moral obligation. Under the theory of utilitarianism, there is a fundamental moral obligation to act when others are in need. Moreover, the greater the benefit to the person in need and the less hardship it causes for the actor, the more important is the obligation to act. *See* Michael A. Santoro, *Human Rights and Human Needs: Diverse Moral Principles Justifying Third World Access to Affordable HIV/AIDS Drugs*, 31 N.C. J. INT'L L. & COM. REG. 923, 936-37 (2006).

21. Moreover, this Note does not argue that patents should not be granted for essential medicines, and recognizes that patent protection may be necessary to promote innovation and technological advances.

resources in the pharmaceutical sector,²² to help impoverished countries that do not have the manufacturing resources to supply their citizens with essential life-saving medicines.²³ In light of this duty, the Life-Saving Medicines Export Act²⁴ was introduced in 2006 to establish a compulsory licensing system that permits U.S. pharmaceutical companies to manufacture generic equivalents of patented medicines for export to developing countries.²⁵ This Note focuses primarily on whether the Life-Saving Medicines Export Act establishes an optimal compulsory licensing system by providing the most effective incentives to generic drug companies to manufacture life-saving medicines for export to developing countries.

First, Part I discusses the development of IPR at the international level and its impact on pharmaceutical policies in the United States. Next, Part II investigates the key provisions of the Life-Saving Medicines Export Act. Then, Part III identifies the key provisions of the Pledge to Africa Act, which established a Canadian compulsory licensing system. Part IV addresses the flaws with the Pledge to Africa Act, and analyzes the improvements that the Life-Saving Medicines Export Act has made over its Canadian counterpart. Furthermore, it examines whether the improvements made in the Life-Saving Medicines Export Act are sufficient to incentivize generic companies to participate in the compulsory licensing system, thereby insuring that the legislation will succeed in increasing access to essential medicines for those who need them the most. This Note argues that while the Life-Saving Medicines Export Act eases procedural barriers and increases economic incentives for generic pharmaceutical companies, these changes alone are not enough. No matter how altruistic a generic company may be, or how severe a pandemic—like AIDS—may become, failure to incorporate greater financial incentives will render the Life-Saving Medicines Export Act useless in the fight to improve the life or death problem of access to essential medicines.

22. See generally PHRMA, ANNUAL REPORT 2006–2007 19 (2006). In 2005, PhRMA member companies invested approximately \$39.4 billion in new R&D. *Id.* at 19.

23. In addition to altruistic reasons for assisting poorer countries, the United States should be motivated by its own self-interests. For example, such legislation would help improve U.S. relations in the international community. In addition, by addressing public health crises in other countries, the United States also decreases the chances of those health crises spreading to the United States. Furthermore, the United States ensures that these developing countries will be able to sustain their roles within the global economy. See 152 CONG. REC. S233-01, S5245 (daily ed. May 25, 2006) (statement of Sen. Leahy).

24. See *infra* Part II.

25. See 152 CONG. REC. S233-01, S5245 (daily ed. May 25, 2006) (statement of Sen. Leahy).

I. HISTORICAL BACKGROUND ON THE PATENT SYSTEM IN THE UNITED STATES AND AT THE INTERNATIONAL LEVEL

When the World Trade Organization (“WTO”) was created in 1995 as the successor to the General Agreement on Tariffs and Trade (“GATT”),²⁶ “ideas and knowledge” were becoming more significant in international trade.²⁷ At the same time, varying levels of protection and enforcement of intellectual property rights were causing greater strain in international economic relations.²⁸ As a result, the WTO member states agreed upon and codified minimum standards that each state government had to meet in order to protect domestic IPR, as well as the IPR of other WTO member states.²⁹ With respect to patents, WTO member states agreed that patents must be available to inventors, and patent holders should enjoy a minimum set of exclusive rights to the invention for an initial period of time.³⁰ However, concern later arose over ensuring that the WTO standards did not prevent WTO member states from addressing issues of public health.³¹ As a result, the WTO adopted a new approach to assisting people in developing countries who suffer from life-threatening diseases.³² The WTO now permits countries such as the United States, who possess robust pharmaceutical sectors, to produce and sell generic drugs to nations in need of the life-saving medication.³³

26. See WTO, The Multilateral Trading System—Past, Present and Future, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm (last visited Oct. 9, 2007).

27. WTO, Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Oct. 9, 2007). Intellectual property, consisting of ideas and knowledge, is best explained through examples:

Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved. Films, music recordings, books, computer software and on-line services are bought and sold because of the information and creativity they contain, not usually because of the plastic, metal or paper used to make them.

Id.

28. See *id.*

29. See *infra* Part I.A.

30. See *id.*

31. See *infra* Part I.B.

32. See *infra* Part I.C.

33. See *id.*

A. The Agreement on Trade-Related Aspects of Intellectual Property Rights

On January 1, 1995, the WTO implemented the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”).³⁴ The objective of the TRIPS Agreement is to protect and enforce intellectual property rights in order to reward and promote technological inventions.³⁵ At the same time, the TRIPS Agreement recognizes the need to transfer and disseminate this new knowledge to benefit social and economic welfare.³⁶ The provisions of the TRIPS Agreement that concern patents require that WTO member states provide a patent for any technological invention that is new, non-obvious, and useful.³⁷ In exchange for these rights, a patent applicant must disclose information about the invention that would allow a “person skilled in the art” to create the product.³⁸ If the application is granted, the patent holder has the ability to prevent others from “making, using, offering for sale, selling, or importing” the invention.³⁹ These exclusive rights are protected for twenty years from the date that the applicant files the patent application.⁴⁰

However, there are some exceptions to the exclusive rights that have been granted to the patent holder. Specifically, Article 31 of the TRIPS Agreement permits WTO member states to use the invention without the patent holder’s authorization.⁴¹ Included in such allowed use is government use and government-authorized third-party use pursuant to a “compulsory license.”⁴² Before the government authorizes use of the inven-

34. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. The WTO was created on January 1, 1995 as the successor to GATT. WTO, What is the World Trade Organization?, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm (last visited Oct. 9, 2007). The TRIPS Agreement is one of several WTO agreements that serve as the WTO’s rules on trade. WTO, Overview: A Navigational Guide, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm1_e.htm (last visited Oct. 9, 2007).

35. TRIPS Agreement, *supra* note 34, art. 7.

36. *See id.*

37. *See id.* art. 27(1). Extending far beyond pharmaceuticals, patents are available for “products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” *Id.*

38. *Id.* art. 29(1).

39. *Id.* art. 28(1).

40. *See id.* art. 33.

41. *See* TRIPS Agreement, *supra* note 34, art. 31.

42. *See id.* The TRIPS Agreement does not use the term “compulsory licensing.” Instead, Article 31 discusses “Other Use Without Authorization of the Right Holder.” Compulsory licensing is only one example of such “other use.” *See* WTO, Obligations

tion, it must ensure that the patent holder's rights are respected. First, the compulsory license applicant must first make "efforts to obtain authorization from the right holder on reasonable commercial terms and conditions" and have been unsuccessful "within a reasonable period of time" prior to filing the compulsory license application.⁴³ Nevertheless, the government may waive this required effort in cases of "national emergency or other circumstances of extreme urgency," or for "public non-commercial use."⁴⁴ Second, Article 31 requires that "adequate remuneration" be paid to the patent holder for use of the invention.⁴⁵ Article 31(h) explains that the payment will take into account "the circumstances of each case" and "the economic value of the authorization."⁴⁶

Article 31 also allows only limited use of the invention by the compulsory license applicant. Because the patent holder is still entitled to use of the invention, the compulsory licensee's rights are non-exclusive.⁴⁷ In addition, the compulsory license applicant may not use the invention beyond the scope for which the compulsory license was granted.⁴⁸ Furthermore, Article 31 limits the government's authority to grant compulsory licenses to inventions used predominantly in the domestic market.⁴⁹

B. The Doha Declaration on TRIPS and Public Health

The TRIPS Agreement raised concerns that poor countries may face greater difficulties in obtaining drugs because of the TRIPS Agreement's safeguards on intellectual property.⁵⁰ In response, WTO member states adopted the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") on November 14, 2001 at the WTO's Fourth Ministerial Conference in Doha, Qatar.⁵¹ First, the Doha Declaration "recognize[d] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."⁵² Second, al-

and Exceptions, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Oct. 9, 2007).

43. TRIPS Agreement, *supra* note 34, art. 31(b).

44. *Id.*

45. *Id.* art. 31(h).

46. *Id.*

47. *See id.* art. 31(d).

48. *See id.* art. 31(c).

49. *See* TRIPS Agreement, *supra* note 34, art. 31(f).

50. *See* WTO, *The Separate Doha Declaration Explained*, http://www.wto.org/english/tratop_e/trips_e/healthdeclxpln_e.htm (last visited Oct. 9, 2007).

51. *See* WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1 (2002) [hereinafter Doha Declaration].

52. *Id.*

though the Doha Declaration acknowledged that the protection of IPR promotes the development of new medicines, it also recognized that the patent system causes increased drug prices.⁵³ Third, the Doha Declaration affirmed that the TRIPS Agreement “should not prevent Members from taking measures to protect public health . . . 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.”⁵⁴

The Doha Declaration therefore provides flexibility to the TRIPS Agreement to ensure that intellectual property protection does not create obstacles to the management of public health problems.⁵⁵ For example, the Doha Declaration recognizes the right of WTO member states to grant compulsory licenses to generic drug companies to permit manufacturing of patented brand name drugs.⁵⁶ In addition, the Doha Declaration allows each WTO member state to determine the grounds for granting compulsory licenses.⁵⁷ WTO member states also have the right to define “national emergency or other circumstances of extreme urgency,”⁵⁸ under which the TRIPS Agreement permits a WTO member state to waive the requirement that the generic drug manufacturer must have unsuccessfully attempted to negotiate with the patented drug manufacturer before the proposed user may obtain a compulsory license. Specifically, the Doha Declaration explains that “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁵⁹ The Doha Declaration, however, leaves unresolved the problem of WTO member states that lack manufacturing capabilities in the pharmaceutical sector to effectively use compulsory licensing, in what is referred to as “Paragraph 6.”⁶⁰ The Declaration recognizes the problem, and instructs the TRIPS Council to report back to the General Council with a solution to the problem by the end of 2002.⁶¹ In the interim, be-

53. See Doha Declaration, *supra* note 51, para. 3.

54. *Id.* para. 4.

55. See *id.* para. 5.

56. See *id.* para. 5(b).

57. See *id.*

58. *Id.* para. 5(c).

59. Doha Declaration, *supra* note 51, para. 5(c).

60. See *id.* para. 6.

61. See *id.* para. 6 (“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.”).

cause Article 31(f) of the TRIPS Agreement limits products made under compulsory licenses to domestic use, the Doha Declaration left countries without the resources to produce pharmaceuticals without access to life-saving medications.⁶²

C. The Decision of the General Council of 30 August 2003

On August 30, 2003, the General Council approved a draft decision ("2003 Decision") which amended the TRIPS Agreement by implementing Paragraph 6 of the Doha Declaration.⁶³ The 2003 Decision makes it easier for poor countries, unable to manufacture medicines themselves, to import generic drugs made in other countries under compulsory license.⁶⁴ The 2003 Decision lifted the ban on exporting generic drugs made under compulsory licensing by permitting export of such generic drugs to "eligible importing Members."⁶⁵ An eligible importing country is one which is a "least-developed country" ("LDC"),⁶⁶ or a WTO mem-

62. Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

63. See WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 43 I.L.M. 509 (2003) [hereinafter 2003 Decision].

64. See 2003 Decision, *supra* note 63, at 509 ("[n]oting . . . the instruction . . . in paragraph 6 of the [Doha Declaration] to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement").

65. 2003 Decision, *supra* note 63, at 510.

66. The UN Committee for Development Policy reviews the list of least-developed countries every three years. In the 2003 Report of the UN Committee for Development Policy, qualification for the category of "least-developed country" ("LDC") is based on three criteria:

- (1) low-income, measured by the country's average of the gross national income (GNI) per capita;
- (2) human resource weakness, measured by the country's human assets index, which factors in the country's nutrition, health, education, and adult literacy; and
- (3) economic vulnerability, measured by the country's economic vulnerability index, which factors in the country's structural vulnerability rather than vulnerability resulting from government policy.

To be added to the list, a country must meet all three criteria. To become eligible to graduate from the list, a country must meet minimum threshold levels for two of the three criteria. To qualify for graduation, a country must meet two of the three criteria for two consecutive reviews. See UN Office of the High Representative for the Least Developed

ber state that has notified the TRIPS Council that it is importing “in the case of a national emergency or other circumstances of extreme urgency or public non-commercial use.”⁶⁷ A WTO member state seeking to import generic drugs manufactured under compulsory license must notify the TRIPS Council of the specific names and quantities of requested medicines.⁶⁸ In addition, the eligible importing country must confirm that it is a “least-developed country” or has “insufficient or no manufacturing capacities in the pharmaceutical sector” for the requested medicines.⁶⁹

The 2003 Decision also includes provisions that ensure that the medicines are used to protect public health, and not for industrial or commercial policy objectives.⁷⁰ For instance, compulsory licenses must limit the medicine production to only the amount necessary to meet the needs of the importing country.⁷¹ In addition, the generic drugs produced under compulsory license must be physically differentiated from their patented equivalents, using means such as special packaging or special colors or shapes of the drugs.⁷² The 2003 Decision also charges the importing country with taking “reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products.”⁷³ Furthermore, all countries are required to have legal safeguards to prevent importation of these drugs in violation of this compulsory system.⁷⁴

On December 6, 2005, WTO member states approved the 2003 Decision’s changes to permanently amend the TRIPS Agreement.⁷⁵ Although the amendment will not take effect until two-thirds of WTO member states have ratified the changes by the December 1, 2007 deadline, these changes remain in effect until then.⁷⁶

Countries, Landlocked Developing Countries, and Small Island Developing States, The Criteria for the Identification of the LDCs, <http://www.un.org/special-rep/ohrrlls/ldc/ldc%20criteria.htm> (last visited Oct. 9, 2007); UN Econ. & Soc. Council [ECOSOC], Sub-Comm. for Dev. Policy, *Report on the Sixth Session (2 March – 2 April 2004)*, 15–18, UN Doc. E/2004/33 (2004).

67. See 2003 Decision, *supra* note 63, at 510.

68. See *id.*

69. See *id.*

70. See WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports, *supra* note 62.

71. See 2003 Decision, *supra* note 63, at 510.

72. See *id.*

73. *Id.* at 511.

74. See *id.*

75. See Press Release, WTO, Members OK Amendment to Make Health Flexibility Permanent, WTO Doc. Press/426 (Dec. 6, 2005).

76. See *id.*

D. Changing U.S. Viewpoints on Intellectual Property Rights and Public Health

The United States arguably has the strictest patent system of WTO member states.⁷⁷ This adherence to intellectual property protection is reflected in the U.S. response to South Africa's Medicines and Related Substances Control Amendment Act, which was introduced in 1997.⁷⁸ The Act took several steps to promote access to cheaper drugs in order to combat the AIDS epidemic in South Africa.⁷⁹ The Act was enacted in an attempt to reduce drug prices by: (1) prohibiting price markups, (2) encouraging generic drugs, and (3) allowing South Africa's health minister to ignore its patent laws when a health crisis exists.⁸⁰ In response, thirty-nine pharmaceutical companies, with the support of the U.S. government, sued the South African government for enacting legislation that violated the TRIPS Agreement.⁸¹ Moreover, the U.S. government threatened trade sanctions against South Africa if it implemented the Act.⁸² However, the dispute ended when the pharmaceutical companies dropped their lawsuit because of the public protest over the lawsuit.⁸³

In 2001, this strict U.S. policy on patent protection reached a turning point. Just as the nation changed dramatically in the aftermath of the September 11th attacks, so too did the U.S. government's views on patent protection.⁸⁴ In October 2001, there were numerous cases of deaths resulting from anthrax exposure, which created fear of a bioterrorism attack.⁸⁵ Despite a shortage of Cipro—the only anthrax antibiotic the

77. See also Erika Mullenbach, Comment, *The Influence of Disease on the Evolution of U.S. Patent Law and Policy Towards Foreign Patent Laws in the Late Twentieth to Early Twenty-First Century*, 7 TUL. J. TECH. & INTELL. PROP. 227, 229–32 (2005) (explaining that the U.S. pharmaceutical industry, and the United States in general, criticize the TRIPS Agreement for providing flexibility to “strict, U.S.-style” patent protection).

78. See Donald G. McNeil Jr., *Medicine Merchants: Patent and Patients; As Devastating Epidemics Increase, Nations Take On Drug Companies*, N.Y. TIMES, July 9, 2000, § 1, at 18.

79. See Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES, Apr. 20, 2001, at A1.

80. See *id.*; McNeil, *supra* note 78.

81. See Swarns, *supra* note 79.

82. See McNeil, *supra* note 78. The U.S. Department of Commerce placed South Africa on a watch list, which is the first step leading to trade sanctions. In addition, Congress passed a bill that required South Africa to drop the Act in order to receive any U.S. aid. Moreover, President Clinton also voiced his disagreement to President Nelson Mandela. See *id.*

83. See Swarns, *supra* note 79.

84. See generally Mullenbach, *supra* note 77, at 239.

85. See Philip Shenon, *A Nation Challenged: The Disease; U.S. is Stepping Up Plan for Handling Anthrax Threat*, N.Y. TIMES, Oct. 15, 2001, at A1.

U.S. Food and Drug Administration (“FDA”) had approved—pharmaceutical company Bayer A.G.⁸⁶ refused to permit other companies to manufacture Cipro.⁸⁷ The U.S. government wanted to purchase a stockpile of Cipro to treat Americans in the event of a widespread attack, but was unable to convince Bayer to significantly lower their prices.⁸⁸ In response, the U.S. government threatened to bypass the Cipro patent and follow Canada’s lead in resorting to generic alternatives to combat the anthrax attacks.⁸⁹ However, the United States did not need to override the Cipro patent; Bayer agreed to further reduce the price of Cipro, and a deal between Bayer and the U.S. government was reached.⁹⁰ The U.S. response to the anthrax scare, in light of its reaction to South Africa’s Medicines and Related Substances Control Amendment Act, was strongly criticized as “blatant hypocrisy.”⁹¹ The United States was viewed as having a double standard—one standard “regarding the accessibility of patent relaxation in the context of health emergencies which confront ‘us,’” and a different standard “in the context of health emergencies which constantly confront ‘them’ in the developing world.”⁹² Although five people died as a result of the anthrax attacks in 2001,⁹³ the severity of the national emergency was far from comparable to the HIV/AIDS crisis in countries such as South Africa.⁹⁴ Therefore, in light of this evident double standard that Western countries may hold, WTO member states—both developed and developing countries—easily agreed that the TRIPS Agreement should be interpreted to improve public health.⁹⁵

The U.S. Trade Representative welcomed the 2003 Decision, which “allow[s] countries to override patent rights when necessary to export life-saving drugs to developing countries that face public health crises

86. *See id.*

87. *See* Keith Bradsher, *A Nation Challenged: The Antibiotic; Bayer Insists Cipro Supply is Sufficient; Fights Generic*, N.Y. TIMES, Oct. 21, 2001, at B7. Bayer’s Cipro patent was not scheduled to expire in the United States until 2003. *See id.*

88. *See* Keith Bradsher with Edmund L. Andrews, *A Nation Challenged: Cipro; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001, at B7.

89. *See id.* The Canadian Health Ministry overrode Bayer’s Cipro patent and ordered a Canadian pharmaceutical company to produce a generic equivalent to Cipro. *See id.*

90. *See id.*

91. Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425, 447 (2003).

92. *See id.*

93. *See id.* at 447 n.110.

94. *See id.* at 447.

95. *See id.*

but cannot produce drugs for themselves.”⁹⁶ Moreover, international organizations such as the WHO CIPIH urge: “Countries should provide in their legislation powers to use compulsory licensing, in accordance with the TRIPS agreement, where this power might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.”⁹⁷ To that same end, the Life-Savings Medicines Act of 2006 was introduced as “the catalyst for saving the lives or improving the health of millions of families in impoverished nations.”⁹⁸

II. LIFE-SAVING MEDICINES EXPORT ACT OF 2006

Senator Patrick Leahy introduced the Life-Saving Medicines Export Act to Congress on May 25, 2006.⁹⁹ The purpose of the Life-Saving Medicines Act is to promote public health by establishing the infrastructure to permit U.S. generic drug companies to manufacture life-saving medicines in the United States under compulsory license, and then export these medicines to developing countries with insufficient or no manufacturing capability in the pharmaceutical sector to produce the life-saving medicines themselves.¹⁰⁰

The Life-Saving Medicines Export Act seeks to amend Title 35 of the United States Code, which governs patents.¹⁰¹ Specifically, it establishes procedures for granting authority to the Under Secretary for Commerce for Intellectual Property and Director of the Patent and Trademark Office to issue compulsory licenses.¹⁰² Moreover, the Life-Saving Medicines Export Act also establishes an office within the Patent and Trademark Office (“PTO”) to assist countries seeking medicines to identify pharmaceutical companies that may manufacture such medicines under compulsory license.¹⁰³ The Act also explicitly states that the generic company’s action under the compulsory licensing system is not an infringement of the patent.¹⁰⁴

96. Life-Saving Medicines Export Act of 2006, S. 3175, 109th Cong. § 2(b)(1) (2006).

97. WHO CIPIH, *Public Health: Innovation and Intellectual Property Rights*, *supra* note 17, at 176.

98. *See* 152 CONG. REC. S233-01, S5245 (daily ed. May 25, 2006) (statement of Sen. Leahy).

99. *See id.*

100. *See generally* S. 3175 § 2.

101. *See id.*

102. *See id.*

103. *See id.* § 3(a).

104. *See id.* § 4.

The pharmaceutical company seeking to produce the essential medicine (“generic company”) must submit an application to the PTO, identifying the eligible importing country in need of the medicine (“importing country”).¹⁰⁵ An importing country must be: an LDC,¹⁰⁶ a WTO member state that has certified to the WTO General Council of its intent to participate in the compulsory licensing system, or a non-WTO member state that lacks the manufacturing capacity to produce the drug itself.¹⁰⁷ Moreover, the generic company may apply for a multi-country license for the production of medicine that will be exported to multiple countries.¹⁰⁸ Although only eligible countries may import medicines through the proposed compulsory licensing system, the application may also include the names of any nongovernmental organization (“NGO”) that will assist the importing country with the medicines.¹⁰⁹

The generic company may apply for a license for any pharmaceutical product,¹¹⁰ but must specify the scope of the drug production. The generic company must first specify the name of the drug it seeks to produce and export, as well as the patented equivalent,¹¹¹ where the patented drug has received either WHO or U.S. FDA approval.¹¹² In addition, the generic company must estimate the quantity of medicines to be produced and exported.¹¹³ Before an application is approved by the PTO, the generic company must show that it made efforts to negotiate directly with the patent holder.¹¹⁴ Specifically, the generic company’s application must include a copy of a written request to the patent holder asking for a voluntary license to produce the drug, as well as a description of any subsequent negotiations.¹¹⁵ The generic company is also required to wait at least sixty days after sending the request before submitting an application to the PTO for a compulsory license.¹¹⁶

105. *See* S. 3175 § 3(a).

106. *See supra* note 66 and accompanying text (defining least-developed country).

107. *See* S. 3175 § 3(a).

108. *See id.*

109. *See id.*

110. *See id.* The Life-Saving Medicines Export Act defines a “pharmaceutical product” eligible for generic production as “any patented product, or pharmaceutical product, including components of that product, manufactured through a patented process, of the pharmaceutical sector including any drug, active ingredient of a drug, diagnostic, or vaccine needed to prevent or treat potentially life threatening public health problems.” *Id.*

111. *See id.*

112. *See id.*

113. *See* S. 3175 § 3(a).

114. *See id.*

115. *See id.*

116. *See id.*

Once the application has been submitted, the PTO must approve or deny the application within sixty days.¹¹⁷ A denied applicant must appeal the decision to the U.S. Court of Appeals for the Federal Circuit, subject to final review by the Supreme Court upon certiorari.¹¹⁸ If the application is approved, the generic company is limited to producing the medicine for only the importing country listed in the application, and must export the medicine only to the importing country.¹¹⁹ The compulsory license is effective for seven years, but the generic company may apply for a license renewal once, which would extend the license for an additional seven years.¹²⁰ Moreover, if the generic company notifies the PTO that the original estimated quantity of the drug will not be sufficient to meet the importing country's need, the PTO may increase the licensed drug quantity without need for a new license application.¹²¹ A compulsory license may cease to exist, however, if the PTO determines, pursuant to a petition by the patent holder, that the circumstances warranting the compulsory license no longer exist and will not reoccur.¹²²

The generic company is also responsible for distinctly labeling and packaging the medicine so that it is distinguishable from the patented drug, and is identifiable as created under the compulsory licensing system.¹²³ However, this requirement may be waived if it is not feasible, or if doing so would significantly impact the price of producing the drug.¹²⁴ Moreover, the requirement may be waived "under urgent circumstances for limited quantities."¹²⁵

The Life-Saving Medicines Export Act also requires a generic company granted a compulsory license to pay remuneration to the patent holder within forty-five days after the generic company exported the drugs to the importing country.¹²⁶ In order to set a reasonable royalty

117. See S. 3175 § 3(a). The PTO has the option of denying an application but requesting additional information. The generic company must submit the supplemental information within thirty days of the PTO's request. The PTO then makes a final decision within sixty days of receipt of the additional information. See *id.*

118. See *id.* The Federal Circuit Court of Appeals may set aside the PTO decision if it finds the decision to be: (1) "arbitrary [or] capricious," (2) "contrary to constitutional right," (3) "in violation of a statutory right," or (4) "without observance of procedure required by law." *Id.*

119. See *id.*

120. See *id.*

121. See *id.*

122. See *id.*

123. See S. 3175 § 3(a).

124. See *id.*

125. *Id.*

126. See *id.*

amount, the PTO consults with Health and Human Services, the National Institutes of Health, the U.S. Agency for International Development, and the Centers of Disease Control.¹²⁷ The remuneration is capped at four percent of the commercial value of the drug, but in determining the royalty amount, the PTO considers: “[T]he need for the [generic company] . . . to make a reasonable return sufficient to sustain a continued participation in humanitarian objectives,” “[t]he humanitarian and noncommercial reasons for issuing a compulsory license,” “[t]he economic value to the importing country,” “[t]he need for low-cost pharmaceutical products by persons in eligible countries, in the importing country,” “[t]he ordinary levels of profitability in the United States . . . and any relevant international trends in relevant prices as reported by the United Nations or other appropriate humanitarian organizations.”¹²⁸ In addition, if the importing country is on the UN Human Development Index (“HDI”), or suffers from circumstances similar to a country on the index, the required royalty payment is much lower than the four percent cap.¹²⁹

The Life-Saving Medicines Export Act also provides safeguards to ensure that medicine production is not impeded by onerous procedures during times of emergency.¹³⁰ Therefore, if the importing country is in a state of “a national emergency or other circumstances of extreme urgency,” the PTO may employ expedited approval procedures.¹³¹ Moreover, the PTO may waive any requirement of the compulsory licensing system—including the requirement that the generic company first negotiate with the patent holder—or may postpone the royalty calculation until after the application has been approved.¹³²

The Life-Saving Medicines Export Act also directs the PTO to establish the National Advisory Board on Implementation of the General Council Decision to provide guidance with the compulsory licensing system, including determining appropriate royalty amounts.¹³³ Recognizing the importance of expert advice, the Board will include scholars and ex-

127. See S. 3175 § 3(a).

128. See *id.*

129. See *id.* If the country is on the HDI, the rate for royalty calculation is as follows:

$$\frac{1 + (\text{total number of HDI countries}) - (\text{importing country's HDI rank})}{(\text{total number of HDI countries})} \times 0.04$$

See *id.*

130. See *id.*

131. *Id.*

132. See *id.*

133. See S. 3175 § 5.

perts in fields affecting, as well as those impacted by, the compulsory licensing system.¹³⁴

III. CANADA'S BILL C-9: AN ACT TO AMEND THE PATENT ACT AND THE FOOD AND DRUGS ACT ("THE JEAN CHRÉTIEN PLEDGE TO AFRICA ACT")¹³⁵

On May 14, 2004, Canada amended its Patent Act to authorize compulsory licenses for the production of generic drugs for export to eligible developing countries.¹³⁶ By enacting this legislation, Canada became the first Group of Eight¹³⁷ country to implement the WTO General Council's

134. See S. 3175 § 5(c). The Board shall include the following ten members: one "academic expert on the subject of pharmaceutical matters and patent law;" two "individual[s] with expertise relating to the WTO, the TRIPS/health solution, and the General Council Decision;" two "individual[s] with expertise relating to the needs of persons living in least-developed and developing nations with respect to access to low-cost patented pharmaceutical products;" two "individual[s] who represent international organizations, such as the United Nations, the World Bank, international nongovernmental organizations, and religious faiths, and who have expert knowledge regarding the General Council Decision and the issues raised by that decision;" one "physician with experience in treating persons with HIV/AIDS, malaria, tuberculosis, or other infectious diseases;" one "individual representing major pharmaceutical manufacturers in the United States;" and one "individual representing major generic manufacturers of pharmaceutical products in the United States." *Id.*

135. The Jean Chrétien Pledge to Africa Act, together with supporting regulations, comprises what is now referred to as Canada's Access to Medicines Regime ("CAMR"). See Canada's Access to Medicines Regime, http://camr-rcam.hc-sc.gc.ca/intro/context_e.html (last visited Oct. 4, 2007).

136. See The Jean Chrétien Pledge to Africa Act, 2004 S.C., ch. 23 (Can.).

137. The Group of Eight (G8) is "an unofficial forum of the heads of the leading industrialized democracies." The Group holds summits regularly as a forum "to harmonize attitudes to acute international problems" by reaching informal agreements on individual measures each country can take to achieve the Group's goals. Although it is not a formal international organization, the G8 has working groups, expert groups, and task forces. See Official Web site of the G8 Presidency of the Russian Federation in 2006, <http://en.g8russia.ru/g8/history/shortinfo/> (last visited Oct. 9, 2007). The G8 was founded in 1975, when leaders of France, Japan, the United States, Britain, and Italy met to discuss current economic problems existing at that time. Canada joined the Group the following year, and Russia became a member in 1998. Because the G8 includes all of the world's major economic and political powers, their decisions on key global issues have great impact. For example, the G8 countries donated \$1.4 billion to set up the Global Health Fund, which is used for different projects that fight AIDS, tuberculosis, and malaria around the world. See What is the G8 Summit?, <http://www.g8.gov.uk/servlet/Front?pagename=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1078995913300> (last visited Oct. 9, 2007).

Decision of August 2003.¹³⁸ The stated purpose of the legislation is “to facilitat[e] access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹³⁹ The Pledge to Africa Act received the support of NGOs, civil society groups, and even the pharmaceutical industry.¹⁴⁰ Nevertheless, widespread criticism within these same groups resulted in a general consensus that the bill’s flaws may prevent it from achieving its goal of improving access to life-saving medicines.¹⁴¹ Harsher critics accuse the Canadian government of betraying people in developing countries by passing legislation that “perpetuate[s] inequitable access to medicines by inviting anti-competitive behaviour by multinational pharmaceutical companies, protecting these companies’ monopolies and [profiting] at the expense of the lives of patients.”¹⁴² During its drafting, however, the Canadian government implemented suggestions by brand name pharmaceutical companies, generic companies, and civil society organizations to address potential weaknesses with the legislation.¹⁴³ Nevertheless, more

138. See Rachel Kiddell-Monroe, *Canada’s Generic Drug Law is All Talk, No Action*, GLOBE AND MAIL (Toronto), Aug. 14, 2006, at A15; Mark D. Penner & Prakash Narayanan, *Amendments to the Canadian Patent Act to Address Drug Access: Is Help on the Way?*, 60 FOOD & DRUG L.J. 459, 460–61 (2005).

139. 2004 S.C., ch. 23 § 21.01.

140. See generally Press Release, United Nations Children’s Fund [UNICEF], UNICEF Hails Canada’s Move to Expand Access to AIDS Drugs (Sept. 29, 2003) (praising Canada’s Pledge to Africa Act as “the first major move by a major, industrialised country to overcome a key structural hurdle in getting life-saving medicines to people who desperately need them”).

141. See e.g., CANADIAN HIV/AIDS LEGAL NETWORK, THE JEAN CHRÉTIEN PLEDGE TO AFRICA ACT AND ITS IMPACT ON IMPROVING ACCESS TO HIV/AIDS TREATMENT IN DEVELOPING COUNTRIES 4 (Aug. 1, 2006), <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=696> (identifying the main flaws as: (1) the Act limited pharmaceutical products available for compulsory license, (2) the Act had additional requirements for non-WTO members compared to WTO members, (3) and a compulsory license granted under the Act had a short lifespan).

142. Press Release, Médecins Sans Frontières [MSF], Amending Canada’s Drug Patent Law: A Betrayal of Patients in Developing Countries (Feb. 26, 2004), available at <http://www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=459>.

143. See News Release, Canadian HIV/AIDS Legal Network, Canada Proceeds with Bill C-9 on Cheaper Medicine Exports: NGOs Say Initiative is Important, and Urge Other Countries to Avoid the Flaws in the Canadian Model (Apr. 28, 2004), available at <http://www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=453>. A number of civil society groups contributed their expertise to the Canadian Parliament by proposing amendments to the Pledge to Africa Act to improve the legislation’s efficacy. See *id.* Additionally, amendments to the Pledge to Africa Act included recommendations by members of the Canadian generic pharmaceutical industry. See News Release, Cana-

than three years after the Pledge to Africa Act was introduced into Canadian law, no developing country has received life-saving medicines through the new Canadian compulsory licensing system.¹⁴⁴

Under the Pledge to Africa Act, the Canadian government may issue a compulsory license for a defined set of patented medicines for export to a defined set of developing countries.¹⁴⁵ The medicines available for generic production are limited to the pharmaceutical products that were on the WHO list of essential medicines¹⁴⁶ and were patented in Canada at the time that the Pledge to Africa Act was enacted.¹⁴⁷ The Pledge To Africa Act also limits export of the generic medicines to countries that are: LDCs,¹⁴⁸ WTO member states that have not declined to use the system as importers, or WTO member states that have stated an intent to participate in the compulsory licensing system only if they face national emergency or insufficient manufacturing capacity for the medicine they seek under the license.¹⁴⁹ However, the Pledge to Africa Act includes procedures for updating the lists of medicines and eligible countries.¹⁵⁰ The Minister and the Minister of Health may recommend the addition of any patented product that addresses a health problem in a developing country.¹⁵¹

dian Generic Pharmaceutical Ass'n [CGPA], Government Amendments to Bill C-9 Fall Short (Apr. 20, 2004), available at http://www.canadiangenerics.ca/en/news%5Capr_20_04.shtml.

144. See *infra* note 177 and accompanying text.

145. See 2004 S.C., ch. 23 § 21.04, Schedule 1–4.

146. See WHO, Essential Medicines, http://www.who.int/medicines/services/ess_medicines_def/en/index.html (last visited Oct. 9, 2007). The WHO Expert Committee on the Selection and Use of Essential Medicine compiles the essential medicines list by selecting products that satisfy priority health care needs, and takes into consideration the disease prevalence, as well as the comparative efficacy, safety, and cost-effectiveness of medicines. See *id.*

147. See Lalita Acharya & Kristen Douglas, Canada Library of Parliament, Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Legislative Summary 2 (Mar. 3, 2004); Pledge to Africa Act, *supra* note 136, at Schedule 1.

148. See *supra* note 66 and accompanying text (defining least-developed country).

149. See Acharya & Douglas, *supra* note 147, at 2. The Pledge to Africa Act includes three schedules of eligible importing countries. Schedule two lists all countries that the UN has determined are LDCs. Schedule three lists all WTO member states that have not declined to use the compulsory licensing system to import medicines. Schedule four lists all WTO member states who have stated an intention to use the compulsory licensing system only in the event of a national emergency or other extreme urgency situation. See *id.*

150. See 2004 S.C., ch. 23 § 21.03.

151. See *id.* § 21.03(1)(a). Based on a recommendation by the Minister and Minister of Health, the Governor in Council may add “any patented product that may be used to address public health problems afflicting many developing and least-developed countries,

Moreover, the Minister of Foreign Affairs, the Minister for International Trade, and the Minister for International Cooperation may recommend additional eligible importing countries.¹⁵² Furthermore, a non-WTO member state may be added if it is on the Organization for Economic Cooperation and Development's ("OECD")¹⁵³ list of countries that are eligible for official development assistance, the country faces "a national emergency or other circumstances of extreme urgency," and has "insufficient[] pharmaceutical capacity to manufacture that product."¹⁵⁴

Like the Life-Saving Medicines Export Act, the generic company must submit an application specifying the name and quantity of the drug it seeks to produce and export and its patented brand-name equivalent.¹⁵⁵ In addition, the generic company must have made a written request to the patent holder for a voluntary license, and must wait at least thirty days after such unsuccessful negotiation before filing an application for the compulsory license.¹⁵⁶

The Pledge to Africa Act also requires that the generic company pay remuneration to the patent holder.¹⁵⁷ The Governor in Council determines an appropriate royalty amount in light of the humanitarian and non-commercial reasons behind the compulsory license.¹⁵⁸ However, the patent owner may seek a Federal Court order that requires a royalty payment greater than the amount that the Governor in Council has determined.¹⁵⁹ The Federal Court may only order a higher royalty payment if the Court finds that the Governor in Council's remuneration determination is inadequate, when considering the humanitarian and non-commercial reasons behind the compulsory license and the medicine's economic value to the importing country.¹⁶⁰

When a compulsory license is granted in Canada, it is valid for two years, with the opportunity to renew the license for an additional two

especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." See 2004 S.C., ch. 23 § 21.03(1)(a)(i).

152. See *id.* §§ 21.03(1)(b)–(d).

153. The thirty member states of the Organization for Economic Co-operation and Development are "committed to democracy and the market economy." OECD, About OECD, http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html (last visited Oct. 9, 2007).

154. 2004 S.C., ch. 23 § 21.03(1)(d)(ii).

155. See *id.* § 21.04(2). Compare *id.* with S. 3175 § 3(a) (discussing the Life-Saving Medicines Export Act compulsory license application).

156. See 2004 S.C., ch. 23 § 21.04(3)(c).

157. See *id.* § 21.08.

158. See *id.* §§ 21.08(1)–(2).

159. See *id.* §§ 21.08(4)–(6).

160. See *id.* § 21.08(7).

years.¹⁶¹ The generic company must produce medicine that is physically distinguishable from the patented equivalent through distinct “marking, embossing, labelling, and packaging.”¹⁶² In addition, the Minister of Health must approve the generic drug as meeting the requirements of Canada’s Food and Drugs Act.¹⁶³

The patent owner may apply to the Federal Court for an order terminating the compulsory license.¹⁶⁴ The patent holder must show that either the application for the compulsory license contained inaccurate information, or that the generic company did not follow provisions of the license, such as paying the specified remuneration to the patent holder or exporting only to the authorized importing country.¹⁶⁵ The patent owner may assert that: (1) the compulsory license application contained inaccurate information; (2) the generic company failed to set up a Web site required to disclose information about the generic medicines;¹⁶⁶ (3) the generic company failed to notify the patentee, importing country, or the medicine purchaser within fifteen days of exporting the medicines;¹⁶⁷ (4) the generic company has failed to pay the required royalty within the prescribed time; (5) the generic company failed to provide the Commissioner or the patent holder with a copy of the agreement underlying the compulsory license application;¹⁶⁸ (6) the medicines were re-exported with the generic company’s knowledge; (7) the medicines were exported to somewhere other than the authorized importing country; (7) the quantity of exported medicines exceeded the authorized amount; or (8) the medicines exported to a non-WTO member state have been used for commercial purposes.¹⁶⁹

161. See 2004 S.C., ch. 23 §§ 21.09, 21.12(1)–(4).

162. *Id.* § 21.04(3)(b). See generally Anthony P. Valach, Jr., *TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries*, 4 CHI.-KENT J. INTELL. PROP. 156, 168–70 (2005) (explaining that the generic company must consider that changes to pill size, shape and color may incidentally affect the generic medicine’s bio-equivalence to the patented medicine).

163. See 2004 S.C., ch. 23 § 21.04(3)(b).

164. See *id.* § 21.14.

165. See *id.*

166. See *id.* § 21.06 (requiring the generic company to establish a Web site to disclose information on the product, the importing country, and the distinguishing features of the generic medicine, as well as the date when the medicine is exported).

167. See *id.* § 21.07 (requiring the generic company to notify the parties involved that the generic medicines will be exported within fifteen days).

168. See *id.* § 21.16 (requiring the generic company to provide a copy of the underlying agreement and a statement defining both the monetary value of the agreement and the number of units to be sold pursuant to the agreement).

169. See 2004 S.C., ch. 23 § 21.14.

The Federal Court may also terminate the license if it finds that the underlying agreement to sell the generic medicines is “commercial in nature.”¹⁷⁰ If the Court terminates the license because of a commercial agreement, the Federal Court may order the generic company to turn over any remaining medicines to the patent holder, as though the generic company had infringed on the patent.¹⁷¹

The Pledge to Africa Act provides for an advisory committee to facilitate the administration of Canada’s compulsory licensing system.¹⁷² However, unlike the advisory board created pursuant to the Life-Saving Medicines Export Act,¹⁷³ the Canadian advisory committee’s duties are extremely limited. The advisory committee only advises the Minister and the Minister of Health in the recommendations that the Minister and the Minister of Health make to the Governor in Council regarding additions and deletions to the list of approved patented products.¹⁷⁴

IV. A MORE EFFICIENT COMPULSORY LICENSING INFRASTRUCTURE IN LIGHT OF THE CRITICISMS OF THE PLEDGE TO AFRICA ACT

When the Life-Saving Medicines Export Act was introduced, U.S. lawmakers were confident that it addressed the flaws found in other countries’ similar legislation.¹⁷⁵ Specifically, lawmakers identified key provisions of Canada’s compulsory licensing legislation that made generic companies reluctant to participate.¹⁷⁶ The most striking criticism, however, is that more than three years after the legislation was passed, a

170. 2004 S.C., ch. 23 § 21.17. The agreement may be deemed “commercial in nature” if the generic medicine is sold for more than twenty-five percent of the price of either the patented medicine or any equivalent medicine that has been produced with the patent holder’s consent. However, this determination also takes into account the generic company’s need to make a reasonable return on the medicines, the normal profitability of commercial pharmaceutical agreements, and international pricing trends for products supplied for humanitarian purposes. *See id.* § 21.17(1)–(2). In finding a commercial agreement, the Federal Court may fashion a remedy on “any terms that it considers appropriate.” *Id.* § 21.17(3). Rather than terminating the license, the Court may instead require the generic company to pay the patent owner a royalty amount that adequately compensates for the commercial use of the medicine. *See id.* § 21.17(3)(b).

171. *See id.* § 21.17(4)(a). In the alternative, the patent holder may nevertheless permit the generic company to release the remaining medicines to the importing country. *See id.* § 21.17(4)(b).

172. *See id.* § 21.18.

173. *See S.* 3175 § 5. *See also supra* notes 133–34 and accompanying text.

174. *See* 2004 S.C., ch. 23 § 21.18.

175. *See* 152 CONG. REC. S233-01, S5246–47 (daily ed. May 25, 2006) (statement of Sen. Leahy).

176. *See id.*

single pill has not left Canada.¹⁷⁷ The Life-Saving Medicines Export Act was touted as addressing the concerns over a Canadian law that “permits dilatory and needless litigation, omits important medicines from a complex list of covered drugs, and creates unnecessary bureaucratic hoops.”¹⁷⁸ Nevertheless, even if the United States does succeed in addressing these so-called flaws, lawmakers must look at whether this is enough to allow the U.S. law to succeed. Unfortunately, no country has established a benchmark TRIPS-compliant compulsory licensing system that has effectively increased access to essential life-saving medicines.¹⁷⁹ However, by addressing the concerns raised over the Pledge to Africa

177. See Lisa Priest, *Canadian Companies Agree to Share Generic AIDS drugs with Rwanda*, GLOBE AND MAIL (Toronto), Aug. 9, 2007, at A3. However, the first pills may leave Canada in the near future. On July 19, 2007, Rwanda became the first country to inform the WTO of its intent to use the 2003 Decision to access life-saving medicines. See WTO: 2007 News Items, http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm (last visited Sept. 29, 2007). Rwanda, a country with 250,000 people infected with HIV, seeks to import antiretrovirals under Canada’s compulsory licensing system. See Lisa Priest, *supra*, at A3. Multinational pharmaceutical company Glaxo-SmithKline (“GSK”) subsequently gave its consent under the Canadian compulsory licensing system to permit the Canadian company Apotex to produce an antiretroviral that contains two molecules that have been patented by GSK. See Press Release, Glaxo-SmithKline, GSK Gives Consent Under Canada’s Access to Medicines Regime for Generic Version of HIV/AIDS Medicine for Use in Rwanda (Aug. 8, 2007). Moreover, GSK has agreed to waive royalties provided that Apotex supplies the drugs to Rwanda on a no-profit basis. See *id.* On September 25, 2007, a compulsory license was granted to Apotex, permitting it to proceed with manufacturing the antiretroviral. See *ApoTriavir Approved by Health Canada Under CAMR Provisions*, ANTI-INFECTIVE DRUG NEWS, Sept. 25, 2007. If the agreement is completed, up to 16 million tablets of the antiretroviral will be sent to Rwanda, or enough to treat 21,000 Rwandans for one year or 200,000 Rwandans for one month. See Lisa Priest, *supra*, at A3. Apotex, however, cautioned that not all barriers to access have been removed. See *id.* Apotex must still reach similar agreements regarding the other patented molecules contained in the antiretroviral that are not patented by GSK. See *id.* (quoting Apotex’s director of public and government affairs: “The bottom line is that the patentees have not lifted all of the barriers to shipment. . . . Apotex cannot ship tomorrow.”).

178. See 152 CONG. REC. S233-01, S5247 (daily ed. May 25, 2006) (statement of Sen. Leahy).

179. It may be helpful to note Brazil’s Industrial Property Law permitting compulsory licensing. Although the law is not used to produce generic medicines, Brazil has successfully negotiated with multinational pharmaceutical companies by threatening to grant compulsory licensing to generic companies. As a result of these threats, patent holders have negotiated affordable antiretroviral drugs. Therefore, although Brazil did not issue a compulsory license, it attained a price reduction of essential medicines that may not have been possible without compulsory licensing legislation. See Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on Trips and Public Health*, 15 ALB. L.J. SCI. & TECH. 433, 443 (2005).

Act, the Life-Saving Medicines Export Act is off to a good start creating an effective compulsory licensing system. Most of the arguments over the Pledge to Africa Act point out that the Canadian compulsory licensing system incorporates stringent regulations that are not necessarily required by the WTO's 2003 Decision.¹⁸⁰ Moreover, critics emphasize that the Pledge to Africa Act involves burdensome bureaucratic red tape and procedural barriers, which may prevent essential medicines from getting to people that need them in developing countries.¹⁸¹ More importantly, however, a compulsory licensing system will only succeed if it gives generic companies the economic incentive to participate. If the Life-Saving Medicines Export Act does not provide sufficient financial motivation, generic companies will not produce affordable essential medicines, regardless of how many people might die as a result.¹⁸² Unfortunately, despite a praiseworthy attempt, the incentives provided by the Life-Saving Medicines Export Act will not be enough to succeed. If the U.S. government passes the legislation as it currently stands, it will follow in the footsteps of the Pledge to Africa Act; not a single pill will leave the United States.

A. Provisions Unnecessary to Comply with the WTO Agreements

One focus of strong criticism of the Pledge to Africa Act is its limitation on medicines that can be produced under compulsory license.¹⁸³ The Canadian government only permits compulsory licenses for pharmaceutical products that were on the WHO list of essential medicines and were protected by Canadian patent when the Pledge to Africa Act was en-

180. See Canadian HIV/AIDS Legal Network, Canada Proceeds with Bill C-9 on Cheaper Medicine Exports: NGOs Say Initiative is Important, and Urge Other Countries to Avoid the Flaws in the Canadian Model, *supra* note 143.

181. See *supra* notes 141–42 and accompanying text (discussing criticism by NGOs, civil society groups, and the pharmaceutical industry).

182. See RICHARDS, *supra* note 15, at 163.

183. The argument that the Pledge to Africa Act, as well as any other legislation of its kind, should not be limited to a specific list of medicines is grounded in a broad interpretation of the Doha Declaration. Paragraph 1 “recognize[s] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” *Doha Declaration*, *supra* note 51. As such, the Doha Declaration should extend to all public health needs. Furthermore, the Doha Declaration affirms “that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” *Id.* By making such a general statement, the WTO can be seen as addressing all health issues, and not just a set of specific diseases. See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and Protection of Public Health*, 99 AM. J. INT’L L. 317, 328 (2005).

acted.¹⁸⁴ However, this original list omits “even the most widely sought fixed-dose combination of anti-retrovirals.”¹⁸⁵ Although the Minister and the Minister of Health may review and approve new medicines,¹⁸⁶ this process may find itself stuck in bureaucratic red tape for months. The Life-Saving Medicines Export Act addresses this issue by permitting the production of any pharmaceutical product used to combat life-threatening public health problems.¹⁸⁷ Because it does not limit the list of approved medicines, the Life-Saving Medicines Act addresses current public health issues, as well as unforeseeable future issues. In addition, the proposed U.S. system eliminates the procedural barriers involved in maintaining and updating a list of approved medicines.

Critics of the Pledge to Africa Act also object strongly to the limitations on eligible importing countries. The original list includes UN-determined LDCs and WTO member states that have either: (1) not declined to import under the compulsory licensing system, or (2) stated an intention to use the system for national emergency or insufficient manu-

184. See 2004 S.C., ch. 23 Schedule 1. See also *supra* notes 146–47 and accompanying text. The Canadian government has amended the original list of permissible pharmaceutical products since the Pledge to Africa Act was passed. See Order Amending Schedule 1 to the Patent Act (Oseltamivir Phosphate) SOR/2006-204 (Can); Order Amending Schedule 1 to the Patent Act (Lamivudine + Nevirapine + Zidovudine) SOR/2005-276 (Can).

185. See Kiddell-Monroe, *supra* note 138.

186. See 2004 S.C., ch. 23 § 21.03(1)(a). See also *supra* note 151 and accompanying text. The medicine approval process was put to the test when a generic pharmaceutical company sought to add oseltamivir phosphate to Canada's list of approved medicines. Oseltamivir, better known as the patented drug Tamiflu, is effective against various strains of influenza, such as the fatal H5N1 strain of avian flu. See *Legal Network Calls for Compulsory Licensing of Tamiflu*, NETWORK NEWS, Mar. 2006, at 6. On February 13, 2006, generic pharmaceutical company Biolyse formally requested that oseltamivir phosphate be added to the Patent Act's Schedule 1 drugs that are eligible for export. See Letter from Joanne Csete, Executive Director, Canadian HIV/AIDS Legal Network, to Susan Bincoletto, Director General, Marketplace Framework Policy Branch, Industry Canada (July 26, 2006), available at www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=706. On July 1, 2006, the Departments of Industry and Health published a proposed order that would amend Schedule 1 of Canada's Patent Act, which lists the approved medicines. See *id.* However, the Canadian federal government did not add oseltamivir to Schedule 1 until over seven months later. See Helen Branswell, *Canada Agrees to Add Tamiflu to List of Drugs That Can Be Made Off Patent*, CANADIAN PRESS, Sep 27, 2006.

187. See S. 3175 § 3(a). See also *supra* notes 110–12 and accompanying text. It is interesting to note that the United States called for a “limited approach” during WTO negotiation talks concerning the TRIPS Agreement, and wanted to limit the diseases that the Doha Declaration covered. By doing so, the United States sought to limit the number of patents that would be overridden by compulsory licenses and to diminish the risk that pharmaceutical revenues would be jeopardized. See Abbott, *supra* note 183, at 327–29.

facturing capacity.¹⁸⁸ Additionally, a non-WTO member state may be added to the list of approved countries if it is on the OECD's list of countries eligible for official development assistance.¹⁸⁹ Nevertheless, because Canada's original list includes only WTO members states, it fails to recognize that many developing countries' citizens have no access to essential medicines, regardless of whether the country is a WTO member state or not.¹⁹⁰ Although the Pledge to Africa Act includes procedures for adding eligible importing countries, such procedures cannot happen immediately, and a country may have to wait months to be reviewed and approved. In addition, as countries are added or removed from the UN list of LDCs or acquire WTO membership, Canada's list of eligible countries must be updated, resulting in an additional administrative burden. The Life-Saving Medicines Export Act, on the other hand, avoids this unnecessary red tape; there is no specific list of eligible importing countries.¹⁹¹ Instead, the U.S. compulsory licensing system may export to: UN-determined LDCs, WTO members that have stated their intention to use the system, and non-WTO member states that lack adequate manufacturing capabilities to produce the requested drug.¹⁹² Therefore, the United States reduces the administrative costs of maintaining a list, and more importantly, does not exclude any countries that are in need of life-saving medicines.

188. See 2004 S.C., ch. 23 Schedules 2–4. See also *supra* notes 148–49 and accompanying text. Countries such as East Timor and Lebanon are excluded from the list of eligible importing companies because they are neither LDCs nor WTO members. See Policy Statement, Development & Peace, Urgent Appeal to Amend Bill for Cheap Medicines to HIV/AIDS Patients (Mar. 1, 2004), available at http://www.devp.org/testA/policy/declarations04_2-e.htm.

189. See 2004 S.C., ch. 23 §21.03(d)(ii). See also *supra* notes 153–54 and accompanying text.

190. MSF, Amending Canada's Drug Patent Law: A Betrayal of Patients in Developing Countries, *supra* note 142, quoting Richard Elliott, Director of Legal Research and Policy at the Canadian HIV/AIDS Legal Network ("People in all developing countries struggle with poverty and public health needs, and should benefit from this important legislation regardless of whether their country belongs to the WTO.").

191. See S. 3175 § 3(a). See also *supra* notes 106–07 and accompanying text. Again, as with the "limited approach" to medicines eligible for generic production under compulsory license, the United States ironically sought to limit the countries "with insufficient or no manufacturing capacities in the pharmaceutical sector" that were provided for in the Doha Declaration. Abbott, *supra* note 183, at 334–35. In doing so, the United States and other developing countries could limit the number of patents that would be overridden, as well as minimize the amount of revenues that would be lost by patent-owning pharmaceutical companies. See *id.*

192. See S. 3175 § 3(a). See also *supra* notes 106–07 and accompanying text.

The Pledge to Africa Act is also widely criticized for requiring generic companies to enter into export agreements only with state governments.¹⁹³ Therefore, NGOs, such as Médecins Sans Frontières/Doctors without Borders, are not granted access to life-saving medicines under the Canadian system.¹⁹⁴ International agencies and NGOs play a critical role in treating public health needs in developing countries and often have more knowledge about a country's large-scale health epidemic than government officials.¹⁹⁵ Moreover, NGOs may also know the best way to administer the life-saving medicines to improve public health.¹⁹⁶ The Life-Saving Medicines Export Act acknowledges this problem and permits licensees to include the names of NGOs that will assist the importing country with the medicines.¹⁹⁷ However, this provision does not permit export agreements between a generic company and an NGO. If an NGO seeks essential medicines, it must work with a country's government to obtain these medicines. Moreover, if an NGO wants to supply essential medicines for a given disease in multiple countries, it must coordinate with each country's government. NGOs may face roadblocks if a government lacks resources, or is simply reluctant, to collaborate in this effort. Unnecessary procedures such as these decrease the chances that essential medicines will reach people in need. Although the drafters of the Life-Saving Medicines Export Act specifically wanted to include NGOs in the U.S. compulsory licensing system, the existing provision is not optimal. Instead, generic companies should be permitted to enter into export agreements directly with NGOs, provided that the NGOs supply the generic medicines to eligible importing countries.

B. Procedural Barriers

The Pledge to Africa Act also creates “unnecessary bureaucratic hoops” by potentially requiring generic companies to unnecessarily file

193. See 2004 S.C., ch. 23 Schedules 2–4. See also *supra* notes 148–49 and accompanying text. In making amendments to the proposed Pledge to Africa Act, the Canadian government recognized the need for generic companies to contract directly with NGOs, and consequently proposed an amendment to address the issue. However, this amendment was removed in the process of last-minute changes. See Canadian HIV/AIDS Legal Network, Canada Proceeds with Bill C-9 on Cheaper Medicine Exports: NGOs Say Initiative is Important, and Urge Other Countries to Avoid the Flaws in the Canadian Model, *supra* note 143.

194. See Acharya & Douglas, *supra* note 147, at 2; Penner & Narayanan, *supra* note 138, at 467.

195. See Valach, *supra* note 162, at 172.

196. See *id.*

197. See S. 3175 § 3(a). See also *supra* note 109 and accompanying text.

many compulsory license applications.¹⁹⁸ First, a Canadian compulsory license permits a generic company to produce a *specific* quantity of medicine for only *one* country. Therefore, if the importing country needs an increased quantity of the same medicine, the generic company must submit an application for a new license, which authorizes the additional drug quantity.¹⁹⁹ A new application for an increased drug quantity, which could feasibly occur on a regular basis, is an unnecessary waste of time and resources. Moreover, if multiple countries need the medicine, the generic company must submit a compulsory license application for each country. Again, this requirement creates needless paperwork for both the generic company and the Canadian government.²⁰⁰ Second, the Governor in Council has only two options in deciding an application—either grant the application or deny it. Therefore, if the generic company fails to include one piece of necessary information, the application is denied and the generic company must start the application process from the beginning.

The Life-Saving Medicines Export Act addresses each of these deficiencies. First, a generic company need not submit separate applications if the quantity of medicine they seek to produce changes or multiple countries need the medicine. If the generic company discovers that the importing country needs additional medicines, the generic company notifies the PTO, and the PTO may increase the authorized amount of medicines if it is appropriate.²⁰¹ Second, the Life-Saving Medicines Export Act provides for multi-country licenses, in which the generic company submits one application for authorization to export medicines to multiple specified countries.²⁰² In addition, when the PTO considers a compulsory license application, it has three options for its decision. In addition to granting or denying the application, it may also deny the application with a request for more information, giving the generic company thirty days to respond without having to start a new application. A new application would not only require the burden of redundant paperwork, but would also require the generic company to request a voluntary license from the patent holder, and then wait an additional sixty days after submitting that request to submit a compulsory license application to the PTO.

198. 152 CONG. REC. S233-01, S5247 (daily ed. May 25, 2006) (statement of Sen. Leahy).

199. See Valach, *supra* note 162, at 168.

200. See *id.* at 169.

201. See S. 3175 § 3(a). See also *supra* note 121 and accompanying text.

202. See S. 3175 § 3(a). See also *supra* note 108 and accompanying text.

The Pledge to Africa Act has also been criticized as “permitting dilatory and needless litigation.”²⁰³ The Pledge to Africa Act grants the patent holder the right to petition the Federal Court to review the authorized license for numerous reasons.²⁰⁴ Although many of the grounds for termination ensure that the compulsory licensing system is not abused, other grounds for termination penalize the generic company for technical administrative violations. For example, a license may be terminated if the generic company fails to maintain or update a Web site that is required by the Act, or fails to notify the proper parties during the exporting process.²⁰⁵ The patent holder may use these administrative grounds to frustrate the generic company or to delay the production of the essential medicines. Consequently, a generic company may be deterred from participating in the compulsory licensing system because of the threat of litigation.

In addition, the patent holder has the right to litigate in Federal Court over whether the export agreement is “commercial in nature.”²⁰⁶ Unlike the above-mentioned grounds for Federal Court, the Court applies a balancing test to determine whether an export agreement is commercial in nature.²⁰⁷ Because the result of a balancing test is always uncertain, and there is no case law that predicts the outcome, generic companies may be reluctant to take this risk, especially if they are not expecting high enough levels of profit from the license agreements to cover the cost of drawn-out litigation.

The Life-Saving Medicines Export Act reduces the grounds upon which the patent holder may challenge a compulsory license. A patent holder may petition the PTO for review of a compulsory license only if

203. 152 CONG. REC. S233-01, S5247 (daily ed. May 25, 2006) (statement of Sen. Leahy).

204. See 2004 S.C., ch. 23 §21.14; Penner & Narayanan, *supra* note 140, at 467–69 (“[A] more significant roadblock for the use of the authorization under the Pledge to Africa Act may be the potential uncertainty associated with any such authorization. This uncertainty arises from the ability of the Federal Court, at the request of the patentee, to review and possibly amend the terms of the authorization.”). See also *supra* notes 164–69 and accompanying text.

205. See 2004 S.C., ch. 23 §21.14. Jim Keon, President of CGPA, explained that “[i]t is unlikely that a generic company would spend the time and money fighting the brands in court over these contracts Once the brand company initiated litigation, the generic firm would probably withdraw its request for a license.” CGPA, Government Amendments to Bill C-9 Fall Short, *supra* note 143. See also *supra* notes 164–69 and accompanying text.

206. See 2004 S.C., ch. 23 §21.17. See also *supra* notes 170–71 and accompanying text.

207. See 2004 S.C., ch. 23 §21.17(2). See also *supra* note 170 and accompanying text.

the patent owner believes that “the circumstances that have led to the granting of the license cease to exist and it appears probable that such circumstances will not reoccur.”²⁰⁸ Although it seems like this single provision encompasses all of the enumerated administrative provisions of the Pledge to Africa Act, the Life-Saving Medicines Export Act nevertheless does away with the provision permitting the patent holder to challenge a compulsory license because it is “commercial in nature.” As such, this omission decreases the risk that a compulsory license will be revoked after the generic company has spent multiple years and millions of dollars developing the medicines.²⁰⁹

One must further analyze the Life-Saving Medicines Export Act to determine whether it streamlines compulsory licensing while sustaining compliance with the TRIPS agreement. One of the most important issues a country must address is whether the law eliminates injunctive relief to the patent holder.²¹⁰ The Life-Saving Medicines Export Act avoids this potential obstacle by amending the patent laws to expressly state that production of medicines pursuant to the Life-Saving Medicines Export Act does not constitute patent infringement.²¹¹ Therefore, patent holders are not entitled to injunctive relief against the generic company.²¹²

In addition, an optimal compulsory licensing system must eliminate procedural barriers in times of exigency.²¹³ The Life-Saving Medicines Export Act provides for such expedited approval for “emergencies and circumstances of extreme urgency,” including waiving the required prior negotiation with the patent holder, as well as postponing the royalty determination until after the compulsory license has been granted.²¹⁴

Moreover, a compulsory licensing system is more efficient if it utilizes administrative review procedures instead of judicial review.²¹⁵ The Life-

208. S. 3175 § 3(a). *See also supra* note 122 and accompanying text.

209. *See* CGPA, Government Amendments to Bill C-9 Fall Short, *supra* note 143.

210. *See* JAMES LOVE, *Four Practical Measures to Enhance Access to Medical Technologies*, in *NEGOTIATING HEALTH* 241, 245 (Pedro Roffe et al. eds., 2006).

211. *See* S. 3175 § 4. *See also supra* note 104 and accompanying text.

212. Current patent laws provide the patent holder with injunctive relief. *See* 35 U.S.C. § 281 (“A patentee shall have remedy by civil action for infringement of his patent.”); 35 U.S.C. § 283 (“The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”).

213. *See* LOVE, *supra* note 210, at 245.

214. S. 3175 § 3(a). *See also supra* notes 130–32 and accompanying text.

215. *See* LOVE, *supra* note 210, at 245 (identifying the need that “a remedy to an anti-competitive practice be . . . administrative rather than a judicial procedure”). The Life-Saving Medicines Export Act grants compulsory licenses to improve access to medicines, and not to remedy anti-competitive pricing or practices. Nevertheless, the same analysis

Saving Medicines Export Act provides that a generic company may appeal the denial of its application for a compulsory license in the U.S. Federal Circuit Court of Appeals.²¹⁶ Judicial review in the federal courts can be more time-consuming and the status of a compulsory licensing application may not be resolved for years. Therefore, initial review by an administrative body may be more desirable in the interest of expediency. An example of such an administrative body would be the PTO Board of Patent Appeals and Interferences, where a patent applicant may first appeal a final patent rejection before appealing to the U.S. Federal Circuit Court of Appeals.²¹⁷

Furthermore, a provision requiring compulsory licenses in certain cases should be considered. Such mandatory licensing is advantageous because it: reduces transaction costs and uncertainty about whether a compulsory license will be available, ensures that policy goals are served; prevents patent holders from coercing government officials into blocking a compulsory license; and stops opportunities for corruption by generic companies or patent holders.²¹⁸ Nevertheless, it is difficult to think of a minimum basis for a mandatory compulsory license that would not face extreme resistance by both the pharmaceutical sector and IPR proponents. Consequently, the United States should omit any such mandatory provision from the Life-Saving Medicines Export Act and seek to establish a fundamental system, rather than risking the entire compulsory licensing system. Once a basic system is implemented pursuant to the 2003 Decision²¹⁹ and successfully increases access to essential medicines, then legislators can consider additional provisions such as one granting mandatory authorization in limited circumstances.

The Life-Saving Medicines Export Act also attempts to create a compulsory licensing system that is smarter than its Canadian equivalent by creating an advisory board to consider the conflicting interests that a compulsory license would affect—the rights of both patent-owning and generic pharmaceutical companies, the severity of health pandemics, and the needs of impoverished countries.²²⁰ However, the advisory board's

would apply to review of compulsory licenses granted pursuant to the Life-Saving Medicines Export Act. The basic argument is simply that administrative procedures are more expeditious than the judicial process.

216. See S. 3175 § 3(a). See also *supra* note 118 and accompanying text.

217. See U.S. PTO, Appeal to the Board of Patent Appeals and Interferences and to the Courts, <http://www.uspto.gov/web/offices/pac/doc/general/index.html#appeal> (last visited Oct. 9, 2007).

218. See LOVE, *supra* note 210, at 245.

219. See *supra* Part I.C.

220. See S. 3175 § 5. See also *supra* notes 133–34 and accompanying text.

role is more significant under the Life-Savings Medicines Export Act than its Canadian counterpart, whose role is limited to only assisting in recommendations for approved medicines.²²¹ Because a compulsory licensing system involves many conflicting interests, the National Advisory Board on Implementation of the General Council Decision was designed so that no interest is completely disregarded. Such an advisory board is critical in guiding the U.S. compulsory licensing system to success.

C. Economic Incentives

More important than procedural efficiencies is the need to provide generic companies with financial incentives. The CIPIH summarized this point best when it said: “Although their business models are different, generic companies share with the research-based industry the common motivation of serving the interests of their shareholders. The mechanism will not be used if the financial incentives for participation, taking account of the risks involved, are deemed inadequate.”²²² The problem here is twofold. First, as a private, profit-seeking firm, a generic company will not produce essential medicines—even if they do save lives—if the market does not allow the generic company to meet its minimum rate of return on development of the medicines.²²³ Second, developing countries need these life-saving medicines the most, but lack the funding required to allow generic companies to meet their minimum rates of return.²²⁴ Because it is outside of the scope of this Note to address the problem of poverty in developing countries, this Part focuses on whether the Life-Saving Medicines Export Act allows generic companies to exceed their minimum rates of return, thus motivating them to participate in the compulsory licensing system.

The Pledge to Africa Act, the model or template for the Life-Saving Medicines Export Act, also fails to provide adequate economic incentives.²²⁵ For instance, the two-year lifespan of a Canadian compulsory license lifespan is too short.²²⁶ Even though the license may be extended

221. See 2004 S.C., ch. 23 § 21.18. See also *supra* notes 172–74 and accompanying text.

222. WHO CIPIH, *Public Health: Innovation and Intellectual Property Rights*, *supra* note 17, at 136.

223. See RICHARDS, *supra* note 15, at 163.

224. See *id.*

225. See CGPA, Government Amendments to Bill C-9 Fall Short, *supra* note 143.

226. See 2004 S.C., ch. 23 § 21.09; CANADIAN HIV/AIDS LEGAL NETWORK, THE JEAN CHRÉTIEN PLEDGE TO AFRICA ACT AND ITS IMPACT ON IMPROVING ACCESS TO HIV/AIDS TREATMENT IN DEVELOPING COUNTRIES 5, *supra* note 141.

for an additional two years²²⁷ and the generic company may apply for another license after expiration of the first license, the short compulsory license term does not provide adequate economic incentives to produce drugs under the new system.²²⁸ The financial costs and associated risks of applying for a compulsory license may exceed the revenue generated during the short license term.²²⁹ Because a generic company must still incur R&D costs—albeit not as high as new drug R&D—the generic company must also be permitted to recover these costs during the lifespan of the compulsory license. The Life-Saving Medicines Export Act improves this situation by setting the lifespan of a U.S. compulsory license at seven years, with a potential extension for another seven years.²³⁰ Although the lifespan of a U.S. compulsory license is over three times as long as its Canadian equivalent, it is nevertheless still insufficient to allow a generic company to recoup its production costs. If a patent is set to expire in fewer than seven years, a generic company will not apply for a compulsory license to produce the medicine because it will fear that other companies will produce generic equivalents once the patent expires,²³¹ which may undercut the generic company's profits. Moreover, most of the generic company's seven-year window will be devoted to the task of having to reverse-engineer the medicine without the patent holder's assistance.²³² Therefore, a generic company will refuse to participate when a short compulsory lifespan creates such a great risk of economic loss.

Moreover, a longer lifespan will not significantly increase the profits of a generic company when the compulsory license limits the quantity of medicines that can be produced, and consequently limits the profits that may be earned. Therefore, the United States must do more to ensure that the Life-Saving Medicines Export Act reduces the economic burdens that may deter generic companies from producing essential medicines for

227. See 2004 S.C., ch. 23 § 21.12(1)–(2). See also *supra* note 161 and accompanying text.

228. CANADIAN HIV/AIDS LEGAL NETWORK, THE JEAN CHRÉTIEN PLEDGE TO AFRICA ACT AND ITS IMPACT ON IMPROVING ACCESS TO HIV/AIDS TREATMENT IN DEVELOPING COUNTRIES 5, *supra* note 141.

229. See *id.*

230. See S. 3175 § 3(a). See also *supra* note 120 and accompanying text.

231. See F. M. Scherer & Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries* 28 (Comm'n on Macroeconomics & Health, Working Paper No. WG4:1, 2001).

232. See *id.* at 30.

developing countries.²³³ Specifically, the United States must assess the costs and risks involved in producing medicines under the Life-Saving Medicines Export Act, and attempt to minimize both.

1. The Cost and Risk to the Generic Company

Even though a generic company does not incur the high costs of new drug R&D, it must bear the significant burden of front-end investment.²³⁴ The pharmaceutical industry is knowledge intensive, and most of the cost lies in R&D of new drugs.²³⁵ However, a generic company must still incur the costs of producing the medicine, which involves reverse-engineering the drugs without assistance from the patent holder.²³⁶ The patent specifications may not provide the generic company with enough information to facilitate quick and easy reproduction of the medicine.²³⁷ Moreover, the most efficient process for manufacturing the medicine may be protected by a different patent, which may be owned by yet another pharmaceutical company.²³⁸

A generic company also incurs the cost of royalty payments to the patent holder, which must be paid within forty-five days of exporting the medicine,²³⁹ regardless of whether the generic company has seen any sales profit from the medicines. Although the Life-Saving Medicines Export Act caps the maximum royalty payment at four percent of the patented medicine's commercial value,²⁴⁰ this payment may still be relatively costly. Because patented medicines enjoy market exclusivity, and are therefore priced high to recoup hefty R&D expenses,²⁴¹ a seemingly low maximum royalty of four percent may nevertheless burden the generic company if the medicine has high commercial value.

Moreover, a generic company faces the risk that the market demand for the medicines will not be great enough within the importing country, despite the discounted prices, to meet supply. Because the generic company

233. The WHO CIPIH recognizes that generic companies, like patent-owning companies, are driven by corporate profits. See WHO CIPIH, *Public Health: Innovation and Intellectual Property Rights*, *supra* note 17, at 120.

234. See Scherer & Watal, *supra* note 231, at 6.

235. See PhRMA, Key Industry Facts/About PhRMA, *supra* note 19.

236. See Scherer & Watal, *supra* note 231, at 30.

237. See PEDRO ROFFE WITH CHRISTOPH SPENNEMANN & JOHANNA VON BRAUN, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in *NEGOTIATING HEALTH* 9, 14 (Pedro Roffe et al. eds., 2006).

238. See *id.* at 14–15.

239. See S. 3175 § 3(a). See also *supra* note 126 and accompanying text.

240. See S. 3175 § 3(a). See also *supra* note 128 and accompanying text.

241. See *supra* note 19 and accompanying text (discussing new drug development costs).

may only export the medicines to the specified importing country, the generic company must bear the loss if it is unable to sell enough medicine to that country.

2. Reducing the Cost and Risk to the Generic Company

First, turning to the generic drug production cost specifically addressed in the Life-Saving Medicines Export Act, a generic company licensee must pay remuneration to the patent holder.²⁴² The determination of the amount of royalty payment is important because it must compensate the patent holder while also permitting the generic company to sell the medicine at a low price to the impoverished individuals who need access to these life-saving essential medicines.²⁴³

242. See S. 3175 § 3(a). See also *supra* notes 126–32 and accompanying text.

243. In the case of compensation to a patent holder for patent infringement, U.S. patent laws award damages that are “adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer.” Scherer & Watal, *supra* note 231, at 22 (citing 35 U.S.C. § 284). If a compulsory licensing system were to similarly grant royalty payments that were “adequate to compensate” as measured by the profits lost by the patent holder, the royalty payments would be so high that the generic company could not afford to reduce a drug price lower than that of the patented drug, and there would be no increase in accessibility to patented essential medicines. *Id.* at 23.

While there are countless ways to calculate remuneration, James Love looks at four commonly used methods. First, the most basic royalty determination is outlined in the 2001 UN Development Programme Human Development Report, which recommends a royalty set at four percent of the selling price of the generic medicine. In addition, generic companies could pay an extra one to two percent for medicines with special therapeutic value, or one to two percent less when R&D has received at least partial public funding. Second, the Japanese Patent Office established a royalty standard of two to four percent, with higher rates paid to inventions with higher profit margins. This determination also takes into account the “utilization factor,” or the relative importance of the patent in the complete product. This determination works well where there are multiple patented products or processes covering one medicine, such as with HIV/AIDS combination drugs. Third, the Canadian royalty determination under the Pledge to Africa Act utilizes a sliding scale from 0.02 to 4 percent, with the highest royalty paid when medicines are imported by the most highly developed countries as determined by the Human Development Report:

$$\frac{178 - (\text{importing country's HDI rank})}{177} \times 0.04$$

While this royalty determination is only slightly connected to the affordability of medicines in the importing country, it also takes into account the generic manufacturing cost. Lastly, the more complex 2005 Tiered Royalty Method starts with a four percent royalty for high-income markets, which is decreased based on capacity to pay (as measured by per capita income or relative gross domestic product). Under this last method, royalties

The Life-Saving Medicines Export Act uses a case-by-case royalty determination considering several factors, yet also provides that an alternate royalty rate formula may be used, which closely resembles that of the Pledge to Africa Act.²⁴⁴ By using such a formula, a patent holder receives a lower royalty payment when the importing country is a less developed country. While the Life-Saving Medicines Export Act does factor in the humanitarian reasons for issuing the compulsory license, as well as the need for low-cost medicines, this royalty formula, as well as the discretion given in determining the royalty, fails to factor in the medicine's therapeutic value or the ability of the generic company to pay the royalty amount.²⁴⁵ It is crucial that the PTO ensures that a royalty amount is low enough so that a generic company is not dissuaded from applying for a compulsory license.

While it has been argued that insufficient royalty payments would discourage R&D-based pharmaceutical companies from continuing their innovations, it is unlikely that these minimal royalty payments would have a significant impact on the patent holder. The pharmaceutical sector is the most lucrative industry in the United States and its profits more than make up for its R&D costs.²⁴⁶ In addition, the prices of generic medicines have arguably little correlation to the actual cost of producing the drugs, and therefore could be drastically reduced without undercutting funds for R&D innovations.²⁴⁷ Furthermore, the estimate of R&D costs by pharmaceutical companies does not factor in the generous tax incentives they receive.²⁴⁸ Therefore, because there would be no overwhelming burden placed on patent holders by reduced royalty payments for a relatively small market, there is no clear reason why the United

are therefore lower for countries with both low income and high incident of disease. *See* LOVE, *supra* note 210, at 246–48.

244. *See* S. 3175 § 3(a). *See also supra* notes 127–29 and accompanying text.

245. *See* S. 3175 § 3(a).

246. *See* Marcia Angell, *The Truth About the Drug Companies*, N.Y. REV. OF BOOKS, July 15, 2004. The Public Citizen's Congress Watch reported that, in 2000, the drug industry ranked "more profitable than any other" in the Fortune 500 review of America's largest companies. The eleven pharmaceutical companies in the Fortune 500 saw nineteen percent return on revenue, while all the other Fortune 500 countries saw only a five percent return on revenue. *See* PUBLIC CITIZEN'S CONGRESS WATCH, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 11 (2001).

247. *See* Angell, *supra* note 246.

248. *See* Joseph, *supra* note 91, at 433. The Public Citizen's Congress Watch noted that the pharmaceutical industry enjoys a thirty-four percent tax deduction on R&D expenditures. In addition, from 1993–1996, the industry's effective tax rate, the tax liability owed to the government, was sixteen percent, compared to the twenty-seven percent paid by other industries. *See* RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD," *supra* note 246, at 15–16.

States should lower royalty payments to ease the burden on generic companies.

In addition to ensuring low royalty payments, the Life-Saving Medicines Export Act must also reduce the front-end investment as much as possible for the generic company.²⁴⁹ The cost of manufacturing the generic medicines would be lower if the patent holder assisted the generic company in the re-engineering process. One possible way to motivate the patent holder to enter into such an agreement would be to set a higher royalty payment if the patent holder assists the generic company in developing the medicine. However, this alternative royalty calculation would need to take into account the cost to the patent holder in assisting the generic company, the cost savings to the generic company in receiving such assistance, and the need to keep the royalty payments as low as possible to permit the generic company to charge low drug prices to the importing country. In the alternative, public funding could offset the costs of the re-engineering effort. Options for public assistance include granting government subsidies to the generic company to be used solely to reverse-engineer the medicines, providing tax incentives to the generic company to help defray costs in general,²⁵⁰ or directly assisting with the development effort by directing government-run facilities to aid in the reverse-engineering effort.

In addition to the motivation created by lower front-end investment, a generic company is also more likely to produce generic medicines for export when the prospective market is large, and therefore, the generic company anticipates that sales will compensate its investment costs.²⁵¹ While the Life-Saving Medicines Export Act does increase the potential market size by permitting multi-country applications,²⁵² generic companies should be permitted to enter into export agreements directly with NGOs. The potential market size would be much greater, since NGOs could use the medicines to service multiple countries.²⁵³ However, de-

249. See Scherer & Watal, *supra* note 231, at 6.

250. See *id.* at 54–59. Section 170(e)(3) of the U.S. Internal Revenue Code permits corporations to deduct charitable donations “used by the donee solely for the care of the ill, the needy, or infants,” which would allow a pharmaceutical company to recover some of the cost of donated medicines. I.R.C. § 170(e)(3). However, as the tax law is currently designed, it is likely that the tax incentive is not great enough to encourage charitable donations of life-saving medicines, as the donor may incur substantial net cost in producing the medicines. Instead, the tax laws must be reworked to impose zero net cost on the donor. See Scherer & Watal, *supra* note 231, at 58.

251. See *id.* at 6.

252. See S. 3175 § 3(a). See also *supra* note 108 and accompanying text.

253. MSF, for instance, is an “international humanitarian aid organization that provides emergency medical assistance to populations in danger in more than [seventy] countries.”

spite such potentially large markets, there is still no guaranteed market for generic medicines. Just as patent protection ensures a patent holder that a sufficient market exists to allow the patent holder to meet its minimum rate of return, the Life-Saving Medicines Export Act also needs a mechanism to ensure a sufficient market. This may require the United States, or other financial donors, to enter into precommitments to purchase the generic medicines on behalf of the importing country if the importing country is unable to afford the medicines.²⁵⁴

CONCLUSION

Even though the TRIPS Agreement authorizes compulsory licensing²⁵⁵ and the 2003 Decision permits export of medicines produced under compulsory licenses,²⁵⁶ it is still unclear how a country can implement such a system effectively. While Canada's Pledge to Africa Act was praised as the first legislation of its kind by a highly developed country, it has failed to increase access to essential life-saving medicines in the impoverished, underdeveloped world. Undoubtedly, the U.S. position on compulsory licenses for public health problems has made great progress since the days when the government staunchly opposed similar actions by South Africa in 1997.²⁵⁷ However, the United States still has a long way to go to do its part in improving access to medicines. In view of this goal, the United States hopes to follow in Canada's footsteps with the Life-Saving Medicines Export Act. Unfortunately, as it stands, the Life-Saving Medicines Export Act may also suffer the same fate as the Pledge to Africa Act; even if the bill survives and is passed into law, it is not likely that generic companies or importing countries will be eager to participate in the U.S. system. Because developing countries do not make the most attractive market for profit-seeking generic companies, the United States must greatly increase the economic incentives and reduce the procedural barriers of the Life-Saving Medicines Export Act.

See MSF, About MSF: The MSF Role in Emergency Medical Aid, http://www.msf.org/msfinternational/invoke.cfm?objectId=130CB2BA-E018-0C72-097046C7C42A8573&component=toolkit.indexArticle&method=full_html (last visited Oct. 9, 2007).

254. *See* WHO CMH, *supra* note 11, at 84 (using a similar argument to assert that precommitment by donors to purchase essential medicines would incentivize R&D-focused pharmaceutical companies to allocate resources to target diseases only affecting poorer developing countries).

255. *See supra* Part I.A.

256. *See supra* I.C.

257. *See supra* I.D.

Moreover, skeptics of compulsory licensing schema are reluctant to put great reliance on these licenses:

[P]olicy-makers should view non-voluntary licensing of patented inventions as but one item in an arsenal of tools that may be used to promote national systems of innovations . . . excessive reliance on compulsory licensing of patented inventions may simply mask deeper structural problems and make them harder to solve in the long run.²⁵⁸

These critics argue that differential pricing of patented medicines and voluntary license agreements should be favored over government-authorized compulsory licenses.²⁵⁹ However, given the substantial urgency for essential life-saving medicines to treat diseases such as the HIV/AIDS pandemic,²⁶⁰ the Life-Saving Medicines Export Act may be a good start in developing a temporary solution to the problem. It is understandable that a pharmaceutical patent holder must be rewarded for its medical innovations, and must also be permitted market exclusivity to recoup the economic outlay for its extensive R&D. Nevertheless, the United States must step up and address the public health crises of developing countries that those countries cannot tackle themselves. At the very least, the United States can succeed as it did with Cipro,²⁶¹ and use the threat of compulsory licensing under the Life-Saving Medicines Export Act to compel patent-holding pharmaceutical companies to reduce prices, thereby increasing access to the most essential life-saving medicines for the world's most destitute and powerless individuals.

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258. See ROFFE, *supra* note 237, at 14 (citing Jerome H. Reichman with Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (UN Conference on Trade and Dev. & Int'l Ctr. for Trade and Sustainable Dev., Issue Paper No. 5, 2003)).

259. For a discussion on differential pricing and voluntary licensing agreements between patent holders and generic companies, see WHO CMH, *supra* note 11, at 87–91.

260. See *supra* notes 1–10 and accompanying text (discussing the status of the AIDS pandemic in 2006).

261. See *supra* notes 84–90 and accompanying text (explaining the anthrax scare in 2001 and the U.S. government's threat to override the Cipro patent).

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