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**Importing Western Style, Exporting Tragedy:
Changes in Indian Patent Law and
Their Impact on AIDS Treatment in Africa**

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Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa

By Pooja Van Dyck*

¶1 In March 2005, new patent laws were passed in India to comply with World Trade Organization (WTO) regulations and, specifically, the Trade Related Aspects of Intellectual Property Rights Agreement. These patent laws convey protections that are similar to a Western-style patent system. India's role as a supplier of inexpensive generic drugs to Africa gives its new laws impact far beyond the sub-continent. The new laws will potentially limit the production and sale of inexpensive drugs treating acquired immunodeficiency syndrome (AIDS) in Africa. The new system allows production of generic first-generation drugs. However, it prevents the production of generic second-generation drugs, which are important to AIDS patients who have become resistant to first-generation drugs.

¶2 The AIDS crisis in Africa is reaching mammoth proportions — 25.8 of the 40.3 million people infected worldwide live in sub-Saharan Africa.¹ Although India's new patent laws will likely have little positive impact on western pharmaceutical companies because there is little to no profit in the parts of Africa that are serviced by Indian pharmaceutical companies, the impact on the AIDS crisis in Africa has the potential to be devastating. Therefore, these new laws produce tragic consequences with little benefit, except possibly to India's developing pharmaceutical industry.

¶3 This comment discusses the background and impacts of the new Indian patent law system. The first section is a general introduction to the issue. The second section outlines the current state of the AIDS crisis in Africa and India. Section three discusses the background of international regulations and India's changing patent system in response. The fourth section discusses the impact on Indian pharmaceutical companies and AIDS in Africa of the new patent laws and potential solutions. Finally, the last section concludes with the prospects for the response to the AIDS crisis given the new patent laws in India.

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¹ Joint United Nations Programme on HIV/AIDS & World Health Organization, *AIDS Epidemic Update: December 2005*, 3 (Dec. 2005), http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/epi-update2005_en.pdf.

I. INTRODUCTION

A. GATT, WTO, TRIPS, and the Doha Declaration

¶4 In 1995, the WTO came into being through trade talks between the members of the General Agreement on Tariffs and Trade (GATT).² The GATT was an agreement between countries to regulate trade between nations by reducing tariffs.³ It had governed international trade since the end of World War II.⁴ However, GATT was not sufficient to cover modern international trade, and therefore, the international community created the WTO. The GATT is part of the WTO's framework, but the WTO also created processes for problems that were not resolved under GATT.⁵

¶5 The purpose of the WTO was to promote free trade, provide a forum to discuss new and existing trade rules, review trade policies of each member state periodically, and settle international trade disputes.⁶ Members can bring disputes to the WTO when they believe a country is violating the WTO rules.⁷ If the complaining party prevails and the country does not implement the WTO's recommendations, the WTO is authorized to allow the imposition of sanctions on the violating country.⁸

¶6 The WTO oversees international intellectual property through an agreement entitled Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS agreement established a uniform intellectual property standard in member states.⁹ The Council on TRIPS reviews the intellectual property laws of member states and determines TRIPS compliance. The TRIPS agreement regulates how member countries deal with international intellectual property in the following areas:

- (1) application of basic principles of the trading system and other intellectual property agreements;
- (2) adequacy of protection of intellectual property agreements;
- (3) internal enforcement of intellectual property rights;
- (4) dispute resolution among WTO member states; and
- (5) transitional arrangements for new member states.¹⁰

¶7 A country joining the WTO must bring its intellectual property laws into compliance with the TRIPS agreement. For example, a patented invention must be given

² World Trade Organization, The GATT Years: From Havana to Marrakesh, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited Nov. 28, 2007).

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ World Trade Organization, What is the World Trade Organization?, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm (last visited Nov. 28, 2007).

⁷ World Trade Organization, WTO Agreements, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr03_e.htm (last visited Nov. 28, 2007).

⁸ Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 377-78 (2004).

⁹ *Id.* at 361-62.

¹⁰ World Trade Organization, Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Nov. 28, 2007).

20 years of protection.¹¹ The end result is intellectual property protection in member states that is uniform and that closely reflects the type of intellectual property protection familiar in Western countries.¹² If a country fails to comply, a dispute case may be brought and the WTO may sanction the failing country by allowing other countries to impose duties, taxes, and tariffs.¹³

¶8 The WTO regulations grant a certain amount of time to comply with TRIPS depending on the state of development of each member country. Developed countries have one year in which to comply.¹⁴ Developing countries have five years and least developed countries have 11 years.¹⁵ However, if a developing country has to radically alter its patent system because it provided no patent protection in a certain area, it has 10 years to make the change.¹⁶

¶9 In 2001, some member countries of the WTO met in Doha, Qatar, to discuss the intersection of patent rights with health crises. They issued the Declaration on TRIPS and Public Health (Doha Declaration), which interpreted certain articles of TRIPS.¹⁷ The Doha Declaration stated that member countries had the right to issue compulsory licenses during a public health crisis while also recognizing the importance of intellectual property protection.¹⁸ The Doha Declaration is an intervention mechanism whose principle purpose is to lower the cost of critical drugs during a public health crisis. Although the Doha Declaration is an interpretive statement and changes none of the language of TRIPS, most countries have accepted its terms.¹⁹

¶10 The Doha Agreement recognizes the rights of a member state to determine, under the member state's own definition, that a public health crisis exists.²⁰ It further allows the member state to issue compulsory licenses to pharmaceutical companies to produce patented drugs, without permission of the patent holder, where the patent holder does not sell or sells at an unaffordable price the designated drug in the member state.²¹ Some compensation is given to the patent holder, but the amount is determined by the state issuing the compulsory license.²²

¶11 Countries lacking the capability of manufacturing their own drugs for public health crises can employ parallel importation under the Doha Declaration.²³ Parallel importation allows a state to buy pharmaceuticals from a cheaper source outside the

¹¹ *Id.* Another requirement of TRIPS is that patents will be enforced through the legal system somehow.

¹² *Id.*

¹³ Sherman & Oakley, *supra* note 8, at 377-78.

¹⁴ See Intellectual Property: Protection and Enforcement, *supra* note 10.

¹⁵ *Id.* This has been extended another 10 years for least developed countries to 2016.

¹⁶ *Id.*

¹⁷ World Trade Organization, Doha Declaration Explained, http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Nov. 28, 2007).

¹⁸ *Id.*

¹⁹ Sherman & Oakley, *supra* note 8, at 380.

²⁰ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Nov. 28, 2007).

²¹ Sherman & Oakley, *supra* note 8, at 369.

²² See Declaration on the TRIPS Agreement and Public Health, *supra* note 20. There is an obvious conflict of interest when a country using compulsory licenses in order to reduce the price of drugs is permitted to determine what compensation the patent holder will receive.

²³ World Trade Organization, TRIPS and Public Health: the Situation in 2005, http://www.wto.org/english/tratop_e/trips_e/health_background_e.htm (last visited Nov. 28, 2007).

country and market them in direct competition with the patent holder at a much lower price.²⁴

¶12 The WTO regulations and TRIPS are the international agreements that regulate intellectual property rights. These agreements require member states to change their patent systems to conform. The Doha Declaration clarifies TRIPS to allow countries to use compulsory licenses to combat health crises.

B. India's Generic Drug Industry and New Patent Laws Passed in Compliance with TRIPS

¶13 India joined the WTO at its formation in 1995.²⁵ However, at that time, India only provided protection of process patents for medicines.²⁶ Process patents are patents that protect the method of making something, rather than the object or substance itself. India had set up a weak system of patent protection in 1970 in order to foster a domestic drug industry.²⁷ Therefore, India needed to radically amend its patent system to protect product patents and was given the 10-year compliance period ending in January 2005. Because India only protected process patents, before 1995, pharmaceutical companies could easily alter a step in the process and produce drugs without violating the patents.²⁸ Therefore, India had a flourishing generic drug industry because copying process-patent drugs could be done within the law.

¶14 Today, this generic pharmaceutical industry produces inexpensive drugs for India and Africa. For example, in Africa, generic AIDS drugs produced by Indian companies are \$20 per month, whereas non-generic drugs, produced by the patent holder or licensee, are \$395 per month.²⁹ This reduced cost makes AIDS drugs more widely available to people in Africa.³⁰ However, in order to comply with TRIPS, India made a series of changes to its patent system to protect product patents. These changes have the potential to be detrimental to the response to the AIDS crisis in Africa.

¶15 The latest change to the Indian patent system was made in March 2005 and brought India into full compliance with TRIPS.³¹ The change allows Indian pharmaceutical companies to continue to manufacture generic drugs that were in production prior to 1995, but prevents them from applying process changes to drugs that were patented after 1995. The new laws effectively shut down the Indian generic drug industry for all drugs patented after 1995.

²⁴ Sherman & Oakley, *supra* note 8, at 372-73. This phenomenon has recently been a controversial subject in the U.S. with people ordering drugs from Canada where prices are much lower.

²⁵ World Trade Organization, India and the WTO, http://www.wto.org/english/thewto_e/countries_e/india_e.htm (last visited Nov. 28, 2007).

²⁶ Although this sounds unusual, other countries did the same at the time. See Suresh Koshy, Note, *The Effects of TRIPs on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, ¶ 14 (1995).

²⁷ Sherman & Oakley, *supra* note 8, at 381.

²⁸ See Koshy, *supra* note 26, ¶ 21.

²⁹ *Global, AIDS POL'Y LAW*, Apr. 8, 2005.

³⁰ Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L. & COMP. L. REV. 613, 615 (2004).

³¹ Compliance also requires patents to be enforced; however, India's legal system is slow and backlogged. Therefore, enforcement of patents may be a problem despite the new patent laws.

¶16 This prohibition has a special impact on AIDS treatment because of the nature of the virus. A patient with AIDS can develop resistance to a course of treatment with first-generation drugs even when taken properly.³² New drugs must then be developed to respond to the mutated strains — the second- and third-generation drugs. It is this class of drugs, developed and patented post-1995, that fall under the new Indian patent laws. While the Indian process-pharmaceutical industry can continue its manufacture of first-generation drugs, patients who require second-generation therapy are forced to meet much higher prices for these drugs, which are now protected from process changes prohibited by the new Indian patent law that responds to TRIPS requirements. These drugs can be up to 50 times more expensive.³³

II. AIDS: AFRICA AND INDIA

¶17 In Africa, AIDS is spreading at alarming rates. More people need drugs to live with AIDS. In sub-Saharan Africa, the infection rate is 7.2 percent.³⁴ The next highest infection rate of 1.6 percent is in the Caribbean.³⁵ Of the approximately 40.3 million people living with AIDS worldwide, 25.8 million live in sub-Saharan Africa (this is approximately two-thirds of all AIDS cases).³⁶ In 2005, there were approximately 3.1 million deaths worldwide from AIDS, with 2.4 million in Africa alone.³⁷ “At best one in ten Africans ... in need of antiretroviral treatment were receiving it in mid 2005.”³⁸

¶18 The United Nations Program on HIV/AIDS and the World Health Organization stated that “sustained progress in the response against AIDS will only be attained by intensifying HIV prevention and treatment simultaneously.”³⁹ Fifty-five percent of future infections expected to occur until 2020 could be prevented with a prevention and treatment plan.⁴⁰ The situation in Africa is dire, and world organizations are calling for provision of more treatment to AIDS patients in Africa.⁴¹ Any reduction in available treatment would significantly impact people living with AIDS. Success of treatment programs also depends on the availability of second-generation drugs.

¶19 AIDS in India is also a major problem. In 2003, 5.1 million people were living with HIV in India and the numbers are increasing.⁴² Approximately 12.6 percent of the globally infected population resides in India.⁴³ These statistics show there is a need for inexpensive AIDS drugs and the need is increasing.

³² Press Release, Doctors Without Borders, As WHO and UNAIDS Call For Global Treatment Scale-Up, MSF Asks: Where Will the Essential Drugs Come From? (Mar. 28, 2006), *available at*: <http://www.doctorswithoutborders.org/pr/2006/03-28-2006.cfm>.

³³ Press Release, Doctors Without Borders, People Not Getting Treatment They Need to Stay Alive (Nov. 29, 2006), *available at*: <http://www.doctorswithoutborders.org/pr/2006/11-29-2006.cfm>.

³⁴ See Epidemic Update: December 2005, *supra* note 1, at 4.

³⁵ *Id.*

³⁶ *Id.* at 3.

³⁷ *Id.* at 2.

³⁸ *Id.* at 5.

³⁹ *Id.* at 7.

⁴⁰ See Epidemic Update: December 2005, *supra* note 1, at 7.

⁴¹ *Id.*

⁴² *Id.* at 33.

⁴³ *Id.*

III. INDIA'S PATENT SYSTEM, EARLY STAGES AND CHANGES TO COMPLY WITH WTO AND TRIPS

¶20 This section discusses the Indian pharmaceutical industry and the evolution of the Indian patent system from inception to recent changes for compliance with TRIPS. India joined the WTO in 1995 and had to change many of its laws in order to comply with WTO regulations, including TRIPS. This section also discusses the details of TRIPS and the Doha Declaration. The new patent laws in India allow continued limited generic drug production under certain circumstances in light of the Doha Declaration.

A. *Early Development of India's Patent System and the Pharmaceutical Industry — Pre-WTO*

¶21 India's patent system began in 1856 with the granting of exclusive rights for a period of 14 years.⁴⁴ India created its modern patent system in 1970 by passing the Patents Act.⁴⁵ It granted patent protection for process patents and specifically excluded product patents for medicine.⁴⁶ Granted patents conferred rights for a period of 14 years.⁴⁷ Further, the patent must have been worked within India to receive protection;⁴⁸ a patent would not have been granted for a solely imported product.⁴⁹ The Patents Act contains a section allowing a compulsory license for a "patented invention not available to the public at a reasonable price."⁵⁰ This section is in force today, potentially allowing the Indian government to issue compulsory drug licenses for domestic health crises.

¶22 The Indian government created this patent system to cultivate a domestic pharmaceutical industry.⁵¹ At the time of passage, India had very high drug prices and foreign companies owned most of the patents.⁵² India created the protectionist system to foster domestic industry, promote import substitution, and reduce prices.⁵³ This patent system created a flourishing domestic generic pharmaceutical industry because drug product patents were not allowed and patented processes could easily be altered, thereby losing their patent protection.

¶23 As a result of this patent regime, India is currently a major exporter of generic AIDS drugs to African countries suffering from the AIDS crisis. Not only did Indian pharmaceutical companies benefit from Indian law during its developmental stages, citizens of African countries benefited as well. Indian generic AIDS drugs were available for \$20 per month, whereas Western pharmaceutical companies charged \$395 per

⁴⁴ Government of India Office of the Controller General of Patents, History of the India Patent System, <http://ipindia.nic.in/ipr/patent/history.htm> (last visited Apr. 2, 2006). This system was based on the British Patent Law of 1852.

⁴⁵ *Id.*

⁴⁶ Koshy, *supra* note 26.

⁴⁷ *Id.* at 8.

⁴⁸ *Id.* at 10. "Worked" means the process must be implemented or used in India. Patents that were "worked" in foreign countries did not garner patent protection.

⁴⁹ *Id.*

⁵⁰ The Patents Act, No. 39 of 1970; India Code (1999), § 84(5), *available at* <http://www.patentoffice.nic.in/ipr/patent/patAct1970-3-99.html>.

⁵¹ *Id.* at 12.

⁵² *Id.*

⁵³ *Id.*

month.⁵⁴ Also, Indian companies were able to bring together various AIDS drugs, each owned by a different Western pharmaceutical company, and combine them into one pill.⁵⁵ This made taking the medication much easier, especially for those Africans who are poor or uneducated.

B. TRIPS and the Doha Declaration

¶24 The TRIPS agreement was part of the original agreement establishing the WTO and was signed in 1994.⁵⁶ It represented an acknowledgement of the importance of protecting intellectual property and of the role intellectual property plays in furthering economic development.⁵⁷ The international community and future WTO members created TRIPS to reduce impediments to trade while considering the technological needs of least-developed countries.⁵⁸

¶25 The TRIPS agreement requires certain patent protection for member states, such as patent life of 20 years, equal treatment for all member states, and patent protection for both processes and products.⁵⁹ However, TRIPS also provides exceptions to full protection for patents. In article 27 of TRIPS, a government is allowed to exclude inventions from full patent protection that protect human life or health.⁶⁰

¶26 Further, Article 31, titled “Other Use Without Authorization of the Right Holder,” allows governments to grant compulsory licenses.⁶¹ It states, “[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government,” compulsory licenses may be granted according to certain provisions.⁶² It also requires notification to the patent holder, although this may be waived during emergencies,⁶³ and compensation to the patent holder to be determined by the issuing government.⁶⁴ However, products of such licenses must be used predominantly in the

⁵⁴ See *Global*, *supra* note 29.

⁵⁵ This was something Western pharmaceuticals had not done, probably because of the cost of negotiating with all the patent owners.

⁵⁶ World Trade Organization, Overview: the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 28, 2007).

⁵⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments — Results of the Uruguay Round, 33 I.L.M. 81, 84 (1994) [hereinafter TRIPS Agreement].

⁵⁸ *Id.*

⁵⁹ See Intellectual Property: Protection and Enforcement, *supra* note 10.

⁶⁰ TRIPS Agreement, *supra* note 57, art. 27.2 (“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”); see Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT’L TRADE L.J. 57 (2002).

⁶¹ TRIPS Agreement, *supra* note 57, art. 31.

⁶² *Id.* Although Article 31 does not use the term “compulsory licensing,” this is how it has been interpreted. See Sara M. Ford, Comment, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941 (2000); Susan V. Vaughan, Note, *Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?*, 25 HASTINGS INT’L & COMP. L. REV. 87 (2001) (discussing compulsory licensing).

⁶³ TRIPS Agreement, *supra* note 57, art. 31(b).

⁶⁴ *Id.* art. 31(j).

domestic market.⁶⁵ These articles were interpreted in the Doha Declaration on TRIPS and Public Health to clarify the use of compulsory licenses during health crises.

¶27 The Declaration stated that the TRIPS agreement included flexibilities when it comes to public health.⁶⁶ Those flexibilities were:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood 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.⁶⁷

Therefore, governments may grant compulsory licenses for public health problems they determine are of “extreme urgency” or “national emergency,” in addition to the recognized epidemics of AIDS, tuberculosis, and malaria.

¶28 There has been some debate as to what constitutes an “extreme urgency” or “national emergency,” but this subject is beyond the scope of this paper. The AIDS epidemic is an internationally-recognized crisis. The Declaration left open for debate the problem of countries that have little or no infrastructure to produce their own drugs under compulsory licenses. Specifically, paragraph 6 of the Declaration stated:

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 2002.⁶⁸

¶29 In August 2003, in response to the open question in paragraph 6, the WTO agreed on the *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*.⁶⁹ The WTO implemented a process by which least developed countries could import generic drugs produced under compulsory licenses in other countries.⁷⁰ The first step in this process was to determine whether the least developed country had insufficient or no infrastructure to produce the drug.⁷¹ Then, the process

⁶⁵ *Id.* art. 31(f).

⁶⁶ World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, ¶4, WT/MIN(01)/Dec/2, (Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

⁶⁷ *Id.* ¶5.

⁶⁸ *Id.* ¶6.

⁶⁹ World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003), http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

⁷⁰ *Id.*

⁷¹ *Id.* Annex.

required the least developed country to issue a compulsory license and report expected quantities to the Council for TRIPS.⁷² Finally, the exporting country must issue a compulsory license and produce only the reported quantities.⁷³

¶30 Therefore, under TRIPS and in light of the Doha Declaration, an exporting country, like India, may continue to produce generic drugs under certain conditions. These conditions are reasonable for stable importing governments; however there are some African countries where the government does not have the stability or political will to go through the process.

C. India Joins the WTO and Changes its Patent Laws

¶31 In 1995, India joined the WTO in order to enter the global marketplace. The WTO encourages and protects trade between member states by limiting import bans and quotas, reducing custom duties, and creating most-favored-nation treatment with other members.⁷⁴ India began passing various amendments to the Patents Act to comply with WTO regulations. In 1999, India passed the Patents (Amendment) Act, 1999. It allowed patenting of inventions not worked in India, thereby creating patent protection for foreign inventions.⁷⁵ It further clarified that patents granted an exclusive “right to sell and distribute.”⁷⁶

¶32 The 1999 amendment created a separate category for pharmaceutical patents called Exclusive Marketing Rights.⁷⁷ This category allowed protection for new medicines, but exempted drugs that were already in the public domain of India.⁷⁸ The amendment created a “mail box” for applications. This “mail box” would put a hold on all product patent applications from 1995 to 2005. After 2005, India would process the “mail box” product patents in compliance with TRIPS. This was an interim measure enacted to confer full patent protection to drugs invented after 1995 while India modified its patent system. In 2002, India passed the Patents (Amendment) Act, 2002. It extended the patent grant from 14 years to 20 years and reflected other changes to the Indian patent system as required when it joined the Patent Cooperation Treaty.⁷⁹ It also clarified the ability to patent biochemical and biological processes.⁸⁰

¶33 The last amendment to the Indian Patents Act was passed in 2005. This amendment finally removed the language prohibiting medicine product patents and the special category of Exclusive Marketing Rights for medicine patents created in the 1999 amendment.⁸¹ This amendment ended the “mail box” system because drugs could now receive product patents. The amendment also included language about compulsory

⁷² *Id.* ¶2.

⁷³ *Id.*

⁷⁴ World Trade Organization, Principles of the Trading System, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm (last visited Nov. 28, 2007).

⁷⁵ The Patents (Amendment) Act, No. 17 of 1999; India Code (1999), *available at* http://ipindia.nic.in/ipr/patent/patact_99.PDF.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ The Patents (Amendment) Act, No. 38 of 2002; India Code (2002), *available at* <http://ipindia.nic.in/ipr/patent/patentg.pdf>.

⁸⁰ *Id.*

⁸¹ *Id.*

licensing for export.⁸² This compulsory licensing section mimicked the language adopted by the WTO in August 2003 in the Doha Declaration.⁸³ These amendments brought India's patent system into compliance with TRIPS.

¶34 India's pharmaceutical industry flourished under the previous weak patent system; however, it had been limited to a generic pharmaceutical industry for the very same reason. The industry could not only evade the process patents legally, it also did not have to worry about being sued for violating patents because of the laws and the sluggishness of the Indian legal system.⁸⁴

¶35 Today, India's domestic pharmaceutical industry controls most of the domestic market and its generic drug industry is a global competitor.⁸⁵ Some of its facilities are inspected by the U.S. Food and Drug Administration and it exports drugs to the U.S. and Canada.⁸⁶ However, Indian pharmaceutical companies have not invested in research and development because of the lax patent system.⁸⁷ Therefore, the industry will take some time before it can produce drugs of its own invention. But, given the new patent laws, the high cost of drugs in the West could be lowered by outsourcing pharmaceutical production to India because of its modern pharmaceutical facilities and inexpensive labor force.

IV. THE FUTURE OF INDIA'S PHARMACEUTICAL INDUSTRY AND AIDS IN AFRICA

¶36 This section discusses the impacts of the changes in the patent system and the potential response to the problem. Section A describes the changes to the Indian pharmaceutical industry and the AIDS crisis. Section B focuses on the process and problems of supplying drugs to Africa through TRIPS. The industry can continue to supply Africa until people require new, patented drugs. At that point, India must decide whether to follow the process outlined in its laws and TRIPS to produce second generation drugs. If India does not produce these drugs, the AIDS crisis in Africa may worsen. Section C discusses alternative solutions to this problem.

A. *Impacts of Changes in Patent Law*

¶37 The current patent law system in India could endanger the export of AIDS drugs to Africa. The current or first-generation AIDS drugs that India currently exports to Africa were grandfathered-in by the amendments to the Patents Act.⁸⁸ This means Indian generic pharmaceutical producers can continue to produce and export current generic AIDS drugs to Africa with no bureaucracy involved. However, as people become resistant to first-generation drugs, second generation drugs will not be as readily

⁸² The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), Sec. 92A, available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

⁸³ See *Id.*; see also Implementation of Paragraph 6, *supra* note 69, ¶¶ 1, 2a.

⁸⁴ Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 924 (2003).

⁸⁵ *Id.*

⁸⁶ Sreenivasarao Vepachedu & Martha M. Rumore, *Patent Protection and the Pharmaceutical Industry in the Indian Union*, INTELL. PROP. TODAY, Oct. 2004.

⁸⁷ Barnes, *supra* note 84, at 926.

⁸⁸ See Sherman & Oakley, *supra* note 8, at 387.

available, or at all, because they have protection under the new system. The new patent system requires substantial government intervention before an Indian pharmaceutical company can export second-generation generic AIDS drugs to Africa.

¶38 The new patent system also creates incentives for Indian pharmaceutical companies to invest in research and development because it now provides product protection to new drugs. The Indian market is growing and will be a lucrative market for new drugs. Further, Western pharmaceutical companies have not been focusing on diseases in India. Therefore, Indian pharmaceutical companies can create new drugs in a growing market and be assured of protection for their investment.

¶39 The changes in Indian patent law potentially affect the future of the AIDS crisis in Africa. Although first generation generic drugs will still be available cheaply despite the changes in the patent system, Indian pharmaceutical companies cannot produce second generation drugs without substantial government intervention. African countries have the legal right to produce generic drugs under compulsory licenses for their AIDS crises. However, most of them do not have the resources to create a domestic generic pharmaceutical industry; instead, these countries will have to resort to the cumbersome TRIPS procedures.

B. Supplying Second-Generation Drugs to Africa Through the TRIPS Process

¶40 To request generic drugs from India, an African country must submit a report of the type of drug and its quantity to the Council of TRIPS, establish that it has insufficient or no manufacturing capabilities, and grant a compulsory license to a pharmaceutical company.⁸⁹ Then, India has to grant its own compulsory license, produce only the amounts requested, and label the product as produced as part of this request.⁹⁰ Further, both exporting and importing countries have to compensate the patent holder.⁹¹ The importing African country must ensure that the drugs it receives through such requests are not used for other purposes or exported to other countries.⁹²

¶41 Although this process sounds straightforward, there are problems with requiring a poor country that cannot afford non-generic medicines to ensure that the medicine is not exported. Countries with no manufacturing capabilities are unlikely to have the infrastructure or resources to seal its borders. As of the date of this paper, no countries have requested importation or exportation of drugs produced under compulsory licenses through the TRIPS process.⁹³ Therefore, there is no evidence of whether the TRIPS process is feasible for both importing and exporting countries.

¶42 Once India's pharmaceutical companies begin competing on a global level with patented drugs of their own, what incentives do they have to produce low-priced drugs for Africa? Additionally, Indian pharmaceutical companies may not have the high profits that Western companies do. Exporting new drugs to the lucrative Western market for higher profits may use resources of Indian pharmaceutical companies that will no longer be available to manufacture AIDS drugs for Africa. In addition, Indian companies may

⁸⁹ See Implementation of Paragraph 6, *supra* note 69, ¶ 2.

⁹⁰ *Id.*

⁹¹ *Id.* ¶3.

⁹² *Id.* ¶4.

⁹³ World Trade Organization, Notifications by Importing WTO Members, http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited Apr. 2, 2006).

begin research and development on diseases found in India that are not researched by Western companies. These new drugs may divert resources that could have been used to produce generic AIDS drugs (e.g., manufacturing plants, workers, etc.).

¶43 Furthermore, working within the framework of the WTO would mean more bureaucracy for the Indian government. Besides the problem of its slow-working nature and miles of red-tape, the Indian government may be reluctant to issue compulsory licenses because of the potential for dispute cases. In addition, the Indian government may want to encourage foreign investment and may not be willing, from a political standpoint, to use compulsory licenses for products from potential investors.

¶44 With respect to the African side of the equation, many African countries have unstable or ruthless governments that may not follow the process laid out by the WTO. People in these countries may continue to suffer even if drugs are available for people in other countries whose governments are willing to use the TRIPS process. The WTO process for exporting generic drugs does not seem to allow for non-governmental organizations to request and distribute the drugs.

¶45 On the other hand, Indian pharmaceutical companies may choose to produce AIDS drugs in violation of patents. Fear of the Indian legal system may not be much of a deterrent to Indian companies because of the back-log and lengthy case time.⁹⁴ Therefore, Indian companies that are violating patents may be shielded from suit within the country from Western pharmaceutical patent holders. Patent holders would have to bring suit against the Indian government for violation of patents through the WTO settlement process. This process requires the company's home country government to bring the suit to the WTO. For U.S. pharmaceutical companies, this means working with different administrations with varying levels of interest in participating in international institutions.⁹⁵

¶46 Therefore, continued Indian production of generic AIDS drugs is not a guaranteed solution to the crisis in Africa.

C. Other Solutions to Africa's AIDS Problem

¶47 If India stops producing AIDS drugs for Africa beyond the first-generation drugs, the situation in Africa will further deteriorate unless another source emerges. Other developing countries, including Brazil and South Africa, will soon face the same WTO and TRIPS compliance issues currently faced by India.⁹⁶ However, South Africa, which also has a large AIDS epidemic, may be more willing to use compulsory licensing. China, in contrast, who has only recently joined the WTO, has more time to amend its patent laws to comply with TRIPS.⁹⁷ Conceivably, China could pick up where India left off until full compliance with TRIPS is required. However, this would present little more than a stop-gap measure. African countries could manufacture the drugs themselves, but

⁹⁴ However, non-enforcement of patent rights is a violation of the TRIPS agreement. This could lead to dispute cases brought against the Indian government.

⁹⁵ Lately, U.S. pharmaceutical companies have been backing off from suing countries for using compulsory licenses because of ill-will and political pressure. *See* Sherman & Oakley, *supra* note 8.

⁹⁶ *See id.*

⁹⁷ *See* Peng Jiang, Comment, *Fighting the Aids Epidemic: China's Options Under the WTO TRIPS Agreement*, 13 ALB. L.J. SCI. & TECH. 223 (2002).

the countries most in need of the drugs also lack the infrastructure and capital to create a highly technical industry.

¶48 Brazil has repeatedly used the threat of compulsory licensing to negotiate lower prices for drugs with pharmaceutical companies.⁹⁸ Although this could be a valuable tool for African countries, most of the countries lack the resources to make the threat credible. However, threatening to use a compulsory license to import generic AIDS drugs may be an effective means of negotiating lower prices with Western pharmaceutical companies. One important caveat is that the drugs' production costs are both more than an average African country can afford and more than the price charged by Indian pharmaceutical companies.

¶49 Another potential solution is for generic drug companies in India to continue making drugs for specific African countries by obtaining licensing from patent holders at a reduced cost. This type of arrangement would significantly reduce the costs of the drugs because Indian pharmaceutical companies are able to access a cheaper labor force and would not need to acquire the needed manufacturing technologies. Western pharmaceuticals could license their patented drugs to an Indian generic company as part of a public relations campaign to create access for Africans to AIDS drugs.

¶50 One problem with this solution is that multiple companies own the patents for AIDS drugs. To make the drug cocktail necessary for AIDS treatment, Indian generic companies would need licenses from many companies. Further, Western pharmaceutical companies may be hesitant to license their patents for little to no cost because it creates a precedent or because it would create another supply for their drug. Consumers in the lucrative U.S. market may use the AIDS drugs as an example in the face of an epidemic or threat to health, like anthrax or avian flu. In addition, Western pharmaceutical companies may fear importation into the West from the Indian generic companies.⁹⁹ However, if the hurdles could be overcome, this plan would ensure a steady supply to Africa.

¶51 Another possible outcome is that there are no new drugs available for poor Africans with AIDS, a possibility that entails a further deterioration of the African situation. However, the AIDS crisis is well known by most Westerners, and such a scenario would likely prompt both public outcry and a response by foreign aid organizations. In addition, Western pharmaceutical companies already have been increasing their help to African countries by providing AIDS drugs at reduced or no cost,¹⁰⁰ a response partially precipitated by the availability of generic drugs produced in India.¹⁰¹ However, no matter how generous Western pharmaceutical companies may be, high production costs and little or no return will threaten the sustainability of these programs.¹⁰²

⁹⁸ *Roll out, Roll Out: AIDS in Brazil*, ECONOMIST, July 28, 2005, available at http://www.economist.com/research/articlesBySubject/displayStory.cfm?story_ID=4221475&subjectid=348867.

⁹⁹ The U.S. already has a problem with this because people in the U.S. are importing drugs from Canada at a significantly lower price. Allowing India to produce drugs may create another supplier for these imports.

¹⁰⁰ Stephanie A. Barbosa, Note, *Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals*, 36 RUTGERS L. J. 205, 243 (2004).

¹⁰¹ See *Global*, *supra* note 29; Sherman & Oakley, *supra* note 8, at 382-84 (stating the price reductions offered by Western pharmaceutical companies after Cipla, an Indian company, offered to sell drugs to South Africa at a substantial discount).

¹⁰² Furthermore, in the U.S., pharmaceutical companies are besieged with calls to reduce prices

¶52 Even if Western pharmaceutical companies continue to offer price reductions on AIDS drugs, many African countries may still be unable to afford them; however, Indian companies could provide drugs below even the discounted Western rates and within reach of African countries.¹⁰³ Furthermore, without the combination of a drug cocktail into one pill, there is an increased chance of the patient developing resistance to AIDS drugs because of the difficulty in maintaining the drug schedule.¹⁰⁴

¶53 Finally, much hope rests on an AIDS vaccine. Although this would be the best solution for the AIDS epidemic, it does not exist today.¹⁰⁵ Hopefully, if a vaccine were to be developed, it would be widely available to sub-Saharan Africans. A treatment that has the potential to protect so many at-risk people is invaluable, but it should be produced inexpensively so that African countries have a chance of obtaining it.

V. CONCLUSION

¶54 The potential for profits in selling AIDS drugs to Africa is minimal for Western pharmaceutical companies. The ideal solution to the lack of inexpensive AIDS drugs in Africa would be for Western patent owners to license their drugs to Indian generic drug manufacturers for specific countries in Africa that are extremely poor and lack the ability to work through the WTO. Indian companies can produce drugs more cheaply than Western patent owners because of lower labor costs and the ability to combine the drugs without fearing a suit for violating patents. The Indian government also does not fear dispute cases being brought against it in the WTO. This solution seems unlikely because of the amount of negotiation required between Indian pharmaceutical companies and the many Western ones that hold the patents on the various AIDS drugs.

¶55 Therefore, the Indian government should work closely with African countries and the WTO to use compulsory licensing to produce future AIDS drugs. The process to do this is both in TRIPS and the amended Indian Patents Act. The only obstacle is the incentive for the Indian government and pharmaceutical companies to continue to produce generic AIDS drugs.

domestically. Some states are trying to import drugs from other countries.

¹⁰³ Sherman & Oakley, *supra* note 8, at 384.

¹⁰⁴ Baker, *supra* note 30, at 615.

¹⁰⁵ There are a few vaccines in various clinical phases of trial, but it is not known when a finished product will be available. *See* Sherman & Oakley, *supra* note 8.