2011

Tripping over Trips and the Global HIV/AIDS Epidemic: Legislation and Political Decisions in Brazil and the United States

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TRIPPING OVER TRIPS AND THE GLOBAL HIV/AIDS EPIDEMIC: LEGISLATION AND POLITICAL DECISIONS IN BRAZIL AND THE UNITED STATES

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I. INTRODUCTION

There is an ongoing ethical and legal battle concerning the extent of property rights granted over pharmaceutical treatments and medicines for patients afflicted with life-threatening diseases that promises to have extensive repercussions on the future definitions of international legal standards and institutions. On the one hand, based on humanitarian and ethical arguments, contenders defend the right to disregard intellectual property rights when it involves fighting an epidemic of global proportion such as Acquired Immune Deficiency Syndrome ("AIDS") caused by the Human Immunodeficiency Virus ("HIV").


2. Infection with the Human Immunodeficiency Virus (HIV) weakens the immune system and leads to Acquired Immune Deficiency Syndrome (AIDS) by destroying important immune system cells that fight disease and infection. What is HIV/AIDS?, AIDS.GOV, http://www.aids.gov/hiv-aids-basics/hiv-aids-101/overview/what-is-hiv-aids/ (last updated June 20, 2011). See generally Global HIV/AIDS at CDC, CENTERS FOR

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at the center of their argument is whether or not it is ethical to protect the profit of pharmaceutical companies when doing so can endanger the lives of millions of people worldwide. This question is often politically influenced particularly in the underdeveloped world.\(^3\) Since launching an aggressive program to fight HIV/AIDS in 1996, Brazil has been a pioneer in challenging the property rights of pharmaceutical companies thereby pressuring them to accept a humanitarian reasoning and reduce the excessively high prices of their medicines.\(^4\)

On the other hand, there is the pharmaceutical companies’ position, which is heavily anchored on strict intellectual property laws that grant exclusive rights to their products. This position also calls on ethical values, for example, when they argue that intellectual property laws provide the incentive for the continuous research that makes possible the development of treatments for the diseases that plague modern humanity.\(^5\) According to this argument, laboratories will not invest the billions of dollars\(^6\) needed to

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research and develop medical treatments for those diseases, or perhaps even discover a cure. The market price of a drug or treatment includes the cost of production, the recovery cost of years of research necessary to develop it, and the continuous research necessary for the development or improvement of other medicines and treatments. Additionally, investments in the development of new medicines are often considered high-risk investments with doubtful return; pharmaceutical laboratories often spend fortunes in research programs that simply do not reach a successful outcome. Finally, receiving governmental authorizations for commercial distribution requires a long testing period to assess the effectiveness and potential side effects of the medication. All of these steps preceding the commercial distribution of medications compound the operational costs of the pharmaceutical companies and must be recovered ultimately through the commercial sale of their products.

Thus, intellectual property laws provide incentives for research laboratories and pharmaceutical companies to promote the development of treatments and medicines. The protection provided by these laws guarantees that pharmaceutical companies will have a chance to profit from the product of their investment. Considering the high risk and long-term investment that laboratories and pharmaceutical companies undertake, pharmaceuticals that reach the consumer market are often prohibitively

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12. Id.
expensive and inaccessible to the general public.\textsuperscript{13} On average, it takes ten to fifteen years to place a pharmaceutical drug in the consumer market.\textsuperscript{14} Moreover, if the patent period for a certain pharmaceutical drug runs for twenty years, the companies that own the patent will have only about eight to twelve years to recover their investment and continue investing and developing newer treatments and cures.\textsuperscript{15}

Legally, generic medications enter the market as soon as the replicated drug’s patent period expires.\textsuperscript{16} This intermingled system of intellectual property and patent rights granted to pharmaceutical companies is the implied contract between society and those who invest in innovation. Yet, diseases that have a large-scale impact on global health, such as HIV/AIDS, Tuberculosis,\textsuperscript{17} and Malaria,\textsuperscript{18} have sparked debates on whether these implied contracts are just and ethical, especially when increased costs and

\begin{itemize}
\item \textsuperscript{14}\textsuperscript{14} Kelly, supra note 6.
\item \textsuperscript{15} Patents normally are taken out toward the end of the discovery phase of a new medicine. Given the length of the development stage, the patent life remaining by the time the product reaches the market typically is between 8 and 12 years, and often less. The inventor therefore has only a limited time to recover research and development costs and to make a profit before copies appear. \textsc{Michael L. Burstall et al., Inst. of Med., The Changing Economics of Medical Technology} 129 (1991), available at http://www.nap.edu/openbook.php?record_id=1810&page=129.
\item \textsuperscript{16} A generic drug can enter the market only after the brand-name patent or other marketing exclusivities have expired and FDA approval is granted. \textit{Greater Access to Generic Drugs}, U.S. Food and Drug Admin., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucml43545.htm (last updated Aug. 12, 2011).
\item \textsuperscript{17} \textit{Tuberculosis: A Global Emergency}, NFID.ORG (Apr. 1999), http://www.nfid.org/old1/content/factsheets/tb.html ("Tuberculosis (TB) is the number one single infectious disease killer, taking nearly 3 million lives per year. So great is concern about TB that in 1993, the World Health Organization (WHO) declared TB a ‘global emergency.’").
\item \textsuperscript{18} Paul H. Lambert, \textit{Malaria-Global Impact}, NOBELPRIZE.ORG (Dec. 9, 2003), http://nobelprize.org/educational/medicine/malaria/readmore/global.html ("Malaria is by far the world’s most important tropical parasitic disease, and it kills more people than any other communicable disease, except tuberculosis.").
\end{itemize}
reduced accessibility to these treatments are a consequence. Ultimately, the argument stresses that all those compounded costs are necessary and result into extraordinary benefits for humanity as a whole.

This particular debate is important. First, it unveils the earliest major disagreement between positions sustained by legal arguments of domestic reach, as well as arguments based on international law, international trade interests, and compelling ethical variables. Second, the contention is not limited to divergent positions between Brazilian officials and pharmaceutical companies; it has broader and important repercussions for a large part of the world’s population. Finally, because epidemics such as HIV/AIDS have global implications, possible negotiated solutions for the disagreement should be considered with global perspectives and humanitarian repercussions.

This Note examines the conflicts between patent rights and ethics when humanitarian values are at stake and argues for the implementation of legislative reform in low, middle, and high income countries as essential to the global fight against contagious diseases. This Note then closely examines Brazil’s decision to bypass patent rights in the name of humanitarian and ethical arguments, and the cases for and against Brazil’s actions. Furthermore, this Note considers the legal ramifications international agreements may raise in the future and the impact on the laboratories that manufacture the pharmaceuticals needed in the fight against contagious and life-threatening diseases.

II. THE GLOBAL HIV/AIDS EPIDEMIC

A. The Current Status of the Global HIV/AIDS Epidemic

According to the September 2010 progress report on HIV/AIDS interventions in the health sector released by the World Health Organization (“WHO”) in collaboration with The United Nations Children’s Fund (“UNICEF”) and The Joint United Nations Programme on HIV/AIDS (“UNAIDS”), a total of 33.4 million people are living with HIV worldwide.19 The same report discloses that in 2008 alone, 2.7 million people were infected with HIV.20 Thus, access to quality prescription drugs


20. Id.
can mitigate the HIV global health crisis, which impacts a large segment of the population.\textsuperscript{21} There is strong evidence that important gains have been made towards the attainment of global universal access to anti-HIV drugs and treatments, but considerable challenges remain.\textsuperscript{22} Universal access is defined as providing access to HIV testing, prevention, treatment and care for at least eighty percent of the country’s population in need.\textsuperscript{23} Some low and middle income countries have successfully attained the universal access eighty percent standard and “[f]or a good number of countries, universal access is within clear reach by the end of 2010.”\textsuperscript{24} However, “on a global scale, targets for universal access to HIV prevention, treatment and care will not be met by 2010.”\textsuperscript{25} In addition, there is widespread concern that “the [current] financial crisis and resulting economic recession have prompted some countries to reassess their commitments to HIV programmes.”\textsuperscript{26} As a result of the financial crisis, funding for HIV services and international assistance has not experienced the usual steady increase over the current period and all the gains from the past several years risk being reversed.\textsuperscript{27} Thus, “[i]n the context of a global financial crisis, [the 2010 progress] report underscores the urgency of continuing to mobilize support by countries, donors and global agencies in order to respond to the HIV epidemic.”\textsuperscript{28}


\textsuperscript{22} WHO PROGRESS REPORT 2010, supra note 19, at 3.

\textsuperscript{23} Id. at 5.

\textsuperscript{24} Id. This report shows that, among 144 low and middle income countries reporting program data this year, eight had already achieved universal access to antiretroviral therapy at the end of 2009, providing treatment to at least 80% of patients in need. Id. at 9. Furthermore, 15 countries had achieved the 80% target for coverage with antiretroviral prophylaxis to prevent mother to child transmission of HIV. Id.

\textsuperscript{25} Rosen, supra note 21.

\textsuperscript{26} Id.

\textsuperscript{27} Id.

\textsuperscript{28} Id.
On June 10, 2011, the United Nations General Assembly adopted the Political Declaration on HIV/AIDS. The declaration calls on all United Nations Member States to redouble their efforts to achieve universal access to HIV prevention, treatment, care, and support by 2015. According to the United Nations Secretary-General, “2011 marks a unique opportunity to take stock of progress and to critically and honestly assess the barriers that keep us shackled to a reality in which the epidemic continues to outpace the response.”

B. TRIPS and the Impact on Universal Access Goals

Many governments around the world have granted their innovators and creators rights over their inventions hoping to encourage and produce ideas that benefit society. However, “[t]he extent of protection and enforcement of these rights varied widely around the world; and as intellectual property became more important in trade, these differences became a source of tension in international economic relations.” The World Trade Organization (“WTO”) Trade-Related Aspects of Intellectual Property Rights Agreement (“Agreement”), negotiated in the 1986-1994 Uruguay Round, established common international rules governing intellectual property.


30. Id.


33. Id. at 39.

property rights and set the minimum level of protection that each government must give to the intellectual property of fellow WTO members. Of the 153 member states of the WTO, the top traders are the European Union, the United States, Japan, and China. These countries are also among the top producers and exporters of pharmaceuticals needed by HIV/AIDS programs in underdeveloped and developing countries.

Before the WTO was created, two main international agreements of the World Intellectual Property Organization ("WIPO") existed: the Paris Convention for the Protection of Industrial Property governing, inter alia, patents and industrial designs, and the Berne Convention for the Protection of Literary and Artistic Works governing copyrighted material. These conventions did not encompass all areas of intellectual property and "[i]n some cases, the standards of protection prescribed were thought inadequate." Thus, the TRIPS Agreement "add[ed] a significant number of new or higher standards." Furthermore, one of the basic principles of the Agreement is that "intellectual property protection should contribute to technical innovation and the transfer of technology. Both producers and users should benefit, and


37. The WTO is 'rules-based,' supra note 32, at 53.


39. The WTO is 'rules-based,' supra note 32, at 40.

40. Id.

41. Id.
economic and social welfare should be enhanced . . . ." 42 With regards to patent rights, Article 27.1 of the Agreement provides that patents shall be available “in all fields of technology," 43 and Article 33 provides for an enforceable protection period of at least twenty years. 44 In addition, Article 31 45 of the Agreement permits governments to issue compulsory licenses without authorization of the holder “under certain conditions aimed at safeguarding the legitimate interests of the patent-holder." 46 These conditions include:

[The obligation . . . to grant such licences only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time . . . pay adequate remuneration . . . taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher authority. 47]

Thus, the compulsory license provision grants governments certain flexibilities in interpreting the Agreement. 48 However, many countries voiced their concern with the inherent uncertainties in interpreting the compulsory license provision and the lack of a clear delineation of the allowances given to countries that choose to take advantage of the provision. 49 Another concern raised by many countries is the Article 31

42. See Understanding the WTO IP, supra note 35.


44. Id. at 334.

45. Id. at 333-34.

46. Understanding the WTO IP, supra note 35.


48. Understanding the WTO IP, supra note 35.

49. Id.
requirement that the use of compulsory licenses be "authorized predominantly for the supply of the domestic market."\(^{50}\) This requirement precludes developing countries that lack the financial and technological means to manufacture needed pharmaceuticals domestically from importing those pharmaceuticals.\(^{51}\) In addition, some governments seek to "ensure [that] patent protection for pharmaceutical products does not prevent people in poor countries from having access to medicines—while at the same time maintaining the patent system's role in providing incentives for research and development into new medicines."\(^{52}\)

Moreover, in an attempt to clarify further the scope of TRIPS and the compulsory license provision, the WTO released a statement in 2001 known as the Doha Declaration aimed at "promoting both access to existing medicines and research and development into new medicines."\(^{53}\) The Doha Declaration "emphasizes that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health."\(^{54}\) Paragraph 5.c recognizes that "[e]ach 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."\(^{55}\) Rather than the common misconception that a state of national emergency must exist before a compulsory license can be issued, the Agreement allows a country to bypass the Article 31

\(^{50}\) TRIPS Agreement, supra note 43, at 333.


\(^{52}\) Understanding the WTO IP, supra note 35.


\(^{55}\) Doha Declaration, supra note 53.
requirement of negotiating a voluntary license, which can save valuable time when a national emergency is declared.\textsuperscript{56} In either circumstance, the owner of the patent rights still must be adequately compensated in accordance with the scope of his or her ownership of the patent as provided by the TRIPS Agreement.\textsuperscript{57}

III. THE BRAZILIAN STI/AIDS PROGRAM

In the early 1980s, when the first cases of AIDS were being diagnosed and documented in Brazil, the nation's system of governance was shifting from a military dictatorship to the democratic process.\textsuperscript{58} Thus, the political and social circumstances in which AIDS and public health concerns emerged made Brazil's response to the HIV/AIDS epidemic unique.\textsuperscript{59} The political shift led to a re-organization of Brazil's public health system, the establishment of the Unified Health System (Sistema Único de Saúde, “SUS”) and the newly adopted 1988 Constitution, which considered access to treatment a legal right.\textsuperscript{60} Today, access to treatment is recognized as an inalienable human right and specifically delineated in Title II Article 5 of the Brazilian Constitution.\textsuperscript{61}


\textsuperscript{57} Id.


\textsuperscript{59} Id. at 1110.

\textsuperscript{60} Id. at 1112.

\textsuperscript{61} CONSTITUIÇÃO FEDERAL [C.F.] [CONSTITUTION] Title II art. 5 (Braz.), English Translation, available at http://pdba.georgetown.edu/Constitutions/Brazil/english96.html#mozTocId550508.
Furthermore, Brazil is at the forefront of the global access to medication debate when it comes to HIV/AIDS. In Brazil, an estimated 730,000 people live with HIV. Moreover, only an estimated 190,101 of those "seropositive" patients who have been positively diagnosed with HIV are being treated with antiretroviral drugs. Since the beginning of the global HIV epidemic in the 1980s, there have been 544,846 positive diagnoses and 217,091 AIDS-related deaths in Brazil. Each year, the Brazilian Ministry of Health receives and documents 33,000 to 35,000 new AIDS cases. Concern over this ominous public health crisis led to the institution of a national STI ("sexually transmitted infection")/AIDS program in 1996.


64. Jacqueline Matuza, What is HIV Seropositive?, eHOW.COM, http://www.ehow.com/about_5094950_hiv-seropositive.html (last visited Oct. 04, 2011). ("Serostatus is a word used to describe whether particular antibodies are present in the body. . . . If someone is seropositive for HIV it means their body has been producing antibodies for HIV, which can be detected with an HIV antibody test, the most common type of HIV test used.").


67. Id.

Sustained by the Brazilian Ministry of Health with the objective of attaining the universal access standard, this program guarantees free treatment to those diagnosed with HIV/AIDS and has decreased AIDS mortality by half. In addition, the program has provided pregnant seropositive women with access to antiretrovirals that help prevent transmission of HIV to the newborn. Furthermore, treating HIV infections is a complex process requiring the combination of at least three antiretrovirals, the so called “AIDS cocktail,” and the treatment itself calls for frequent and continuous medical supervision to evaluate the patient’s adaptations to the antiretrovirals, possible side effects, or possible difficulties in continuing treatment. Treatment alone can be very costly and the Brazilian STI/AIDS program primarily aims to: (i) reduce these expenses, (ii) increase the general public’s access to essential antiretrovirals, and (iii) increase the medical supervision paramount to ensure successful treatment.

In order to obtain the antiretrovirals required for their treatment program, the Brazilian government threatened to issue compulsory licenses as provided by a clause in the Agreement during negotiations with international pharmaceutical companies. Generally, the Agreement introduced intellectual property rules into the multilateral trading system in “an attempt


70. What is HIV Antiretroviral Drug Treatment? Introduction to HIV/AIDS Treatment, AVERT.ORG, http://www.avert.org/treatment.htm (last visited Dec. 10, 2011) (“The aim of antiretroviral treatment is to keep the amount of HIV in the body at a low level. This stops any weakening of the immune system and allows it to recover from any damage that HIV might have caused already. The drugs are often referred to as: antiretrovirals, ARVs, anti-HIV or anti-AIDS drugs.”).


73. Id.

to narrow the gaps in the way these rights are protected around the world[,] 
... bring them under common international rules[,]" and provide guidelines 
for settling intellectual property disputes between members of the WTO.\textsuperscript{75} 
Within the Agreement, Article 8 §1 provides that "[m]embers may, in 
formulating or amending their laws and regulations, adopt measures 
necessary to protect public health and nutrition, and to promote the public 
interest in sectors of vital importance to their socio-economic and 
technological development, provided that such measures are consistent with 
the provisions of this Agreement."\textsuperscript{76} Article 8 §1 has been construed to 
allow WTO member countries to override patent laws and produce reduced-
cost generic drugs during public health emergencies.\textsuperscript{77} Article 8 §2 further 
expounds that these appropriate measures "may be needed to prevent the 
abuse of intellectual property rights by [patent] right holders or the resort to 
practices which unreasonably restrain trade or adversely affect the 
international transfer of technology."\textsuperscript{78} One example of an appropriate 
measure is the May 4, 2007, Brazilian Decree 6.108, which provides for 
compulsory licenses of patented medications for public, noncommercial use 
in cases of "public interest."\textsuperscript{79} In turn, Brazilian Decrees 3.201 and 4.830 
consider those items related to public health to be of public interest.\textsuperscript{80} 

Although those Decrees have broadened the scope of what is considered 
to be public interest in compliance with and within the confines of the 
Agreement, there is neither a clear definition nor a consensus as to what

\textsuperscript{75} THE WTO IS ‘RULES-BASED,’ supra note 32, at 39; see also TRIPS Agreement, 
\textit{supra} note 43, at 330.

\textsuperscript{76} TRIPS Agreement, \textit{supra} note 43, at 323.

\textsuperscript{77} Doha Declaration, \textit{supra} note 53.

\textsuperscript{78} \textit{Id.}

\textsuperscript{79} \textsc{Decree No. 6.108, De 4 De Maio De 2007}, Diário Oficial da União (May 4, 
Decreto/D6108.htm}. This decree provides for compulsory licensing of patents for 
Efavirenz, for reasons of public interest when meant for public noncommercial use. \textit{Id.}

\textsuperscript{80} FOREIGN TRADE INFORMATION SYSTEM, SICE: TRADE POLICIES AND PRACTICES BY 
MEASURE: BRAZIL 106 (2009), \textit{available at} \url{http://www.sice.oas.org/ctyindex/BRZ/
WTO/ENGLISH/WTTPRS140_3_e.doc}. 
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constitutes a public interest. Furthermore, in issuing these compulsory licenses the Brazilian government assumes significant risks, particularly, the impact these compulsory licenses might have on the nation’s reputation for compromising intellectual property rights and the desirability level of investments in pharmaceutical research.

In 1995, the American pharmaceutical company, Merck, conducted trials of the AIDS drug Crixivan in Brazil and concluded that a combination of antiretrovirals posed significant health benefits to those infected with HIV. In light of those conclusions, activist groups sued Merck and the Brazilian federal government for not providing combination therapy to all patients in the trial—especially those patients in the control group that received a placebo treatment—and pressured the Brazilian Ministry of Health to declare that antiretrovirals would be provided at no cost to those who needed them. The response of the Brazilian legislature to the demand for access to antiretrovirals resulted in Article 68 of Law No. 9.279/96, which adopted the TRIPS compulsory license provision and allowed for compulsory licenses to be issued when there is “non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process.” However, The Office of the United States Trade Representative (“USTR”) argued that “Article 68 conflicted with Articles 27.1 and 28.1 of the TRIPS Agreement which ensure non-discrimination in the protection of patents and exclusive rights of patent holders.” Thus, the United States filed a


83. Id.


complaint against Brazil with the WTO but political pressure against the United States government and widespread support for Brazil’s approach led the United States to withdraw the WTO case and opt instead for a separate United States-Brazil Consultative Mechanism. The United States-Brazil mutually agreed upon solution communicated to the WTO panel states:

Without prejudice of the US and Brazil’s different interpretations of the consistency of Article 68 with the TRIPS Agreement, the US Government will withdraw the WTO panel against Brazil concerning the issue, and the Brazilian Government will agree, in the event it deems necessary to apply Article 68 to grant compulsory license on patents held by US companies, to hold prior talks on the matter with the U.S. These talks would be held within the scope of the US-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.

Regardless of this mutually agreed upon solution, the conflict between the United States and Brazil was further exacerbated in 2003 when the Brazilian Ministry of Health issued the first compulsory licenses for the antiretrovirals Lopinavir/Ritonavir, Efavirenz, and Nelfinavir, patented by Abbott, Merck, and Roche Laboratories to be produced at the Brazilian manufacturer, Instituto Farmanguinhos. In compliance with TRIPS requirements, Brazil asked Merck, Abbott, and Gilead Laboratories to grant voluntary licenses for pharmaceuticals manufactured by these companies and required the companies to transfer their technology to Brazilian drug producers for domestic manufacturing. For example, when Brazil’s Minister of Health threatened to break United States manufacturer Abbott Laboratories’ patent on Kaletra (“Lopinavir”), “Abbott ultimately agreed to lower the price of its medication by 46%—and distribute it free-of-charge to 163,000 of the


88. Id.

89. Tren et al., supra note 85, at 3.

90. Id. at 3-4.
600,000 carriers of the HIV virus in Brazil." Thus, Brazil’s agreement with Abbott lowered the cost of Kaletra ("Lopinavir") from $1.17 to 63 cents a pill, while still protecting the drug’s patent. Currently, these pharmaceutical companies continue to negotiate price reductions with the Brazilian government hoping to reach a consensus that circumvents violation of the companies’ patent rights without undermining the need to provide universal access to treatment.

Brazil’s aggressive negotiation tactics, however, could be extremely damaging to Brazil’s reputation for attracting pharmaceutical investments in the long-run. According to Jorge Raimundo, president of the consultative council of Interfarma (the Brazilian association for scientific research), employment in Brazil’s scientific research sector has dropped to about 20,000 from a total of 24,000 jobs in 1999 and annual investments worth about $350 million have dropped to about $90 million; “the pharmaceutical industry is becoming increasingly cautious about making new investments in Brazil . . . [a]nd it will only create problems for attracting capital to Brazil.” Moreover, the steep drop in employment and annual investments are a result of the pharmaceutical industry’s decreased confidence in their ability to profit substantially from their investments in Brazil. Thus, aggressive negotiations, aiming at lower prices and liberated patent restrictions, often tip the scale in favor of Brazil at the expense of the pharmaceutical companies. As a result, pharmaceutical companies would be less inclined to invest in Brazil, consequently resulting in harm to the Brazilian pharmaceutical industry as a whole.

91. Generic Drugs In Brazil Are a Hard Pill for Big Pharma to Swallow, KNOWLEDGE@WHARTON, UPENN.EDU (Mar. 01, 2006), http://knowledge.wharton.upenn.edu/article.cfm?articleid=1338 [hereinafter Generic Drugs in Brazil].

92. Id.


94. Generic Drugs in Brazil, supra note 91.

95. Id.
On the other hand, Michael Ryan, director of the Creative and Innovative Economy Center of George Washington University Law School, suggests that in reality Brazil has been moving in two directions on intellectual property policy: "Although the federal government has pursued a hard line in public against [intellectual property] rights, 'a quiet, little-noticed revolution has been taking place over the past decade . . . [w]ith the aim of increasing technology innovation in the marketplace and overcoming debilitating institutional problems . . . ."

Furthermore, John Kilama, president of the Global Bioscience Development Institute, suggests that the Brazilian government should consider the long-term positive impact of stronger intellectual property protection on the country's entire population rather than focus on the short-term benefits for the poor alone: "[T]he problem is how to get Brazil to use its enormous private sector, which is very innovative, to create wealth that enables the poor to afford access to drugs, instead of going out and making it difficult for Brazilian companies to compete."

IV. UNITED STATES PERSPECTIVE AND PATENT LEGISLATION

In the United States, intellectual property and patent rights legislation are administered by Title 35 of the United States Code and Article 1 Section 8 of the United States Constitution which provides: "[T]he Congress shall have Power to . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ." The United States Congress, often encouraged and pressured by pharmaceutical giants, is a keen advocate of stronger protection and enforcement of intellectual property rights. Accordingly, the United States' policy on trade strongly

96. The Two Faces of Intellectual Property in Brazil, Knowledge@Wharton, UPENN.EDU (Mar. 01, 2006), http://knowledge.wharton.upenn.edu/article.cfm?articleid=1339.

97. Id.


supports restricting the number of countries that have access to generic exports from developed producer countries.101 In the United States' view, developing countries that have sufficient manufacturing capacity such as the Philippines, India, and China should not be eligible to import generics from abroad.102 But, under the Agreement and the Doha Declaration, the Philippines, India, and China can legally issue compulsory licenses and produce lowest cost, standard quality generics. Furthermore, in order to increase the entry of generics into low income countries, it will be necessary to aggregate the markets of middle-income countries with large populations and meaningful purchasing power.103 Thus, after the implementation of the Doha Declaration, the United States government and the Pharmaceutical Research and Manufacturers of America ("PhRMA") zealously campaigned against the Doha Declaration and promoted other trade agreements that minimized its effect on the Agreement.104

In 2003, the WHO amended a provision of the Agreement that "prevented governments from licensing the production of generic versions of patented drugs exclusively for export to countries unable to make the medicines."105 This amendment, the "Paragraph 6" system ("Par.6"), removed the domestic market requirement that restricted issuing compulsory licenses solely for the production of exported generics.106 In other words, the predominant part of


102. Id.

103. Id.

104. Id.

105. Little-used 'Par.6' system will have its day, WHO tells Intellectual Property and Health Review, WORLD TRADE ORG. (Oct. 27, 2010), http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm.

106. Id.
the produced generics had to go to the domestic market and only what was left could be exported.\textsuperscript{107} According to the WHO, "the ‘Par.6’ system will become more important as newer HIV/AIDS medicines are needed in the future . . . to increase competition from generics" when developing countries such as India and Brazil have introduced full patent protection in the pharmaceutical sector.\textsuperscript{108} In addition, the exported generic drugs cannot be exported solely for commercial or industrial purposes and must be readily identifiable by a unique packaging and coloring to prevent disruptions to the pharmaceutical market in developed countries.\textsuperscript{109} The purpose of the unique packaging and coloring requirement for generic medications produced under a compulsory license issued by an exporting country is to protect pharmaceutical companies against diversion, by ensuring that generic products are clearly distinguishable to customs authorities and other pharmaceutical manufacturers.\textsuperscript{110}

In 2003, the Bush administration created The United States President’s Emergency Plan for AIDS Relief ("PEPFAR") recognizing the distribution of generic medications as an effective strategy to fight the global HIV/AIDS epidemic.\textsuperscript{111} According to the November 2010 PEPFAR Operational Plan, treatment priorities include: procurement of generic ARVs at over 80% of the value of all purchases, accommodating patients failing first-line therapy by increasing the percentage of drug procurement committed to second-line regimens in anticipation of phased-out

\textsuperscript{107} Id.

\textsuperscript{108} Id.


Clinton HIV/AIDS Initiative funding, and preparing for an expected shift to a tenofovir-based first line regimen later in 2010.\(^{112}\)

The implementation of PEPFAR greatly increased the amount the United States government was spending on combating HIV/AIDS outside of the United States with an increase to $6 billion in 2008 compared with $1.5 billion in 2003.\(^{113}\) Moreover, prior to the implementation of PEPFAR, most financial expenditures towards HIV/AIDS occurred via bilateral agreements between the United States and another country, such as the Mother-to-Child Prevention Initiative\(^{114}\) that continued and became part of PEPFAR.\(^{115}\) Towards the end of PEPFAR’s founding administration, the Obama presidential campaign pledged to increase PEPFAR funding and President Obama’s first budget proposed $366 million for PEPFAR in 2010.\(^{116}\) However, there is widespread fear that the current economic funding will significantly jeopardize PEPFAR funding.\(^{117}\) In fact, many clinical research centers in low income countries that partnered with the United States under PEPFAR have already reported detrimental effects to their programs caused by a lack of new funding.\(^{118}\)

As a result of the global economic crisis, the Obama administration and USTR Ambassador Ron Kirk are advocating opposition to protectionist
economic policies that limit and restrain free trade.119 In the context of intellectual property and patent rights specifically, protectionist provisions in free trade agreements—such as strict intellectual property and patent restrictions—benefit large pharmaceutical corporations and place an economic burden on domestic companies by limiting their ability to compete with unburdened companies abroad.120 Thus, in the long-run, protectionist provisions can harm the domestic market rather than contribute to the good of society as a whole.121

Furthermore, the current financial crisis has also emphasized the necessity of obtaining lower cost generic medications. Several billion dollars of the PEPFAR budget is allocated to purchase of HIV antiretrovirals but PEPFAR’s stringent requirement that all generic antiretrovirals must be approved by the Food and Drug Administration (“FDA”) further impedes the availability of generic drugs to be distributed by the program.122


121. See Spruiell, supra note 120.

122. M. Asif Ismail, PEPFAR Policy Hinders Treatment in Generic Terms: Critics say FDA approval rule has meant greater use of high-cost drugs at expense of helping fewer patients, THE CENTER FOR PUBLIC INTEGRITY (Dec. 13, 2006), http://projects.publicintegrity.org/aids/report.aspx?aid=836. “Estimates released by PEPFAR reveal that in 2004 and 2005, its first two fully funded years, the plan allocated only about 5 percent of its overall ARV drug budget—less than $15 million—for generic drugs.” Id. “A key reason for that lies in PEPFAR’s own rules: only ARVs approved by the U.S. Food and Drug Administration (or given tentative FDA approval through an
However, by 2005, fifteen generic drugs received FDA and WHO approval and were being distributed by PEPFAR.\textsuperscript{123} By 2007, seventy-three percent of all antiretroviral drugs distributed by PEPFAR were lower-cost generics, saving PEPFAR partners an estimated $64 million.\textsuperscript{124} Another area of debate between the United States and Brazil with regards to HIV/AIDS funding began as a consequence of PEPFAR’s funding restriction against organizations “that do not explicitly state they oppose prostitution,” as part of the United States moral agenda.\textsuperscript{125} Because of this “anti prostitution loyalty oath” as a precondition for funding, Brazil refused $40 million of PEPFAR funds in 2005 in favor of “preserv[ing] its autonomy on issues related to national policies on HIV/AIDS as well as ethical and human rights principles.”\textsuperscript{126} The Brazilian government and many other organizations favoring a non-judgmental approach to funding allocation have expressed concern that “adopting the PEPFAR [anti prostitution loyalty oath] would be a serious barrier to helping sex workers protect themselves and their clients from infection.”\textsuperscript{127} Several international nongovernmental organizations, such as Oxfam and Médecins Sans Frontières, have lobbied for urgent reform in global patent legislation and demanded changes to the worldwide system for selling and distributing antiretrovirals.\textsuperscript{128} Those organizations have requested that the United States government and international pharmaceutical companies in

\textsuperscript{123.} See PEPFAR, supra note 113.


\textsuperscript{125.} See PEPFAR, supra note 113.

\textsuperscript{126.} Id. See also Sarah Boseley and Suzanne Goldenberg, Brazil spurns US terms for Aids help. THE GUARDIAN (May 4, 2005, 19:00 EDT), http://www.guardian.co.uk/world/2005/may/04/brazil.aids/print.

\textsuperscript{127.} See Boseley and Goldenberg, supra note 126.

developed countries change their policies on medicines and patents to increase availability and access to treatment for low income countries.\textsuperscript{129} More specifically, they have asked for the United States to "stop using . . . the threat of trade sanctions to oblige Brazil and other countries to institute levels of intellectual-property protection that harm public health and economic development."\textsuperscript{130} Moreover, Oxfam has particularly requested that pharmaceutical companies "issue voluntary licenses to allow local manufacture of these medicines by third parties, or should agree to sell them at prices comparable to those of generic manufacturers, such as companies based in India."\textsuperscript{131}

V. THE PROPOSED LEGISLATIVE REFORM

It has been suggested that, although highly successful, the approach of the Brazilian HIV/AIDS program and Brazilian legislators will not work for other countries unless there are similar cultural and economic situations.\textsuperscript{132} Rather than advocating a "Brazilian Model," some experts have argued that "[e]ach country must fashion its own response in consideration of its own peculiarities, economy, politics, and social and cultural values."\textsuperscript{133} For example, sub-Saharan African countries have a much higher HIV prevalence and a much lower per capita health care budget, and "[a] crucial element in any successful [antiretrovirals] program is ensuring there are enough sufficiently trained medical staff to treat patients . . . Brazil has 206 physicians for every 100,000 inhabitants. The ratio is far worse in sub-Saharan Africa . . . ."\textsuperscript{134} While the Brazilian approach can still be considered and applied to developing countries with similar economic and cultural structures, those countries with a different level of socioeconomic

\textsuperscript{129} Id. at 332.

\textsuperscript{130} Id.

\textsuperscript{131} Id.


\textsuperscript{133} Id.

\textsuperscript{134} Tren et al., supra note 85, at 6.
status are likely to adopt their own unique and customized approach to the HIV/AIDS epidemic. In 2001, United Nations member states met at the United Nations General Assembly Special Sessions on HIV/AIDS and agreed to:

Enact, strengthen or enforce as appropriate legislation, regulations and other measures to . . . ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS . . . in particular to ensure their access to, inter alia education, inheritance, employment, health care, social and health services, prevention, support, treatment, information and legal protection.\(^{135}\)

In 2006, The United Nations General Assembly “emphasized that legal, regulatory and political barriers in countries continue to block peoples’ access to effective prevention programmes” and called on parliaments to enact legislation aimed at removing these barriers.\(^{136}\) The Assembly also requested parliamentarians to “ensure that they pass national laws that allow their governments to use existing global trade rules [such as the WTO’s TRIPS Agreement and the Doha Declaration] to ensure access to affordable HIV medicines.”\(^{137}\)

According to UNAIDS, legislators in low, middle, and high income countries can take significant steps to increase the availability of treatment and support for their HIV/AIDS patients.\(^{138}\) These steps include reforming national intellectual property legislation and national patent laws, taking an active role in trade negotiations, advocating increased bilateral budget support, and opposing any provisions in bilateral, regional, or multilateral treaties that create more extensive intellectual property protection and


\(^{137}\) Id. at xi-xii.

undermine the flexibilities inherent in the TRIPS Agreement.\textsuperscript{139} Thus, UNAIDS has proposed a special approach involving legislative reform in countries of differing levels of economic status.

\textit{A. Legislation in Low, Middle, and High Income Countries}

In expectation of promoting access to affordable pharmaceuticals, UNAIDS proposes legislative reform of intellectual property laws in low and middle income countries to ensure that TRIPS flexibilities are incorporated into the national laws of these countries, as recommended by the United Nations General Assembly.\textsuperscript{140} UNAIDS also proposes reform of national patent laws in the least developed countries to “allow national authorities the option of not providing any patent protection in the pharmaceutical sector until 2016, as provided in the WTO Doha Declaration.”\textsuperscript{141} This framework will allow sufficient time for least developed countries to take advantage of and implement the flexibilities inherent in the TRIPS Agreement into their national laws. Moreover, UNAIDS proposes that low and middle income countries “take an active role in trade negotiations to ensure that governments do not enter into regional and bilateral trade agreements that include intellectual property provisions with more extensive patent protection than required by the TRIPS Agreement.”\textsuperscript{142} Thus, low and middle income countries that actively participate in trade negotiations can tip the scale in their favor and oppose any overly stringent intellectual property provisions in bilateral or multilateral agreements.

On the other side of the economic spectrum are the laboratories based in high income countries that manufacture the pharmaceuticals required for the success and effectiveness of HIV/AIDS programs in low and middle income countries. For this reason, UNAIDS has requested that legislators in those high income countries “ensure that trade sanctions are not threatened or imposed by governments of low and middle income countries” and “oppose any provisions in bilateral, regional or multilateral treaties that create more extensive intellectual property protection than what has been agreed under global trade rules or that undermine the flexibilities in the TRIPS

\textsuperscript{139} See HANDBOOK FOR PARLIAMENTARIANS, \textit{supra} note 136, at 121-25.

\textsuperscript{140} \textit{Id.} at xix.

\textsuperscript{141} \textit{Id.}

\textsuperscript{142} \textit{Id.}
Therefore, UNAIDS recommends that high income countries also take a stance against overly stringent intellectual property provisions, and instead, opt for agreements allowing low and middle income countries to take advantage of the flexibilities inherent in the Agreement as provided by the Doha Declaration.

B. Proposed Legislative Reform—Legal and Political Ramifications

Whether the legislative reform proposed by UNAIDS will have the desired results will substantially depend on whether it strikes a balance between public health concerns and promoting innovation. However, contrary to the UNAIDS proposal, governments of many low and middle income countries are adopting stronger domestic intellectual property legislation in conformity with “the mandates of ‘free’ trade agreements signed with the United States.” These agreements stipulate intellectual property provisions that “extend beyond the patent law standards . . . which promised to balance the exigencies of public health and patent holders.”

A possible explanation for why these countries are submitting to stronger intellectual property legislation, for the sake of concluding trade agreements with the United States, is provided in a statement by Dr. Margaret Chan of the WHO: “[C]ountries unskilled in trade negotiations fear they will be tricked or duped . . . fear they will be punished by trade sanctions imposed in retaliation . . . [and] fear that pharmaceutical companies will use unfair tactics . . . to reduce competition from lower-priced generics.” For that reason, the UNAIDS legislative reform proposal’s ultimate goal will also substantially depend on whether low and middle income countries are able to enter into trade agreements via more aggressive negotiations favoring a broader representation of their need for lower-priced generics.

143. Id. at xviii-xix.


145. Id.

VI. CONCLUSION

Assuming that every life-threatening disease is a humanitarian and ethical concern and in taking that assumption to the extreme, one may conclude that all patent rights must be violated. However, patent violations, particularly under the protection or motivation of the state, might negatively affect investment in research for new treatments and therapies. Supporters of breaking patent laws in the name of ethical reasons—such as the avoidance of a humanitarian disaster—make a valid point. Nevertheless, would it be ethical and humanitarian to withhold from future generations the possibility of a cure for life-threatening disease? There is no easy answer.

Although the pharmaceutical industry as a whole is not forthright about how much profit is lost by the anti-intellectual property actions of some countries, the more pressing concern is the absence of economic drivers for pharmaceutical companies to make serious global health threats, such as HIV/AIDS, a research priority. Given all of the controversy surrounding HIV/AIDS drugs, pharmaceutical companies are more likely to fund research for health threats that are less stigmatized, such as Tuberculosis, Malaria and cancer. Companies might sense more incentive to invest and engage in research for other diseases that are not as likely to lead to controversy and threats to intellectual property rights and overall market profit. One question that remains unanswered is why antiretrovirals, as opposed to medications and treatments for other life-threatening diseases, are at the center of so much controversy and dispute. This occurrence may be due to the ease of manipulation of people with HIV, often underprivileged and uneducated, and not because of a true global interest in eradicating the virus and fighting AIDS.

To complicate matters further, in Brazil accusations abound of waste and misuse of resources by the Brazilian Ministry of Health, often in the value of hundreds of millions of dollars.147 To consider the intellectual property system as the sole problem or reform to intellectual property laws as the sole solution would exclude several other issues that also considerably impact accessibility to pharmaceuticals. This issue seems to fall outside the legal realm but needs to be taken into consideration when drafting legislation that involves intellectual property rights.

Moreover, some pharmaceutical companies have used “compensatory” policies and strategies to water down criticism. For example, Novartis’s

generous contributions and funding have allowed the WHO to provide and distribute medications and treatments for patients with Hansen’s disease (“leprosy”) free of charge since 1995. According to official reports, the global registered prevalence of leprosy stood at 213,036 cases at the beginning of 2009 but fortunately, the disease is curable with the appropriate medication and treatment. Thus, in this case, financial costs and intellectual property rights are not interfering with accessibility and availability of medical treatments.

Finally, this case suggests another complex paradox: Although, in principle, acknowledging and conceding to intellectual property rights seems to be aligned with obvious values and morals, this is an alignment far from definitive. For example, employing defenses against bioterrorism or a widespread pandemic would entail producing and providing large supplies of a medication to a large number of people in the fastest, most efficient method possible. The only way to satisfy such large and rapid demand would be to increase the number of manufacturers by issuing compulsory licenses. In this case, overzealous protection of intellectual property rights would truly be trumped by a global necessity. A crisis situation—such as the HIV/AIDS epidemic may be interpreted to be—can easily invoke the same ethical and moral variables that trump any necessity to defend intellectual property rights.


149. See Leprosy, Fact Sheet No. 101, WORLD HEALTH ORG. (Feb. 2010), http://www.who.int/mediacentre/factsheets/fs101/en/. See also Maria A.B. Trindade et al., Delayed Diagnosis of Multibacillary Leprosy: A Report of Eight Cases, 13 BRAZ. J. INFECTIOUS DISEASES 155, 155 (2009), http://www.scielo.br/pdf/bjid/v13n2/v13n2a17.pdf (“more than 250,000 new cases were registered in 2007, including about 40,000 in Brazil and 140,000 in India”).