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UNNECESSARY DEATHS AND UNNECESSARY COSTS: GETTING PATENTED DRUGS TO PATIENTS MOST IN NEED

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Abstract: Medical epidemics that are constrained in the developed world are wrecking havoc on developing countries, which are bearing the brunt of HIV/AIDS, malaria, tuberculosis, and other infectious diseases. Because medicines used to treat these conditions are patented, they are expensive and inaccessible to poor countries. In 1994, the United Nations established a system of international patent protection through the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and simultaneously tried to accommodate its commitment to making life-saving pharmaceuticals available to developing countries. When TRIPS failed to accomplish this goal, Article 31bis, an amendment to TRIPS, was introduced in 2003, seeking to make it easier for developing countries to acquire low-cost drugs. However, the amendment has been criticized and has largely gone unused. This Note addresses ways in which Article 31bis can be employed to deliver treatment to the neediest. In particular, this Note advocates that, whether or not the amendment is used, life-saving drugs must be provided at low-cost to developing countries.

Introduction

The poorest regions of the world have the highest concentrations of people with treatable diseases such as HIV/AIDS, tuberculosis, and malaria.[1] Each year in developing countries, approximately three mil-

* Managing Editor, Boston College Third World Law Journal (2008–2009).

[1] *See* UNAIDS & World Health Org., AIDS Epidemic Update 2 (2005), *available at* http://www.who.int/hiv/epi-update2005_en.pdf; World Health Org., Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health 2–3 (2006) [hereinafter WHO, Public Health], *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf; World Health Org., Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector: Progress Report 5 (2007) [hereinafter WHO, Towards Universal Access], *available at* http://www.who.int/hiv/mediacentre/universal_access_progress_report_en.pdf. Treatable diseases are also referred to as diseases of poverty, since they are most prevalent in poor countries but

lion people die from HIV/AIDS, two million from tuberculosis, and one million from malaria.[2] Over two-thirds of all people infected with HIV live in sub-Saharan Africa.[3] Seventy-two percent of the worldwide fatalities caused by HIV/AIDS occurred in this region.[4]

One reason for the disproportionate concentration is that one third of the world's population—close to two billion people—lacks regular access to essential medicines.[5] In the poorest regions, such as parts of Africa and Asia, approximately ninety-four percent of the inhabitants fall into this category.[6] In low- and middle-income countries, a full seventy-two percent of people have no access to antiretroviral treatments.[7] A report by the World Health Organization (WHO) found that average per capita spending in low-income countries is one hundred times *less* than what is spent in high-income countries.[8] Furthermore, WHO reported that only fifteen percent of the world's population consumed up to ninety percent of all available pharmaceuticals.[9]

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have often been cured or significantly combated in developed regions. *See* WHO, Public Health, *supra*, at 2.

[2] WHO, Public Health, *supra* note 1, at 8. Comparatively, in developed countries in 2002 approximately 49,000 people died of HIV/AIDS, 49,000 of tuberculosis, and 150 of malaria. World Health Org., *Revised Global Burden of Disease (GBD) 2002 Estimates: Estimates by Level of Development: Mortality,* 2002, http://www.who.int/healthinfo/bodgbd2002revised/en/index.html (last visited Oct. 10, 2008) [hereinafter WHO, *Revised GBD 2002*]. The World Bank classifies developing countries as having either low- or middle-incomes per capita. WHO, Public Health, *supra* note 1, at 2. Low-income countries have a per capita income of less than $825 and middle-income countries have a per capita income of $3255. *Id.*

[3] UNAIDS & World Health Org., *supra* note 1, at 10.

[4] *Id.*

[5] World Health Org., WHO Medicines Strategy: Countries at the Core 2004–2007, at 3 (2004) [hereinafter WHO, WHO Medicines Strategy]; Bill Clinton, *My Quest to Improve Care*, Newsweek, May 15, 2006, at 50.

[6] WHO, WHO Medicines Strategy, *supra* note 5, at 3.

[7] WHO, Towards Universal Access, *supra* note 1, at 5. In December 2006, only two million of the seven million people suffering from HIV/AIDS in low- and middle-income countries received treatment. *Id.*

[8] WHO, WHO Medicines Strategy, *supra* note 5, at 3. Approximately four hundred dollars are spent per person in high-income countries as compared to four dollars per person in low-income countries. *Id.* It is important to note the interrelationship between health and wealth: an abundance of poor health contributes to status as a poor country, just as being a poor country translates into high concentrations of poor health. *See* Robert Langreth, *The Rwanda Cure*, Forbes, Oct. 29, 2007, at 142. For example, in examining the relationship between malaria and poverty, economist Jeffrey Sachs declared that a severe malaria problem reduced a country's economic growth by 1.3 percentage points per year. *Id.*

[9] WHO, WHO Medicines Strategy, *supra* note 5, at 15.

Studies show that improved access to medications would drastically alleviate the disproportionate death tolls in developing countries.[10] One set of researchers estimates that antiretroviral medicines (combined with comprehensive treatment programs) could save between 5.8 and 10.1 million lives in sub-Saharan Africa by 2020.[11] That is, between sixteen and twenty–five percent of deaths caused by HIV/AIDS could be averted.[12] It is further estimated that up to 10.5 million lives could be saved annually by providing existing medicines, commonplace in the developed world, that treat infectious diseases, maternal and perinatal conditions, childhood diseases, and noncommunicable diseases.[13] Another study found that of the 9.7 million deaths per year worldwide of children under the age of five years old, six million could be prevented using existing technologies.[14] As an example, generic antibiotics could cure almost all of the 1.8 million who die every year from bacterial pneumonia.[15] Further, the measles vaccination—which was invented over forty years ago and has proven safe and reliable—can reduce the 390,000 deaths per year that that infliction causes.[16] As it stands, over ninety-five percent of measles deaths occur in developing countries.[17]

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[10] *See* WHO, Public Health, *supra* note 1, at 8; John Salomon et al., *Integrating HIV Prevention and Treatment: From Slogans to Impact*, 2 PLoS Medicine 50, 52 (2005), *available at* http://medicine.plosjournals.org/archive/1549–1676/2/1/pdf/10.1371_journal.pmed.0020016-S.pdf; Michael Westerhaus & Arachu Castro, *How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?*, 3 PLoS Medicine 1230, 1232 (2006).

[11] Salomon et al., *supra* note 10, at 53.

[12] *Id.*

[13] WHO, WHO Medicines Strategy, *supra* note 5, at 13. Another example is examination of the town of Mayange, Rwanda. Langreth, *supra* note 8. Until 2006, over 100 children per year under the age of five were dying in their homes because they could not afford the town's eighteen-bed clinic. *Id.* In 2007, a functioning health center was started to provide basic services such as generic antibiotics, rehydration fluids for diarrhea, malaria medicines, insecticide-treated bed nets, and AIDS drugs. *Id.* As a result, in 2007, only twenty-eight children under the age of five died. *Id.*

[14] Langreth, *supra* note 8.

[15] *Id.*

[16] *Id.*; Muhammad Saleem, *Measles Still a Leading Cause of Death Among Children*, Bus. Recorder, Mar. 1, 2008, *available at* http://www.brecorder.com (search "Measles Still a Leading" and follow hyperlink) ("Measles vaccination, one of the most cost-effective public health interventions, is available for preventing death caused by the disease."). The measles vaccination was invented in 1963. Langreth, *supra* note 8.

[17] Saleem, *supra* note 16.

There are many reasons why developing countries are unable to obtain the medicines their people need.[18] Among the leading factors are high costs.[19] Cutting-edge drugs are usually patented and are therefore prohibitively expensive because the patent-holder is free to price the drug without limits.[20]

Patents on pharmaceuticals in the international arena are generally governed by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[21] This agreement confers on the patent owner a series of traditional intellectual property rights (IPRs), one of which is a twenty-year license to prevent third parties from making, using, offering for sale, selling, or importing the patented product or process.[22] Because this grants a two-decade monopoly to the patent holder, the drugs can be sold at lucrative prices free from competition and allegations of anti-

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[18] Langreth, *supra* note 8. Columbia professor Joshua Ruxin, who runs the clinic in Mayange, lamented that "the hardest truth for people to come to terms with is that the practical solutions are already out there, but they are not being applied." *Id.*

[19] *See* WHO, Towards Universal Access, *supra* note 1, at 61. In developing countries, medicines account for twenty-five to seventy percent of total health expenditures. WHO, WHO Medicines Strategy, *supra* note 5, at 14. In most high-income countries, medicines only account for fifteen percent of health care costs. *Id.* There is, however, existing literature that argues that patent protection is not the number one impediment to accessing antiretroviral drug treatment in African countries. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1890 (2001). "It is doubtful that patents are to blame for the lack of access to antiretroviral drugs in most African countries." *Id.*

[20] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, arts. 27–34, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS]; Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provision*, 10 J. Int'l Econ. L. 921, 971 (2007) (noting the theory that there is no incentive to set low prices because there is no competition).

[21] TRIPS, *supra* note 20, at 27–34. The WTO is an international organization governing trade laws globally. *See generally* WTO, www.wto.org, (last visited Oct. 10, 2008). As of July 2008, 153 countries were members. *Id.* The TRIPS agreement covers the seven principal facets of intellectual property: copyright, trademark, geographical indications, industrial designs, patents, layout designs of integrated circuits, and undisclosed information including trade secrets. J. Michael Finger, *The WTO's Special Burden on Less Developed Countries*. 19 Cato J. 425, 429 (2000) *available at* http://www.cato.org/pubs/journal/cj19n3/cj19n3–9.pdf. Additionally, TRIPS requires some protection of plant varieties. *Id.*

[22] TRIPS, *supra* note 20, arts. 28(1)(a) and 33.

trust violations.[23] However, such right results in high prices which in turn prevent poor countries from purchasing the patented drugs.[24]

To accommodate needy countries to which IPRs have a detrimental effect, TRIPS carves out certain exceptions.[25] Article 31—titled, Other Use Without Authorization of the Right Holder—confers to a member-state the right to use "the subject matter of a patent without the authorization of the right holder."[26] Under Article 31(f), a WTO member may bypass a patent holder's rights in order to create low-cost generic drugs under a set of conditions, most notably that "such use shall be authorized predominantly for the supply of the domestic market" of that member.[27]

Such a provision sounds promising, but, unfortunately, the limitation of this exception, that domestic production can only be for domestic use, has proven unworkable for most developing countries that are the neediest.[28] A member-state is only permitted to bypass the patents of its own domestic rights holders and subsequently distribute and use the products domestically.[29] Yet most countries in need do not have pharmaceutical manufacturers within their borders.[30] And those member-countries that are home to manufacturers are forbidden from exporting them.[31] In 2003, the WTO General Council set out to address this paradox and proposed an amendment to Article 31.[32] The amendment, Article 31bis, allows developed countries to export to developing countries where there is a national health problem.[33]

This Note examines the palpable conundrum of developing countries that are overcome with death and suffering induced by an inability both to treat diseases that are treatable in the developed world and to

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[23] *See id.*; Bruce H. Schneider & Matthew W. Siegal, *New Challenges of Proving "Market Power" in Patent Tying Cases*, 18 PRAC. LITIGATOR 13, 18(2007) *available at* http://files.aliaba.org/thumbs/datastorage/lacidoirep/articles/PLIT_PLIT0703-SCHNEIDER-SIEGAL_thumb.pdf.

[24] WHO, TOWARDS UNIVERSAL ACCESS, *supra* note 1, at 6.

[25] TRIPS, *supra* note 20, art. 30.

[26] *Id.* art. 31.

[27] *Id.* art. 31(f).

[28] *See* World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

[29] TRIPS, *supra* note 20, art. 31(f).

[30] WHO, PUBLIC HEALTH, *supra* note 1, at 120, 152.

[31] TRIPS, *supra* note 20, art. 31(f).

[32] World Trade Organization (WTO) General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, ¶ 2, WT/L/540 (Aug. 30, 2003) [hereinafter WTO General Council].

[33] *See id.*

obtain medications that could easily be made available. Part I highlights the concentration of treatable diseases in developing countries and explores why these regions are unable to access fundamental treatments. Part II outlines the United Nations' (U.N.) process of establishing a system of international patent protection through TRIPS, while simultaneously trying to accommodate its commitment to making life-saving pharmaceuticals available to developing countries. Part III outlines the progression of Article 31bis, an amendment to TRIPS that seeks to make it easier for developing countries to acquire low-cost drugs.[34] This section also looks at why the amendment is not being used. Part IV explores ways in which Article 31bis can be employed, directly and indirectly, to get treatment to the people who need it most. In particular, this Note advocates that in order to treat curable disease, developing countries must be able to afford the treatment that has proven to be life-saving in developed parts of the world.

I. How Patent Law Affects World Health

A. *The Disparity in World Disease*

People in developing countries are dying in large numbers from diseases and medical conditions that have proven to be preventable or treatable in developed countries.[35] In these countries, over half of all deaths are caused by communicable maternal, perinatal, and nutritional conditions.[36] Thirty-four percent of all deaths are caused by infectious and parasitic diseases, such as HIV/AIDS.[37] In comparison, infectious and parasitic diseases—diseases that usually can be easily treated or prevented—account for only two percent of deaths in devel-

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[34] "Bis" means two times in number or amount. Oxford Latin Dictionary 234–35 (1983). In this context, Article 31bis is a provision that comes after Article 31. Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005) [hereinafter WTO Dec. 6, 2005], *available at* http://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

[35] *See* Salomon et al., *supra* note 10, at 54.

[36] WHO, *Revised GBD 2002*, *supra* note 2. Communicable maternal, perinatal, and nutritional conditions include: infectious and parasitic diseases, respiratory infections, maternal conditions (including maternal hemorrhage, maternal sepsis, hypertensive disorders, and obstructed labor), perinatal conditions (including low birth weight, and birth asphyxia/trauma), and nutritional deficiencies (including protein-energy malnutrition, vitamin A deficiency, and iron-deficiency anemia). *Id.*

[37] *Id.* Infectious and parasitic diseases include tuberculosis, STDs, diarrheal diseases, childhood cluster diseases (including pertussis, poliomyelitis, diphtheria, measles, and tetanus), meningitis, and hepatitis B and C. *Id.*

oped countries.[38] Instead, the top trigger of death in developed countries, answering for eighty-six percent of all deaths, is noncommunicable diseases, including cardiovascular disease and cancers, conditions that have limited or no prevention or treatment.[39]

B. *Accessibility of Medicines for Treatable Conditions*

People in developing countries are dying from treatable diseases because they cannot access the medicines that are needed to prevent or remedy these conditions.[40] Domestic conditions, such as poverty and insufficient health infrastructure, poor drug quality, inadequate national health policies, understaffed clinics and hospitals, lack of political commitment, and under-financing of treatment programs are commonly-cited obstacles that inhibit access.[41]

Cost is the forefront barrier to accessing necessary medicines.[42] Developing countries simply cannot afford innovative medicines.[43] It is lack of competition, more often than not, which drives up prices, and it is patent law that confers monopolistic rights to the creators of these medicines, thus allowing the creators to set prices without restraint.[44] Absent patent rights, patent-holders would be constrained by antitrust laws that prohibit monopolies and artificial price-setting.[45] Competitors could acquire or reverse-manufacture recipes for drugs and introduce competition to the market, thus driving down prices.[46]

Examining current AIDS treatment in developing countries illustrates one aspect of the patent problem.[47] First-line AIDS drugs, therapy that was first introduced over fifteen years ago, have improved and

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[38] *Id.*; Salomon et al., *supra* note 10, at 54.

[39] WHO, *Revised GBD 2002*, *supra* note 2.

[40] *See* Westerhaus & Castro, *supra* note 10, at 1232. There are other reasons that developing countries suffer the most from infectious diseases, including the lack of sanitary conditions that facilitate the spread of communicable disease. Mary Gail Hare, *Carroll Relief Group Receives $25 Million; U.S. Grant to Support Health Care in Congo*, BALT. SUN, Aug. 11, 2001, at 1A.

[41] Attaran & Gillespie-White, *supra* note 19, at 1890; Westerhaus & Castro, *supra* note 10, at 1232.

[42] *See, e.g.*, WHO, PUBLIC HEALTH, *supra* note 1, at 112.

[43] Attaran & Gillespie-White, *supra* note 19, at 1891; Westerhaus & Castro, *supra* note 10, at 1232. Ghana, Nigeria, and Tanzania have annual national health care budgets of only eight dollars or less per capita. Attaran & Gillespie-White, *supra* note 19, at 1891.

[44] *See* Abbott & Reichman, *supra* note 20, at 971.

[45] Thomas Chen, *Exclusivity Periods and Authorized Generic Drugs*, HEALTH LAW WEEK, Nov. 9, 2007, at 33; *see* Schneider & Siegal, *supra* note 23, at 18.

[46] Abbott & Reichman, *supra* note 20, at 927–28.

[47] *See* Lara Santoro, *Forget the Patents on AIDS Drugs: Third World Nations Have the Right, and the Duty, to Produce Generic Versions*, L.A. TIMES, Oct. 9, 2007, at 17.

extended the lives of countless citizens in developing countries.[48] But, over the years, many AIDS patients have developed resistance to the old antiretrovirals and now require newer, updated drugs.[49] Unfortunately, second- and third-line AIDS drugs are presently protected by patents and are essentially inaccessible to patients who cannot pay the exorbitant costs.[50] Without access to these successive drugs, people die while waiting for patents to expire.[51] Buddhima Lokuge, the United States manager of Doctors Without Borders, characterizes such a situation as "starting from zero again," since the earlier, first-line treatment went to waste because the subsequent treatments are not available to these patients for financial reasons.[52]

II. The International Approach to Patented medicines

A. *The Push for International Patent Regulation*

One reason pharmaceutical patent holders set prices high is because there is a market that is willing, and financially able, to buy.[53] Partially as a result of patent protection permitting high prices, many poor countries have refused to recognize pharmaceutical patent rights altogether.[54] Some of these are countries only marginally concerned with patent protection because little research and development, an activity IPRs seek to ensure, occurs within their borders.[55] However, one effect of such disregard for patents is to make patent-holders resistant to sell

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[48] *Id.*

[49] Mark A. Wainberg & Gerald Friedland, *Public Health Implications of Antiretroviral Therapy and HIV Drug Resistance*, 279 JAMA 1977, 1977 (1998).

[50] Alexander G. Higgins, *Canada Tells WTO It Will Be First to Export Cheap, Generic AIDS Drugs*, Oct. 5, 2007, http://www.aegis.com/news/ads/2007/AD072099.html.

[51] WHO, Public Health, *supra* note 1, at 112; *see* Wainberg & Friedland, *supra* note 49, at 1980. Strict adherence to antiretroviral therapy is essential to successful treatment. Wainberg & Friedland, *supra* ntoe 49, at 1980. Using less than effective combinations also lowers achievement rates. *Id.*

[52] Santoro, *supra* note 47.

[53] Abbott & Reichman, *supra* note 20, at 971. Patent holders can set high prices because there is lack of competition, and there is a market of affluent persons, even in developing countries, that makes their businesses profitable. *Id.*

[54] *See* Carlos M. Correa, Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 271 (2007). Prior to 1994, approximately fifty countries did not recognize IPRs with respect to medicines. *Id.* Other countries recognized patent rights on the *process* of making the medicine, but not on the resulting *product. See, e.g.*, *Parliament Amends Patent Law*, Facts on File World News Digest, Mar. 31, 2005, at 215B1.

[55] *See* Raj Bawa, *Nanotechnology Patent Proliferation and the Crisis at the U.S. Patent Office*, 17 Alb. L.J. Sci. & Tech. 699, 713 (2007).

their medicines in these countries.[56] Such holders have argued that future research and development will be stifled because their companies will be unable to recover costs.[57] Though international patent protection dates back to the 1883 Paris Convention, it was not until a century later that the international community's interest in worldwide standards of patentability—commonly known as patent law harmonization—piqued.[58] Prior to this time, developed countries had little interest in working with the World Intellectual Property Organization (WIPO), the entity entrusted with facilitating harmonization.[59]

However, due to the growing disregard for patent rights, large multinational corporations (MNCs) began to lobby for international protection, looking for tight regulation and strict standards, while developing countries argued for minimal provisions.[60] The MNCs of the developed countries made headway on their quest when, in the mid-1980s, the U.N. publicized its intention to revise the existing international trade agreement, the General Agreement on Tariffs and Trade (GATT), and received universal support.[61]

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[56] Bernard Pécoul et al., *Access to Essential Drugs in Developing Countries: A Lost Battle?*, 281 JAMA 361, 365 (1999).

[57] Correa, *supra* note 54, at 275. Companies were also worried about parallel importation, which occurs when a manufacturer sells a drug to poor country *A* for price *X*, and *A* sells the drug to developed country *B* for a price slightly higher than *X*, but less than *Y*, which is the amount the manufacturer charges *B* for the same drug. *See* Sisule F. Musungu & Cecilia Oh, Comm'n on Intellectual Prop. Rights, Innovation & Pub. Health (CIPRIH), The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? 27 (2005).

[58] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]; Robert P. Merges et al., Intellectual Property in the New Technological Age 346 (2007). The Paris Convention chiefly concerned mapping out procedures for filing for patent protection in multiple countries. Paris Convention, *supra*, art. 4.

[59] Merges et al., *supra* note 58, at 346. Western businesses considered the WIPO to be unfriendly to their interests. *Id.* The WIPO was established in July 1967 as a specialized agency of the U.N. World Trade Org., Frequently Asked Questions About TRIPS in the WTO, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Oct. 10, 2008) [hereinafter WTO, FAQs]. Its objective is "to promote intellectual property protection throughout the world through cooperation among states and, where appropriate, in collaboration with any other international organization." *Id.*

[60] *See* Jason Nardi, *The TRIPS Traps for Health and Knowledge*, Inter. Press Serv. News Agency, Dec. 19, 2005, *available at* http://www.ipsnews.net/news.asp?idnews=31487. Multinational pharmaceutical corporations, often based in the United States or Western Europe, played a significant role in the development of international law. *Id.* Some activists claim that the resulting international agreement "was introduced against the will of developing countries, under the pressure of multinational companies from the U.S. and Japan." *Id.*

[61] *Id.* The resulting international agreement was developed according to the model of existing patent rights in industrialized, developed countries. Finger, *supra* note 21, at 430.

B. *The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*

In late 1993, at the end of the Uruguay Round of negotiations on this matter, representatives announced both the creation of the World Trade Organization (WTO) and the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[62] The objective of the WTO, an organization established to replace the GATT, is to "help trade flow smoothly, freely, fairly and predictably."[63] The purpose of TRIPS is to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[64]

TRIPS—which came into force on January 1, 1995—provides strong protection for all types of IPRs, including copyrights, trademarks, industrial designs, patents, and undisclosed information.[65] The agreement requires members to comply with certain minimum standards for the protection of IPRs, but members are free to implement laws that give more extensive protection.[66] Obligations apply equally to all member-states, but developing and least-developed countries have

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This places a burden on developing countries in the form of implementation costs (or, alternatively, building a defense against adopting it). *Id.* at 430–31; MERGES ET AL., *supra* note 58, at 346. The GATT was instituted in 1947 and did not cover IPRs in its framework. WTO, FAQs, *supra* note 59.

[62] TRIPS, *supra* note 20; MERGES ET AL., *supra* note 58, at 347.

[63] World Trade Org., The WTO in Brief (2007), *available at* http://www.wto.org/english/res_e/doload_e/inbr_e.pdf.

[64] TRIPS, *supra* note 20, art. 7.

[65] WTO, FAQs, *supra* note 59. *See generally* TRIPS, *supra* note 20, art. 7. Important provisions of TRIPS, as it relates to patents, include: testing patent applications for both the presence of an inventive step and industrial application, including almost all commercial fields within the ambit of patentable subject matter (including pharmaceutical patents), including the right of the patent-holder to control the market for imports of the patented product, and eliminating the practice of granting compulsory licenses for patented technology. *Id.* arts. 27–28. These changes most affected the laws of developing countries. MERGES ET AL., *supra* note 58, at 347. Important provisions of TRIPS that conflicted with U.S. law include: extending the patent term to twenty years (as opposed to seventeen), opening up the "first-to-invent" system by allowing members of the WTO to introduce evidence of inventive acts in their home country for purposes of establishing priority, and expanding the definition of infringement to include acts of unauthorized offering for sale and importing. *Id.*

[66] Finger, *supra* note 21, at 430; WTO, FAQs, *supra* note 59. TRIPS is often characterized as a "minimum standards" agreement. *Id.* This means that each member must institute *at least* the specified levels of protection, but is free to provide more protection. Finger, *supra* note 21, at 430.

been permitted extra time to implement the changes.[67] With regards to patents, one of the key purposes in creating TRIPS was to recognize the interest for patent protection for food, beverage, and medicinal products.[68] The resulting TRIPS provisions on patents, set out in Articles 27–34, are largely a result of the pharmaceutical industry's ability to convince lawmakers to link intellectual property and trade matters.[69]

C. *Article 31: Compulsory Licensing*

TRIPS has significant ramifications for pharmaceutical companies.[70] Principally, it *requires* patent protection for pharmaceuticals, a right that drug-makers in certain countries did not previously have.[71] Moreover, TRIPS significantly extends the period under which drugs are inaccessible to those in developing countries.[72] Such protection, while hailed by patent-holders, has had devastating effects on some countries.[73] A study that looked at the impact of introducing patents on four domestic antibiotics in India (which recently had to come into international compliance) found that the total annual welfare losses would be nearly $305 million, a loss caused by price increases and access limits.[74] Fortunately for these countries, in the midst of these rights, TRIPS provides an important exception to patent protection for pharmaceuticals.[75] Article 31 allows temporary suspension of

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[67] MERGES ET AL., *supra* note 58, at 347. Least-developed countries have until 2016 to make the transition. Westerhaus & Castro, *supra* note 10, at 1230–31. "Least developed" countries are designated based on U.N. indicators including income, nutrition, health, education, literacy, and economic vulnerability. *Id.* The criteria for this designation are available at http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm. *Id.* at 1235 n.5. Industrial countries had until January 1996 to conform to TRIPS' standards, and developing and transition economies had until January 2000. Finger, *supra* note 21, at 429 n.2. The WTO has 109 developing and transition economy members. *Id.* at 435.

[68] CORREA, *supra* note 54, at 271.

[69] TRIPS, *supra* note 20, arts. 27–34; CORREA, *supra* note 54, at 271.

[70] *See* TRIPS, *supra* note 20, arts. 27–34.

[71] *Id.* art. 27; CORREA, *supra* note 54, at 271. When TRIPS was negotiated, about fifty countries did not grant patent protection to pharmaceuticals. *Id.*

[72] TRIPS, *supra* note 20, art. 33; Peng Jiang, Comment, *Fighting the Aids Epidemic: China's Options Under the WTO TRIPS Agreement*, 13 ALB. L.J. SCI. & TECH. 223, 228–29 (2002).

[73] *See* Shubham Chaudhuri et al., *The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market* 35 (Nat'l Bureau of Econ. Research, Working Paper No. 10159, 2003), *available at* http://www.nber.org/papers/W10159.

[74] *Id.*

[75] TRIPS, *supra* note 20, art. 31.

a patent holder's claims in cases of national or extreme emergency.[76] Such an exception is known as a compulsory license.[77] Compulsory licensing—authorization by a government to use a patented product absent an owner's permission—is one way to ensure availability of cutting-edge drugs in nations that are unable to afford them.[78]

Certain conditions accompany such use.[79] The proposed user must "[make] efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."[80] Yet, "in the case of a national emergency or other circumstance of extreme urgency" the above-mentioned requirement may be bypassed, as long as the right holder is "notified as soon as reasonably practical."[81]

Unfortunately, Article 31 also imposes a condition that has rendered the provision essentially useless to many developing countries.[82] Article 31(f) limits use to situations "predominantly for the supply of the domestic market of the Member authorizing such use."[83] That is, a country may issue a compulsory license only to a domestic manufacturer.[84] This creates a precarious situation, because the countries that need the drugs the most are countries that do not have manufacturing capabilities.[85] Under this provision, compulsory export licenses cannot be conferred upon non-domestic suppliers, and manufacturers in one country cannot infringe on a patent in order to supply another country in need.[86] Accordingly, Article 31 has not been used by those who need low-cost drugs the most.[87]

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[76] *Id.* art. 31(b).

[77] *Id.*

[78] James Packard Love, Knowledge Ecology Int'l, Recent Examples of the Use of Compulsory Licenses on Patents 2 (2007), *available at* http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf.

[79] *See* TRIPS, *supra* note 20, art. 31(b).

[80] *Id.*

[81] *Id.* Additionally, the scope and duration of use must be limited to the purpose for which it was authorized and use must be non-exclusive and non-assignable. *Id.* art. 31(c)–(e).

[82] *See* Nardi, *supra* note 60.

[83] TRIPS, *supra* note 20, art. 31(f).

[84] *See id.*

[85] Matthew Royle, *Compulsory Licensing and Access to Drugs*, Pharma Marketletter (U.K.), Dec. 17, 2007 (on file with author).

[86] *See* TRIPS, *supra* note 20, art. 31(f).

[87] *See* Nardi, *supra* note 60.

D. *The Doha Declaration of 2001*

In 2001, the WTO took initial steps to respond to the problem Article 31(f) posed.[88] On November 14, following the WTO's Ministerial Conference at Doha, Qatar, the Declaration on the TRIPS Agreement and Public Health was issued.[89] This is colloquially referred to as the Doha Declaration.[90] The Doha Declaration did not set out specific solutions, but rather publicly recognized problems and uncertainty with TRIPS and committed to developing remedies.[91] The ministers agreed that TRIPS should be interpreted and implemented in a way that supports public health.[92] In addition, they committed the WTO to creating flexibility for countries unable to manufacture pharmaceuticals domestically.[93] Paragraph six of the Declaration reads:

> We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[94]

In making this declaration the WTO ministers took the opportunity to encourage member-states' right to make use of Article 31, and reiterated their prerogative to circumvent patent rights in order to secure better domestic access to necessary medicines.[95]

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[88] *See* Doha Declaration, *supra* note 28, ¶¶ 4, 6.
[89] *Id.* ¶¶ 1–7.
[90] *Id.*
[91] *Id.*
[92] *Id.* ¶ 4.
[93] Doha Declaration, *supra* note 28, ¶ 5.
[94] *Id.* ¶ 6.
[95] *Id.* ¶¶ 4–6. Paragraphs four and five read:

> 4. The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
>
> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (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,

E. *The Waiver of 2003*

Two years later, on August 30, 2003, the WTO General Council announced a solution.[96] The solution, in the form of an interim waiver, allows developed countries to export medicines to needier countries with national health problems.[97] Article 31bis, eponymously "Paragraph Six," amends Article 31 to allow compulsory export licenses for "products of the pharmaceutical sector needed to address the public health problems."[98]

In contrast with Article 31(f)—which restricts compulsory licenses to internal use—Article 31bis authorizes a developed member-state to compel compulsory licenses from its own manufacturers, create generic versions of medications, and export those medications to countries in need.[99] An exporting member must devise a license designating that it will: produce only the amount necessary to meet the needs of the importing member, export the entirety of the production to the specified country, clearly identify products as generic versions under this exception (including distinguishing the products through special packaging, coloring, and/or shaping), post on a website the quantities being supplied to each destination and the distinguishing features of the generic product.[100]

On its end, an importing member must specify the names and expected quantities of product needed and, if the desired medicine is patented in its territory, confirm that it has issued a compulsory li-

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> in its objectives and principles; (b) Each Member has the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] 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; [and] (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Id. ¶¶ 4–5.

[96] WTO General Council, *supra* note 32. The WTO Director-General praised the result, commenting that "it proves once and for all that the organization can handle humanitarian as well as trade concerns." Press Release, World Trade Org., Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003) [hereinafter WTO Aug. 30, 2003 Press Release], *available at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

[97] WTO Aug. 30, 2003 Press Release, *supra* note 96.

[98] WTO General Council, *supra* note 32.

[99] *Id.*

[100] *Id.* ¶ 2(b)(i)–(iii).

cense.[101] In addition, an importing member-state must fulfill one of two conditions: it must be a least-developed country, or it must make a convincing case that it has insufficient or no manufacturing capacity for the product it seeks.[102] All WTO members are eligible to import medicines under Article 31bis.[103]

The provision immediately, however, was resisted.[104] Right away, twenty-three members, all developed countries, voluntarily vowed not to use the system to import.[105] Others committed to only using the provision in real emergencies.[106] Some developed countries urged instituting constraints on the scope of covered diseases.[107] The United States, for one, specifically sought to restrict application to HIV/AIDS, malaria, tuberculosis, and a few other specific diseases.[108] The European Commission suggested making a list of "grave" public health problems.[109] Pharmaceutical companies generally oppose compulsory licensing, claiming that it hurts research and development for new medicines.[110]

Conversely, developing countries worked to expand the definition of eligible diseases and treatments.[111] This time, the developing countries were most successful in negotiations.[112] The resulting waiver defined the covered subject matter broadly, and permitted compulsory licensing for all products in "the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of

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[101] *Id.* ¶ 2(a)(i), (iii).

[102] *Id.* ¶ 2(a)(ii).

[103] WTO General Council, *supra* note 32, ¶ 1(b).

[104] *Id.*; Abbott & Reichman, *supra* note 20, at 933.

[105] WTO General Council, *supra* note 32, ¶ 1(b). These countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States. *Id.* n.3.

[106] WTO Aug. 30, 2003 Press Release, *supra* note 96. These countries include: Hong Kong, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and the United Arab Emirates. *Id.*

[107] Abbott & Reichman, *supra* note 20, at 936.

[108] *Id.*

[109] *Id.* This idea failed, in part, because it could be arbitrary for trade officials to decide which diseases were covered and which were not. *Id.*

[110] *Id.* at 953–54.

[111] Abbott & Reichman, *supra* note 20, at 953–54

[112] *Id.* at 937. The scope of medications and treatments covered in the pending amendment is broad. WTO General Council, *supra* note 32, ¶ 1(a).

the Doha Declaration."[113] Paragraph 1 has no limitation on specific diseases or medicines.[114]

The United States also advocated that the waiver "not be [used] for commercial gain."[115] This, too, was rejected by developing countries.[116] The WTO chair of the General Council did, however, issue a statement that, "members recognize that the system that will be established by the Decision should be used in good faith to protect the public health and . . . not be an instrument to pursue industrial or commercial policy objectives."[117]

F. *The Amendment of 2005: Article 31bis*

On December 6, 2005, the waiver became the first-ever amendment to TRIPS.[118] Designated as Article 31bis, and alternatively identified as a "Protocol Amending the TRIPS Agreement," the amendment will be permanently attached to the TRIPS agreement following Article 31 once it is duly accepted.[119] It will be accepted when two-thirds of WTO-members ratify it.[120]

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[113] Abbott & Reichman, *supra* note 20, at 937.

[114] WTO General Council, *supra* note 32, ¶ 1(a). Paragraph 1 of the Doha Agreement reads, "[w]e recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Doha Declaration, *supra* note 28, ¶ 1.

[115] Abbott & Reichman, *supra* note 20, at 946.

[116] *Id.*

[117] *Id.* at 945–46.

[118] WTO Dec. 6, 2005, *supra* note 34 (noting that the proposed amendment marked "the first time a core WTO agreement [was] amended"); World Trade Organization, Amendment of the TRIPS Agreement, Decision of Dec. 6, 2005, WT/L/641, (Dec. 6, 2005) [hereinafter WTO Decision of Dec. 6, 2005]. The amendment is a compromise among members representing interests of 1) researching and developing, 2) manufacturing and developing, 3) prescribing and treating, and 4) advocating on behalf of patients. Abbott & Reichman, *supra* note 20, at 984.

[119] WTO Decision of Dec. 6, 2005, *supra* note 118; WTO Aug. 30, 2003 Press Release, *supra* note 96.

[120] World Trade Org., Members Accepting Amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Oct. 10, 2008) [hereinafter WTO, Members Accepting Amendment]. In April 2008, Taiwan was the latest to approve the amendment. Ben Shankland, *TRIPS Amendment to Ease Generic Drug Exports Gets Cabinet Approval in Taiwan*, World Markets Research Centre, Apr. 3, 2008 (on file with author). The country still needs to adopt it. *Id.* The proposed amendment was initially open for acceptance until December 1, 2007. WTO Decision of Dec. 6, 2005, *supra* note 118. The final date was later amended to December 31, 2009. World Trade Org., Decision of the General Council of 18 December 2007, Amendment of the TRIPS Agreement—Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement, WT/L/711 (2007) [hereinafter WTO, Extension for Acceptance].

III. Use of the Amendment

A. *Adoption and Creation of Corresponding Legislation*

Member-states have slowly, but gradually, adopted the amendment.[121] By August 2008, forty-four WTO member-states—approximately twenty-nine percent—had ratified Article 31bis.[122] Canada, in May 2004, was the first to implement law to carry out the amendment's mission.[123] The Canadian government passed *An Act to Amend the Patent Act and Food and Drug Act*, legislation authorizing Canada's Commissioner of Patents to grant compulsory licenses permitting the manufacture and export of low-cost versions of patented pharmaceuticals.[124] To facilitate this task, the Act established a legal framework, titled Canada's Access to Medicines Regime (CAMR), which took form the following year.[125]

CAMR's goal is to facilitate timely access to generic, low-cost versions of patented drugs to least-developed and developing countries, to fight HIV/AIDS, malaria, tuberculosis, and other diseases.[126] In keeping with the WTO decision's guidelines, CAMR strives to present a process that is as transparent as possible.[127] It defines safety, effectiveness, quality, and issuance requirements for drugs to be exported.[128]

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[121] *See* WTO, Members Accepting Amendment, *supra* note 120.

[122] *Id.* In ascending order, member-states who have accepted the amendment are as follows: United States (December 2005), Switzerland (September 2006), El Salvador (September 2006), Republic of Korea (January 2007), Norway (February 2007), India (March 2007), Philippines (March 2007), Israel (August 2007), Japan (August 2007), Australia (September 2007), Singapore (September 2007); Hong Kong (November 2007), China (November 2007), the twenty-seven European Communities (November 2007), Mauritius (April 2008), Egypt (April 2008), Mexico (May 2008) and Jordan (August 2008). *Id.* Because less than half the necessary member-states had endorsed the waiver, the WTO extended the deadline from December 2007 to December 2009. WTO, Extension for Acceptance, *supra* note 120. The document granting the extension explains that acceptance by two-thirds of members "is taking longer than initially foreseen." *Id.*

[123] Canada's Access to Medicines Regime (CAMR), Background, http://camr-rcam.hc-sc.gc.ca/intro/context_e.html (last visited Oct. 10, 2008) [hereinafter CAMR, Background].

[124] *Id.*

[125] Douglas Clark & Brigitte Zirger, Government of Canada, Canada's Access to Medicines Regime—Consultation Paper 2, (2006), http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.pdf. The act is also known as "Bill C-9" and the "Jean Chrétien Pledge to Africa." CAMR, Background, *supra* note 123; Clark & Zirger, *supra*, at 13 n.3.

[126] CAMR, Background, *supra* note 123.

[127] Canada's Access to Medicines Regime (CAMR), Features of the Regime, http://camr-rcam.hc-sc.gc.ca/intro/regime_e.html (last visited Oct. 10, 2008) [hereinafter CAMR, Features of the Regime].

[128] *Id.*

Generally, it limits eligible pharmaceuticals to the World Health Organization's Model List of Essential Medicines, but reserves the right to add products to the list.[129] CAMR permits exportation to all countries, regardless of WTO-member status.[130] In order to distinguish them from the patented versions sold in Canada, CAMR requires that the generic drugs be distinguished by special markings, coloring, and labeling.[131] If the cost of the resulting generic product turns out to be more than twenty-five percent of the cost of the patented version in Canada, the framework authorizes patent holders to challenge a compulsory license in court.[132] It also sanctions Health Canada to expeditiously review requests for the drugs in order to avoid delay in emergencies.[133]

Norway, the Netherlands, India, Korea, and China followed suit.[134] In June 2006, the European Union (EU) passed Regulation 816/2006.[135] Article One of Regulation 816/2006 similarly "establishes a procedure for the grant of compulsory licenses in relation to patents concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems."[136] Article Four permits exportation of generic versions of patented medications to all countries with insufficient manufacturing capacity and any country recognized by the U.N. as being a least-developed country (LDC).[137]

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[129] *Id.* An up-to-date version of the World Health Organization's Model List of Essential Medicines is available at http://www.who.int/medicines/publications/essentialmedicines/en/. The concept of essential drugs came about in the 1970s, and the first list was published in 1975. WHO, WHO Medicines Strategy, *supra* note 5, at 16.

[130] *See* CAMR, Features of the Regime, *supra* note 127.

[131] *Id.*

[132] *Id.*

[133] *Id.* Health Canada is Canada's federal health department. Government of Canada, About Health Canada, http://www.hc-sc.gc.ca/ahc-asc/index_e.html (last visited Oct. 10, 2008).

[134] Clark & Zirger, *supra* note 125, at 21. Norway passed legislation in June 2004, the Netherlands in December 2004, India in January 2005, Korea in December 2005, China in January 2006, and the EU in June 2006. *Id.* Switzerland drafted an amendment in November 2005, but it was never enacted. *Id.*

[135] Council Regulation 816/2006, Compulsory Licensing of Patents Related to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems 2006 O.J. (L 157) 1.

[136] *Id.* at 2.

[137] *Id.* at 3. The U.N. List of LDCs is available at http://www.un.org/special-rep/ohrlls/ldc/list.htm.

B. *Use*

Despite the handful of countries that have adjusted or created domestic laws to comply with the amendment, and even more that have articulated support for it, to date, only two sets of countries have chosen to make use of Article 31bis.[138]

1. Canada and Rwanda

On July 19, 2007, Rwanda took the first step in the Article 31bis process and informed the WTO of its intention to import compulsory-licensed pharmaceuticals for public health reasons.[139] In September 2007, Canada became the first country to issue a compulsory export license and granted Apotex, a Canadian generic drug manufacturer, permission to supply TriAvir, a combination AIDS drug, to Rwanda.[140]

In keeping with the conditions of the Canadian legislation, Apotex reported failed attempts at negotiations with TriAvir's patent holders, but will go forward with the license, and pay nominal royalties, which are calculated based on the value of the medication and Rwanda's ranking on the U.N. Human Development Index (UNHDI).[141] If the patent-holder is dissatisfied with the amount paid or any of the other

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[138] *See* Sarah Hiddleston, *Manufacture of Patented Drugs for Export Under Study*, HINDU (India), Feb. 24, 2008, at 9.

[139] Royle, *supra* note 85. An estimated 2.1 percent of Rwandans are infected with HIV. Higgins, *supra* note 50. The Rwandan government used the World Bank model forms to issue its notification. Abbott & Reichman, *supra* note 20, at 941–42.

[140] John Boscariol, *Canada Is First to Grant WTO Compulsory Licence for Export of Generic Drug*, MONDAQ BUS. BRIEFING, Nov. 2, 2007, *available at* http://www.mondaq.com/article.asp?articleid=53944. Apotex plans on distributing 250,000 doses. TriAvir is a fixed-dose, three-combination cocktail consisting of zidovudine, lamivudine, and nevirapine. *Id.* Britain's GlaxoSmithKline owns the patents on the first two antiretrovirals; Germany's Boehringer Ingelheim owns the third. *Id.* Apotex's website documents its mission and posts the statement:

> In the quest to bring quality affordable medications to the world, Apotex was the only company to research and develop a Canadian made triple combination AIDS drug under Canada's Access to Medicines Regime (CAMR). As part of our objective to give back to our communities we decided that we would offer Apo-TriAvir on a "not for profit" basis to countries that would apply through the CAMR. Why are we doing this? It's the right thing to do to alleviate human suffering and save the lives of thousands of people who would otherwise die without access to life saving medicines.

Apotex.com, http://www.apotex.com/apotriavir/abouttriavir.asp (last visited Oct. 10, 2008). The company plans to import around 260,000 packs of TriAvir over the span of two years. Royle, *supra* note 85. The generic version will be called Apo-triAvir. Boscariol, *supra*.

[141] Boscariol, *supra* note 140. Rwanda has a low UNHDI ranking, so the royalties paid will likely be low. *Id.*

terms of the license, it may appeal to the Federal Court to terminate the license.[142] To ensure a successful appeal, the patent-holder must demonstrate that the relevant medication had been re-imported to Canada, exported to a country other than Rwanda, or prove that the generic drug is being sold for greater than twenty-five percent than the cost of the patented original.[143] CAMR seeks to guarantee that generic exports are not commercial in nature; that is, the generic manufacturer must not be making a business out of its right to the compulsory license.[144] Furthermore, Apotex is obligated to report to the patent-holder the quantity of medication in each export and the name of the parties that will handle the medication when it is delivered to the receiving country.[145] In September 2008, Apotex was set to send seven million doses of the generic drug.[146]

2. India and Nepal

In early 2008, Nepal became the second country to apply for an import-license under Article 31bis.[147] Indian drug-manufacturer Natco Pharma responded, and sought out a compulsory license to produce generic versions of two anti-cancer drugs.[148] Natco has proposed to manufacture 45,000 doses of the drugs, and, subject to Article 31(h), remunerate the patent-holders a five percent royalty.[149] The Indian government is currently considering the matter.[150] At the end of February 2008, the proceedings were indefinitely postponed to permit one of the patent-holders the opportunity to lobby for the right to attend the full hearing.[151] As of early April, the hearing was still delayed.[152] It is

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[142] *Id.*

[143] *Id.*

[144] Clark & Zirger, *supra* note 125, at 6.

[145] Boscariol, *supra* note 140.

[146] *TRIPS Mechanism Set to Fail as Apotex Ships ARV*, Pharma Marketletter, Sept. 23, 2008 (on file with author).

[147] Hiddleston, *supra* note 138.

[148] *Id.* The two drugs are erlotinib, owned by Swiss company Roche, and sunitinib, owned by the U.S. company Pfizer. *Id.*

[149] *Id.*; TRIPS, *supra* note 20, art. 31(h).

[150] Hiddleston, *supra* note 138. In India, compulsory licenses are governed by S.92A of the Patent Act, which provides that a license will be issued to supply medicines "to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems." S.92(A)(1), The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

[151] *"Secret" Compulsory License Hearings in India for Roche's Tarceva Under TRIPS Rule*, Pharma Marketletter, Mar. 18, 2008 (on file with author).

[152] *See id.*

likely that the license will be granted if Natco shows that Nepal lacks the local manufacturing capacity to produce generic drugs and if its order request clearly articulates that the drugs will be used for emergency need.[153]

C. *Disuse*

1. Alternatives

The majority of member-states are not seeking to use Article 31bis.[154] A country in need that does not use the TRIPS provision has limited options in procuring low-cost, life-saving drugs.[155] One option is to solicit drugs from countries that are not WTO-members and do not have patent protection for pharmaceuticals.[156] In November 2006 and May 2007, Thailand and Brazil, respectively, took steps to import efavirenz, a cocktail to treat AIDS symptoms, from India to supply 200,000 people for five years.[157] However, this practice cannot continue much longer, as India is a WTO member and, under international law, must comply with the TRIPS terms in the near future.[158]

A second option is to make use of domestic manufacturers' patented products by using the already-accepted Article 31 to issue compulsory licenses.[159] In January 2007, Thailand granted its drug manufacturers the rights to produce generic versions of Kaletra, an AIDS drug.[160]

2. Obstacles

Countries may not be utilizing the TRIPS provision because of the obstacles it involves.[161] In the aftermath of Canada's application process, the Canadian firm Apotex has been openly critical of the procedure for obtaining a compulsory export license.[162] It says the

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[153] *Id.*

[154] *See* WTO, Members Accepting Amendment, *supra* note 120.

[155] *See, e.g.*, Royle, *supra* note 85; Abbott & Reichman, *supra* note 20, at 950–51.

[156] Abbott & Reichman, *supra* note 20, at 950–51.

[157] Royle, *supra* note 85. Merck & Co. holds the efavirenz patent. *Id.* The waiver decision did not apply to the government-issued licenses issued by Brazil and Thailand. Abbott & Reichman, *supra* note 20, at 950–51.

[158] Westerhaus & Castro, *supra* note 10, at 1233.

[159] Santoro, *supra* note 47.

[160] *Id.* Abbot Laboratories owns the patent for Kaletra. *Id.*

[161] *See, e.g.*, Royle, *supra* note 85.

[162] *Id.*

system was "unnecessarily complex," that it "did not adequately represent the interests of those who required treatment, and that the process delayed the act of supplying for over a year.[163] On the other side, one of the patent-holders issued a press release announcing that it "not only does not object to the grant of this authorization under Canada's Access to Medicines Regime but does support the CIPO (Canada Patent Office) decision in this respect."[164]

But bad press from those who have used Article 31bis is not enough to explain why countries are not issuing compulsory licenses.[165] Developing countries may lack the legal and technical expertise necessary to draft appropriate legislation in compliance of TRIPS.[166] Membership in the WTO requires that member-states adhere to all major WTO treaties, including TRIPS.[167] In order to take advantage of TRIPS's exceptions, a member-state must construct its own laws to come into compliance with the other terms of TRIPS.[168] For example, to comply with TRIPS, the United States had to increase its term of patent protection from seventeen years to the twenty years mandated by TRIPS.[169] The agreement gives countries, depending on their levels of economic development, a certain term of years in which to comply with TRIPS's requirements, and some still have not crafted the required legislation.[170]

WTO rules might be unmanageable and too complicated for poor countries to interpret and utilize.[171] The process for issuing a compulsory license is arduous, as evidenced by Apotex's public comments.[172] First, there must be a national emergency, a term which the WTO does not define.[173] Once an emergency has been identified, the country must request a license from the patent-holder and attempt to agree on licensing terms.[174] Many patent-holders have traditionally taken advan-

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[163] *Id.*

[164] Higgins, *supra* note 50.

[165] *See, e.g.*, John Zarocostas, *WTO to Offer Its Trademark Expertise*, J. Com., Jul. 24, 1998, at 3A.

[166] *Id.*

[167] WTO, FAQs, *supra* note 59.

[168] *See id.*

[169] Love, *supra* note 78, at 3.

[170] TRIPS, *supra* note 20, art. 65.

[171] Westerhaus & Castro, *supra* note 10, at 1232.

[172] TRIPS, *supra* note 20, art. 31(b).

[173] *Id.*

[174] *See* Steven Seidenberg, *Drug Companies Lobby to Stall WTO's New Compulsory License Provision*, Inside Counsel, Feb. 2008, at 20.

tage of this requirement and stretched negotiations on for years.[175] If no agreement is reached, the country must jump through substantial administrative hoops before it can issue a compulsory license.[176]

The exact procedures of issuing a compulsory license remain unclear.[177] As evidenced by international disapproval when Thailand tried to navigate the exception, countries seem to have little support in figuring out the rules and processes.[178] Many of the provisions are undefined, and, until recently, have gone untested.[179] For example, the term "developing country" remains without a universal definition: EU Commissioner Peter Mandelson argued that Thailand did not fit into this category, but the issue was never concretely resolved.[180]

3. Resistance

Experience shows that when a country does decide to invoke Article 31, it is received with animosity.[181] When Thailand issued a compulsory license in 2007, both the United States and the European Union condemned its actions, censuring the country and putting it on a "priority watch list."[182]

Furthermore, countries, developed and developing alike, don't want to make enemies of powerful drug companies.[183] MNCs are powerful international entities that bring jobs and economic stabil-

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[175] *Id.*

[176] *Id.*

[177] *See* Westerhaus & Castro, *supra* note 10, at 1231.

[178] *See id.*

[179] *Id.*

[180] *European Parliament in Push for Greater Access to Generic Drugs*, World Generic Mkts., Nov. 7, 2007; Santoro, *supra* note 47; Westerhaus & Castro, *supra* note 10, at 1231.

[181] *See* Santoro, *supra* note 47.

[182] *Id.* The U.S. Trade Representative stated that:

> [I]n Thailand, in late 2006 and 2007, there were further indications of a weakening of respect for patents, as the Thai government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval.

Abbott & Reichman, *supra* note 20, at 954.

[183] Santoro, *supra* note 47; Seidenberg, *supra* note 174.

ity.[184] To cross them might mean losing them.[185] Developing countries and least-developed countries are resistant to bypassing patents of powerful pharmaceuticals because they do not want to scare them off or detract future investors.[186] Governments of countries plagued with disease are faced with a double-edged sword.[187] They feel the need to help their people, yet do not want to blacklist themselves with corporations that could affect their economic sustainability in the future.[188]

Pharmaceutical companies have many reasons to feel threatened by compulsory licensing.[189] One concern is that countries that take advantage of compulsory licensing will resell the drugs in developed countries to make a profit instead of providing them to their own people.[190] Pharmaceutical companies are also concerned that if manufacturers lower their prices in some countries, political pressure will mount in developed countries for the companies to lower their prices to comparable levels.[191] Additionally, companies fear that once one developing country uses Article 31, many other countries will follow suit, and create a domino effect of issuing cheap medicines.[192] Seventy percent of the world's forty million people currently infected with HIV/AIDS live in Africa, a continent full of countries eligible to use Article 31.[193] Pharmaceutical companies worry that if one African country successfully navigates the exception, the rest will follow.[194]

IV. How to Get Drugs to Countries in Need

Rwandan Jennifer Uwimana is just one success story that shows the life-saving effects of accessing necessary treatments.[195] In 2006, at age one, Uwimana suffered from AIDS and tuberculosis and weighed

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[184] H.D.S. Greenway, Op-Ed., *Globalism Reaches Deep into Our Lives*, Boston Globe, May 17, 2002, at A19.

[185] Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS, and an Overview of the Practice in Canada and the USA* 6 (2003), *available at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf.

[186] Seidenberg, *supra* note 174.

[187] *See* Santoro, *supra* note 47.

[188] *Id.*

[189] Seidenberg, *supra* note 174.

[190] *Id.*

[191] *See id.*

[192] Santoro, *supra* note 47; Seidenberg, *supra* note 174.

[193] Santoro, *supra* note 47; Seidenberg, *supra* note 174.

[194] *See* Santoro, *supra* note 47; Seidenberg, *supra* note 174.

[195] Langrath, *supra* note 8.

just forty percent of normal weight.[196] Because her mother was able to get Uwimana to a clinic, the toddler now has a healthy weight and receives treatment for her HIV infection.[197]

A. *Lower Drug Prices*

The cost of treatments for infectious diseases must be reduced.[198] New York University economist William Easterly believes millions of people every year in developing countries are not dying from infectious diseases such as malaria and tuberculosis, but rather from conditions that do not have scientific names such as lack of basic prerequisites necessary for delivering care.[199] In order to get the international community to take these conditions seriously, Easterly wants to assign important-sounding Latin names to situations such as "missing health worker," or "stolen drugs."[200] Another killer, that he does not mention, might as well be "expensive treatments."[201]

To ease pain and suffering, drugs need to be made more affordable.[202] There are many cases that prove that infectious diseases can be eradicated through providing adequate medication to those in need.[203] The program of major pharmaceutical giant, Merck, to tackle onchocerciasis (river blindness which is spread by black flies in parts of Africa) has treated over 530 million cases with its antiparasitic ivermectin, and has prevented 40,000 cases per year.[204] The efforts of the Carter Center to confront cases of Guinea worm (a parasite that slowly burns through the skin) have reduced the number of infections from 3.5 million in 1986 to 25,000 in 2007.[205] However, there are only so many private donors and good-will grants.[206] A more comprehensive plan must

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[196] *Id.*

[197] *Id.*

[198] *See* Attaran & Gillespie-White, *supra* note 19, at 1891. Poor countries cannot pay for treatments. *Id.* Indeed, even if antiretroviral drug prices continue to decline, the poorest nations still will not be able to afford them. *Id.*

[199] Langrath, *supra* note 8.

[200] *Id.*

[201] *See id.*

[202] Attaran & Gillespie-White, *supra* note 19, at 1891.

[203] *See* Langrath, *supra* note 8.

[204] *Id.*

[205] *Id.*

[206] *See* WHO, WHO Medicines Strategy, *supra* note 5, at 57. Private sources of funding have become more important in the past decade, but countries with high HIV/AIDS mortality are still incapable of spending the necessary amount on medicines. *Id.*

be established to ensure the availability of low-cost generic medications.[207]

B. *Recognize That Compulsory Licensing Does Not Stifle Innovation*

A fundamental theory of patent law is to provide market-driven incentives, that is, full economic rewards, to a creator in order to get him or her to devote time and money to developing an innovative product.[208] Pharmaceutical manufacturers argue that compulsory licensing undermines the production of new drugs by stifling innovation.[209]

At first glance, this assertion makes sense.[210] However, it has frequently proven to be a weak argument.[211] First, studies demonstrate that there is no uniform decline in scientific innovation when compulsory licensing is put in play.[212] Second, more than half of all retroviral drugs, such as the one replicated by Thailand, were researched completely on funding from U.S. grants.[213] In the United States, pharmaceutical companies receive extensive tax breaks on research and development of medicines.[214] These studies have revealed that pharmaceutical companies actually spend seventy-five percent less than what they claim to spend in order to create a drug.[215] Furthermore, of the twenty-one most influential drugs introduced between 1965 and 1992, only five were developed entirely by the private sector.[216] Third, current patent protection has not created incentives to develop drugs most needed by developing countries, such as medicines to treat malaria and tuberculosis.[217]

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[207] *See id.*

[208] Merges et al., *supra* note 58, at 127. The U.S. Constitution and U.S. case law frequently emphasize the incentive theory. *Id.* at 11.

[209] Westerhaus & Castro, *supra* note 10, at 1232.

[210] *See* Merges et al., *supra* note 58, at 10–17.

[211] *See* Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 Berkeley Tech. L.J. 853, 876–78 (2003).

[212] *Id.* at 877.

[213] Santoro, *supra* note 47.

[214] *How Much Does It Really Cost to Manufacture a Drug?*, Guardian (London) (Special Supplement), Feb. 18, 2003, at 10.

[215] *Id.*

[216] Cong. Budget Office, Research and Development in the Pharmaceutical Industry 27 n.1 (2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10–02-DrugR-D.pdf.

[217] Attaran & Gillespie-White, *supra* note 19, at 1890; Pécoul et al., *supra* note 56, at 364.

Indeed, between 1975 and 1997, only 13 out of 1223 new drugs were specifically targeted towards diseases disproportionately affecting developing countries.[218] There is little economic incentive to cater to antiretroviral drug research in developing countries as opposed to more profitable markets such as that of the United States.[219] Other reasons large pharmaceutical companies have little interest in patent protection in the developing world are costs of litigation and poor judicial systems.[220]

In a study published in 2003, attorney Colleen Chien explored whether past compulsory licenses over drugs were accompanied by a reduction in innovation, and found that in five of the six cases she studied, there was no measurable decline.[221]

Furthermore, the argument that patents are provided to encourage innovation and ensure further research and development is getting in the way of accomplishing the purpose for which these medicines should be created.[222] That is, medicines should be made to treat sickness and disease. But if these same medicines are unavailable to those who can most benefit from them (because of high costs or other factors), the reasons for their existence cease to matter.[223]

Existing research suggests that two factors must be present for compulsory licenses to affect innovation: predictability of the license being granted and the significance of the market affected by the license.[224]

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[218] Pécoul et al., *supra* note 56, at 364. Two of the thirteen were updated versions of existing treatments. *Id.* Only four of the thirteen were direct results of research and development by the pharmaceutical industry. *Id.*

[219] Attaran & Gillespie-White, *supra* note 19, at 1890. The African pharmaceutical market is only 1.1% of the global market. *Id.* The market share of antiretroviral drugs sold to the poorest third of the world is a mere 0.5%. *Id.*

[220] *Id.*

[221] Chien, *supra* note 211, at 856–57. Chien studied six cases in which the Federal Trade Commission (FTC) issued compulsory pharmaceutical licenses in the 1980s and 1990s for antitrust purposes. *Id.* at 880–81.

[222] *See* Correa, *supra* note 54, at 275; Merrill Goozner, The $800 Million Pill: The Truth Behind the Cost of New Drugs 237 (2004). In November 2001, the Tufts University Center for the Study of Drug Development, predominantly funded by the pharmaceutical industry, released an estimate that the average cost of a new drug was $802 million. Goozner, *supra.* The researchers attribute this price to the cost of research and development. *Id.*

[223] *See* Westerhaus & Castro, *supra* note 10, at 1232.

[224] Chien, *supra* note 211, at 880. These factors are necessary, but not sufficient. *Id.* at 881.

C. *Encourage Compulsory Licensing*

Compulsory licensing is one way, both directly and indirectly, to advance access to medicines.[225] Directly, compulsory licensing bypasses a patent holder's IPRs and allows for cheaper, generic versions to be manufactured.[226] Rwanda and Canada, and most recently, Nepal and India, have sought to use this route of obtaining affordable medications.[227] Indirectly, compulsory licensing often forces patent-holders to lower their prices significantly in order to remain the sole provider of a medicine.[228] In some cases, the pending amendment worries pharmaceutical companies.[229] As a result, backed by the threat of compulsory licensing, poorer governments have been enabled to negotiate lower prices with drug companies.[230] Thailand, for example, was able to produce low-cost generic drugs by dishonoring a patent.[231] By doing so, multinational pharmaceutical companies dropped their prices significantly.[232]

Another sixty WTO members are still required to ratify Article 31bis, but, along with the rest of Article 31, it has potential to increase drug accessibility.[233]

D. *Follow the Lead of Canada*

Canada appears to be an achievable prototype to follow since the country has a vibrant history of freely and comprehensively issuing

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[225] *See* Abbott & Reichman, *supra* note 20, at 953; *Activists Say Thai Generic Drugs Scheme "Beacon" for Poor*, Nov. 24, 2007, *available at* http://www.essentialaction.org/access/index.php?/archives/90-Thai-Generic-Drugs-Scheme-a-Beacon-for-Poor-Activists.html.

[226] *Activists Say Thai Generic Drugs Scheme "Beacon" for Poor, supra* note 225.

[227] Hiddleston, *supra* note 138; Higgins, *supra* note 50.

[228] *See* Abbott & Reichman, *supra* note 20, at 953. After the Thai government issued a public use license for Merck's efavirenz, Merck reduced its price from double the generic cost to only twenty percent more than the generic cost. *Id.*

[229] Seidenberg, *supra* note 174.

[230] Abbott & Reichman, *supra* note 20, at 953.

[231] Sarah Boseley, *Trade Terrorism: U.S. Attempts to Stop Developing Countries Producing Cheap AIDS Drugs Have Become a Political Bomb*, GUARDIAN (London), Aug. 11, 1999, at 18.

[232] *Id.* In 1992, the AIDS drug zidovudine cost $324 per dosage in Thailand. *Id.* By 1995, the manufacturer reduced it to $87. *Id.* Similarly, once three Thai companies began making a generic version of fluconazole (an antibiotic used to treat meningitis), Pfizer dropped its price of the brand version from $14 a dose to $1 a dose. *Id.*

[233] *See European Parliament in Push for Greater Access to Generic Drugs, supra* note 180. Fifty-six member-states were needed as of March 2008. *Id.*; WTO, Members Accepting Amendment, *supra* note 120.

compulsory licenses on patented pharmaceuticals.[234] Studies show that innovation in Canada has not been curbed, and, in the past century, the country has been able to build a strong domestic generic drug industry in order to stop patent abuse.[235] Making use of its history in dealing with patent-holders and generic manufacturers, in implementing the provisions of Article 31bis, the Canadian government engaged in meaningful discussions with major players that would be affected by its decision.[236]

The United States's experience with compulsory licenses is markedly different.[237] In a 1980 decision, the Supreme Court noted that usage of compulsory licensing in the American patent system was rare and was never widely adopted.[238] That said, the United States frequently uses compulsory licensing as a remedy to antitrust violations.[239] The United States has also threatened to use Article 31 many times in the past.[240] And the United States is an important player in the pharmaceutical world. In the 1990s, one half of the global pharmaceutical innovation, 370 new drugs, was created by U.S. industry.[241]

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[234] *See* Chien, *supra* note 212, at 876; Reichman & Hasenzahl, *supra* note 185, at 20. Throughout the twentieth century, Canada had a policy of encouraging local manufacture of patented products. Reichman & Hasenzahl, *supra* note 185, at 20. Prior to the 1930s, local licensing had to occur within two-years after the patent was issued. *Id.* The 1935, 1970, and 1985 revisions of the Patent Act loosened this policy a little in favor of patent protection, but still liberally granted compulsory licenses in the face of any patent abuse. *Id.* Reasons for this policy included "made-in-Canada for Canada" pride and an interest in promoting the public interest, even at the expense of patent rights. *Id.*

[235] Chien, *supra* note 212, at 876. In a 1985 comparison of research and development intensities in Canada to intensities in other small, developed countries, the Eastman Commission found that compulsory licensing did not significantly affect innovation under Canada's system. *Id.* at 877. Instead, lack of Canadian patent protection had minimal influence on research and development. *Id.*

[236] CAMR, Features of the Regime, *supra* note 127; *see* Clark & Zirger, *supra* note 125, at 12.

[237] *See* Reichman & Hasenzahl, *supra* note 185, at 21.

[238] Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 215 & n.21 (1980).

[239] Correa, *supra* note 54, at 313. *See, e.g.*, United States v. Nat'l Lead Co., 332 U.S. 319 (1947); Hartford-Empire Co. v. United States, 323 U.S. 386 (1945).

[240] Love, *supra* note 78, at 3–4. In 2001, Department of Health and Human Services (DHHS) Secretary Tommy Thompson threatened to use a compulsory license to authorize imports of generic ciprofloxacin to be used against a possible anthrax attack. *Id.* at 3. In November 2005, DHHS Secretary Michael Levitt testified before Congress that he had required the patent owners of Tamiflu, an avian flu medication, to make their drug available in bulk in the United States should there be a pandemic. *Id.* In a case that came to a head in 2007, Zoltek Corporation, who holds a patent on a process for making material used in F-22 fighter jets, complained that the United States government was importing the product from an unlicensed manufacturer abroad and not paying royalties to Zoltek. *Id.* at 3–4.

[241] Goozner, *supra* note 222, at 7.

Conclusion

Millions of lives are unnecessarily lost every year because of the price of medications. With studies that show that compulsory licensing does not significantly inhibit innovation or production, these prices are unnecessarily high as well. In order to improve world health, all countries with people suffering from treatable diseases *must* be able to afford medicines that can save their lives. Though the United States, for one, has always used a market-based approach in encouraging the creation of new medicines, financial reward is not the only inducement that incentivizes innovation. In an essay and art contest—titled, What I Really Want That Money Can't Buy— "an overwhelming number [of entrants] identified world peace as the number one thing they want that money can't buy."[242] Improving the quality of life and ultimately saving lives for the people of just one African country suffering from treatable diseases is enough to qualify as creating world peace.

The privately-funded and good-will projects that have been carried out show that putting medications into the hands of sick people *will* save lives. Small pox has been eradicated and measles is at an all-time low.

The lobbying powers of pharmaceutical companies will always be mammoth and intimidating. It is up to the developed countries, such as the United States, to issue compulsory licenses and help provide for suffering people. Developing countries will understandably be hesitant in standing up to these interests, and it is up to the wealthier and more influential to care for those in need.

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[242] Betsy Taylor, What Kids Really Want That Money Can't Buy: Tips for Parenting in a Commercialized World 110 (2004). Over 1700 entries were considered in the contest. New American Dream, Essay/Art Contest, http://www.newdream.org/kids/contest.php (last visited Oct. 10, 2008).