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Stephanie Skees

THAI-ING UP THE TRIPS AGREEMENT: ARE COMPULSORY LICENSES THE ANSWER TO THAILAND'S AIDS EPIDEMIC?

Stephanie Skees*

"The patent system added the fuel of interest to the fire of genius." - Abraham Lincoln

I. INTRODUCTION

In November 2006, Thailand met with international praise after announcing its intention to issue compulsory licenses for the HIV/AIDS[1] drug efavirenz (Stocrin).[2] A compulsory license

* J.D. Candidate, California Western School of Law, Spring 2008. B.A., University of California, Santa Barbara. The author would like to thank all of her friends and family for their patience and support and expresses many thanks to Professor Gloria Sandrino for her generous guidance.

[1] *See* Department for Health and Human Services, Centers for Disease Control and Prevention, Basic Information, http://www.cdc.gov/hiv/topics/basic/index.htm#hiv (last visited Apr. 21, 2008). Human immunodeficiency virus (HIV) is the retrovirus that causes AIDS. *Id.* Unlike most viruses, HIV attacks the immune system, specifically white blood cells called T cells or CD4 cells. *Id.* Acquired immune deficiency syndrome (AIDS), is the final stage of HIV infection. *Id.* Even without treatment, it can take years for a person infected with HIV to reach this final stage. *Id.* Having AIDS means that the virus has weakened the immune system to the point at which the body has a difficult time fighting infections. *Id.* A person is diagnosed with AIDS when that person has one or more of these opportunistic infections and a low number of T cells. *Id.* There is presently no cure for HIV/AIDS. *Id.*

[2] Letter from the Department of Disease Control to Merck Sharp and Dohme (Nov. 29, 2006), *in* MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE THAIL., FACTS AND EVIDENCE ON THE 10 BURNING ISSUES RELATED TO GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND 47-48 (Vichai Chokevivat ed., 2007), http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf [hereinafter 10 BURNING ISSUES]. Thailand has received little opposition for issuing three compulsory licenses. U.S. Senators Joseph Lieberman, Thomas Carper, Robert Menendez, Dianne Feinstein, and Frank Lautenberg wrote a letter to Susan Schwab of the Office of the United States Trade Representative (USTR) to "express concern" over the Thai government's program of compulsory licensing. Letter from Senator Joseph Lieberman and Four U.S. Senators to Ambassador Susan F. Schwab (March 20, 2007), *available at* http://www.keionline.org/misc-docs/liebermanplus4.pdf [hereinafter Letter from Senator Lieberman]. Additionally,

forces the patent holder to license its patent to the issuing government, allowing the government to produce or import generic[3] copies of the drug while paying little compensation to the patent holder.[4] In December, more than 140 organizations and individuals sent letters to Secretary of State Condoleezza Rice and to Susan Schwab of the Office of the United States Trade Representative (USTR) asking the US to refrain from interfer-

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Thailand was elevated from the "Watch List" to the "Priority Watch List" on the USTR's 2007 "Special 301" Report due to "a concern that the past year has been characterized by overall deterioration in the protection and enforcement of intellectual property rights (IPR) in Thailand." Office of the United States Trade Representative, USTR 2007 Special 301 Report, *available at* http://www.ustr.gov/Document_Library/Reports_ Publications/2007/2007_Special_301_Review/Section_Index.html?ht., at 27. Pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1998 and the Uruguay Round Agreements Act, under Special 301 provisions, the "USTR must identify those countries that deny adequate and effective protection for IPR or deny fair and equitable market access for persons that rely on intellectual property protection." *Id.* at 17. The "Special 301" report is issued annually by the USTR and carefully reviews the adequacy and effectiveness of IPR protection in 87 countries. *Id.* at 2. Countries that have "the most egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products are designated as Priority Foreign Countries." Countries on the "Priority Watch List do not provide an adequate level of IPR protection or enforcement." *Id.* Countries on the "Watch List merit bilateral attention to address underlying IPR problems." *Id.* In reaction to Thailand's elevated placement in the "Special 301" report, thirty five members of Congress sent a letter to the USTR demanding that Thailand be removed from the Priority Watch List. Letter to Ambassador Susan F. Schwab from Representative Henry Waxman and 34 Members of Congress (June 20, 2007), *available at* http://www.house.gov/waxman/pdfs/thailand%20letter%20to%20ustr%2006-20-07.pdf (arguing that Thailand's elevation to the Priority Watch List was in retaliation to their recent issuance of compulsory licenses). Ambassador Schwab responded that although the compulsory licenses for medications were considered, Thailand was placed on the Priority Watch List for a broad range of long term IPR concerns related to copyrights, trademarks, and patents. Letter to Representative Henry Waxman and 34 Members of Congress from Ambassador Susan F. Schwab (July 9, 2007) (on file with author).

[3] *See* U.S. Food and Drug Administration, Office of Generic Drugs, http://www.fda.gov/cder/consumerinfo/generic_info/generics_question_brochure.htm (last visited Apr. 27, 2008). After a drug patent has expired, other companies may sell a drug under its generic name or another brand name. *Id.* A generic version of a drug is required to be biologically equivalent to the previously approved drug. *Id.* A biologically equivalent drug has the same rate and extent of absorption and produces the same blood concentration levels when the two drugs are given in the same dose and the same dosage form. *Id.*

[4] *See* Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237, 243-44 (2002).

ing with Thailand's actions.[5] After receiving such a positive response, Thailand issued two more compulsory licenses, one in January for the AIDS drug Kaletra®[6] and one in February for the heart disease drug clopidogrel bisulfate (Plavix).[7] Since then, Thailand has announced that it is considering breaking the patents of eleven other drugs and intends to issue at least two more compulsory licenses by the end of 2007.[8]

There is no doubt that Thailand as well as many other developing countries[9] have a serious need for affordable prescription drugs. However, pharmaceutical companies[10] are not non-

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[5] Tove Iren S. Gerhardsen, *Thailand Compulsory License On AIDS Drug Prompts Policy Debate*, INTELLECTUAL PROPERTY WATCH, Dec. 22, 2006, http://www.ip-watch.org/weblog/index.php?p=499&print=1&res=1280&print=1.

[6] Letter from Department of Disease Control to Abbott Laboratories Ltd. (Jan. 26, 2007), 10 BURNING ISSUES, *supra* note 2, at 49-50.

[7] Letter from the Permanent Secretary Office to Sanofi-Synthe'labo (Thailand) Ltd. (Feb. 12, 2007), 10 BURNING ISSUES, *supra* note 2, at 51-52.

[8] James Hookway & Nicholas Zamiska, *Thai Showdown Spotlights Threat to Drug Patents*, WALL ST. J., Apr. 24, 2007, at A1; *Thai Government to Issue Compulsory Licenses for Two More Drugs*, KAISER DAILY HIV/AIDS REPORT, May 30, 2007, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=45220.

[9] There are no UN or WTO definitions for "developed" or "developing" countries. World Trade Organization, Who are the Developing Countries in the WTO?, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Apr. 27, 2008). Members decide for themselves whether they are "developed" or "developing." *Id.* In regards to its WTO membership, Thailand has declared itself a developing country. According to the UN:

> [A] country is classified as a [Least Developed Country] LDC if it meets three criteria based on: 1. low income (three year average GNI per capita of less than U.S. $750, which must exceed $900 to leave the list, 2. human resource weakness (based on indicators of nutrition, health, education, and adult literacy), and 3. economic vulnerability (based on instability of agricultural production, exports of goods and services, economic importance of non-traditional activities, merchandise export concentration, and handicap of economic smallness). To qualify as an LDC, a country must meet all three criteria.

United Nations, *The Criteria for the Identification of the LDCs*, http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm (last visited Apr. 27, 2008).

[10] In this article, "pharmaceutical companies" refers to the research based pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers of America (PhRMA) trade association. Pharmaceutical companies have traditionally been categorized as either research companies (e.g. Pfizer, Merck) or generic companies without significant research programs (e.g. Mylan Labs, Cipla Ltd.). *See* Pharmaceutical Research and Manufacturers of America, http://www.phrma.org (last visited Apr. 27, 2008). The international trade association of pharmaceutical research companies is the International Federation of Pharmaceutical Manufacturers Association (IFPMA). *See* International Federa-

profit organizations. They make products that save millions of lives and that improve the quality of life for millions more, but pharmaceutical companies are not charities. Drug manufacturers, like every other company, are in business to make money. Additionally, the products made by these companies incur huge research and development (R&D) costs.[11] The United States is a capitalist country and corporate social responsibility is not mandated by American laws.[12] Moreover, there are many other factors affecting the affordability of and access to drugs in developing countries other than the price set by pharmaceutical companies. Poor health care infrastructures and a lack of adequately trained doctors and nurses contribute significantly to the inadequate accessibility of drugs in developing countries.[13] Additionally, hidden costs in the procurement of essential

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tion of Pharmaceutical Manufacturers Association, http://www.ifpma.org (last visited Apr. 27, 2008). Generic drug companies have their own trade associations, such as Generic Pharmaceutial Association (GPhA). *See* Generic Pharmaceutical Association (GPhA), http://www.gphaonline.com (last visited Apr. 27, 2008). Biotechnology companies differ from pharmaceutical companies in that rather than mixing chemicals to generate conventional drugs, biotech companies create far more complex substances that mimic those produced by the human body. These substances are made by growing live cells, extracting and then purifying their excretions. *See generally* What is Biotechnology?, http://www.bionewsonline.com/9/what_is_biotechnology.htm (last visited September 11, 2008). Most American biotech companies belong to the trade association Biotechnology Industry Organization (Bio). *See* Biotechnology Industry Organization (Bio), http://www.bio.org (last visited Apr. 27, 2008).

[11] On average, it costs $800 million to develop a single new drug. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? AND OTHER QUESTIONS ABOUT YOUR MEDICINES (2005), http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf [hereinafter Cost of Prescription Drugs].

[12] *See generally* Cynthia A. Williams, *Corporate Social Responsibility in an Era of Economic Globalization*, 35 U.C. DAVIS L. REV. 705 (2002) (discussing the predominant academic and legal view in the U.S. on corporate social responsibility).

[13] "Limited basic infrastructure, especially in rural areas, limited health care infrastructure and equipment, limited human resources, limited training, poor food security and poor access to clean water, psychological and social issues, treatment and monitoring costs, compliance with therapy, and logistical challenges of supply chain management" are some of the biggest challenges to drug access. Dr. Harvey Bale, Director General, IFPMA, Presentation at the G8 Summit: Improving Health Care in Africa 12 (May 31, 2007), http://www.ifpma.org/Events/content/Past_Events/pdfs/HB%20Improving%20Health%20Care%20Africa%2031May07.pdf [hereinafter G8 Summit].

medicines[14] can more than double the price of medicines between manufacturer and patient.[15] If countries continue to ignore these underlying problems and abuse compulsory licenses, not only will developing countries suffer in the long run, but it is the U.S. consumer that will pay the price.[16]

This article will discuss how current international patent law affects developing countries' access to medications and whether compulsory licensing is the solution to the AIDS epidemics in Thailand and other developing countries. It will specifically focus on Thailand's issuance of compulsory licenses and the ultimately harmful ramifications it will have, not only on Thailand and other developing countries, but also on the U.S. consumers that will be forced to unfairly bear the burden of pharmaceutical and biotechnology R&D costs. Part II will discuss Thailand's recent actions with regard to intellectual

[14] Essential medicines are those that satisfy the priority health care needs of the population. *See* World Health Organization, Essential Medicines, http://www.who.int/topics/essential_medicines/en (last visited April 27, 2008). They are selected based on efficacy, safety, and comparative cost-effectiveness. *Id.* They are intended to be available within health care systems at all times in adequate supply, with assured quality, and at a price the individual and the community can afford. *Id.* The drugs are classified by their name and their therapeutic group. *See id.* The WHO list of essential medicines has been updated every two years since 1977. The current list is the fifteenth version dated March 2007. *See* World Health Organization, *WHO Model List of Essential Medicines*, http://www.who.int/medicines/publications/EssMedList15.pdf (last visited Apr. 27, 2008).

[15] The price a patient pays for medicines includes the base price (i.e. the manufacturers' price) as well as additional costs for transportation, storage, import tariffs and taxes, wholesale and retail markups, staff salaries, stock losses, and procurement practices. Libby Levinson & Richard Laing, *The Hidden Costs of Essential Medicines*, 33 WHO ESSENTIAL DRUGS MONITOR 20 (2003), http://mednet2.who.int/edmonitor/33/edm33_en.pdf. These additional costs are due to government health and taxation policies and health systems with outdated and inefficient procurement practices. Libby Levinson, Policy and Programming Options for Reducing the Procurement Costs of Essential Medicines in Developing Countries (2003) (unpublished Concentration Paper, on file with author and Boston University School of Public Health). Thailand is among the 20% highest countries for customs duties on retail medicaments (15%) and for EU pharmaceutical imports (10%). *Developing Countries' Duties and Taxes on Essential Medicines Used in the Treatment of the Major Communicable Disease* (European Commission, Dir. Gen. for Trade, Working Document, 2003), http://trade.ec.europa.eu/doclib/docs/2003/june/tradoc_113184.pdf.

[16] *See* Letter from Senator Lieberman, *supra* note 2; *see also* Press Release, PhRMA, PhRMA Meets with Thai Health Minister; Highlights Consequences of Compulsory Licenses (May 22, 2007), http://www.phrma.org/news_room/press_release/phrma_meets_with_thai_health_minister/ [hereinafter PhRMA Meets with Thai Health Minister].

property rights and the reactions and concerns those actions raised. It will also address other options Thailand has in fighting HIV/AIDS. Additionally, Part II will consider the situation through the pharmaceutical companies' perspective. Part III will discuss international intellectual property law as administered by the World Trade Organization through the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and the Doha Declaration on TRIPS and Public Health. It will also discuss Thailand's Patent law and how it deals with compulsory licenses. Part IV will argue that Thailand's actions are misguided and in the long run will actually decrease the availability of affordable medications in developing countries, as well as scare off the foreign investors that so many developing countries desperately need. This article will also argue that if drug manufacturers are forced to relinquish their patent rights and to give away their products to developing countries, then not only will medical innovation suffer, but U.S patients will have to pay higher drug costs to support pharmaceutical R&D. This section suggests that, although the flexibility of TRIPS that allows for compulsory licenses is desirable in aiding developing countries in need of emergency access to medication, it needs to be more narrowly interpreted in order to prevent abuse.

II. THAILAND VS. THE PHARMACEUTICAL INDUSTRY

A. *The Thai Dilemma*

In 2004, Thailand introduced a government funded healthcare plan to provide basic health care to all Thai citizens.[17] Additionally, at Thailand's 15th International AIDS Conference in Bangkok, the government pledged to include HIV/AIDS patients under the umbrella of its new health care plan.[18] Providing free medication to HIV/AIDS patients is an admirable objective and with a growing economy and a new focus on health care, it appeared to be an attainable goal. Thailand has a relatively strong gross domestic product (GDP),[19] current ac-

[17] *See* Hookway & Zamiska, *supra* note 8.

[18] *Id.*

[19] Thailand's GDP (PPP) is $515.3 billion and $8090 per capita. TIM KANE, ET AL., INDEX FOR ECONOMIC FREEDOM 363 (The Heritage Foundation & Wall St. J. eds., 2007), *available at* http://www.heritage.org/index/.

count surplus,[20] and impressive export performance.[21] With an increase in budgetary resources for health care, help from international aid agencies, and already discounted drug prices,[22] hopes were high that the government would be able to provide medicine to the estimated 10,000 Thai's[23] who require second-line treatment.[24]

When Thailand's armed forces took power in a military coup in September 2006, pro-business Prime Minister Thaksin Shinawatra was exiled and the new military installed regime chose to break pharmaceutical patents rather than use government money to fund health care for HIV/AIDS patients.[25] Dr. Mongkol na Songkhla, a former senior bureaucrat, was appointed Thailand's new health minister and quickly took the opportunity to seize the patent rights of several U.S. drug manufacturers.[26] Dr. Mongkol claims that Thailand previously

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[20] Thailand's current account surplus is 1.6% of its GDP in 2006. World Bank, Thailand Economic Monitor, http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_overview.pdf (last visited Oct. 23, 2007).

[21] Thailand's exports topped over $130 billion worth of products in 2006. *Id.* It is the world's number one exporter of rice, exporting 6.5 million tons of milled rice annually. Other major exports include "textiles and footwear, fishery products . . . rubber, jewelry, automobiles, computers and electrical appliances." Central Intelligence Agency, The World Fact Book 2007, https://www.cia.gov/library/publications/the-world-factbook/geos/th.html (last visited Apr. 27, 2008).

[22] In general, pharmaceutical companies charge different prices for medication in different countries depending on the average income of the individual country. *Id.* Many times medicine is given away or sold at a discount price. Associated Press, *U.S. Firm, Thailand Face-off in HIV Drug Patent Feud*, EAST VALLEY SCOTTSDALE TRIBUNE, June 11, 2007, *available at* http://www.eastvalleytribune.com/story/91345.

[23] Songphol Suckchan, Editorial, *Thailand's Compulsory Drug Licensing*, WALL ST. J., May 16, 2007, at A19 (Thailand's Director of Press Division defending Thailand's decision to issue compulsory licenses).

[24] The WHO recommends that one particular combination of ARVs be taken for most people when they begin HIV treatment – this is the first-line treatment. *See* World Health Organization, Antiretroviral Therapy for HIV Infection in Adults and Adolescents in Resource-limited Settings: Towards Universal Access - Recommendations for a Public Health Approach (2006), http://www.who.int/hiv/pub/guidelines/artadultguidelines.pdf When the first-line treatment becomes ineffective or resistant, a new combination of drugs is taken, which has been dubbed a second-line treatment. *Id.* The new second-line treatment will ideally include at least three new drugs with at least one from a new class to increase the likelihood of treatment success and to decrease the chance of cross resistance. *Id.*

[25] BBC News, Thai Government Hires PR Company, BBC NEWS, Apr. 30, 2007, http://news.bbc.co.uk/2/hi/asia-pacific/6608181.stm

[26] *See* Hookway & Zamiska, *supra* note 8.

attempted to negotiate with pharmaceutical companies for lower cost drugs.[27] Whatever the truth may be, the fact remains that just prior to the issuance of the first compulsory license the pharmaceutical companies were at the table willing to negotiate. Nevertheless, the Thai government proceeded to issue not one, but three compulsory licenses.[28]

It is easy for the new Ministry of Public Health to impose such a radical agenda because as part of an unelected military installed government, they are not accountable to anyone. The health ministers of the current interim government are comfortable imposing their agenda and letting the next elected government clean up the mess. Thailand's latest policies will garner public favor but the government has obviously not considered the long term consequences that will ultimately harm its citizens and its relationship with foreign investors, a relationship which was partly based on Thailand's past respect for patents.

Thailand's new government policies do not agree with the country's strong history of supporting intellectual property rights. In fact, Thailand's King, His Majesty Bhumibol Adulyadej, just recently received the World Intellectual Property Organization's (WIPO) Global Leaders Award, "in recognition of his remarkable contribution to intellectual property both as an inventor and as an active proponent of intellectual property as a tool for development."[29] It is difficult to reconcile Thailand's new stance with the country's past progressive pro-intellectual property policies and initiatives.

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[27] *Id.*

[28] Abbott v. Thailand Fact Sheet, www.amsa.org/global/aids/AbbottThailand FactSheet.doc (last visited Aug. 19, 2008).

[29] The Global Leaders Award is WIPO's most prestigious award to recognize world leader's efforts to support intellectual property and to promote development. *See* World Intellectual Property Organization, *King of Thailand to Receive WIPO's First Global Leaders Award* (Jan. 29, 2007), *available at* http://www.wipo.int/pressroom/en/articles/2007/article_0004.html. King Bhumibol Adulyadej is an inventor and has been a strong proponent of intellectual property rights. *Id.* He owns over 20 patents and 19 trademarks, many of which have been used to aid Thai communities. *Id.*

1. *What Has Happened to Date*

The first casualty was Merck & Co.'s AIDS drug efavirenz.[30] On November 29, 2006, the Thai government sent a letter to Merck informing the company that Thailand was planning on breaking Merck's patent and importing a generic version of efavirenz.[31] In February 2007, Merck announced that it would reduce the price of efavirenz by 14.5% in countries that have especially serious AIDS problems.[32] This would include Thailand. By dropping the price down to 65 cents per day per patient, Merck would make no profit.[33] Despite the fact that Merck had announced it was committed to reaching a negotiated agreement, the Thai government proceeded to import copies of efavirenz made by India's Ranbaxy Laboratories Ltd.[34]

Abbott Laboratories was the next to be hit. Two months after Merck, Abbott received a similar letter from the Thai government regarding the AIDS drug Kaletra.[35] Abbott had already cut the yearly price of Kaletra down to $2200 per year[36] in several developing countries, including Thailand, and were prepared to further reduce the price if need be. A meeting had been scheduled between Abbott and the Thai Ministry of Health to discuss such price negotiations, but once the compulsory license notice had been sent, the Ministry cancelled the meeting.[37] According to an Abbott spokesperson, Abbott was told by the Ministry that the compulsory license would stand regardless of what Kaletra was priced at.[38]

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[30] *See* Letter from the Department of Disease Control to Merck Sharp and Dohme, 10 BURNING ISSUES, *supra* note 2, at 47-48

[31] Letter from the Department of Disease Control to Merck Sharp and Dohme, 10 BURNING ISSUES, *supra* note 2, at 47-48.

[32] *See* Hookway & Zamiska, *supra* note 8.

[33] *Id.*

[34] *Id.*

[35] Letter from the Department of Disease Control to Merck Sharp and Dohme, 10 BURNING ISSUES, *supra* note 2, at 49-50.

[36] Abbott reduced the annual price of Kaletra from a cost of $7500 in the U.S to $2200. The Henry J. Kaiser Family Foundation, *Drug Access: Abbott to Reduce Cost of Kaletra in Thailand, Other Developing Countries* (Apr. 11, 2007), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=44162. Abbott already provides the drug for $500 annually in 69 of the least developed countries, including all of Africa. *Id.*

[37] *See* Hookway & Zamiska, *supra* note 8.

[38] *Id.*

After Dr. Mongkol announced that Thailand was considering breaking the patents of 11 more drugs,[39] Abbott retaliated. Abbott pulled the applications for seven medications it had been seeking approval of through Thailand's Food and Drug Administration.[40] The applications included drugs for arthritis, high blood pressure, and other conditions.[41] It also included an application for the new AIDS drug Aluvia®, which contains the same active ingredient as Kaletra but does not need to be refrigerated.[42]

As a result of its actions, Abbott was hit with a deluge of backlash from non-governmental organizations (NGOs) across the world. In April, after discussions with the World Health Organization (WHO), Abbott was willing to compromise.[43] Abbott agreed to sell Kaletra to more than 40 developing countries, including Thailand, for $1000 per patient annually,[44] so long as its patent was kept intact. Abbott has also said it will reinstate its Aluvia application and sell the drug for $1000 per patient per year if Thailand agrees to respect its patent.[45] At this point the fate of the other six applications is unresolved; Abbott is not giving in but has shown it is willing to negotiate with the Thai government.[46]

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[39] After this announcement, Thai officials affirmed that they reserved the right to issue compulsory licenses but had no immediate plans to do so. *Id.*

[40] *Id.*

[41] *Id.*

[42] In addition to Aluvia®, Abbott pulled applications for Brufen® (ibuprofen), Abbotic® (clarithromycin), Clivarine® (heparin), Humira® (adalimumab), Tarka® (trandolapril/verapamil HCL ER), and Wemplar® (paricalcitol). Sean Flynn, *Thailand's Lawful Compulsory Licensing and Abbott's Anticompetitive Response*, (Apr. 26, 2007), at 2 n.7, *available at* http://www.wcl.american.edu/pijip/documents/Thailandreport426.2_001.pdf?rd=1 (discussing how Thailand's issuance of compulsory licenses is legal under Thai law as well as under the WTO TRIPS agreement and how Abbott's actions violate Thailand's Competition Act).

[43] Press Release, Abbott Laboratories, Abbott Agrees with WHO Director-General to Expand Access to Kaletra/Aluvia (Apr. 10, 2007), *available at* http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0442.htm.

[44] This price is lower than any generic price available and is approximately 55% less than the current average price in developing and least developing countries. *Id.*

[45] *See id.* at 1.

[46] *See* Hookway & Zamiska, *supra* note 8.

In February, Thailand issued a third compulsory license.[47] This one for the blood-thinning drug Plavix, developed by Sanofi-Aventis of France and marketed by the U.S. company Bristol-Meyers Squibb.[48] This compulsory license has drawn more criticism than the previous two because Plavix is a preventative drug.[49] It weakens Thailand's stance because, although heart disease is a serious health concern, there are many more affordable and off-patent alternatives available.[50] Thus, the compulsory license for Plavix demonstrates the new Thai government's contempt for patents rather than a genuine effort to relieve a public health crisis.

2. *What Other Options Does Thailand Have?*

If the Thai government genuinely wants to protect its people and fight HIV/AIDS, it has many other options that would not invite such detrimental consequences. Thailand's decision to issue compulsory licenses is short sighted and will likely result in more harm than good. Moreover, treating the symptoms of AIDS is only a band-aid solution and will not fix the underlying problems that have resulted in so many people contracting HIV and having inadequate access to medicine. For Thailand's health care goals to have any chance of success it needs to spend more money on its health care policies, discontinue the use of substandard generic drugs which are causing resistance, and focus more on prevention.

a. Thailand's Health Care Expenditures

The U.N. estimates that as of 2006, there are 39.5 million people living with HIV worldwide.[51] A disproportionate amount

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[47] Third World Network, Thailand to Import Plavix Generics from India, THIRD WORLD NETWORK INFO SERVICE ON INTELLECTUAL PROPERTY ISSUES (Aug. 29, 2007), http://www.twnside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.080701.htm.

[48] Letter from the Permanent Secretary Office to Sanofi-Synthe'labo (Thailand) Ltd., 10 BURNING ISSUES, *supra* note 2, at 51-52.

[49] *See id.*

[50] *Drugs in Thailand: The Government Should Take Care About Ripping Up Patents*, FIN. TIMES (London), Jan. 31, 2007, at 14.

[51] U.N. Programme on HIV/AIDS & World Health Organization, *UN/WHO AIDS Epidemic Update: December 2006*, at 1, UNAIDS/06.29E (2006), *available at* http://data.unaids.org/pub/EPiReport/2006/2006_EpiUpdate_en.pdf (last visted Apr. 27, 2008).

of those living with HIV are in developing and least developed countries, particularly African countries. The UN and WHO estimate that there are 580,000 Thais living with HIV, a prevalence rate of 1.4%.[52]

Despite Thailand's laudable intention to support a universal health care system for its citizens, the government spends relatively little on health care.[53] Thailand's GDP is ranked in the top 10% of wealthiest countries in the world,[54] yet it spends a total of only 3.5% of its GDP on health care.[55] This is far less than even much poorer countries such as Cambodia and Lebanon who spend 12% and 11.6% on health care respectively.[56]

Thailand claims that healthcare for its citizens is a top priority, yet instead of directing state funds towards public health, the newly installed government has approved a $3.2 billion dollar military budget, an almost fifty percent increase from

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[52] *Id.* at 32.

[53] *But see* Sukchan, *supra* note 23.

[54] Letter from Kenneth L. Adelman to Members of Congress (May 9, 2007) (on file with author), *available at* http://usaforinnovation.org/images/2007_adelman letter.pdf; PhRMA Meets with Thai Health Minister, *supra* note 16 (Thailand is the worlds 21st largest economy out of more than 200).

[55] World Bank, Health Nutrition Population Stats Thailand, http://devdata.worldbank.org/hnpstats/HNPSummary/country Data/GetShowData.asp?sCtry=THA,Thailand (last visited Sept. 4, 2007). Notwithstanding its very modest health care expenditures, Thailand still reaps a high return on its investment. Overall Thailand is a healthy country. Two important indicators for the health of a nation are its under-5 mortality rate and its maternal mortality rate. Thailand's is 21 per 1000 live births and 44 per 100,000 live births respectively. World Health Organization, Mortality Country Fact Sheet 2006, http://www.who.int/whosis/mort/profiles/mort_searo_tha_thailand.pdf. The average life expectancy for men and women is 70 years. *Id. See also* JEREMIAH NORRIS, THE UNRAVELLING OF COMPULSORY LICENSES: EVIDENCE FROM THAILAND AND INDIA 3 (Int'l Policy Press 2007), *available at* http://www.fightingdiseases.org/pdf/unravelling_of_CLs_norris.pdf (low rates of child and maternal mortality rates and the high life expectancy indicate Thailand is shifting from relatively inexpensive parasitic and infectious diseases to more costly chronic disorders); World Bank, Thailand Data Profile, http://devdata.worldbank.org/external/CPProfile.asp?PTYPE=CP&CCODE=THA (last visited Sept.4, 2007).

[56] World Health Organization, *Tough Choices: Investing in Health for Development: Experiences from the Follow-up to the Commission on Macroeconomics and Health* elec. annex C (Health Expenditure Trends in Selected Countries) (Geneva 2006), at 2, *available at* http://www.who.int/macrohealth/documents/Electronic_Annex_C.pdf; World Bank, Health Nutrition Population Stats Lebanon, http://devdata.worldbank.org/hnpstats/HNPSummary/countryData/GetShow Data.asp?sCtry=LBN,Lebanon (last visited Sept. 4, 2007).

2006.[57] This new budget does not include allocations for new arms, which will be funded by diverting money from "low priority projects."[58] The military junta has also formed its own 14,000-strong security force at a cost of an additional $15 million outside the $3.2 billion budget.[59] The inefficiencies and bureaucracies of the Thai military are astounding.[60] About two-thirds of Thailand's military spending pays for the salaries of hundreds of desk bound high-ranking officers whose job descriptions are ambiguous at best.[61] Such a top-heavy structure leaves little money for such things as soldiers' salaries, arms, training, and upgrades which have to be funded from elsewhere. With such a system in place it is no wonder that there are little resources left over for health care.

b. Thailand Created a Need for Patented Drugs by Using Substandard Generic Drugs that have Led to Resistant Strains of AIDS

Unlike many developing countries, Thailand has it own pharmaceutical manufacturing facilities. The state-owned and historically corrupt[62] Government Pharmaceutical Organiza-

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[57] *$3.2 billion USD Budget Approved for Thai Military Spending*, XINHUA GENERAL NEWS SERVICE, Dec. 8, 2006, *available at* http://news3.xinhuanet.com/english/2006-12/11/content_5470335.htm.

[58] *Id.*

[59] *Winners and Losers Six Months After Thai Coup*, AGENCE FRANCE PRESSE, March 18, 2007, *cited in Thailand's Military is Sucking Money Away from Public Health*, USA FOR INNOVATION, April 26, 2007, http://usaforinnovation.org/news/display_article.cfm?ID=24.

[60] *Id.*

[61] Editorial, *Military Now Has to Shape Up*, THE NATION (THAILAND), Dec. 8, 2007, *available at* http://www.nationmultimedia.com/2006/12/08/opinion/opinion_30021038.php.

[62] In 2002, Auditor-General Jaruvan Maintaka issued a report saying the GPO sold about 60% of its medical products to government agencies at above market prices. Daniele Ten Kate, *Safe at Any Cost?*, ASIA SENTINEL (HONG KONG), Jan. 24, 2007, *available at* http://www.asiasentinel.com/index.php?option=com_content&task=view&id=351&Itemid=34. In some cases, products were marked up 1,000 percent. *Id.* Jaruvan alleged that the purchase of drugs through GPO has many faults and they provide officials with the chance to reap personal benefits. *Id.* According to Anuthin Charnveerakul, the deputy public health minister under Thaskin, in 2003, the GPO made a net profit of 624.2 million baht on revenues of 3.7 billion baht. *Id.* A year later, revenues topped 4 billion baht, and rose to five billion in 2005. Profits for the GPO topped one billion baht in 2005. *Id.* Anuthin has publicly criticized the GPO for spending a mere 19 million baht, just two percent of net profit, on research and development. *Id.* The report said that the GPO,

tion (GPO) has been the main supplier of a generic triple combination antiretroviral (ARV)[63] drug called GPO-Vir.[64] In 2002, the Global Fund to Fight HIV/AIDS granted the GPO $133 million to upgrade its plant to meet international quality standards for GPO-Vir.[65] However, the GPO continually failed to meet WHO standards and in 2006, the Fund withdrew the money remaining from its donation.[66] After four years of testing GPO-Vir, the drug still has not been listed on the WHO's prequalification program.[67] Dr. Lembit Rago, coordinator for WHO's quality assurance and safety program, stated that, "[d]rugs that are not WHO pre-qualified may not directly kill people, but they could foster resistance to AIDS drugs."[68] Since

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dubbed the "skimming profits" agency by cynical Thai observers, pilfered about 486 million baht, or about $13.3 million, from government coffers each year from 1998 to 2002. *Id.*

[63] National Institute of Allergy and Infectious Disease, Treatment of HIV Infection, http://www.niaid.nih.gov/factsheets/treat-hiv.htm (last visited Oct. 29, 2007). ARVs are drugs used to fight retroviruses, specifically HIV. *Id.* ARVs are only a treatment used to suppress HIV levels, not a cure. There are three major classes of ARVs. *Id.* The first are reverse trascriptase inhibitors; this type of ARV interferes with reverse transcription, a critical step in the HIV life cycle. *Id.* Secondly, there are Protease Inhibitors which "interfere with the protease enzyme that HIV uses to produce infectious viral particles." *Id.* Thirdly, there are Fusion Inhibitors which interfere with the virus' ability to fuse with the cellular membrane, thereby blocking entry into the host cell. *Id.* As HIV reproduces itself, different strains of the virus emerge, some that are resistant to antiretroviral drugs. Therefore, doctors recommend patients infected with HIV take a combination of antiretroviral drugs known as highly active antiretroviral treatment (HAART). *Id.* This strategy, which typically combines drugs from at least two different classes of antiretroviral drugs, has been shown to effectively suppress the virus when used properly. *Id.*

[64] *See* Thai Government Scales Up Antiretroviral Treatment Efforts (October 2003) , *available at* http://www.amfar.org/cgi-bin/iowa/asia/news/?record=17.

[65] Daniel Ten Kate, *Safe at Any Cost?*, ASIA SENTINAL, Jan. 24, 2007, *available at* http://www.asiasentinel.com/index.php?Itemid=34&id=351&option=com_content&task=view.

[66] Roger Bate, Thailand and the Drug Patent Wars, AMERICAN ENTERPRISE INSTITUTE FOR PUBLIC POLICY RESEARCH (Apr. 3, 2007), http://www.aei.org/docLib/20070404_HPO.pdf.

[67] *See* Norris, *supra* note 55, at 4.

[68] *Id.* Sadly there have been deaths related to governments producing medications without adhering to international standards. *Id.* In Panama, a cough syrup produced by a government run manufacturer was found to contain diethylene glycol, a toxic chemical used in anti-freeze and paint. *Id.* Approximately 30 people died from the cough syrup and many more were hospitalized. *See* Kate, *supra* note 62. Between 1995 and 1996 there were a string of child deaths in Haiti. *See* Stephanie Barbosa, *Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals*, 36 RUTGERS L.J. 205 (2004) at 227. Again investigators found

2002, WHO has recommended that GPO-Vir not be sold outside Thailand because of the GPO's failure to prove bioequivalence.[69]

In 2005, the drug's efficacy came into question when a Mahidol University study found that resistance to GPO-Vir had grown radically in the past few years and is only expected to get worse.[70] Because of the increased rate of resistance, more people must switch to more expensive patented medications for effective treatment. The NGO Medecins Sans Frontieres (MSF),[71] one of Thailand's most vocal supporters in the issuance of compulsory licenses, has also been complicit in the increased resistance due to GPO-Vir. Despite documented drug resistance and WHO admonitions, MSF continues to distribute the drug to patients in Thailand, Cambodia, and Burma.[72]

It is not yet clear whether the GPO will manufacture efavirenz, Kaletra, and Plavix in its factory that still has not met WHO standards. GPO officials announced they plan to start local production this year, which is a minimum of two years before the construction could be completed on a new production facility that meets WHO standards.[73] If Thailand produces the drugs in a factory that does not meet international standards, the results are likely to cause more harm than good to the thousands of HIV/AIDS patients in need of medication.

c. HIV Prevention is the Key

To defeat HIV/AIDS, the focus should be on prevention, not just treatment. Throughout the epidemic, across the world, prevention has been the best defense against HIV/AIDS. If countries cannot afford to treat the people who currently have HIV/

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diethylene glycol in the locally manufactured acetaminophen syrup. *Id.* In 1998, 200 women reported unwanted pregnancies after taking Brazilian manufactured birth control pills that contained wheat flour instead of the active ingredient. *Id.*

[69] Norris, *supra* note 55, at 4.

[70] Arthit Khwankhom, *HIV Drugs Losing Their Power*, THE NATION (THAILAND), July 19, 2005, *available at* http://www.nationmultimedia.com/2005/07/15/headlines/index.php?news=headlines_18039782.html. *But see* Kate *supra* note 62 (stating that both the GPO and MSF disagree that GPO-Vir causes resistance in AIDS. MSF believes there are other reasons for the resistance and the GPO claims that the drug is of the same quality of other WHO approved drugs).

[71] Also known as "Doctors Without Borders" in English.

[72] *See* Kate, *supra* note 62.

[73] *Id.*

AIDS they are certainly not going to be able to treat future patients.

i. Regulation of Thailand's Widespread Sex Trade

According to Dr. Edward C. Green, a renowned Harvard social scientist, most cases of HIV are contracted through sex, and "multi-partnering" drives epidemics.[74] There are different types of epidemics. Generalized epidemics[75] are primarily spread through heterosexual sex. However, in countries such as the U.S. and Thailand, with lower HIV prevalence, HIV transmission occurs primarily within core transmitter groups such as prostitutes, men who have sex with men, and IV drug users.[76] In Thailand prostitutes are the primary core transmitter group.[77]

Thailand is considered the capital of the sex-trade industry.[78] It is estimated that there are over 300,000 women and

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[74] Kate Hendricks & Patricia Thickstun, *Thailand's 100% Condom Use Policy: Success is in the Eye of the Beholder 2* (Medical Institute for Sexual Health Technical Paper No. MISH/MCHB/TP-20050728, July 28, 2005), *available at* http://www.medinstitute.org/includes/downloads/MCHB_TP_20050728.pdf.

[75] Generalized epidemics are defined as epidemics in which HIV prevalence is consistently greater than 1% in pregnant women. *Id.* at 2.

[76] *Id.*

[77] *Id.*

[78] ASIA WATCH & THE WOMEN'S RIGHTS PROJECT, A MODERN FORM OF SLAVERY: TRAFFICKING OF BURMESE WOMEN AND GIRLS INTO BROTHELS IN THAILAND 2 (Human Rights Watch 1993), *available at* http://www.hrw.org/reports/1993/thailand/ [hereinafter ASIA WATCH & THE WOMEN'S RIGHTS PROJECT]:

> [L]in Lin was thirteen years old when she was recruited by an agent for work in Thailand. Her father took $480 from the agent with the understanding that his daughter would pay the loan back out of her earnings. The agent took "Lin Lin" to Bangkok, and three days later she was taken to the Ran Dee Prom Brothel. "Lin Lin" did not know what was going on until a man came into her room and started touching her breasts and body and then forced her to have sex. For the next two years, "Lin Lin" worked in various parts of Thailand in four different brothels, all but one owned by the same family. The owners told her she would have to keep working until she paid off her father's debt. Her clients, who often included police, paid the owner $4 each time. If she refused a client's demands, she was slapped and threatened by the owner. She worked everyday except for the two days off each month she was allowed for her menstrual period. Once she had to borrow money to pay for medicine to treat a painful vaginal infection. This amount was added to her debt. On January 18, 1993 the Crime Suppression Division of the Thai police raided the brothel in which "Lin Lin" worked, and she was taken to a shelter run by a local non-gov-

children being exploited across Southeast Asia.[79] Some of the workers are orphans, others are sold off by their families, while some are outright kidnapped.[80] According to the Chulalongkorn University Political Economy Centre in Bangkok, Thailand's sex-trade generates annual revenues of over U.S. $4 billion.[81] Yet the government does not recognize the trade, putting this lucrative business in an economic and legal twilight zone. Further blurring the line, Thai commerce laws sanction sex work as a "personal service," notwithstanding the fact it has been illegal under anti-prostitution laws since 1960.[82] Thus the law ac-

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ernmental organization. She was fifteen years old, had spent over two years of her young life in compulsory prostitution, and tested positive for the human immunodeficiency virus or HIV.

Id.

[79] Anthony C. LoBaido, *Sex-trade Flourishes in Thailand*, WORLDNETDAILY, Feb. 3, 2002, *available at* http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=26296. This is a conservative estimate; some NGOs estimate there are 800,000 to two million prostitutes currently working in Thailand. ASIA WATCH & THE WOMEN'S RIGHTS PROJECT, *supra* note 78, at 1.

[80] Anthony C. LoBaido, *Sex-trade Flourishes in Thailand*, WORLDNETDAILY, Feb. 3, 2002, *available at* http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=26296.

[81] Betty Rogers, *Bitter Harvest*, MS. MAGAZINE, Oct. 1999, *available at* http://www.msmagazine.com/oct99/bitterharvest.asp.

[82] ASIA WATCH & THE WOMEN'S RIGHTS PROJECT, *supra* note 78, at 12. After the abolition of slavery in 1905 by King Rama V, prostitution in Thailand rapidly increased as former slaves were drawn into the sex trade. *Id.* Prostitution was legal from 1905 to 1960 and was regulated by the Control and Prevention of Venereal Disease Act of 1909. *Id.* The Act allowed the government to control the sex trade by establishing a system of licensing and fees. *Id.* Additionally, the Act required prostitutes to be "free of infectious disease." *Id.* In 1928, the Thai government passed an Anti-Trafficking Act which expressly prohibited the trafficking of women and girls for the purpose of having sexual intercourse. *Id.* at 13. Prostitution itself did not become criminalized until 1960 when the government passed the Suppression of Prostitution Act which is still in effect today. *Id.* In 1966, the government introduced the Entertainment Places Act, which regulated nightclubs, dance halls, bars, and places for baths and massages. *Id.* at 14. The Entertainment Act coincided with a greater presence of American soldiers in Thailand. *Id.* The U.S. established military bases in Thailand and allowed soldiers stationed in Vietnam to visit Thailand for rest and relaxation. *See id.* at 20-24. In November 2003, Thailand proposed to again legalize prostitution. *See* Associated Press, *Thailand Holds Debate on Legalizing Prostitution*, TAIPEI TIMES, Nov. 28, 2003, *available at* http://www.taipeitimes.com/News/world/archives/2003/11/28/2003077555. The government claimed that if legalized, prostitutes would receive health care, social services and protection from abuse. *Id.* Legalization would also help ferret out corruption among police, politicians, and business owners. Legalizing prostitution would also allow the government to tax the $4.3 billion industry, creating a boost

knowledges the economic advantages of prostitution while effectively making sex-workers criminals.[83]

For centuries, Thai men have been visiting brothels.[84] Prostitution has long been an accepted form of entertainment that wives expect and tolerate and men introduce their sons to.[85] According to a Ministry of Public Health study, nearly three quarters of all Thai males visit prostitutes on a regular basis and that roughly half of all teenage boys are initiated into sexual activity by prostitutes.[86]

Until recently, the Thai government seemed to be indifferent to the health dangers posed by the sex-trade industry. It was the spread of HIV that finally spurred the government to take action. In the early 1990s the government began an AIDS prevention and education campaign.[87] Even then, many brothel owners refused to encourage condom use, because those that did lost business. As a result, the 100% condom program was implemented and businesses that refused to comply risked government closure.[88]

The success of the government's program is debatable. At first look it seems as though the increase in availability and use of condoms in the sex trade decreased the spread of HIV.[89] However, upon closer look this may not be completely accurate. Although the rate of HIV infection decreased dramatically among Thai military conscripts between 1993 and 1999,[90] HIV infection has actually increased among the general adult population. The program has had little effect on the spread of HIV between male customers of prostitutes and their regular sex

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for the Thai economy. *Id.*; *See also* CNN.com, Thailand Debate Sex Trade (Nov. 27, 2003), http://www.cnn.com/2003/WORLD/asiapcf/southeast/11/27/thailand.sex.ap.

[83] *See* Rogers, *supra* note 81.

[84] *See* Donald Wilson and David Henley, *Prostitution in Thailand: Facing Hard Facts*, BANGKOK POST, December 25, 1994, *available at* http://www.Hartford-hwp.com/archives/54/072.html.

[85] Betty Rogers, *Bitter Harvest*, MS. MAGAZINE, October 1999, *available at* http://www.msmagazine.com/oct99/bitterharvest.asp.

[86] *See* Rogers, *supra* note 81.

[87] *See* ASIA WATCH & THE WOMEN'S RIGHTS PROJECT, *supra* note 78, at 25.

[88] *See* Hendricks & Thickstun, *supra* note 74, at 3.

[89] *Id.*

[90] The rate of HIV infection among Thai military personnel decreased from 3.7% in 1993 to approximately 1% in 1999. *Id.* at 3.

partners (wife or girlfriend).[91] Overall, the infection rates among prostitutes first increased and then decreased, but still remain high.[92] Studies have shown that Thai female sex workers requested condom use 63% of the time, but overall condom use was only 51%. Condom use differs by patrons' country of origin. Westerners use condoms 76% of the time, foreign Asians 52%, and native Thai men only 27%.[93] These results are significantly less than the goal of 100% condom use in Thai brothels.[94]

Clearly Thailand's 100% condom program alone is not the answer to curb the spread of HIV. The best solution would be to abolish the sex trade industry completely but because of economic reasons this is probably unlikely. If the government is going to allow the sex trade to continue it should at the very least closely regulate the industry. The government needs to be able to enforce the 100% condom program and should mandate that sex workers be tested for HIV and other STDs on a regular basis.

ii. Education as a Form of Prevention

One of the most important aspects of HIV prevention is education. To stop the spread of HIV it is important to not only educate people about the disease itself but also about prevention and treatment. One important aspect of prevention is condom use. The public needs to be educated about and encouraged to use condoms. The Thai government has done this to a certain extent but because native Thai men are the least likely prostitute patron (27%) to use a condom, public health initiatives

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[91] *See* U.N. Programme on HIV/AIDS & World Health Org., *supra* note 51, at 33.

[92] One study found 5.5% of sex workers who began working before 1989 were HIV infected, 8.0% of workers who began in 1990-1993 were infected, and 12.5% of those who began work in 1994-1999 were infected. Peter H. Kilmarx, et al., *Seroprevalence of HIV Among Female Sex Workers in Bangkok: Evidence of Ongoing Infection Risk After the "100% Condom Program" was Implemented*, 21 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 313 (1999) *cited in* Hendricks & Thickstun, *supra* note 74, at 4.

[93] Robert Buckingham and Edward Meister, *Condom Utilization Among Female Sex Workers in Thailand: Assessing the Value of the Health Belief Model*, 4 CALIFORNIA JOURNAL OF HEALTH PROMOTION 18 (2003), *available at* http://www.csuchico.edu/cjhp/1/4/18-23-buckingham.pdf.

[94] R.W. Buckingham, et al., *Factors Associated with Condom Use Among Brothel-based Female Sex Workers in Thailand*, 17 AIDS CARE 640 (July 2005).

need to especially target this group.[95] The programs need to encourage Thai men to not only use condoms with prostitutes, but also to use condoms with their regular partners if they are not going to be monogamous. Part of the problem of the government sponsored condom program is incorrect condom use. Method failure accounts for decreased risk reduction even with consistent use.[96] Education programs should teach correct condom use as well as inform people that condoms are never 100% effective. Additionally, other programs that educate people on and promote monogamy and/or abstinence may help control the spread of HIV.

B. *The Pharmaceutical Companies*

Over the last decade, 330 new medicines have become available to patients.[97] These include medicines for some of the most devastating and expensive diseases such as AIDS, cancer, and heart disease. In addition, there are over 1,000 new medications in the R&D pipeline.[98] Economists estimate that new medicines are responsible for approximately half of the increase in life expectancy achieved over the past 15 years.[99] The economic gains from medical innovation in the U.S. alone are estimated at more than $500 billion per year.[100] Biotechnology and pharmaceutical companies represent one of the most research-intensive industries and U.S. companies are responsible for most of these new drugs.[101] The reason there are such effective drugs available to fight HIV/AIDS is because developed countries have the resources to invest in developing treatments and have patent protection providing incentive to develop new drugs.

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[95] *Id.* at 643.

[96] *See* Hendricks & Thickstun, *supra* note 74, at 5.

[97] Cost of Prescription Drugs, *supra* note 11, at 7.

[98] *Id.*

[99] *See id.* at 5.

[100] Neil Masia, *The Cost of Developing a New Drug*, Jan. 2006, http://us info.state.gov/products/pubs/intelprp/cost.htm (last visited Nov. 11, 2007).

[101] COST OF PRESCRIPTION DRUGS, *supra* note 11, at 2.

1. *The Cost of Research and Development of New Medicines*

The cost of a new medication is more than the sum of its ingredients. In 2006, U.S. Biotech and Pharmaceutical companies spent an all-time high of $55.2 billion on R&D.[102] The discovery process, development, testing, and obtaining FDA approval for a new medicine is a long and expensive process and there are great risks that a promising line of research will not work out. It takes an estimated 12 to 15 years and approximately $800 million to discover and develop a new drug[103] and it costs an average of $1.2 billion to develop a biologic.[104] On average, only 0.0005% of compounds investigated ever make it to clinical trials.[105] That is only five out of every 10,000 compounds. Only one of those five will be approved for patient use.[106] Revenues from that one successful drug have to cover the costs for all of the compounds that do not pan out.[107]

A common misconception about pharmaceutical development in the U.S. is that the government invents and funds research for most new medicines. Many people believe that the National Institute of Health (NIH), a tax-payer-funded research institute, does most of the R&D work in developing new medicines.[108] The fact is the vast majority of medicines are developed by pharmaceutical research companies.[109] Pharmaceutical companies spend far more on R&D than the NIH and are responsible for the discovery and development of most new medicines. The NIH spends just over half of what pharmaceutical companies spend on R&D.[110] The Government Accountabil-

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[102] Press Release, PhRMA, R&D Spending by U.S. Biopharmaceutical Companies Reaches a Record $55.2 Billion in 2006 (Feb. 12, 2007), *available at* http://www.phrma.org/news_room/press_releases/r&d_spending_by_u.s._biopharmaceutical_companies_reaches_a_record_$55.2_billion_in_2006/.

[103] COST OF PRESCRIPTION DRUGS, *supra* note 11, at 2.

[104] A biologic is a medicine composed of molecules produced by a biological system. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2007, 5 (Mar. 2007), http://www.phrma.org/files/Profile%202007.pdf [hereinafter PHARMACEUTICAL PROFILE].

[105] *See id.* at 6.

[106] *Id.*

[107] COST OF PRESCRIPTION DRUGS, *supra* note 11, at 2.

[108] *Id.*

[109] *Id.* at 8.

[110] *Id.*

ity Office (GAO) found that of the top 100 medicines purchased by the Department of Defense (DOD) and the Department of Veterans Affairs (VA), the government had licensing rights to only six of those purchased by the DOD and only four of those bought by the VA.[111] Government and NIH funded academic scientists contribute a great deal to advancing knowledge about biology and disease, but it is more often the pharmaceutical companies that translate the basic science into practical medicines.

2. *Cost of Drugs in Developed vs. Developing Countries*

Many patented drugs are already sold to developing and least developed countries at a highly discounted price.[112] One example is Gilead Sciences Inc., which began offering its AIDS drug Viread to 68 of the world's poorest countries at cost.[113] The pharmaceutical company offered Viread to nations throughout Africa, as well as to 15 other impoverished countries, for $1.30 per once-daily pill.[114] A year's supply that would cost roughly $4,300 per year in the U.S. costs only $475 annually in qualified countries.[115] This is only one example of many, including the discounted prices Abbott offered on Kaletra to developing countries and LDCs.[116] In general, treatment with ARVs cost between $350 to $1000 annually in most African countries.[117] This is approximately 90% less than yearly treatment costs in the U.S.[118] These discounted prices do not take into account the millions of dollars worth of pharmaceuticals and medical equip-

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111 *Id.*

112 *See supra* text accompanying note 21.

113 *AIDS Drugs Will Be Offered in Poor Countries at Cost*, April 4, 2003, http://www.thebody.com/content/treat/art29635.html.

114 *Id.*

115 *Gilead Sciences Inc.: AIDS Drug Will be Offered in Poor Countries at Cost*, WALL ST. J., April 4, 2003, at C7 (stating that the lower price covers solely manufacturing and distribution costs).

116 *See supra* text accompanying note 31.

117 Michael Fleshman, Global AIDS Treatment Drive Takes Off, 19 AFRICA RENEWAL 1, 8 (2005).

118 Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886 (2001), *available at* http://www.iipi.org/articles/antiretroviral_article.pdf.

ment donated through pharmaceutical companies' philanthropic work.[119]

3. *Philanthropy of the Pharmaceutical Industry*

Pharmaceutical companies contribute money, medicine, supplies, and expertise to many of the world's leading philanthropic organizations.[120] In 2003, the pharmaceutical industry spent an estimated $1.4 to $2.1 billion[121] on global health care. This is more than the annual global health budgets of the WHO, the World Bank, and many other humanitarian organizations.[122] The pharmaceutical industry's contribution to global health accounts for "more than a third of the United States' total healthcare assistance to the developing world."[123] One of the main focuses of the pharmaceutical industry is implementing long-term programs. Many of their programs are more than ten years old and many involve long term goals requiring commitments far into the future. Pharmaceutical industry programs aimed at HIV/AIDS have grown from 24 programs in 2006 to 52 programs in 2007.[124] Tens of millions of people living in over 100 developing and least developed countries have benefited

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119 *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, HEALTH CARE IN THE DEVELOPING WORLD 4 (2004), http://www.phrma.org/files/Global_Partnerships_2004.pdf.

120 *Id.*

121 The discrepancy in estimates is due to data from two different studies. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, HEALTH CARE IN THE DEVELOPING WORLD 4 (2004), http://www.phrma.org/files/Global_Partnerships_2004.pdf [hereinafter Health Care in the Developing World]. The study which puts spending at $1.4 billion does not include the value of drug and in-kind donations made by as many as 24 non-PQMD (Partnership for Quality Medical Donations) pharmaceutical companies to non-PQMD nongovernmental organizations. Nor does it account for donated medical care and other services by company employees. PQMD corporate members include Abbott Laboratories, BD, Boehringer Ingelhein, Bristol-Meyers Squibb Company, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Pfizer Inc., and Wyeth Pharmaceuticals. Humanitarian members include AmeriCares, Catholic Medical Mission Board, Direct Relief International, Heart to Heart International, Interchurch Medical Assistance, Inc., International Aid, MAP International, Mercy Ships, Northwest Medical Teams, Project HOPE, U.S. Fund for UNICEF, and World Vision. *Id.* n.1.

122 This is more than the $1.37 billion spent by USAID and WHO each, the $1.3 billion spent by UNICEF, the $1.03 billion spent by the World Bank, and the $850 million spent by the European Union. *Id.*

123 *Id.*

124 G8 Summit, *supra* note 13, at 12.

from the efforts and finances of the pharmaceutical industry.[125] The extent of programs that have been put into practice and the money and resources that have been donated is overwhelming.

Thailand is one of many countries that has benefited from the generosity of pharmaceutical companies. The list is long but some examples include family planning and HIV/AIDS education to teenagers and young adults, "Rainbow Camps" for HIV-infected children, and hundreds of thousands of dollars in donated ARV medicines through the Thai Red Cross. These are just a few examples and do not represent the many non-medical donations and programs.[126]

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[125] HEALTH CARE IN THE DEVELOPING WORLD, *supra* note 121.

[126] *See* HEALTH CARE IN THE DEVELOPING WORLD, *supra* note 121. Pharmacies that have donated to and helped develop philanthropic programs in Thailand include: Abbott, AstraZeneca, Bristol-Meyers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., Pfizer, and Sanofi-Aventis. *See generally* HEALTH CARE IN THE DEVELOPING WORLD, *supra* note 121; *see generally* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Pharmaceutical Corporate Philanthropy in Asia 1 (2007), *available at* http://www.phrma.org/files/Asia%20Philanthropy%20brochure.pdf. In December 2004, donations of $85,000 were made to the immediate relief efforts following the Asian Tsunami. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL CORPORATE PHILANTHROPY IN ASIA 34 (2007), *available at* http://www.phrma.org/files/Asia%20Philanthropy%20brochure.pdf. Hospitals and health centers in affected areas have received $1.64 million in cash and medicines donated by Pfizer. *Id.* at 37. Eight houses and community centers were rebuilt in Khao Lak, the worst hit area in Thailand, through a $100,000 donation to the Reconstruction Project. *Id.* at 34. In October 2006, pharmaceutical employees volunteered to participate in a government initiative to plant a forest in southern Thailand to renew depleted mangrove forests and protect the coastline and biodiversity. *Id.* at 35. With support from the pharmaceutical industry the Population and Community Development Association will provide family planning, HIV/AIDS and sex education for teenagers in 30 schools in Bangkok. *Id.* This initiative includes a camp to train teachers and students to run programs, a mobile classroom, materials, hotlines, drop-in centers, and web sites. *Id.* The pharmaceutical industry supports the Thai Red Cross efforts to bring life skills and HIV/AIDS education to children and youth in Bangkok slums. *Id.* One pharmaceutical company is working with the Raks Thai Foundation which supports some 160 families in fishing communities in Krabi and Pang Nga provinces, helping them rebuild their lives and livelihoods through a revolving fund that enables families to purchase boats, engines, or fishing equipment. *Id.* The funds are managed by the communities themselves and are part of the long-term rehabilitation plan for their area. *Id.* A part of a $285,000 grant supports rehabilitation activities relating to health and livelihood improvements, natural and environmental management, emergency response and disaster risk management, and social networking. *Id.* at 35-6. In 1997, with rural areas facing a severe nursing shortage, the Rural Nursing Excellence Program was established. *Id.* at 36. The on-going program has awarded over 400 scholarships at 30 nursing colleges. *Id.* Approximately 250 students have graduated and are working in 120

Although the pharmaceutical industry has become an easy scapegoat for many groups to blame for high-priced drugs and inaccessibility to medicine, it is clear that pharmaceutical companies are doing more than their share of humanitarian work. Pharmaceutical companies create life-saving drugs and despite popular belief, they also do their share to help get those

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hospitals and public health centers in 50 provinces. *Id.* The Life Skills Foundation provides life skills education, training, and promotion for children and their families affected by HIV/AIDS. *Id.* It emphasizes psychosocial development to help reduce the stigma and discrimination associated with the disease. *Id.* The Foundation has assisted 169 children and their families and has educated more than 1,600 non-affected children. *Id.* In 1998, the Enhancing Care Initiative was created with a five year, $5 million grant from Merck. *Id.* It is a joint program of the Harvard AIDS Institute and the Francois-Xavier Bagnound Center at the Harvard School of Public Health; it works to improve the care of people living with HIV/AIDS in resource limited settings in Thailand. *Id.* Merck also contributed $1.1 million to support a program jointly conducted by Chiang Mai University's Faculty of Nursing and the Harvard AIDS Institute to improve HIV/AIDS healthcare services. *Id.* at 37 Five Global Health Fellowships has also been established to work on community-based projects with vulnerable populations at high risk for HIV/AIDS. *Id.* Pa Tong Koh (PTK) has brought HIV/AIDS patients and non-infected people together in almost 375 business partnerships for the purpose of reducing stereotypes and breaking down social barriers. *Id.* PTK provides small business loans through Population & Community Development Association since 2004 and is considered a "Best Practice" by UNAIDS. *Id.* Pfizer teamed up with the Department of Mental Health and the Ministry of Public Health to establish a Mental Health Recovery Center and organized post traumatic stress syndrome conferences for psychiatrists, psychologists, social workers, and nurses to deal with the mental health effects of disaster trauma. *Id.* They also organized community outreach and mental health education to the children in the effected area. *Id.* Since 2003, 141 scholarships totaling $148,000 have been awarded to high school and university students who have demonstrated academic performance and financial need. *Id.* The aim is to encourage the study of science, medicine, pharmacy, or public health. *Id.* Since 2004, Pfizer alone has conducted more than 40 global clinical studies in Thailand in many therapeutic disease areas. *Id.* at 38. They have also partnered with the Disease Controls Department, the Thai Food & Drug Administration, public hospitals, medical science departments, and medical schools to conduct "Good Clinical Practice" training for research physicians and healthcare professionals involved in clinical research. *Id.* The Pfizer Thailand Foundation has contributed $195,000 to train 800 physicians, nurses and counselors to provide medical and social care for HIV/AIDS patients. *Id.* On Thailand's highly militarized borders with Burma, the Agency for Information and Mediation for Children (AIM) provides support for refugee children affected by the conflict with ethnic minorities. *Id.* With support from pharmaceutical companies, AIM operates orphanages and schools and offers education in hygiene, medical care, and vocational training for women. *Id.* These programs are only representative of the pharmaceutical industries' work in Thailand, it does not include the many programs and donations made in other developing countries and LDCs.

medicines to people that need them regardless of income or status.

III. The Law: International Patent Rights

A. *International Trade and Intellectual Property Law*

The importance of patents has been recognized since the 13th century when, in an effort to spur the innovation of new technologies, the Venetian Republic enacted legislation in 1474 which is considered to be the first true patent statute.[127] Patent traditions, carried over from England, were practiced early on in many of the English colonies here in the United States and soon found their way into our Constitution.[128] The U.S. Constitution states that the purpose of patents are to, "promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[129] The purpose is not to promote monopolies and price control, as some argue.[130] Patents are a trade off; patent holders disclose their invention in exchange for the right to exclude others from its use for a set period of time.[131] This trade off promotes scientific progress by increasing the amount of knowledge available to the public. Additionally, the prospect of obtaining a patent provides an incentive to invest in research to create new innovations.[132] Strong

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127 *See* Giulio Mandich, *Venetian Patents (1450-1550),* 30 J. Pat. Off. Soc'y 166 (1948).

128 *See generally* Edward C. Waltersceid, *The Early Evolution of United States Patent Law: Antecedents (Part I)*, 78 J. Patent & Trademark Off. Soc'y 615 (1996).

129 U.S. Const. art. I, § 8, cl. 8.

130 *See generally* Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 Brandeis L.J. 623 (2007) (arguing that strong patent rights create monopolies and price controls of specific drugs).

131 *See* 35 U.S.C. §§ 111, 112 (2007). Under U.S. and international law, inventors granted a patent may exclude others from its use for 20 years from the date the patent application was filed. 35 U.S.C. § 154(a)(2) (2007); *see* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

132 *See* Barbosa, *supra* note 68, at 216-32; *see also* John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual property Rights and Compassion*, 7 Widener L. Symp. 175,

intellectual property rights are essential for the innovation and development of new drugs. The United States has recognized this and has been a staunch advocate of protecting intellectual property rights at home and abroad, but as our economy has become increasingly dependent on technology-based industries, intellectual property rights have become an even higher priority to U.S. policy makers and diplomats.[133]

1. *The World Trade Organization: A Global Nexus for International Trade*

The WTO is an international association designed to facilitate trade between its member nations.[134] The philosophy is that free trade will result in greater economic growth.[135] The WTO believes that, "liberal trade-policies—policies that allow the unrestricted flow of goods and services—sharpen competition, motivate innovation, and breed success."[136]

The WTO is the successor to the General Agreement on Tariffs and Trade (GATT).[137] GATT was established in 1947 as part of an effort to promote global economic recovery after World War II.[138] The newly created United Nations asked a committee of 18 countries to draft a charter for the proposed International Trade Organization (ITO).[139] The charter was adopted at the United Nations Conference on Trade and Employment at Havana; however, the agreement was never rati-

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187-88 (2001) (highlighting the debate over the level of patent protection that should be required for pharmaceuticals in developing and least developed countries).

133 *See* Michael L. Doane, *TRIPS and International Property Protection in an Age of Advancing Technology*, 9 AM. U. J. INT'L L. & POL'Y 465, 488 (1994) (discussing the impact that advancing technology has had in the arena of international intellectual property law).

134 *See* World Trade Organization, http://www.WTO.org (last visited May 23, 2008).

135 *Id.*

136 World Trade Organization, Understanding the WTO: Basics, http://www.wto.org/English/thewto_e/whatis_e/tif_e/fact3_e.htm (last visited May 23, 2008).

137 World Trade Organization, What is the WTO?, http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Nov. 18, 2007).

138 The Roots of the WTO, http://www.econ.iastate.edu/classes/econ355/choi/wtoroots.htm (last visited Aug. 19, 2008).

139 DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 3-4 (Sweet & Maxwell Ltd. 2d ed. 2003) (1998).

fied.[140] As a result, the ITO never came into being and instead GATT was born.[141] GATT had very few provisions dealing with intellectual property, and what it did have was woefully inadequate to deal with the emergence of technology over the next 50 years.[142] Towards the end of the century many industrialized nations were pushing to establish new intellectual property standards under GATT.[143] When the Uruguay Round of Multilateral Trade Negotiations[144] began in 1986, the United States and Japan submitted proposals to address international intellectual property rights and their enforcement.[145] It was from the Uruguay Round negotiations that the WTO was derived.[146] The WTO was established on January 1, 1995 and replaced GATT.[147] The WTO not only encompasses the provisions of GATT, but also addresses a wider range of objectives aimed at promoting international trade.[148]

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[140] World Trade Organization, Understanding the WTO - The GATT Years: From Havana to Marrakesh, http://www.wto.org/English/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited Aug. 19, 2008).

[141] *Id.* at 4.

[142] *See id.* at 5-10.

[143] Anna-Liisa Jacobson, *The New Chinese Dynasty: How The United States and International Intellectual Property Laws are Failing to Protect Consumers and Inventors From Counterfeiting*, 7 RICH. J. GLOBAL L. & BUS. 45, 51 (2008).

[144] The Uruguay Round is the largest trade negotiation to date, taking seven and a half years and covering almost all trade across virtually every industry. World Trade Organization, *supra* note 134.

[145] Many developing countries, particularly Brazil and Argentina, opposed intellectual property rights being placed on the negotiating agenda at the Uruguay Round. *See* GERVAIS, *supra* note 139, at 10.

[146] World Trade Organization, Understanding the WTO – The Uruguay Round, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Aug. 19, 2008).

[147] *Id.*

[148] *See* World Trade Organization, Understanding the WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf (last visited Nov. 11, 2007) [hereinafter Understanding the WTO]. As of January 2007, 150 countries belonged to the WTO, constituting the bulk of the world's trading nations. *Id.* The WTO essentially functions as a forum where members can go to negotiate or resolve their trade problems. *Id.* The heart and soul of the WTO are its agreements, which are negotiated and signed by members and serve as the legal ground rules for international commerce. *Id.* Through these agreements, countries are bound to keep their trade policies within certain established parameters. *Id.* This assures other member nations that foreign markets will remain open and stable. *Id.*

The WTO operates under certain fundamental principles.[149] For example, under the WTO, members must trade without discrimination.[150] This is known as most-favored-nation treatment, in which all WTO trading partners must be treated equally.[151] The WTO also believes in lowering trade barriers through peaceful and gradual negotiation.[152] The WTO realizes that opening markets requires adjustment and the agreements allow developing and least developed countries additional time to fulfill their obligations.[153] Overall, the WTO's ultimate goal is to promote principles of fair competition and to encourage development and economic reform through open trade.[154]

One of the most significant changes from GATT to the WTO was the incorporation of a more structured dispute resolution system.[155] WTO agreements are approved by a consensus and ratified by all members' governments; members are bound by those agreements and must uphold the rights promised to other countries.[156] If a member believes a fellow member has violated an agreement, the WTO encourages the parties to discuss the problem and come to a mutual resolution.[157] If the members are not able to resolve the situation on their own, then they have agreed to use the WTO's system of settling disputes rather than take action unilaterally.[158] When the countries have attempted to, and been unable to settle the dispute on their own, the issue is brought before the Dispute Settlement Body (DSB).[159] The DSB appoints a panel of experts, who act as a tribunal, to con-

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149 World Trade Organization, Understanding the WTO – Principles of the Trading System, http://www.wto.org/english/thewto_e/whatise/tif_e/fact2_e.htm (last visited Aug. 19, 2008).

150 *Id.*

151 World Trade Organization, Understanding the WTO – A Unique Contribution, http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm (last visited Aug. 19, 2008) [hereinafter Dispute Resolution].

152 *Id.*

153 *See infra* text accompanying note 128.

154 *See id.*

155 Dispute Resolution, *supra* note 151.

156 *See* Understanding the WTO, *supra* note 135.

157 Dispute Resolution, *supra*, note 151.

158 *See* Understanding the WTO, *supra* note 135.

159 The DRB consists of all WTO Members. *Id.*

sider the case.[160] Once a panel makes a decision, it can only be rejected by consensus of the DSB.[161] If a country loses a dispute and does not abide by the panel's decision, the WTO has the power to authorize trade sanctions against the losing party.[162]

2. *The WTO's Framework for Intellectual Property Law*

a. *The Underlying Principles and Standards of TRIPS*

The Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) was negotiated at the Uruguay Round and adopted on April 15, 1994 at Marrakesh. It is an international agreement administered by the WTO that establishes a detailed set of substantive minimum standards that cover trademarks, copyrights, geographical indications, industrial designs, patents, and undisclosed information.[163] The TRIPS agreement effectively increases harmonization of intellectual property rights among WTO members.[164] According to the WTO, TRIPS is, to date, "the most comprehensive multilateral agreement on intellectual property."[165] The objectives of the TRIPS Agreement are to promote international trade and the adequate protection and enforcement of intellectual property rights (IPRs).[166] TRIPS recognizes that adequate protection of IPRs is essential to the promotion of technological innovation and to the dissemination of technology to the public domain.[167] This is to the mutual advantage of the innovators of technological knowledge as well as to those who use it. However, TRIPS also realizes that promotion of trade and technology should be

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[160] The panel is chosen with input from the countries in dispute. *Id.* If the countries cannot agree on the panel then it is appointed by the WTO Director-General. *Id.*

[161] Dispute Resolution, *supra*, note 151.

[162] *Id.*

[163] World Trade Organization, Overview: the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 11, 2007) [hereinafter Overview of TRIPS].

[164] World Trade Organization, Understanding the WTO – Intellectual Property: Enforcement and Protection, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Aug. 19, 2008). The TRIPS Agreement is an attempt to narrow the gaps in the way intellectual property rights are protected around the world and to bring them under common international rules. *Id.*

[165] *Id.*

[166] TRIPS Agreement , *supra* note 131.

[167] *See* Overview of TRIPS, *supra* note 163.

accomplished in a manner conducive to social and economic welfare.[168] From the outset, TRIPS recognized the need to balance intellectual property rights with social interests.[169] One of the most adversarial aspects of TRIPS is the dichotomy between granting pharmaceutical patents and the need for accessible medicines to protect public health.[170]

The TRIPS Agreement was an exercise in compromise between developed and developing nations. The U.S., the European Union, and other industrialized nations aggressively pursued strong IPRs while developing countries vehemently resisted even minimum standards of protection.[171] Ultimately, the developed world made concessions in agriculture and textile trade positions in exchange for developing countries agreeing to a minimum standard of intellectual property protection.[172]

The minimum standards of IPRs adopted under the TRIPS Agreement must be adhered to by all member countries within an established transitional period.[173] The Agreement sets the standards by incorporating the substantive obligations of the Paris and Berne Conventions.[174] Additionally, TRIPS addresses

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168 TRIPS Agreement, *supra* note 131, art. 7.

169 *See id.*, Preamble.

170 *See* Barbosa, *supra* note 68.

171 *See* Doane, *supra* note 133, at 473-76.

172 *Id.* at 476.

173 TRIPS Agreement, *supra* note 131, arts. 65, 66. Developed countries have one year to comply with the TRIPS Agreement. *Id.*, art. 65(1). Developing countries are granted a five year transitional period. *Id.*, art. 65(2). Least developed countries are given ten years to transition. *Id.*, art. 66(1). On November 29, 2005, just months before the January 1, 2006 deadline, the LDCs were granted an additional seven and one-half years to comply with TRIPS. *See* Press Release, World Trade Organization, Poorest Countries Given More Time to Apply Intellectual Property Rules (Nov. 29, 2005), *available at* http://www.wto.org/English/news_e/pres05_e/pr424_e.htm. The 2005 reprieve expands on a 2002 extension given to all LDCs regarding patents on pharmaceuticals. *Id.* LDCs have until 2016 to provide full patent protection to pharmaceuticals. *Id.*

174 PAUL GOLDSTEIN, INTERNATIONAL INTELLECTUAL PROPERTY LAW 96 (Robert C. Clark, et al., eds., 2001). Goldstein writes:

> The Paris Convention for the Protection of Industrial Property (1883) is important primarily for having obligated its members to offer nondiscriminatory treatment to the nationals of other member countries with respect to industrial property protection that the member provided for its own citizens. It also established an international priority system for the registration of industrial property. The only minimum standards it set were those governing the protection that members were to provide against unfair competition. The Berne Convention for the protection of Literacy and

a number of inadequacies of these treaties.[175] Countries may adopt stronger IPRs, so long as those rights do not contradict any TRIPS provisions.[176]

b. *The Patent Provisions of TRIPS*

This paper only addresses international patent rights under TRIPS. TRIPS Article 27(1) states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[177] There are three enumerated exceptions to the general rule of patentability.[178] The first exception is for inventions contrary to *ordre public* or morality.[179] This expressly includes inventions "dangerous to human, animal, or plant life or health or seriously prejudicial to the environment."[180] The second exception is that members are not required to grant patents for "diagnostic, therapeutic and surgical methods for the treatment of humans and animals."[181] The last exception is that members may exclude "plants and animals other than micro-organisms and essentially biological processes for the production of plants

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Artistic Work (1886), in addition to imposing national-treatment obligations on its members with respect to the literary and artistic works of its own nationals, establishes certain minimum standards for the protection of literary and artistic works. However, a number of countries, including the United States, objected to some of these standards and refused to adhere to the Convention.

Id.; *see generally* J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432, 2434-36 (1994) (discussing the Paris and Berne Conventions as representing two international approaches to intellectual property).

175 Two perceived inadequacies of the Paris and Berne Conventions that TRIPS cures are 1.) the absence of an effective and binding dispute resolution system; and 2.) an absence of rules on the enforcement of rights before a national judicial administrative authority. Moreover, the evolution of the world trading system and the rapid increase in technology required a substantial updating of international intellectual property laws. GERVAIS, *supra* note 139, at 10. *See also* George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 287 (1998).

176 TRIPS Agreement, *supra* note 131, art. 1.

177 *Id.*, art. 27(1).

178 *Id.*

179 *Id.*

180 *Id.*, art. 27(2).

181 *Id.*, art. 27(3)(a).

and animals . . . "[182] Under TRIPS, a patent holder has "the right to prevent third parties from making, using, offering, selling, or importing their invention."[183] Like U.S. law, the agreement confers patent rights for 20 years from the date of filing.[184] All WTO members must comply with TRIPS but are allowed the flexibility of incorporating the provisions into their own legal system and practice.[185]

One industry that TRIPS specifically addresses is pharmaceuticals. At first glance the exception in Article 27(3)(a) that excludes from patentability diagnostic, therapeutic and surgical methods, appears to encompass pharmaceuticals. No doubt this exception was created to promote free use of medical treatments. Nevertheless, this exception does not apply to pharmaceuticals. Article 70(8) expressly requires member countries to grant pharmaceutical patents.[186] Many developing countries had reservations about strengthening IPRs in general and for pharmaceuticals in particular; however, they realized that international trade was essential to their economic growth and the benefits of belonging to the WTO were outweighed by their concerns over IPRs.[187] Recently, these concerns have returned, especially in light of the HIV/AIDS crisis faced by many developing and least developed countries.[188]

TRIPS provides for some uses of a patent that can be made without authorization from the patent holder.[189] In particular, Article 31 allows members to issue compulsory licenses.[190] A compulsory license permits the use and manufacture of a patented invention without permission from the patent holder.[191]

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[182] *Id.*, art. 27(3)(b).

[183] *Id.*, art. 28(1).

[184] *Id.*, art. 33.

[185] *Id.*, art. 33.

[186] *Id.*, art. 70(8).

[187] *See* Harrelson, *supra* note 132, at 176.

[188] Press Release, World Trade Organization, WTO Members to Press on, Following 'Rich Debate' on Medicines, (June 22, 2001), *available at* http://www.wto.org/english/news_e/pres01_e/pr233_e.htm.

[189] *See* TRIPS Agreement, *supra* note 131, art. 31(b).

[190] *Id.*

[191] *See* Margaret Duckett, *Compulsory Licensing and Parallel Importing: What do they mean? Will they improve access to essential drugs for people living with HIV/AIDS?* (July 1999), www.icaso.org/docs/compulsory_english.htm (discussing compulsory licenses and parallel importing as methods for increasing access to AIDS medications).

Non-authorized use of a patent is permitted if, "prior to such use, the proposed user has made 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."[192] This requirement can be waived "in cases of national emergency or other cases of extreme urgency or for public non-commercial use."[193] In these cases the issuing government must notify the patent holder as soon as reasonably possible and the patent holder must be paid an adequate remuneration.[194] Each compulsory license is to be considered on its individual merits and its legal validity is subject to independent review.[195]

Any WTO member may issue a compulsory license to use or manufacture a patented pharmaceutical, but Article 31(f) of TRIPS states that the use must be "predominately for the supply of the domestic market."[196] This has posed a problem for numerous developing and least developed countries that have little or no pharmaceutical manufacturing capabilities.[197] Without means to manufacture domestically, any effort to secure pharmaceuticals from other countries would be in violation of TRIPS.[198] Developing countries sought exception to this provision so that they could import pharmaceuticals produced in countries with manufacturing facilities.[199] This conflict was one of the issues addressed in the Doha Development Agenda.[200]

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192 TRIPS Agreement, *supra* note 131, art. 31(b).

193 *Id.*

194 *Id.*, art. 31(b), (h).

195 *Id.*, art. 31(a), (i).

196 *Id.*, art 31(f).

197 Express Pharma Pulse, Article 31(f) & Article 6: Need for Pragmatic Approach, http://www.expresspharmaonline.com/20021121/patents.shtml (last visited Aug. 19, 2008).

198 TRIPS Agreement, *supra* note 131, art 31(f).

199 Thomas A. Haag, *TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT & TRADEMARK OFF. SOC'Y 945 (2002).

200 World Trade Organization, Ministerial Declaration of 14 November 2001, Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_emindecl_e.htm [hereinafter Doha Declaration].

3. *The Doha Declaration*

In November 2001, the WTO's fourth ministerial conference convened in Doha, Qatar.[201] WTO ministers felt that many developing countries were having problems implementing WTO agreements.[202] The TRIPS agreement was one of many issues on the negotiation agenda.[203] One result of these negotiations was the Doha Declaration on the TRIPS agreement and public health (Doha Declaration).[204] The WTO recognized the seriousness of public health problems in developing and least developed countries and did not want the TRIPS Agreement to prevent members from taking measures to protect public health.[205]

The purpose of the Doha Declaration was to clarify the provisions and to resolve the perceived flaws of Article 31 of the TRIPS Agreement.[206] The Doha Declaration affirms that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[207] Furthermore, the declaration maintains that members may themselves determine what constitutes a national emergency or other circumstance of extreme urgency.[208] The declaration specifies that public health crises related to HIV/AIDS, tuberculosis, malaria, and other epidemics can qualify as a national emergency or other circumstances of extreme urgency.[209] Furthermore, the declaration allows least developed countries to delay implementation of TRIPS with regard to pharmaceuticals until 2016.[210]

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201 World Trade Organization, Doha Development Agenda: Negotiations, Implementation and Development, http://www.wto.org/english/tratop_e/dda_e/dda_e.htm (last visited Aug. 19, 2008).

202 *Id.*

203 World Trade Organization, Understanding the WTO: The Doha Agenda, http://www.wto.org/english/thewto_e/whatis_e/tif_e/doha1_e.htm (last visited Oct. 30, 2007).

204 Doha Declaration, *supra* note 200.

205 *Id.*

206 *See* id. ¶¶ 4-5.

207 Doha Declaration, *supra* note 200, ¶ 5(b).

208 *See* id. ¶ 5(c).

209 Doha Declaration, *supra* note 200, ¶ 5(C).

210 See sources cited and accompanying text *supra* note 128.

Article 31(f) of TRIPS is addressed in what has become known as "Paragraph 6" of the Doha Declaration.[211] Paragraph 6 states that the WTO recognizes that countries with little or no manufacturing capabilities may not be able to effectively issue compulsory licenses under TRIPS.[212] After much debate, the Council for TRIPS finally came to a decision that members may waive their obligations under Article 31(f) of TRIPS if they are a least developed country or if not, they can show that they have insufficient or no manufacturing capacities in the pharmaceutical sector.[213] This allows members without pharmaceutical manufacturing facilities to import generic medicines from other countries under a compulsory license. Many commentators praised this decision and declared it a victory for developing and least developed nations.[214] Others feel that the decision will undermine pharmaceutical companies and be a disaster for open trade.[215]

B. *The Thai Patent Act*

Thailand has a relatively brief history with patent law. As recently as 1964, Thailand's Supreme Court ruled that patent rights were not enforceable under Thai law.[216] However, as a developing nation whose economic development relies on industrialization and technological advancement, the Thai government realized the necessity of patent protection.[217] In 1979,

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[211] World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, http://www. wto.org/english/tratop_e/trips_e/implem_para6_e.htM (last visited Aug. 19, 2008).

[212] Doha Declaration, *supra* note 200, ¶ 6.

[213] WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr. 1 (Sept. 1, 2003), *available at* www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [hereinafter *Paragraph 6*].

[214] C.P. Chandrasekhar & Jayati Ghosh, *WTO Drugs Deal: Does it Really Benefit Developing Countries?*, HINDU BUS. LINE, INTERNET EDITION, Sept.9, 2003, *available at* http://www.thehindubusinessline.com/2003/09/09/stories/2003090900140900.htm.

[215] *Id.*

[216] Jakkrit Kuanpoth, *Major Issues in the Thai Patent System*, L.J THAILAND BARRISTERS ASSN., *available at* THE ONLINE THAILAND LAW JOURNAL (1999), http://www.thailawforum.com/articles/jakpat1.html (last visited Nov. 11, 2007).

[217] *See* Thailand Department of Business Development, History of Department of Business Development, http://www.thairegistration.com/mainsite/index.php?id=4&L=1 (last visited Aug. 19, 2008); *see also*, Kuanpoth, *supra* note 216.

Thailand passed its first patent act.[218] This patent system was enacted as part of Thailand's economic policy to accelerate industrialization and trade expansion.[219] In 1992, Thailand revised its patent act amending the previous law in such areas as the "scope of patentable subject-matter, extension of the term of patent rights, the establishment of a drug price review committee, and the modification of the process for the grant of compulsory licenses."[220] In drafting its patent act the Thai Assembly incorporated many of the basic principles established in the Paris Convention.[221] The Assembly was also influenced by the legal paradigm under the Model Law for Developing Countries, drafted by BIRPI and later WIPO, and the basic rules embodied in the patent legislations of developed countries.[222] However, because Thai patent law is in its infancy, there has been little litigation and few judicial interpretations of the law.[223] The Thai patent act allows compulsory licenses to be issued by the government on its own behalf or to a private individual.[224] Under section 46, a private citizen can apply for a compulsory license for failure to work the patent.[225] Failure to work can arise in two situations. First, section 46 explicitly states that the failure to work arises when a patented product has not been produced or manufactured in Thailand.[226] Importation of a patented invention is not considered working a patent under this section.[227] The patent holder must utilize the patented invention in the country personally or through an authorized licen-

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218 Kuanpoth, *supra* note 216.

219 *Id.*

220 *Id.* Thailand's revised patent act specifically provides protection for pharmaceuticals. *Id.*

221 Kuanpoth, *supra* note 216.

222 *Id.*

223 *Id.*

224 THAI PATENT ACT, § 51 (B.E. 2535). *See also* THAI PATENT ACT, § 46 (B.E. 2535).

225 THAI PATENT ACT, § 46 (B.E. 2535).

226 *Id.*

227 *See* THAI PATENT ACT, § 46 (B.E. 2535). *See also* Letter from Drs. Jakkrit Kuanpoth, Associate Professor, Sukhothai Thammathirat University School of Law, and Jiraporn Limpananont, Associate Professor, Chulalongkorn University, in Response to PhRMA's Thailand Submission to 2000 USTR NTE Report (Jan. 29, 2000), *available at* http://www.cptech.org/ip/health/c/thailand/Response_to_PhRMA_report.html (last visited Aug. 19, 2008).

see.[228] Secondly, a compulsory license can be granted when the demand on the Thai market is not fulfilled. This occurs when the patentee refuses to sell the products protected by the patent in the Thai market in sufficient quantity, or when such products are sold at an excessive price.[229] This section does require the applicant to have "made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances."[230]

Section 51 of Thailand's Patent Act authorizes the government to grant compulsory licenses for the use and production of patented inventions.[231] Section 51 allows any ministry or department of the government to exploit the rights of any patent holder "in order to carry out any service for public consumption" or "to prevent or relieve shortage of food, drugs or other consumption items or for any other public service."[232] This section does not require prior negotiation with the patent holder in order to issue a compulsory license but it does require that the patentee must be paid a royalty and must be notified in writing without delay.[233]

Section 51 further states that the ministry or governmental department issuing the compulsory license must submit the amount of remuneration and conditions of the license to the Director-General.[234] The royalty rate and terms should be set as agreed upon by the government and the patentee and "the provisions of Section 50 shall apply *mutatis mutandis*. Section 50 permits the authorizing body to set the rate absent agreement with the patent holder.[235] In other words, it is inconsequential whether an agreement is reached with the patent holder – the government can set the royalty at whatever it likes. The patent holder's only recourse is to appeal.

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[228] *See* Kuanpoth, *supra* note 216.

[229] THAI PATENT ACT, § 46 (B.E. 2535).

[230] *Id.*

[231] THAI PATENT ACT, § 51 (B.E. 2535).

[232] Sean Flynn, *Thai Law on Government Use Licenses*, Dec. 18, 2006, http://www.wcl.american.edu/pijip_static/documents/ThailandCLLaw.2.doc?rd=1.

[233] THAI PATENT ACT, § 51 (B.E. 2535).

[234] *Id.*

[235] THAI PATENT ACT, § 50 (B.E. 2535).

Section 50 states that the terms of the license, including the applicable royalty, may be appealed.[236] However, under Thai law the patent holder has no right to appeal the grounds for the decision to grant the compulsory license.[237] The government may immediately begin to use the license for production or to purchase generic versions of the patented medicine regardless of whether the terms of the license are under appeal.[238]

IV. CRITICISMS AND CONSEQUENCES

No one would argue that access to drugs and health care is not a major problem throughout the developing world. And pharmaceutical companies are an easy target on which to place the blame. However, instead of shifting the blame onto pharmaceutical companies, governments need to take responsibility for their own citizens. Governments need to address the issues that contribute to medical inaccessibility such as poverty, poor health care infrastructure, and lack of trained personnel. Without fixing these fundamental problems, the issue of how much drugs cost is a moot point.

The benefits that modern pharmaceuticals have brought to the world are incalculable. Pharmaceuticals have eradicated devastating diseases, developed treatments for hundreds of afflictions, and for patients with HIV, these drugs have added years to their lives and given them some hope for what used to be an automatic death sentence. Pharmaceuticals have not only benefited the health of millions of people, but they have also been economically beneficial as well. Aside from the jobs that pharmaceutical companies provide and the money that goes into the American economy, prescription drugs save approximately three dollars in medical care for every one dollar spent on medicine.[239]

The use of unwarranted compulsory licenses puts the future of pharmaceutical companies at risk. The availability of

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[236] *Id.*

[237] *See* Flynn, *supra* note 232, at 4.

[238] *Id.* at 5.

[239] PHARMACEUTICAL PROFILE, supra note 104, at 25. For every one dollar spent on diabetes, $7.10 was saved. *Id.* For every one dollar spent on cholesterol drugs, $5.10 was saved, and for every one dollar spent on blood pressure drugs, $4 was saved. *Id.*

new and improved drugs may diminish the quality of as well as accessibility to affordable drugs. Thailand's use of compulsory licensing is a misguided attempt to help its citizens. What Thailand obviously has not considered is that its imprudent decision may have put its citizens' future access to medicines in jeopardy.

A. *Criticisms*

1. *The Ambiguity of TRIPS Concerning Compulsory Licenses*

The nature of international negotiation is compromise. A consequence of this conciliatory character is that the discussions inevitably result in language that is vague and many times contradictory.[240] The TRIPS agreement is no exception to this and it is especially evident in regards to compulsory licenses.

Article 31 of TRIPS allows countries to waive negotiations with patent holders before issuing compulsory licenses in cases of national emergencies, of extreme urgency, and for non-commercial public use.[241] TRIPS does not define any of these enumerated circumstances which has led to much confusion and debate.[242] The Doha Declaration attempted to clarify these broad conditions but only made the situation more uncertain by allowing countries to determine for themselves what constitutes a national emergency or a case of extreme urgency.[243] By allowing countries such broad latitude in defining a national emergency, TRIPS is giving its members an overwhelming amount of discretion in deciding whether or not to issue compulsory licenses. While the declaration did identify public health crises related to HIV/AIDS, tuberculosis, malaria, and other epidemics as a situations that might qualify as national emergencies, this does not provide much guidance. People in most

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[240] *See generally* John A. Ragosta, *Unmasking the WTO – Access to the DSB System: Can the WTO DSB Live up to the Moniker "World Trade Court"?*, 31 LAW & POL'Y INT'L BUS. 739 (2000) (discussing the short comings of the WTO's dispute settlement system).

[241] TRIPS Agreement, *supra* note 131, art. 31.

[242] See, for example, Christopher Arup, TRIPs FORUM: A Matter of Interpretation, http://eprints.vu.edu.au/archive/00000113/01/conf_tripsforum2004_arup.pdf (last visited Aug. 19, 2008).

[243] Doha Declaration, *supra* note 200, ¶ 5(c).

countries would consider the HIV/AIDS epidemic a public health crisis, but does that mean every country should be allowed to seize patent rights?

Although the Doha Declaration gave members the discretion to determine what constitutes a national emergency or a circumstance of extreme urgency, it was silent on the interpretation of any other language.[244] The only direction the members are given is in paragraph 5(a) which asserts that the provisions of TRIPS should be interpreted by applying the customary rules of interpretation of public international law and read in light of the objectives and principles of the agreement.[245] Articles 7 and 8 of TRIPS address its objectives and principles.[246] Article 7 states that TRIPS objectives are to protect and enforce IPRs in a manner conducive to social and economic welfare.[247] Article 8 allows members to make laws to protect public health and to prevent abuses of IPRs by right holders or practices that restrain trade.[248] On issues of interpretation, one side is going to want to interpret the language in favor of public health and the other side in favor of IPRs. Both issues are part of the objectives and principles of TRIPS, so who is right? Although TRIPS specifically recognizes the importance of affordable medicine, the purpose and intent behind the formation of the WTO was to promote free trade and to address the growing issues in international intellectual property law.[249] Some would argue that the WTO's purpose is not humanitarian in nature and that its agreements should be read in view of its original purposes and not as advocating health care.

There are several terms in the compulsory license provisions of TRIPS that are open to various interpretations. One term whose meaning was left open is "public non-commercial use." The use of the term "non-commercial" leaves the door open

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[244] Sharifah Rahma Sekalala, Beyond Doha: Seeking Access to Essential Medicines for HIV/AIDS Through the World Trade Organisation, http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf (last visited Aug. 19, 2008).

[245] Doha Declaration, *supra* note 200, ¶ 5(a).

[246] TRIPS Agreement, *supra* note 131, arts. 7-8.

[247] TRIPS Agreement, *supra* note 131, art. 7.

[248] TRIPS Agreement, *supra* note 131, art. 8.

[249] World Trade Organization, Understanding the WTO – What is the World Trade Organization?, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm (last visited Aug. 19, 2008).

to various interpretations. West's Legal and Commercial dictionary defines "commercial" as a generic term applied to buying and selling.[250] By its very definition the term is nonspecific. Whoever manufactures the drug is not going to give it away, so that would fall within the definition of commercial. Does "public non-commercial use" mean only governments can produce the licensed generic drugs, as opposed to private manufacturers? Regardless of whether it is a government or private manufacturer, the producer of the drugs will make money on the drug. Is that considered commercial? Without any guidance countries will use their own discretion to determine what constitutes "non-commercial."

TRIPS also neglects to define what adequate remuneration is and how it should be calculated.[251] Developed countries would like full compensation, while developing and least developed countries would like little or none.[252] Should it depend on market value? On profit margin? On the GDP of the issuing country? There are many elements that can be looked at to determine compensation and TRIPS provides no guidance other than that it shall be "adequate" and "take in to account the economic value to the importing Member of the use that has been authorized in the exporting Member."[253] Without any defined boundaries or direction, who is to say what is adequate and what is not? Thailand feels that 0.5% is adequate; many commentators disagree and claim it is far below industry norms of 4-10%.[254] There is no consensus among countries as to how a

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[250] WEST'S LEGAL AND COMMERCIAL DICTIONARY (1st ed. 1986).

[251] Do Hyung Kim, Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries, GLOBALEX, Feb. 2007, http://www.nyulawglobal.org/globalex/TRIPS_Compulsory_Licensing.htm (last visited Aug. 19, 2008) ("Furthermore, TRIPS requires countries utilizing compulsory licensing to pay "adequate remuneration" without specifying a method of calculation.").

[252] *See* Bryan C. Mercurio, TRIPS, Patents, and Access to Life-saving Drugs in the Developing World, 8 MARQ. INTELL. PROP. L. REV. 211, 242-45 (2004).

[253] TRIPS Agreement, *supra* note 131, art. 31(h).

[254] Daniel M. Putterman, *Model Material Transfer Agreements for Equitable Biodiversity Prospecting*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 149 (1996); James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* (2005), http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf (discussing state practice regarding the determination of reasonable royalties and adequate renumeration as nations establish the conditions under which they may issue compulsory licenses).

reasonable royalty should be calculated. In the United States, courts have developed a set of guidelines known as the Georgia Pacific factors.[255] But even within the United States there is argument over whether these factors are economically appropriate.[256] This lack of clarity will only lead to confusion and the potential for abuse.

The Council for TRIPS decided that members could import pharmaceuticals under a compulsory license if they are a LDC or if they can show they have insufficient or no pharmaceutical manufacturing facilities.[257] The Council failed to provide any

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[255] In the United States, the Georgia Pacific guidelines have provided the framework for determining royalties for patent infringement for over 30 years. In *Georgia Pacific*, the court established 15 factors to be used to determine the monetary payments that would compensate for patent infringement. 1) The royalties received by the patent holder for licensing the patent, proving or tending to prove an established royalty, 2) the rates paid by the licensee for the use of other similar patents, 3) the nature and scope of the license, such as whether it is exclusive or nonexclusive, restricted or non-restricted in terms of territory or customers, 4) the patent holder's policy of maintaining its patent monopoly by licensing the use of the invention only under special conditions designed to preserve the monopoly, 5) the commercial relationship between the patent holder and licensee, such as whether they are competitors in the same territory in the same line of business or whether they are inventor and promoter, 6) the effect of selling the patented specialty in promoting sales of other products; the existing value of the invention to the patent holder as a generator of sales of non-patented items; and the extent of such derivative or "convoyed" sales, 7) the duration of the patent and the term of the license, 8) the amount that the patent holder and a licensee would have agreed upon at the time the infringement began if they had reasonably and voluntarily tried to reach an agreement, 9) the opinion testimony of qualified experts, 10) the portion of the realizable profit that should be credited to the invention as distinguished from any non-patented elements, manufacturing process, business risks or significant features or improvements added by the infringer, 11) the portion of the profit or selling price that is customary in the particular business or in comparable businesses, 12) the extent to which the infringer used the invention and any evidence probative of the value of that use, 13) the nature of the patented invention, its character in the commercial embodiment owned and produced by the licensor, and the benefits to those who used it, 14) the utility and advantages of the patent property over any old modes or devices that had been used; and 15) the established profitability of the patented product, its commercial success and its current popularity. Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (1970).

[256] *See generally* William Choi & Roy Weinstein, *An Analytical Solution to Reasonable Royalty Rate Calculations*, 41 L.J. & TECH 49 (2001) (explaining the Nash Bargaining System as a supplement to the Georgia Pacific factors); *see also* Roy J. Epstein & Alan J. Marcus, *Economic Analysis of the Reasonable Royalty Rate: Simplification and Extension of the* Georgia Pacific *Factors*, *available at* http://www.royepstein.com/epstein-marcus_jptos.pdf.

[257] *Paragraph 6*, *supra* note 225.

guidelines as to "insufficient manufacturing capacities."[258] The plain meaning of the text would likely indicate that the issuing country does not have manufacturing capabilities to produce sufficient quantities of the drug. Thailand is not a LDC and because it has been producing GPO-Vir for years it is safe to say it has sufficient manufacturing capacity, yet it has begun importing efavirenz from India.[259] Under the plain meaning of the text Thailand would clearly be in violation of TRIPS. On the other hand, perhaps "insufficient" refers to the quality of product. In that case Thailand would not be in violation of TRIPS since their manufacturing plants are not up to WHO standards.[260] To avoid the abuse of TRIPS and compulsory licenses the WTO needs to establish what its language means, otherwise it is open to interpretation.

These are issues the WTO needs to address. The WTO needs to provide more concrete guidelines and definitions as to what justifies the issuance of a compulsory license; it should not be left to the discretion of the issuing country. Furthermore, a country seeking a license should first be required to make an effort to acquire the drug from the patent holder. It is only fair that under any circumstances, emergency or not, the patent holder be afforded the opportunity to provide the drug at an equitable price. If negotiations with the patent holder are unsuccessful and it has been reasonably determined that a license should be issued, then remuneration should be determined by an independent WTO committee, the patent holder, and the issuing country. Factors such as the importing country's GDP, rates paid for licenses of similar patents, cost of production, the nature and scope of the license, and therapeutic value of the medicine should be considered, as well as any other issues the committee deems relevant.

Although compulsory licenses are subject to review under TRIPS, this can be a lengthy process and the DSB does not grant preliminary injunctions.[261] Additionally, it has been ar-

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[258] *Id.*

[259] Hookway & Zamiska, *supra* note 8.

[260] Apinya Wipatayotin, *Certification Urged for AIDS Drug, New GPO Production Plant is Needed First*, BANGKOK POST, Jan. 5, 2006, *available at* http://www.aegis.org/news/bp/2006/BP060101.html (last visited Aug. 19, 2008).

[261] Aditi Bagchi, *Compulsory Licensing and the Duty of Good Faith in TRIPS*, 55 STAN. L. REV. 1529, 1535-40 (2003).

gued that the DSU of the WTO has many flaws and litigation over how negotiated agreements should be interpreted has led to the creation and imposition of obligations that members never agreed to.[262] In light of the uncertainty that surrounds TRIPS' provisions for compulsory licenses, it is critical that the WTO address these issues and provide some clarity and uniformity.

2. *Demonization of Pharmaceutical Companies*

The focus on patents and prices of pharmaceuticals ignores the complexity of access to health care issues and ultimately prevents policy makers from coming up with any real solutions to the problem. Even the WHO and patient groups have recognized that this single-minded focus on drug prices is simplistic. The European Coalition of Positive People publicly stated with regard to HIV/AIDS drugs that "focusing on patent protection is 'simplistic and fails to take into account the serious practical problems that need to be addressed.'"[263] Drugs could be free and still not be appropriately used without adequate health care systems and infrastructures in place. Moreover, they would rapidly become ineffective due to drug resistance. Kassim Sidibe, a minister of the National Fight Against AIDS, summed up the issue well when he said, "cheap drugs are good, free drugs are better, but they are only a piece of the puzzle."[264] It is clear the issues of patents and prices of drugs should not be the

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[262] *See generally* John Ragosta et al., *WTO Dispute Settlement: The System is Flawed and Must Be Fixed*, 37 INT'L LAWYER 697 (2003) (arguing that binding arbitration is an inappropriate method of dispute settlement when many terms and provisions of the agreements are ambiguous).

[263] *2000 Foreign Policy Overview and the President's Fiscal Year 2001 Foreign Affairs Budget Request: Hearings Before the Subcomm. on African Affairs and Subcomm. on Western Hemisphere, Peace Corps, Narcotics and Terrorism and the Comm. on Foreign Relations*, 106th Cong. 238 (2000) (statement of Dr. Harvey E. Bale Jr., Director-General, International Federation of Pharmaceutical Manufacturers Association, Geneva, Switzerland), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_senate_hearings&docid=f:63628.pdf [hereinafter Bale Testimony] (testifying before the Senate on AIDS in Africa).

[264] Douglas Farah, *Seeking a Remedy for AIDS in Africa*, WASH. POST, June 12, 2001, at A17 (quoting Kassim Sidibe).

primary concerns when some countries cannot even afford to use drugs that have been donated to them.[265]

Access to even the most basic and off-patent medicines is often poor in developing and least developed countries. Patent protections cover less than 5% of the medicines on the WHO's essential drugs list.[266] Many least developed countries still do not have even a rudimentary patent system in place[267] and those that are WTO members are not required to implement patent systems until 2016.[268] A study in the Journal of the American Medical Association looked at the status of fifteen AVRs in 53 African countries and found that two of the drugs were not patented in any of the countries, four were only patented in South Africa, and eleven of the drugs were not patented in more than half the countries.[269] Despite the largely non-existent patent protection, these countries still lack access to these drugs.[270] Furthermore, in countries where patent protection has been introduced in the past decade, there has been no significant impact on access to medicines.[271]

Pharmaceutical companies have been singled out as the bad guys. NGO's and even some governments portray pharmaceutical companies as greedy, heartless, and evil corporate monsters that fuel the injustices of the world.[272] These groups see patents as the mechanism for this injustice.[273] Opponents, and even some advocates, of pharmaceutical companies describe

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[265] Nevirapine is donated to African countries by Boehringer Ingelheim but is rarely used. *Id.* Nevirapine is used in preventing mother to child HIV transmission during birth. *Id.* Attaran & Gillespie-White, *supra* note 118, at 1891.

[266] Harvey E. Bale Jr., *Patents and Public Health: A Good or Bad Mix?*, http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm (last visited Apr. 20, 2008).

[267] *See* Attaran & Gillespie-White, *supra* note 118.

[268] *See* Kevin Kennedy, *The 2005 TRIPS Extension for the Least Developed Countries: A Failure of the Single Undertaking Approach?*, 40 INT'L LAWYER 683, 684 (2006).

[269] Attaran & Gillespie-White, *supra* note 118.

[270] *Id.*

[271] Bale, *supra* note 266.

[272] *See* Richard A. Epstein, Editorial, *The Myth of the Big Bad Drug Companies; They're not Greedy, They're over-regulated. The Result is Fewer Pills to Cure our Ills*, L.A. TIMES, Dec. 22, 2006, at A39.

[273] *See* Mike Adams, *Bad Patents, Evil Corporations and the Rise of Intellectual Imperialism*, NATURAL NEWS, Mar. 1, 2008, http://www.natural news.com/z022755.html.

patents as instruments that create "monopolies."[274] This is a completely inaccurate statement. First, patents give exclusivity rights to a single drug or vaccine, not multiple or entire classes of drugs and vaccines. This does not constitute a monopoly since there are usually alternative treatments to any medicine. For instance, there are a minimum of six patented protease inhibitor AVRs for the treatment of AIDS.[275] The existence of multiple treatment options, spurred by patent protection, ensures medical choice and price competition. Second, although a patent term is technically for 20 years, the patent holder actually only has 5 to 10 years to recover investment costs and to fund new research, since patents are applied for early in the development process and it typically takes 12-15 years of tests and FDA review for new drugs to reach patients.[276]

Opponents also like to argue that it does not matter if patents increase innovation because it is pointless to develop medications that the poor cannot afford.[277] They contend that the discovery of new treatments is not a sufficient reason to advocate patent protection when those new treatments will also enjoy strong patent protection and will thus be out of reach to the world's indigent nations.[278] This argument is illogical and inherently flawed. First, is it better that no one should get the benefit of new and improved medicines because they are not available to everyone? By this logic it is all or nothing, which is even more inherently unjust than the imperfect access that poor countries have now. Secondly, patent protection is temporary. After a patent expires, not only are generic brands available to all, but the knowledge behind the patent has been available in the public domain so that others can use it to develop new and better drugs. If innovation becomes stagnant and new medications are not developed, no one, including the poor, will have access.

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[274] Martin Foreman, Don't let TRIPS Trip up Access to Essential Drugs, PAN AMERICAN HEALTH ORGANIZATION, http://www.paho.org/english/dd/pin/Number16_last.htm (last visited Aug. 19, 2008).

[275] Bale, *supra* note 266.

[276] *Id.*

[277] *See* Julian Morris,*Mercantilism Today: How a Dead Philosophy Comes Back to Life*, NATIONAL REVIEW, Sept. 15, 2003, *available at* http://www.policynetwork.net/main/article.php?article_id=584 (last visited Aug. 19, 2008).

[278] *See generally* Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 BERKELEY J. INT'L L. 524 (2005).

B. *The Consequences of Inaction*

Allowing countries to issue compulsory licenses at whim sets a dangerous precedent. Without firm meaning affixed to TRIPS provisions, countries will interpret the agreement however they want and in whatever way benefits them regardless of the long-term consequences. There is a critical need for more narrow definitions of TRIPS in order to ensure uniform interpretation.

1. *Domestic Consequences: US Consumers and Pharmaceutical Companies.*

High-technology industries and the pharmaceutical industry in particular are an integral part of the American economy.[279] The Pharmaceutical industry has developed and produced dozens of life-saving and life-enhancing medications. They have developed treatments for cancer, heart disease, diabetes, and HIV/AIDS, and have changed the lives of millions of people. The TRIPS agreement as it stands threatens the ability of pharmaceutical companies to realize profits and support their R&D. It is important to protect the industry to ensure profitability and in effect ensure the continued development of vital new medicines.

a. Compulsory Licenses Will Diminish Pharmaceutical Innovation

Weak IPRs threaten the discovery and development of new medications. Private industry funds virtually all discovery and development of any new drug.[280] Investor support for pharmaceutical companies depends on the expected returns of a relative handful of products.[281] Strong patent protection helps assure investors that their high-risk investments might pay off down the line.[282] Conversely, without confidence that discovery

[279] Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 208 (1999) (stating that the pharmaceutical industry is "projected to invest over $20 billion in the United States . . . ").

[280] United States State Department, Focus on Intellectual Property Rights, http://usinfo.state.gov/products/pubs/intelprp/cost.htm (last visited Aug. 19, 2008).

[281] *See id.*

[282] *See* Masia, *supra* note 100.

of a new drug or vaccine can produce a profit, investors in pharmaceutical firms will invest their money elsewhere.[283] Pharmaceutical companies rely on patents to protect their research and their profitability. Patents ensure exclusivity in the market which allows companies to recoup their R&D investment, investment in failed compounds, and to make a profit. Without these assurances there is little incentive for inventors to share their invention with the public. Without exclusivity the best way for an inventor to make a profit is to keep the invention a secret, depriving others of the opportunity to build upon those findings.[284] Without dependable patent protection pharmaceutical companies will not only have trouble bringing in new investors but they may also have problems with their current investors to whom the companies owe certain duties.[285] Like any other public corporation, pharmaceutical companies must answer to their stock holders and if they can not produce the results their investors expect they may face a whole host of legal problems.

The fact is, there is no cure or vaccine for HIV/AIDS.[286] There are viral strains resistant to current drugs and resistance will continue to develop.[287] There is a very real need for new drugs beyond first and second line therapies.[288] There is also a need for new drugs with easier administration, including medicines that only need to be taken once or twice a day, fixed dose combinations, and improved pediatric formulations.[289] Right now there are more than 20 ARVs available but there are 30 more still in human trials.[290] There is a need for a vaccine

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[283] *Id.*

[284] *See* Lisa C. Pavento, et al., *International Patent Protection for HIV-Related Therapies: Patent Attorneys' Perspective*, 17 EMORY INT'L L. REV. 919, 919 (2003).

[285] The predominant view on corporate responsibility in the U.S. is that "corporations have no specific social responsibilities beyond profit-maximizing for the benefit of shareholders but that such profit maximizing must occur within the confines of the law, without deception or collusion." Williams, *supra* note 12, at 713-14.

[286] ThinkHIV, Is There a Cure or Vaccine for HIV/AIDS?, http://www.thinkhiv.org/dp/node/654 (last visited Aug. 19, 2008).

[287] amfAR, Basic Facts About HIV/AIDS, http://www.amfar.org/cgibin/iowa/abouthiv/record.html?record=7 (last visited Aug. 19, 2008).

[288] Bale, *supra* note 266.

[289] G8 Summit, *supra* note 13, at 13.

[290] Avert, Table of Approved AIDS Drugs, http://www.avert.org/drugs-table.htm (last visited Aug 19, 2008).

and of the 75 new drugs in trials, 15 are vaccines.[291] If opponents of pharmaceutical companies want to fight AIDS, finding a cure or vaccine is the best way to do it. In order for that to happen it is imperative that new innovation not be hindered.

b. U.S. Consumers Will Bear the Burden of Pharmaceutical R&D Costs

Another consequence of weak IPRs will be the unfair burden of R&D costs that that U.S. consumers will have to bear. American consumers already assume a large part of pharmaceutical and biotech R&D costs.[292] Although the pharmaceutical market for developing countries is increasing, it is still the U.S., Europe, and Japan that account for the majority of sales.[293] If pharmaceutical companies lose all their revenues from developing countries, U.S. prices are going to increase to make up for those losses. There are already millions of Americans that are without insurance and cannot afford health care.[294] An increase in prices will only exacerbate the problem.

This is a consequence that will primarily affect the United States. Many other developed countries have socialized medicine that allows them to obtain drugs at below market price.[295] In this type of system, the government has almost total control over the health care market and uses this control to negotiate lower prices for bulk drugs.[296] Even though these countries get discounted prices there are also many drawbacks to the system.[297] In the U. S. we have a free market system and

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[291] *Id.*

[292] *See* PhRMA Meets with Thai Health Minister, *supra* note 16.

[293] *See* Hookway & Zamiska, *supra* note 8.

[294] CENTER FOR DISEASE CONTROL, HEALTH INSURANCE COVERAGE: EARLY RELEASE OF ESTIMATES FROM THE NATIONAL HEALTH INTERVIEW SURVEY, 2006 (2007), http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur200706.pdf (last visited Aug. 19, 2008).

[295] Doug Pibel, Sarah van Gelder, Health Care: It's What Ails Us, YES! MAGAZINE, Fall, 2006, http://www.yesmagazine.org/article.asp?ID=1498 (last visited Aug. 19, 2008).

[296] *See* Cost of Prescription Drugs, *supra* note 11.

[297] Many times governments will not pay for the newest medicines available so patients in these countries will not have access to what may be the best drugs available. Additionally, the patients in these countries do not have as many medicines to choose from when designing individual treatment plans. Another drawback of this system is that generic medicines will often cost more in those

the prices are determined by market forces and competition.[298] When patents are broken by compulsory licenses and pharmaceutical profits are threatened, it is the free market systems that will see the biggest increase in prices. If drug prices increase substantially it is likely insurance premiums will also increase, leaving many Americans unable to afford insurance. The rationalization behind compulsory licenses is to assist people in developing countries but the fact is, it is likely to harm American consumers who will no longer be able to afford medication.

2. *Foreign Consequences: Thailand and Other Developing Countries.*

According to the World Bank, Thailand's overall growth performance is not keeping pace with its neighboring countries. Thailand's GDP grew by 5% in 2006, slightly higher than in 2005.[299] However, Southeast Asia has grown 5.5%.[300] China is averaging 10% and Vietnam 8%.[301] Clearly competition for foreign investment, direct or indirect, remains strong. Foreign direct investment has "transferred amazingly little tacit knowledge and technology, as only a handful of companies have set up research establishments in Thailand."[302] It is no wonder with Thailand's conspicuous lack of respect for intellectual property protection. Based on World Bank recommendations, to further develop its economy, Thailand needs to move towards a knowledge economy that promotes innovation.[303]

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countries than in countries with free markets systems. *See* COST OF PRESCRIPTION DRUGS, *supra* note 11.

298 *Id.*

299 THAILAND BOARD OF INVESTMENT, THAILAND INVESTMENT REVIEW (2007) http://www.boi.go.th:8080/issue/200706_17_6/cover.htm (last visited Aug. 19, 2008).

300 Asian Development Bank, Asian Development Outlook 2006 Update – Developing Asian and the World – Subregional Summaries, http://www.adb.org/documents/books/ado/2006/update/part010404.asp (last visited Aug. 19, 2008) (stating that the entire subregion had an average growth of 5.4%.).

301 VietNamNet Bridge, *ADB: 7.8% Economic Growth for Vietnam in 2006*, VIETNAMNET, July 4, 2006, http://english.vietnamnet.vn/biz/2006/04/558167/ (last visited Aug. 19, 2008); ChinaDaily, China's GDP grows 10.7% in 2006, CHINADAILY, Jan. 25, 2007, http://www.chinadaily.com.cn/china/200701/25/content_792311.htm (last visited Aug. 19, 2008).

302 World Bank, *supra* note 20.

303 *Id.*

Compulsory licenses have been viewed as the solution to the drug access issue. Proponents of compulsory licensing only view the issue in terms of decreased consumer prices. However, what they fail to see is that these benefits are small and the long term damage of widespread use of compulsory licensing will be substantial. The WTO is encouraging companies in developing countries, such as India and Korea, to shift from manufacturing generic drugs towards pursuing their own innovative research in pharmaceuticals and biotechnology.[304] However, if lax compulsory licensing rules are promulgated, both the patients and the economies of these countries will ultimately suffer when new competitors withdraw, and companies revert to the business strategy of replicating medicines others have researched, discovered, and developed.

Without respect for intellectual property, many developing and least developed countries' industries and patients risk losing out on the benefits of modern genome-based research that is increasingly the basis of pharmaceutical and biomedical innovation.[305] Thus, the real global threat is that without strong and effective international intellectual property rights the disparity between developed and developing countries will become greater in the future.

CONCLUSION

The pharmaceutical industry has provided the world with hundreds of life-saving drugs and vaccines. These efforts come largely from the ability to protect their research and development through patents. It is crucial that pharmaceutical companies be able to realize a profit or there will no longer be any incentive to invest in the development of new medicines and/or we risk drug prices in the U.S. climbing even higher. Impoverished people worldwide deserve access to medication but compulsory licenses are not the solution. Compulsory licensing has serious and far reaching consequences; it is a short term remedy to a long term problem. If the WTO continues to allow the broad interpretation of TRIPS in which compulsory licenses can

304 Bale, *supra* note 266.

305 *Id.*

be abused, everyone will lose out on the life-saving and enhancing benefits that pharmaceutical and biotech companies provide.