2009

Compulsory Licenses: The Dangers Behind the Current Practice

Jamie Feldman

Follow this and additional works at: http://scholarlycommons.law.hofstra.edu/jibl

Recommended Citation
Available at: http://scholarlycommons.law.hofstra.edu/jibl/vol8/iss1/9

This Note is brought to you for free and open access by Scholarly Commons at Hofstra Law. It has been accepted for inclusion in Journal of International Business and Law by an authorized administrator of Scholarly Commons at Hofstra Law. For more information, please contact lawcls@hofstra.edu.
COMPULSORY LICENSES:
THE DANGERS BEHIND THE CURRENT PRACTICE

Jamie Feldman*

INTRODUCTION

Compulsory licenses are extremely powerful rights granted to governments, which must be used prudently. A compulsory license restricts the rights of a patent holder by authorizing third parties to make, use, and sell patented products without the consent of the patent holder.¹ Ever since the idea for compulsory licenses was first adopted by the 1883 Paris Convention, this tool has become a fixture in patent systems around the world, and has perpetually been a topic of controversy.² Only under extraordinary circumstances should compulsory licenses be granted upon patented pharmaceutical products; otherwise, detrimental effects on global health as well as on the global economy will transpire.

This note will articulate why the current laws governing compulsory licenses are insufficient to safeguard the world against unreasonable uses of compulsory licenses placed upon pharmaceutical products. Part I will give a general overview describing intellectual property rights and compulsory licenses. Part II contrasts the various health issues plaguing the globe against the need for pharmaceutical companies to earn profits from their patented medicines. Part III discusses the origin of compulsory licenses and the current laws that govern the issuance of compulsory licenses. Part IV focuses on the nations of Thailand, Brazil, and Rwanda and why these nations’ recent uses of

* J.D. Candidate, 2010, Hofstra University School of Law. I would like to thank the entire senior staff of the Journal of International Business and Law, particularly Vanessa Tiradentes and Brian Farrar. I would also like to thank my advisor, Professor Efthimios Parasidis, along with Professor Eric Bensen, for providing me with invaluable guidance. A special thanks to my parents, Mitchell and Mauria, and my siblings, Madelyn, Daniel, Billy, Allison, and Jessica, for loving and supporting me in everything I do. Thank you to my best friends, Jenna and Jen, for always being there for me. Lastly, I would like to thank Michael for bringing me happiness everyday.


² Chien, supra note 1.
compulsory licenses have all been headlining news. Thailand and Brazil’s actions have created negative connotations, while Rwanda’s use has been widely praised. Part V highlights four main dangers that are likely to arise if the current laws are not amended. Finally, Part VI lays out several suggestions on how to reform the provisions which govern compulsory licenses.

I. PLANTING THE SEEDS FOR CONTROVERSY

A. Background

The modern patent system is rooted in the Venetian Act, adopted during the early Renaissance era. The Venetian Act, similar to the modern day patent system, called for the registration of new and ingenious devises reduced to perfection. Further molding the modern patent system was the Statute of Monopolies, which was created by the English Parliament in the sixteenth century. The Statute of Monopolies was implemented in response to the English Crown’s practice of granting individuals exclusive rights to produce, import, and sell certain commonplace items such as salt and vinegar. The Statute prohibited these monopolies, but created an exception which permitted a patent to be granted for a 14-year period to a creator of a new invention. These patents granted over novel creations would encourage innovations that would benefit society, as opposed to the Crown created monopolies which restrained the trade of commodities that had previously been in the public domain. Today, the United States’ patent system is protected by the Constitution. Article I, Section 8, authorizes Congress to grant exclusive rights to authors and inventors for their respective discoveries for a limited amount of time. In order to receive a patent, an inventor must submit a patent application to The Patent and Trademark Office (hereinafter the “PTO”). The PTO then reviews the application and grants a patent if several requirements are met. A patent

4 Id.
5 See Lasercomb America, Inc. v. Reynolds, 911 F.2d 970 (4th Cir. 1990).
6 Id. at 975 (explaining that these practices lead to shortages and inflated prices).
7 Id.
8 Id.
9 Id.; see also U.S. CONST. art. I, § 8.
10 MERGES ET AL., supra note 3, at 124.
11 Id. (listing the five requirements of a patent: eligible subject matter, usefulness, novelty, not
grants the patent holder a 20-year exclusive right over his invention, during which time no one, absent authorization by the patent holder, may make, use, or sell the patented product. In exchange for this exclusive right, the patent holder pays his due to society by disclosing the technical information behind how the invention was created, and at the end of the 20-year period the protection expires and the creation enters the public domain.

In the realm of pharmaceuticals, an inescapable tension exists between the aspiration to provide the sick with access to life-saving drugs, and the need to maintain incentives for pharmaceutical companies to create new innovations by ensuring a return on their investments. On one extreme it is argued that "patent protection should end where saving lives or alleviating suffering begins; that is, patent law should be subordinate to certain social interests." At the opposite end of the spectrum, it is argued that pharmaceuticals should be treated like all other commodities, thus the price should be determined by the basic principles of supply and demand. The former approach is motivated by socio-humanitarian objectives because health, wellbeing, and even death are on the line. The latter approach, on the other hand, is driven by the incentive to innovate. Prospective profits have always been the necessary incentive in encouraging the inventions of marketable products. Most opinions on this issue fall somewhere in the middle of these two extremes, believing that some governmental regulation is necessary in guarantying access to essential medicines. However, the question still remains: when does governmental regulation cross the line from being helpful to becoming destructive?

Intellectual property rights are the fundamental driving forces behind the pharmaceutical industry. In light of globalization, transnational

obviousness, and sufficient disclosure to allow others to make and use the invention).

12 Id. at 28.
16 Id. (explaining that patentees are in general able to set the price of their invention, which in turn determines where and to whom the product is sold).
17 Id. (explaining that medicines are unique from other patented products in the sense that they are capable of easing pain and are even able to prolong life).
18 Id.
20 Jenna Greve, Healthcare in Developing Countries and the Role of Business: A Global
pharmaceutical companies have become paramount agents on the world stage.\textsuperscript{21} Due to the massive amount of capital pharmaceutical companies reap each year, they have a crucial impact on the globe's economic order.\textsuperscript{22} Currently, pharmaceutical companies profit over $600 billion each year.\textsuperscript{23} This financial power leads to lobbying power, which in turn leads to political power.\textsuperscript{24} Although often feared for being too influential, dominant pharmaceutical companies are crucial in assuring a continuously improving quality of life. In light of the fact that pharmaceutical companies are capable of earning these immense profits each year, this provides a built-in guarantee that novel drugs will continuously be produced. Absent this ability to earn vast financial gains, pharmaceutical progress will surely come to a halt due to lack of an incentive to innovate.

**B. Compulsory Licenses**

A compulsory license is a prime example of a tool that threatens pharmaceutical companies' ability to develop new drugs. A compulsory license provides a national government with the authority to practice an invention covered by a patent, or authorize another party to do so, without permission from the patent holder.\textsuperscript{25} The practice of issuing compulsory licenses is an exception to the general rule that patent holders have an exclusive right over their invention. In this situation authorization is given to exploit an invention without the patent holder's consent.\textsuperscript{26} The purpose of a compulsory license is to increase access to essential goods by providing a wider use of the invention than the patent holder intended.\textsuperscript{27} As a result, the patent holder is forced to give up a large part of his property right for the purported benefit of the public.\textsuperscript{28}

\textit{Governance Framework to Enhance the Accountability of Pharmaceutical Companies, CORP. GOVERNANCE, September 7, 2008, available at 2008 WLNR 16938575. Pharmaceutical companies are able to patent vital medicines along with lifestyle drugs.}

\textsuperscript{21} Id.

\textsuperscript{22} Id.

\textsuperscript{23} Id.

\textsuperscript{24} Id.

\textsuperscript{25} Cahoy, \textit{supra} note 1, at 141-42.

\textsuperscript{26} \textit{NAT’L BOARD OF TRADE, THE WTO DECISION ON COMPULSORY LICENSING} 7 (2008), http://www.kommers.se/upload/Analysarkiv/Arbetsomr%C3%A5den/WTO/Handel%20och%20skydd%20f%C3%B6r%20immateriella%20r%C3%A4ttigheter%20-%20TRIPS/Rapport%20The_WTO_decision_on_compulsory_licensing.pdf [hereinafter WTO DECISION].

\textsuperscript{27} Cahoy, \textit{supra} note 1, at 133.

\textsuperscript{28} Id.
The issuance of a compulsory license comes at a high price in the world of pharmaceutical products. The patent holder's investment-backed expectation of earning a profit from the patented medicine is disrupted when his exclusive right over his patented product disappears. The practice of compulsory licensing is addressed in the World Trade Organization's agreement on Trade Related Aspects of Intellectual Property Rights. The TRIPS Agreement was negotiated at the 1986-1994 Uruguay Round and is to date the most comprehensive multilateral agreement on intellectual property. The goal of the TRIPS Agreement is to standardize the manner in which intellectual property rights are protected around the world. Although the TRIPS Agreement neither defines 'compulsory license' nor specifies when exactly a compulsory license can be granted, Article 31 of the TRIPS Agreement does authorize any WTO Member to issue a compulsory license after several ambiguous procedures are met.

Taking into consideration the international and domestic law on this issue, an inevitable question arises; how will the current practice of compulsory licensing affect the future of the pharmaceutical industry? As a major force in the international economy, pharmaceutical companies allocate billions of dollars each year into research and development in order to provide the world with life-saving drugs; yet, any Member of the WTO has the authority to essentially override the investment-backed patent a pharmaceutical company holds. This practice will leave the pharmaceutical industry guarded as to
where and what they invest their money into.

C. The Need for Stronger Laws Governing Compulsory Licenses

Stricter and more objective laws are needed to govern the practice of issuing compulsory licenses in order to maintain the delicate balance between the right of access to life-saving medicines and the right pharmaceutical companies have to earn a profit from their inventions. Of course, under very limited circumstances, compulsory licenses can be a beneficial tool. However, there is a fine line dividing when the practice of issuing compulsory licenses is proper and when it will cause disastrous results.

There are at least four detrimental consequences that will arise if the language of the TRIPS Agreement is not amended. First and foremost, if compulsory licenses are too easily obtainable, absent the threat of an acute health crisis, innovation funding will erode. It is the monopoly power pharmaceutical companies are capable of obtaining over their patented medicines that induces invention. Therefore, future investment in pharmaceuticals will be viewed as a risk without this monopoly power. Secondly, a decline in global health will result because pharmaceutical companies will be hesitant to introduce new medications into nations with high rates of disease. Additionally, the nation that will manufacture the generic version of drug after a compulsory license has been issued will generally have lower standards of quality than the country that manufactured the named brand drug. Thirdly, absent strong intellectual property protections foreign investment will decline, causing devastating effects on developing nations. Lastly, the American economy will further suffer based on the large, job-producing pharmaceutical industry in America, which is dependent on strong intellectual property rights protections.

The practice of issuing compulsory licenses is likely to increase in the

up to $288 billion on research and development).


38 Each danger will be discussed in greater detail in Section V infra.

39 Cahoy, supra note 1, at 134.

40 Id.
near future,41 therefore more stringent laws must be implemented to safeguard against abusive issuances.42 The current language of the TRIPS Agreement is not sufficient to protect the world against compulsory license misuse. If more objective laws are not adopted, the world faces the risk of economic turmoil coupled with declining world health. Moreover, strong international intellectual property protections are essential to the continued progress in the field of pharmaceuticals.

II. THE SOURCE OF THE GROWING TENSION

In order to fully comprehend the imminent danger the world faces if stronger intellectual property protections are not adopted, it is crucial to understand both the general theories underlying intellectual property rights, and to acknowledge the current health crises facing various nations throughout the world. To begin with, intellectual property rights are “the rights given to people over the creations of their minds.”43 There is a fundamental difference between ideas and tangible property. With tangible property, your possession is exclusive in the sense that when you possess an object somebody else does not.44 An idea, on the other hand, is capable of being possessed by more than one person at the same time.45 Additionally, tangible goods are rivalrous, meaning they can suffer from exhaustion, while intangible goods are non-rivalrous.46 Although patents place burdens on society, the rationale behind the protection of ideas is that it helps maximize the wealth of the public at large.47

41 See Zolotaryova, supra note 32, at 1109 (explaining that because chronic diseases are now seen as a severe enough health emergency to implement a compulsory license, the use of compulsory licenses is likely to increase).
42 See Outterson, supra note 37.
44 MERGES ET AL., supra note 3, at 2.
45 Id. (explaining that “[i]deas do not have this characteristic of excludability” and that more than one person can use an idea without diminishing the value of the idea).
46 Outterson, supra note 37, at 3. “Tangible goods are rivalrous. They suffer from exhaustion and congestion. But most intangibles are nonrivalrous, including the biomedical knowledge which forms the basis of the pharmaceutical industry.” Id. Most pharmaceutical knowledge is nonrivalrous, and this fact enables a transformation from free riding and piracy to fair following.” Id.
47 Khoury, supra note 15, at 39. See also MERGES ET AL., supra note 3, at 13. “Because intellectual property rights impose social costs on the public, the intellectual property laws can be justified by the public good argument only to the extent that they do encourage enough creation and dissemination of new works to offset those costs.” Id. See also Baucus, supra note 19 (stating industries that rely on intellectual property protection account for most American exports).
There are two fundamental philosophical theories justifying pharmaceutical companies’ rights to have exclusive ownership over their patented products. The first theory is utilitarianism, which elucidates that absent the protection of a patent, an inventor will spend time and money on an invention only to find others imitating his work without incurring the costs; thereby enabling the copied product to be sold for less money. Ultimately the original creator will be inhibited from earning a reasonable, expected return on his invention. As a result, many industry analysts believe the inventor will no longer have an incentive to innovate. Accordingly, it is argued that pharmaceutical companies will be reluctant to spend exorbitant amounts of money on research and development for novel drugs if there is no financial incentive.

The second theory justifying intellectual property rights is the labor theory, which explains that the labor of man and the work of his hands are his and nobody else’s. If pharmaceutical companies are no longer able to have exclusive rights to control their products, they will essentially be robbed of the fruits of their labor.

While there are strong theories supporting why medicines ought to be given patent protection, the controversy arises due to the grave public health problems currently plaguing the globe. Approximately 1.7 billion people living on Earth lack access to vital medicines. Each year infectious diseases kill 14 million people, 90% of which are people living in the developing world. It is estimated that close to 40 million people are infected with HIV/AIDS worldwide. Of those 40 million people, approximately 95% of those living...
with HIV/AIDS reside in developing countries.\textsuperscript{59} In Africa alone, there are 25 million people living with HIV/AIDS.\textsuperscript{60} Moreover, Malaria is responsible for killing over one million people each year.\textsuperscript{61} Infectious diseases are not the only health concern facing the world, non-communicable diseases are on the rise and 80\% of morality rates resulting from non-communicable diseases occur in developing countries.\textsuperscript{62}

After reviewing the various health problems facing the globe it becomes apparent that people around the world, particularly the citizens of developing countries, are in desperate need of medicines. In fact, it has been estimated that if existing medicines were made available to developing countries, millions of lives could be saved each year.\textsuperscript{63} These disheartening figures enhance the argument that patents should be suspended when they come into conflict with serious health issues.\textsuperscript{64}

III. THE TRIPS AGREEMENT’S SHORTFALL IN REGULATING COMPULSORY LICENSES

In the recent past, the extent of intellectual property protection afforded by national governments varied widely across the globe.\textsuperscript{65} As the importance of intellectual property rights became increasingly central to international trade, economic tension between countries arose due to the various levels of intellectual property protections.\textsuperscript{66} The Members of the WTO sought to ease this growing tension by establishing globally recognized minimum levels of protection for intellectual property rights. On January 1, 1995 the WTO achieved this goal by negotiating the TRIPS Agreement, which

the time it was first discovered in 1981).

\textsuperscript{59} Id. at 39.
\textsuperscript{60} HAOCHEN SUN, RESHAPING THE TRIPS AGREEMENT CONCERNING THE PUBLIC HEALTH – TWO CRITICAL ISSUES 3 (2002), http://www.cid.harvard.edu/cidtrade/Papers/haochensun.pdf (explaining that, of the developing world’s citizens infected with HIV/AIDS, only 4\% are receiving antiretroviral treatment).
\textsuperscript{61} WTO DECISION, supra note 26, at 15. Malaria infects 300-400 million people every year, and 90\% of these infections occur in Africa. Id.
\textsuperscript{62} Id. at 42 (explaining a non-communicable disease is a disease which is not infectious and can result from genetics or life-style).
\textsuperscript{64} Some believe that the right to health is a fundamental human right.
\textsuperscript{65} Zolotaryova, supra note 32, at 1100.
\textsuperscript{66} Id.
"standardized the protection of intellectual property rights throughout the world by establishing minimum levels of protection that each WTO Member country must provide for the intellectual property of other WTO members." Pharmaceutical products were among the many inventions required to have a minimum level of protection under the TRIPS Agreement. The overall purpose of the Agreement was to reduce obstructions in international trade while promoting intellectual property protection.

Article 31 of TRIPS is the direct source of the compulsory licensing right. The phrase 'compulsory license' is not used, but the title of Article 31 is: 'other use without authorization of the right holder.' The broad text of Article 31 permits any WTO Member to issue a compulsory license after fulfilling certain ambiguous conditions. First of all, authorization for a compulsory license is based on individual merits. Additionally, if a compulsory license is issued, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization," according to Article 31(h). Moreover, the use of a compulsory license will only be permitted if there have been unsuccessful efforts to obtain authorization from the patent holder under reasonable commercial terms, for a reasonable period of time. However, this negotiation requirement is waived for any WTO Member under three circumstances: (1) in the case of a national emergency, (2) other circumstances of extreme urgency, or (3) in cases of public non-commercial use. Lastly, article 31(f) of the TRIPS Agreement
states that after a nation is authorized to issue a compulsory license, the use must be for the supply of the domestic market.\textsuperscript{75}

Article 31(f) was the source of much criticism because medicine production is concentrated in high-income countries, and many developing countries lack pharmaceutical production capacity all together.\textsuperscript{76} This provision therefore acted like a barrier, preventing countries with insufficient or no manufacturing capabilities from issuing a compulsory license.\textsuperscript{77} Article 31 was essentially useless to the countries that were in need of compulsory licenses the most.\textsuperscript{78}

In response to the backlash on this matter, the Ministerial Conference of the World Trade Organization met in Doha Qatar, and on November 14, 2001,\textsuperscript{79} and adopted a Declaration on the TRIPS Agreement and public health, commonly known as the Doha Declaration.\textsuperscript{80} The Doha Declaration acknowledged the problem developing countries were facing in issuing compulsory licenses due to article 31(f) of the TRIPS Agreement.\textsuperscript{81} Paragraph 6 of the Declaration stated, “[w]e recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement,” and the Declaration called for an expeditious solution to this problem.\textsuperscript{82} The WTO General Council adopted Paragraph 6 of the Doha Declaration on August 30, 2003.\textsuperscript{83} The decision was comprised of three

\textsuperscript{75} Fact Sheet, \textit{supra} note 70. \textit{See also} TRIPS Agreement, \textit{supra} note 33, art. 31(f).

\textsuperscript{76} WTO DECISION, \textit{supra} note 26, at 7.


\textsuperscript{78} Zolotaryova, \textit{supra} note 32, at 1102.

\textsuperscript{79} The Doha Declaration was implemented shortly after the US considered issuing a compulsory license in order to get sufficient amounts of Anthrax antibiotics in a situation on an epidemic.


\textsuperscript{81} WTO DECISION, \textit{supra} note 26, at 7.

\textsuperscript{82} Doha Declaration, \textit{supra} note 77, ¶ 6.

\textsuperscript{83} \textit{See} Abbott, \textit{supra} note 80, at 317; \textit{Implementation of Paragraph 6, supra} note 77 ("'pharmaceutical product' means any patented product, or product manufactured through a
waivers under Article 31. First and foremost, the exporting countries’ duty is waived because a compulsory license is no longer only for the supply of the domestic market under article 31(f).\textsuperscript{84} Secondly, the obligation under 31(h) is waived because only the exporting country, and not the importing country, is responsible for remuneration to the patent holder.\textsuperscript{85} Lastly, re-export of the imported pharmaceutical is allowed among members of a regional agreement.\textsuperscript{86} Following the adoption of Paragraph 6 several nations, including the United States, agreed not to use Paragraph 6 as an importing member.\textsuperscript{87}

Not only did the Declaration move to correct several problems associated with Article 31, but it also addressed how the TRIPS Agreement as a whole should be interpreted. The Doha Declaration affirmed that the TRIPS Agreement should be construed in a manner supportive of WTO Members’ right to protect public health, and the Declaration acknowledged that the TRIPS Agreement provided intentional flexibilities for this precise purpose.\textsuperscript{88} Although Paragraph 1 of the Doha Declaration does not explicitly list what diseases are eligible for prompting the issuance of a compulsory license, it does state, “[w]e recognize the gravity of the public health problems afflicting many developing & least developed countries, especially those resulting from patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration... ‘eligible importing Member’ means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer... ‘exporting Member’ means a Member using the system set out in this Decision to produce pharmaceutical products for and export them to, and eligible importing Member” (quoting the Doha Declaration, supra note 73)).

\textsuperscript{84} Christina Cotter, \textit{The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries}, 5 \textit{LOY. U. CHI. INT’L L. REV.} 177, 191 (explaining that developing countries can now import generic drugs from developed countries).

\textsuperscript{85} Id. (stating that the importing country is no longer burdened with paying the patent holder adequate remuneration).

\textsuperscript{86} Id. (noting that now developing countries with small populations can declare a joint emergency).

\textsuperscript{87} Cahoy, supra note 1 at 158 n.86 (noting countries agreeing not to use paragraph 6 of Doha Declaration as importing members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, UK, and US, since joining the EU the list also includes Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia). \textit{See also Doha Declaration, supra note 73, ¶ 1}.

\textsuperscript{88} Abbott, supra note 80, at 322 (noting that the Doha Declaration reaffirmed the TRIPS Agreement “can & should be interpreted in a manner supportive of WTO members right to protect public health and in particular, to promote access to medicines for all” (quoting Doha Declaration, supra note 73, ¶ 6)); \textit{Implementation of Paragraph 6, supra note 77} (paragraph 7 of Doha states that the TRIPS agreement should be interpreted in a way to promote the objective of paragraph 6: “promoting the transfer of technology and capacity building in the pharmaceutical sector”).
HIV/AIDS, tuberculosis, malaria and other epidemics. Moreover, the Doha Declaration stated, “each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.”

Due to the fact that “each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted,” great subjective power rests with developing nations in the determination of whether to issue a compulsory license. The broad text of the TRIPS Agreement was intended to grant each nation the authority to promote public health, but the wording is too flexible and lacks objective guidelines, thereby providing a perfect atmosphere for compulsory license abuse. Misuses of this strong governmental right will lead to detrimental consequences.

IV. NATIONS THAT HAVE ISSUED COMPULSORY LICENSES

Although compulsory licenses are designed to achieve beneficial outcomes, it is likely that the practice of issuing compulsory licenses will further be abused which will lead to global misfortune. High, middle, and low-income nations have all issued health related compulsory licenses. Examples of high-income countries which have issued compulsory licenses are the United States, Canada, Germany, Italy, and Israel. The United States most recently sought a compulsory license on Bayer’s Ciprofloxacin, an anthrax antibiotic, following the September 11, 2001 attacks. The United States wanted enough antibiotics to treat 10 million people in the event of a mass anthrax attack. Eventually the United States government and Bayer, the German-based manufacturer, came to an agreement in which the United States had the ability to treat 12 million people infected with the anthrax virus.

Following the Doha Declaration large-scale use of compulsory licenses began. In 2002, after facing high rates of HIV/AIDS infections, Mozambique, Zambia, and Zimbabwe authorized compulsory licenses for HIV/AIDS

---

89 Doha Declaration, supra note 77, ¶ 1.
91 Doha Declaration, supra note 77, ¶ 5(b).
93 Examples of Health-Related Compulsory Licenses, supra note 92.
94 Id.
95 Jacobs, supra note 80.
medication on the grounds of a national emergency. These nations locally produced antiretrovirals pursuant to article 31(f) of the TRIPS Agreement. In 2004, Malaysia and Indonesia issued compulsory licenses for HIV/AIDS medications. These nations imported generic HIV/AIDS medications from India and became the first middle-income nations to issue a compulsory license for importation of HIV/AIDS antiretrovirals. Both Malaysia and Indonesia justified the issuance of a compulsory license on the grounds that it was for public non-commercial use. In 2005, Eritrea and Ghana also imported HIV/AIDS medications for public non-commercial use. Starting in 2006 Thailand, a middle-income country joined the group of nations issuing compulsory licenses for HIV/AIDS medications. Thailand imported and domestically manufactured the drug Efavirenz. In 2007, Brazil also a middle-income nation, issued a compulsory license for HIV/AIDS medications. Finally, and most recently, in 2008, Rwanda issued a compulsory license on the HIV/AIDS medication Apo-TriAvir.

The nations of Thailand, Brazil, and Rwanda have all recently issued compulsory licenses, each nation making groundbreaking international news. Thailand and Brazil’s actions illustrate the urgent need for more stringent regulations placed on a nation’s ability to issue compulsory licenses. Rwanda’s

96 Savoie, supra note 90, at 237. See also WTO DECISION, supra note 26, at 34.
97 Savoie, supra note 8, at 237.
98 Id. See also WTO DECISION, supra note 26, at 34.
99 India did not yet have patents on their pharmaceuticals. See Cahoy, supra note 1, at 13 (explaining that developing countries were given a transition period to adopt patents on pharmaceutical products under the TRIPS Agreement). See also Hestermeyer, supra note 36 (explaining India had until January 1, 2005 to start granting product patent protection for pharmaceuticals).
101 Savoie, supra note 90, at 237. See also WTO DECISION, supra note 26, at 34.
102 WTO DECISION, supra note 26, at 34. See also TRIPS Agreement, supra note 33, art. 31(b). Public non-commercial use is one of the exceptions to the general requirement that efforts to compromise with the patent holder must have failed before a nation can issue a compulsory license.
103 Id.
104 Savoie, supra note 90, at 237. See also WTO DECISION, supra note 22, at 34.
105 Savoie, supra note 90, at 237.
practice, on the other hand, represents a successful and responsible issuance of a compulsory license. By taking a closer look at each one of these nations’ uses under the TRIPS Agreement, it will become clearer when an issuance of a compulsory license is a dangerous misuse and when an issuance is a prudent use.

A. Thailand’s Use

Thailand’s most recent practice has caused quite a lot of controversy and deservedly so; their actions demonstrate how the world is rapidly approaching a slippery slope of accepting any nation’s arbitrary issuance of a compulsory license over any type of drug available on the market. Thailand issued three compulsory licenses pursuant to the TRIPS Agreement, within a three-month period.\(^{108}\) First, Thailand issued a license over Merck’s Efavirenz which is an HIV/AIDS medication.\(^{109}\) Subsequently, the Thai government decided to issue two more compulsory licenses over patented prescription drugs, one for Kaletra which treats HIV/AIDS, and another for Plavix which treats heart disease.\(^{110}\)

There are two fundamental reasons why Thailand’s most recent use of compulsory licenses is so controversial. The first reason is because Thailand is a middle-income nation.\(^{111}\) Secondly and most shockingly, the issuing of a license over Plavix, a heart disease medication, represents the first time a compulsory license was authorized for a chronic disease medication,\(^{112}\) as opposed to being issued over an infectious disease medication.\(^{113}\) This issuance might have signaled the start of a new era in which compulsory licenses will be authorized to treat illnesses beyond infectious diseases. The Thai government is


\(^{109}\) WTO Decision, supra note 26, at 34.


\(^{111}\) Zolotaryova, supra note 32, at 1107. But see TRIPS Agreement, supra note 33 (noting that the TRIPS Agreement does not distinguish the income level of WTO Members).

\(^{112}\) Savoie, supra note 90, at 2 (defining chronic disease as “non-communicable diseases that persist for an extended period of time.” Examples include heart disease, stroke, diabetes, cancer and chronic respiratory disease).

\(^{113}\) See Abbott Laboratories, supra note 110 (explaining that Plavix is a blood-thinning drug for cardio-vascular disease).
essentially sending the message that they are willing to invoke a compulsory license over any drug available on the market.\textsuperscript{114}

Thailand justified their need to issue a compulsory license for the heart disease medicine under article 13(b)’s ‘public non-commercial use’ instead of the ‘national emergency’ provision.\textsuperscript{115} ‘Public non-commercial use’ is not defined in the TRIPS Agreement, and therefore Thailand’s action represents how the ‘public non-commercial use’ provision widens the spectrum as to what health issues are considered severe enough to override a patent.\textsuperscript{116} This is disheartening because pharmaceutical companies are now under threat of huge financial losses. The majority of money spent by pharmaceutical companies in research and development goes to drugs that are marketable in the developed world.\textsuperscript{117} While infectious diseases are more prevalent in developing nations, chronic diseases are found everywhere in the world. Now that any patented drug is capable of being overridden by a compulsory license pursuant to the lenient text of the TRIPS Agreement, pharmaceutical companies are in danger of not being able to recoup money from the main drugs that drive their industry - drugs aimed at developed nations’ markets.\textsuperscript{118} This new, unlimited scope of compulsory licenses is likely to cause pharmaceutical companies to decrease investment in all drugs out of fear that they will not earn their expected profits.

Moreover, Thailand angered Abbott Laboratories, the manufacturers of Kaletra when it issued a compulsory license over their AIDS medication because Abbott Laboratories was already selling Kaletra to Thailand at a substantially discounted rate.\textsuperscript{119} Abbott Laboratories complained that the Thai government did not engage in proper negotiations with the pharmaceutical company before issuing the license. However, because Thailand issued the license on ‘public non-commercial use’ grounds, the negotiation requirement was lawfully waived under article 31(b).\textsuperscript{120}

If the type of compulsory licensing exercised by Thailand continues,

\textsuperscript{114} Zolotaryova, supra note 32, at 1109.
\textsuperscript{115} Savoie, supra note 90, at 13.
\textsuperscript{117} Zolotaryova, supra note 32, at 1107 (stating that diseases such as malaria, pneumonia, diarrhea, and tuberculosis receive less than 1% of all private and public investment in health research).
\textsuperscript{118} Contra ICTSD, Thailand, supra note 108 (“The idea that compulsory licensing of patents is limited to treatments for HIV/AIDS or ebola, as opposed to treatments for coronary disease and diabetes, is flat wrong.”).
\textsuperscript{119} Id.
\textsuperscript{120} See generally TRIPS Agreement, supra note 33, art. 31(b) (stating that nations are not required to negotiate with the patent holder if the nation is issuing the license in response to a national emergency, extreme circumstance, or is producing the drug for public non-commercial use).
Thailand along with the rest of the world will suffer damaging consequences. For example, Abbott Laboratories reacted to Thailand’s actions by stating, “Thailand has revoked the patent on our medicine, ignoring the patent system. Under these circumstances we have elected not to introduce new medicines there.” Abbott then withdrew seven registration applications for new pharmaceutical products in Thailand. Five of those applications were targeted at chronic diseases. As a result of Thailand’s abuse of compulsory licenses, Thai citizens will now suffer because they will be deprived of new drugs created by Abbott Laboratories and other cautious pharmaceutical companies.

Thailand’s actions also promoted trade retaliation by the United States. The United States is Thailand’s largest trading partner, but due to Thailand’s recent irresponsible issuances, the United States placed Thailand on its’ Priority Watch List. This list highlights which of the United States’ trading partners the US has concerns over the adequacy and effectiveness of intellectual property right protections. Lastly, Thailand’s recent practice has caused worldwide disproval. The EU Trade Commission has stated that they object to Thailand’s approach to issuing compulsory licenses. Although the EU Trade Commission agrees with the overall underlying theory of authorizing developing nations to issue compulsory licenses, it feels that Thailand’s

"systematic recourse to compulsory licensing in not a sustainable approach." Furthermore, the Trade Commission agrees that this practice will be detrimental to the innovations of new pharmaceuticals. Worldwide disapproval will result in a blow to business confidence in Thailand, which will in turn deter pharmaceutical companies from investing there in the future.

B. Brazil's Use

Brazil's recent practice, similar to that of Thailand, further demonstrates the manner in which national governments are easily able to manipulate the susceptible language of the TRIPS Agreement. President Luiz Inacio Lula da Silva of Brazil agreed on May 4, 2007, to issue a compulsory license on Efavirenz, an HIV/AIDS drug owned by Merck. Before the license was issued, Merck offered to lower the drug price by 30%, but because Brazil justified their issuance of the license under the 'public non-commercial use' category of the TRIPS Agreement, Brazil was not required to negotiate with Merck whatsoever. Brazil claimed that importing a generic form of Efavirenz from India would save the nation's ant-AIDS program $30 million dollars annually. Brazil received the generic import for $0.45 a pill, compared to Merck's offer of $1.11 per pill. Merck, disappointed with Brazil's actions, has stated that Brazil's decision is a major step backward and sets bad policy for two reasons. First of all, Brazil's actions sets bad precedent in the sense that it will encourage overuse of the compulsory license provision. Brazil is an upper-middle income country with the 12th largest economy in the world. Moreover, Brazil has a relatively low rate of HIV/AIDS infection, and has a well-established AIDS program which has been successful in controlling the national spread of HIV/AIDS. Therefore, Brazil has more of an opportunity to pay for HIV/AIDS medications than countries that have less
money and that are hit harder with the epidemic. The second reason Merck condemns Brazil’s practice is because future foreign investment will be discouraged, which will ultimately result in less drugs being introduced into Brazil. This issuance of a compulsory license has had a negative impact on Brazil’s reputation as an industrialized country seeking to attract foreign investment.

Both Thailand and Brazil’s recent actions exemplify a new trend in issuing compulsory licenses, likely to have dangerous effects not only on the imprudent nations which practice these methods, but also on the rest of the world. If there were more stringent laws governing the issuance of compulsory licenses Thailand and Brazil most likely would not have been authorized to issue these compulsory licenses.

C. Rwanda’s use

Compulsory licenses can be a powerful negotiating tool for developing nations in ensuring that the high prices set on drugs do not burden the nation to a point that they are unable to respond to a public health crises. The threat of issuing a compulsory license on a pharmaceutical company’s patented drug gives the developing country some leverage over powerful pharmaceutical companies. In the past, Brazil, for example has successfully used compulsory licenses as a tool to negotiate lower prices from both Merck and Roche. The practice of issuing compulsory licenses, or even the threat of issuing a license, can be an invaluable tool in promoting public health when used in moderation.

Rwanda’s issuance pursuant to the TRIPS Agreement represents how compulsory licenses can be, and were designed to be, a beneficial tool in assisting a nation in need. On July 17, 2007 Rwanda became the first nation to notify the WTO of its’ intention to import the HIV drug Apo-TriAvir from Canada, pursuant to Paragraph 6 of the Doha Declaration. Canada, in turn,
notified the WTO on October 4, 2007 that it had authorized the production of a
generic version of the patented antiviral drug for export to Rwanda. The
Canadian company Apotex was the pharmaceutical company responsible for
manufacturing Apo-TriAvir, which is a drug that has nine related patents.

Rwanda has a population of 9.3 million people, of those citizens, 200,000 are infected with either HIV or AIDS. Less than one-forth of the HIV/AIDS infected people living in Rwanda were receiving anti-viral treatment. On September 24, 2008 the generic AIDS medication left Toronto for Kigali. The shipment contained 7 million doses of Apo-TriAvir. From this shipment, 21,000 Rwandans will be treated for a full year. Apotex will export Apo-TriAvir at a cost of approximately $0.20 per tablet, compared to the three brand name components which would run around $6.00 per dose.

Although Rwanda illustrates a success story, the process laid out in Paragraph 6 of the Doha Declaration has been criticized for being too time-consuming. Rwanda did not receive their shipment of the generic drugs from Canada, for over an entire year after they notified the WTO of their intention to import the drug. Moreover, if Apotex agreed to export this generic version of AIDS medication to another developing country, Apotex would have to go through the entire time-consuming process again. Not only was the process impractical because it took so long, but it also cost the exporting nation a lot of money. Until the process becomes more efficient, developed countries will be deterred from agreeing to manufacture generic drugs for exportation to developing countries in need.

---

146 Id.
147 Hestermeyer, supra note 36 (explaining that of the nine patents associated with the HIV drug, four of them are owned by the Glaxo company, two of them are owned by the Wellcome Foundation, two by Shire Biochem, and lastly, one is owned by Boehringer Ingelheim and Dr. Thomae).
148 Cotter, supra note 84, at 178.
149 Id.
150 Picard, supra note 107 (explaining under Canada’s Access to Medicines Regime they remain the only country in the world which can legally produce low cost generic medicines and deliver them to the developing world).
151 Id.
153 See Picard, supra note 107.
154 Id.
155 Id.
V. THE POTENTIAL DANGERS ARISING FROM COMPULSORY LICENSES

There are four main dangers likely to arise from the ambiguous language of Article 31 of the TRIPS Agreement. More stringent laws must be in place in order to avoid these dangers. The first of these problems is based on the utilitarian theory.\(^{156}\) It is well understood that “[p]atents provide incentives to individuals by offering them recognition for their creativity and material award for their marketable inventions.”\(^{157}\) Compulsory licenses, nevertheless, diminish the incentive to undertake research and development in the pharmaceutical industry because the issuance of a compulsory license causes the patent holder to lose his expected earnings. Human life is continuously advanced because innovation is encouraged by incentives.\(^{158}\) Without incentive, advances in the pharmaceutical industry will quickly subside.

The high price of medicine stems from the costly research and development process, which is necessary to produce safe and effective pharmaceutical products.\(^{159}\) In 2001, funding for global research and development was over $100 billion in the pharmaceutical sector.\(^{160}\) Approximately 56% of this funding was provided by the private sector.\(^{161}\) Moreover, most pharmaceutical research does not conclude in a patented medicine, therefore pharmaceutical companies must secure earnings that not only cover their research and development costs and their running costs, but also the costs of unsuccessful research.\(^{162}\) The monopoly power created by a patent is essential for pharmaceutical companies to earn enough money to stay in business and to finance subsequent research and development projects.\(^{163}\) A decrease in research will certainly reduce the rate of medical progress and innovation across the globe.\(^{164}\)

When a government issues a compulsory license the pharmaceutical company’s incentive to continue to invest their private funds into research and development for new medicines for that nation quickly fades away. A major

---

\(^{156}\) The Utilitarian Theory was previously discussed in Section II supra.

\(^{157}\) Greve, supra note 20, at 5.

\(^{158}\) Id.

\(^{159}\) Id. (arguing that research and development is time consuming and costly).

\(^{160}\) Bird & Cahoy, supra note 14, at 284.

\(^{161}\) Id. (noting that funding was not coming from the public sector or the government). But see Zolotaryova, supra note 32, at 1107 (explaining 21% of all global disease come from malaria, pneumonia, diarrhea, and tuberculosis, but these illnesses receive less than 1% of all private investments).

\(^{162}\) Greve, supra note 20, at 8.

\(^{163}\) See id.

\(^{164}\) Id.
United States drug company, Merck & Co., illustrated this logic when it stated, "[t]his expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world."\textsuperscript{165}

A compulsory license is retroactive in nature, meaning that the product is already patented and the patent holder only loses his exclusive right over the patented product after a compulsory license is issued. The private funds have already been invested into the product, so once a compulsory license is issued the investment cannot be taken away.\textsuperscript{166} However, once a compulsory license is issued, the incentive to invest in the future will be reduced. "You can compel a private company once [with a CL]. After that they will probably leave your boarders, and you lose the opportunity to get the access and technology in the future."\textsuperscript{167}

The second foreseeable danger is that global health will actually suffer due to the subjective language of Article 31, despite the fact that the TRIPS Agreement was implemented and is interpreted to promote public health. The unfortunate decline in global health stems from the utilitarian argument. In light of Article 31, each WTO Member has the authority to issue a compulsory license.\textsuperscript{168} As previously discussed, this practice will reduce the incentive of pharmaceutical companies to invest their private funds into discovering new medicines. Generally, developing nations have weaker intellectual property protections and are therefore more likely to issue compulsory licenses on patented pharmaceutical products than are developed countries.\textsuperscript{169} Thus pharmaceutical companies, out of fear of not recouping the cost of research and development, will stop devoting their time and money into discovering cures for diseases which primarily plague the developing world.\textsuperscript{170} Instead, the pharmaceutical industry will allocate their resources to innovating medicines that are likely to have a successful commercial market in developed countries.\textsuperscript{171} Based on the effect compulsory licenses have on pharmaceutical

\textsuperscript{165} Merck, supra note 137 (noting Merck's reaction to Brazil's decision to issue a compulsory license for Stocrin, an HIV drug).
\textsuperscript{166} Bird & Cahoy, supra note 14, at 290.
\textsuperscript{167} Id.
\textsuperscript{168} WTO DECISION, supra note 26, at 7.
\textsuperscript{169} See SPECIAL 301 REPORT, supra 127, at 2. The Special 301 Report is a tool used to pinpoint problems in intellectual property rights protection in countries which are engaged in trade with the United States. Id. Most of the countries on the Watch List are developing nations. Id.
\textsuperscript{170} See Baucus, supra note 19.
\textsuperscript{171} See Tim Atkinson, Lifestyle Drug Market Booming, 8 NATURE MED. 909 (2002), available at http://www.nature.com/nm/journal/v8/n9/full/nm0902-909.html (explaining that lifestyle drugs treat conditions such as weight loss, anti-smoking, impotence, and hair loss and that the market for these
companies' profits, the pharmaceutical industry will turn their backs on very problematic illnesses found predominately in developing countries. Unfortunately, many developing nations do not have domestic, progressive pharmaceutical manufacturers.\textsuperscript{172} If safeguards are not placed on the right to issue compulsory licenses, ill stricken people living in developing countries will be left with little relief in sight.

The health concerns associated with compulsory licensing are not only that pharmaceutical companies will stop manufacturing drugs directed at illnesses plaguing developing nations, but also that the generic drugs that will either be domestically manufactured or imported into developing countries will be of lower quality than the drugs created by the transnational pharmaceutical companies.\textsuperscript{173} Both India and China have become major international suppliers of generic drugs.\textsuperscript{174} As the manufacturing is allocated to these countries, "the risk to human health is growing exponentially."\textsuperscript{175} The concern about low quality drugs arises from the fact that quality-control inspections are rarely conducted by the Food and Drug Administration in India or China.\textsuperscript{176} In 2005 alone, the FDA conducted 1,222 quality inspections in the United States, but within the past 7 years the FDA only conducted only 200 inspections in China and in India combined.\textsuperscript{177} Of the 200 inspections conducted, few of them measure up to the thorough inspections carried out in the United States.\textsuperscript{178} Unlike the surprise visits routinely practiced in the United States, the inspections in India and China were scheduled in advance which gave the manufacturing plants time to prepare.\textsuperscript{179}

Private investigations have been conducted to uncover the poor conditions in foreign operated plants.\textsuperscript{180} These investigations have exposed that some plants have open walls which invite pests and dust into the production

\textsuperscript{172} WTO DECISION, supra note 26, at 7 (explaining many countries have no production capacity in the pharmaceutical sector).
\textsuperscript{173} Id. (stating "[t]he problem is that, despite the lower costs for developing the medicines, the new producer generally cannot achieve equally effective production as the patent holder.").
\textsuperscript{174} Marc Kaufman, FDA Scrutiny Scant In India, China as Drugs Pour Into U.S., WASHINGTON POST, June 17, 2007, at A01, available at http://www.washingtonpost.com/wp-dyn/content/article/2007 (explaining over the past seven years imports from China and India has grown drastically).
\textsuperscript{175} Id. (quoting Brant Zell, the past chairman of the Bulk Pharmaceuticals Task Force).
\textsuperscript{176} Id. (explaining that the plants are lightly regulated due to very limited government regulation).
\textsuperscript{177} Id.
\textsuperscript{178} Id.
\textsuperscript{179} Id.
\textsuperscript{180} Id.
facility, other plants had different chemical equipment so congested that cross-contamination is inevitable, and one study even discovered a hornet’s nest on top of a drug making vat.  

Based on the increase in importation from developing nations, combined with the low levels of quality inspections in exporting nations, the chance that consumers will receive impure or ineffective generic drugs has greatly multiplied. Unfortunately, it is virtually impossible to determine whether the low quality drugs imported from these lightly regulated plants have caused patients to get more ill or remain ill because the medicines are not effective.

The Doha Declaration clarifies that developing nations unable to domestically manufacture drugs are authorized to import generic drugs from nations with manufacturing capabilities. Thus, developing countries suffering from the most severe epidemics are likely to be importing drugs from these lightly regulated Asian plants. These generic drugs have the potential to be both unsafe and ineffective. This is a very serious danger because once a contaminated or ineffective drug hits the market, injuries and deaths are likely to occur before the source of the problem is tracked down. Therefore, the overall health of these importing nations is at risk if the rules that govern compulsory licensing are not amended.

The third potential danger arising from the use of compulsory licenses under the TRIPS Agreement is the reduction in the amount of money that will be invested into developing nations. In developing countries a substantial amount of investment comes from outside the country, which stimulates the growth of local industry. While strong intellectual property protection results in increased investment, likewise, weak intellectual property rights leads to a decrease in investment. When a pharmaceutical company discovers that the security of their property rights are vulnerable in a given nation, they are likely to avoid engaging in foreign direct investment with that nation. This comes at a heavy price for developing nations because foreign direct investment is a major source of economic growth. When a nation exercises their right to issue a compulsory license that nation is viewed by the rest of the world as

181 Id. (explaining these private investigators were hired by U.S. companies).
182 Id. (quoting Brent Zell the past chairman of the Bulk Pharmaceuticals Task Force).
183 Id. (explaining that it is unlikely that doctors suspect poorly manufactured drugs are the causation of the problem).
184 Implementation of Paragraph 6, supra note 33.
185 Kaufman, supra note 174 (quoting William Hubbard, a former FDA Associate Commissioner).
186 Bird & Cahoy supra note 14, at 284.
187 Id.
188 Id.
189 Id.
having weak intellectual property rights. Therefore, compulsory licensing will cause a heavy loss in the acquisition of foreign investments.

Egypt is a quintessential illustration of the danger of losing foreign direct investment based on weak intellectual property protection. Egypt is a middle-income country with great potential for economic growth, however foreign direct investment here has continued to decline over the past 20 years.\textsuperscript{190} Egypt has one of the poorest records in the Middle East in protecting intellectual property rights, which hinders their ability to expand trade opportunities and lure foreign investment.\textsuperscript{191} In 2002, Pfizer entered the Egyptian market with the drug Viagra.\textsuperscript{192} After only two months on the market, the Egyptian Health Ministry decided to grant authorization to produce Viagra to all Egyptian companies who applied to produce generic versions of the drug.\textsuperscript{193} The generic brand of Viagra would be sold at one-twentieth of the price of Pfizer’s market price.\textsuperscript{194}

Egypt’s actions enraged Pfizer, who eventually cancelled plans to construct a state of the art production facility in Egypt.\textsuperscript{195} Additionally, PhRMA\textsuperscript{196} was deterred from investing $300 million into Egypt’s pharmaceutical sector due to the weak intellectual property protection laws.\textsuperscript{197} Egypt was in desperate need of foreign direct investment from companies like Pfizer to jumpstart their depressed economy. Consequently, Egypt lost a lot by issuing this compulsory license.

The final danger that will arise from issuing compulsory licenses under the current practice is that the United States’ economy will further deteriorate. Approximately 40\% of the United States’ economic growth is dependent upon intellectual property protection in one form or another.\textsuperscript{198} Industries that rely on

\textsuperscript{190} Id. at 289.
\textsuperscript{192} See Bird & Cahoy, supra note 14, at 291.
\textsuperscript{193} Id. (referencing Richard A. Castellano, Patent Law for New Medical Uses of Known Compounds of Pfizer’s Viagra Patent, 46 IDEA 283, 289 (2006)) (explaining the Egypt rationalized its issuance of a compulsory license on Viagra in order to benefit the poor).
\textsuperscript{194} Allam, supra note 191.
\textsuperscript{195} Bird & Cahoy, supra note 14, at 290-91.
\textsuperscript{196} PhRMA, http://www.phrma.org/about_pharma/ (last visited November 1, 2008) (Pharmaceutical Research and Manufacturers of America is a trade group representing the pharmaceutical research and biotechnology research companies in the United states).
\textsuperscript{197} Bird & Cahoy, supra note 14, at 291.
\textsuperscript{198} Baucus, supra note 19, at 5.
intellectual property protection employ approximately 18 million Americans.\textsuperscript{199} For instance, Pfizer is the world’s largest research based pharmaceutical company,\textsuperscript{200} and it alone is responsible for providing 85,000 jobs.\textsuperscript{201} Pfizer invests almost $60 billion each year in the search for new drugs.\textsuperscript{202} The problem of weak intellectual property protection “is of great importance, not just to the U.S. creative community, but to the U.S. economy and to U.S. society as a whole.”\textsuperscript{203}

The biopharmaceutical industry spends more money on research and development than any other industry spends in the United States. Specialists in the field of pharmaceuticals recognize a pattern: “[Intellectual property protection] equals innovation. Innovation equals competitiveness. And competitiveness equals jobs.”\textsuperscript{204} If issuing compulsory licenses becomes an arbitrarily and frequently used tool, which is likely to occur based on the vague language of Article 31, the pharmaceutical industry in the United States will collapse. The failure of the pharmaceutical industry will lead to a devastating impact on the nation’s economy including the loss of tens of thousands of American jobs.

SUGGESTIONS FOR REFORM

It is not contested that the underlying policy behind compulsory licenses is positive, and under certain circumstances this powerful right granted to governments can provide unmatched relief to suffering people around the globe. The fundamental crises that compulsory licenses generate arise from the susceptible language of the TRIPS Agreement and the Doha Declaration, along with bad precedent set by nations like Thailand and Brazil. The law controlling compulsory licenses must be made less ambiguous, more objective, and overall more stringent.

The first problematic aspect of compulsory licenses is Article 5(c) of the Doha Declaration, which affirms that “[e]ach member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency.”\textsuperscript{205} It certainly would be impractical and nearly impossible

\begin{flushleft}
\textsuperscript{199} Id.
\textsuperscript{200} Id.
\textsuperscript{201} Id. at 7 (explaining that these “employees invent, produce, and provide medicines that save and improve lives.”).
\textsuperscript{202} Id.
\textsuperscript{203} Id. at 5 (quoting Senator Marcus Baucus).
\textsuperscript{204} Id. (quoting Jeffery Kindler, CEO of Pfizer).
\textsuperscript{205} Doha Declaration, supra note 73, ¶ 5(c).
\end{flushleft}
COMPULSORY LICENSES

for the WTO to set out an enumerated list classifying which diseases do and which diseases do not constitute a severe enough emergency to justify the issuance of a compulsory license. Not only do new diseases occasionally surface, but each nation also faces different conditions, and therefore an illness in one country could be a serious national emergency, while that same illness in another country could be nothing more than an inconvenience.

While it is clear that it would be idealistic to explicitly define when it is appropriate for a nation to issue a compulsory license, it ought to be required that each nation demonstrate: (1) they are suffering from ‘a national emergency’, (2) they are suffering from ‘a circumstance of extreme urgency’, and (3) the nation will be using the patented medicine for ‘public non-commercial use’. These three factors are already set forth in the TRIPS Agreement, but for a different purpose. In article 31(b) the requirement of reasonable negotiations with the patent holder is suspended under the circumstances of a ‘national emergency’, ‘other extreme circumstances of extreme urgency’, or a ‘public non-commercial use’. These three familiar terms to the TRIPS Agreement should be barrowed from article 31(b), and transformed into a conjunctive requirement that each nation must fulfill before having the option of overriding a patent.

Secondly, The TRIPS Agreement furthered by the Doha Declaration leave the door wide open for abuses by allowing WTO Members absolute subjective power in determining whether to issue a compulsory license. As the TRIPS Agreement reads now, each WTO Member has the authority to determine when their own nation is suffering from a national emergency or circumstance of extreme urgency. This subjective approach is easily manipulated. For example, Brazil abused the system when the nation issued a compulsory license over Efavirenz. Despite the fact that Efavirenz is manufactured to fight the HIV/AIDS epidemic, which is predominantly viewed as a national emergency, Brazil’s use was opposed by many nations. The controversy arose because Brazil is a relatively wealthy nation and compared to other nations did not have an extremely serious HIV/AIDS problem. Controversies such as this would be avoided if a nation, other than the issuing nation, were the determinate of whether circumstances are severe enough to warrant the issuance of a compulsory license.

The decision of whether a nation is suffering from a national emergency or circumstance of extreme urgency should be left to the WTO as a whole. There should be a vote conducted before any nation is authorized to

---

206TRIPS Agreement, supra note 33, art. 31(b).
207See ICTSD, Brazil, supra note 106. See also Merck & Co., Inc. Statement on Brazilian Government’s Decision to Issue Compulsory License for STROCRIN, supra note 137.
issue a compulsory license. Any WTO Member considering issuing a compulsory license should be required to assemble a report addressing the severity of the illness affecting their nation. This report would then be read by a representative from each WTO nation, and then a vote should then be taken. Based on this procedure, less power would lie on the individual nation advocating for the license and more power and control would be held by the WTO as an organization.

Moreover, article 31(b) of the TRIPS Agreement is problematic. It suspends the requirement of reasonable negotiation with the patent holder under the three circumstances: 'national emergency', 'other extreme circumstances of extreme urgency', or 'public non-commercial use'. There are two different approaches of how to make this reasonable negotiation requirement more equitable. First of all, not one of these three exceptions to the prior negotiation rule is defined anywhere in the TRIPS Agreement or in the Doha Declaration. These three exceptions must be defined in order to avoid abuses resulting from the ambiguity of these terms. Additionally, these three exceptions ought be conjunctive and not mutually exclusive. In other words, for a nation to successfully issue a compulsory license without prior negotiation with the patent holder, the nation must be facing a national emergency, circumstances of extreme urgency, and the use must be for public non-commercial use.

The most dangerous of these terms to not be defined is the 'public non-commercial use' exception. An illustration of the dangerous abuse that flowed from this broad terminology is when the Thai government issued a compulsory license on Plavix, the heart-disease medication. The Thai government cleverly justified their authority to issue the license under article 31(b)’s ‘public non-commercial’ use category, thereby avoiding the task of justifying that heart disease was a ‘national emergency’ or a situation of ‘extreme circumstance of extreme urgency’. The ‘public non-commercial use’ exception can be used to validate any nation’s authority, regardless of their wealth, to issue a compulsory license over any medication, not considering the illness the medication is intended to be used for; so long as the nation uses the compulsory license for public non-commercial use, which is not even a defined term. If these three exceptions were each required to be fulfilled before a WTO Member was in a position to issue a compulsory license, instances like that of Thailand would not occur, and pharmaceutical companies could be more confident in introducing new medicines into developing nations without the fear of the nation issuing an arbitrary compulsory license.

The second approach to strengthen article 31(b) is to outright require

---

208 TRIPS Agreement, supra note 33, art. 31(b).
209 Id. (uses the word ‘and’ instead of ‘or’).
prior negotiations with the patent holder before any compulsory license is issued. Under this approach the patent holder would always be given a reasonable amount of time, consisting of at least a set number of weeks, to come to a compromise over the price of their pharmaceutical product. This requirement would lessen the tension between pharmaceutical companies and developing nations because pharmaceutical companies would be guaranteed at least the option of lowering the price of their medicine before their exclusive right was stripped away from them. It is conceivable that under very extraordinary circumstances, a severe emergency could plague a nation to the extent that it would not be plausible to negotiate prices with a pharmaceutical company. This would only occur when there is the possibility that large amounts of people are likely to be infected with a disease within the amount of time it would take to negotiate the price. Under this intense situation, while the WTO representatives were voting as to whether a nation is entitled to a compulsory license, the WTO Members would also have the authority to waive this prior negotiation requirement, if the emergency seemed severe enough.

The TRIPS Agreement would be furthered improved if all of the terms within the agreement were fully defined, resulting in the governing laws of compulsory licenses being less ambiguous. There are several undefined terms throughout the TRIPS Agreement. In order to make the Agreement less ambiguous these terms must be defined. For example, article 31(h) requires the right holder to be paid ‘adequate remuneration’ while taking into account the ‘economic value’ of the authorization. Neither of the terms ‘adequate remuneration’ nor ‘economic value’ are defined in the TRIPS Agreement or in the Doha Declaration. Additionally, article 31(b) requires prior negotiation with the right holder on ‘reasonable commercial terms and conditions’. Again ‘reasonable commercial terms’ is not defined in the TRIPS Agreement or in the Doha Declaration. Essentially, this could allow a nation seeking a license to give the pharmaceutical company an unreasonable ultimatum of either delivering the medicine for the fraction of the market price or having a compulsory license issued on their product. The asking price of the nation requesting the license should be in relation to the economic wealth of that nation along with factoring in the amount of drugs the nation needs to import.

In order to safeguard the world against potential abuse of the TRIPS Agreement, more definite language should be implemented. Words and phrases that are fundamental to issuing compulsory licenses should be clear and

---

210 This time should only be a few weeks, to strike a fair balance between the developing country’s need and the pharmaceutical company’s need.

211 TRIPS Agreement, supra note 33, art. 31(h).

212 Id.
concise. The current inclusion of broad undefined words in the TRIPS Agreement leaves too much wiggle room for WTO Members to issue compulsory licenses under questionable circumstances.

The TRIPS Agreement would further be enhanced if a non-violation complaint provision were implemented, similar to that of The GATT Agreement, which recognizes non-violation complaints pursuant to article XXIII:1(b). A non-violation complaint provision allows a government to go to the Dispute Settlement Body even when an agreement has not technically been violated. Thus, if a government can show that is has “been deprived of an expected benefit because of another government’s action, or because of any other situation that exists,” that nation can contest the license to the WTO Dispute Settlement Board. For example, Brazil cut negotiations with Merck short because Brazil was not legally required to negotiate under article 31(b); under a non-violation complaint provision Merck would be allowed to argue that even though Brazil did not violate any provision in the TRIPS Agreement, the result of their actions were offensive and the license should be revoked. Similar to this belief, the House Democrats understood that Thailand did not necessarily issue any licenses in violation of the WTO rules, but forewarns issuances like these will hinder innovation which in turn will prevent the development of new life-saving medicines. This type of bad-faith issuing would be stopped pursuant to an outlet like the non-violation complaint provision because nations could argue for revocation of a license even when it technically conforms to all the WTO rules.

Article 64.2 of the TRIPS Agreement specifically states that there is to be no non-violation complaint in the TRIPS Agreement. Some countries, however, such as the United States and Switzerland argue that “non-violation cases should be allowed in order to discourage members from engaging in


214 TRIPS: ‘Non-Violation’ Complaints, supra note 213. See also TRIPS Agreement, supra note 33, art. 64.2.

215 TRIPS Agreement, supra note 33, art. 31(b).

216 Id.

217 House Democrats Endorse USTR Pressure on Thai Compulsory License, August 15, available at 2008 WLNR 15320070.

218 TRIPS Agreement, supra note 33, art. 64.2.
‘creative legislative activity’ that would allow them to get around their TRIPS commitment.”219

Lastly, and most importantly strong international intellectual property rights must be maintained worldwide. Strong intellectual property protections are fundamental to ensuring stability of the world’s economy and the health of the world’s citizens. It is each individual nation’s responsibility to implement strong intellectual property protections, and strict punishment for violations of these protections.

CONCLUSION

The controversy that arises from the practice of placing compulsory licenses on pharmaceutical products becomes so complex because peoples’ health and lives are on the line. The underlying aspiration of compulsory licenses is to improve global health, but this goal will not be achieved until more stringent laws govern this practice. The actual benefits that compulsory licenses are capable of affording desperate nations have become overshadowed by imprudently issued licenses that strike apprehension and anger within pharmaceutical companies.

Until the governing laws are amended, nations will abuse the susceptible language of these laws and damaging outcomes, similar to those which occurred in Thailand and Brazil will surely result. In order to protect both the developed and undeveloped world alike, unnecessary issuances of compulsory licenses must be stopped. If only essential compulsory licenses were issued, citizens who were truly in need would be treated and the pharmaceutical companies’ fears of not recouping their investments would be placed at ease.

219TRIPS: ‘Non-Violation’ Complaints, supra note 213.