Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules

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> *"...we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."*
>
> – Text of the World Trade Organization's Doha Declaration, 2001

I. Introduction

The tension between economic policy and health policy is a longstanding dilemma, but one that was brought to the fore with the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994. The pharmaceutical industry has long argued that intellectual property protection (IPP) is vital for innovation. At the same time, there are those who counter that strong IPP negatively impacts the affordability and availability of essential medicines in developing countries. However, actors on both sides of the debate were in agreement that something needed to be done to address the HIV/AIDS crisis, especially in developing countries. In response to sustained and significant pressure from civil society groups, members of the World Trade Organization agreed to the *Declaration on the TRIPS Agreement and Public Health* (the Doha Declaration) in 2001. The Declaration clarified that countries unable to manufacture the needed pharmaceuticals could obtain more affordable generics elsewhere if necessary.

Compulsory licensing has been in use for many decades by a variety of countries in a number of different market sectors. By the early 1990s, as many as one hundred nations embraced some form of compulsory licensing in their national patent laws. In the context of pharmaceuticals, the debate surrounding compulsory licensing has been polarized with the industry vehemently opposing it and the non-governmental community seeking its use. Nevertheless, there has been a consensus on its utilization to address national health care emergencies. Regardless of stakeholder perspective, from a policy research point of view, there is value in analyzing the rationale for introducing compulsory licensing and the success of its application in particular jurisdictions. The recent cases of Canada and Thailand provide a ripe opportunity to examine two very different regimes.

In September 2003, Canada announced that it would take advantage of the flexibilities under TRIPS and initiated the *Jean Chretien Pledge to Africa Act*. The

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Act set in place the regulations and legal framework for Canada's Access to Medicines Regime (CAMR), which came into force in May 2004. The Regime uses compulsory licensing so that less developed countries can gain access to high-quality, Canadian-made, less expensive medicines and medical devices. Canadian residents will therefore not take advantage of any cheaper drugs issuing from this Regime; rather the Regime is intended to benefit those living in less developed countries.

Countries eligible to take advantage of the Regime must have little or no manufacturing capacity, and the drug that they wish to import under the Regime must be granted a compulsory license in Canada and meet Health Canada's regulatory requirements. To date, only Rwanda — facilitated by the activist and humanitarian group Médecins Sans Frontières, or MSF/Doctors Without Borders — has taken advantage of the Regime, and the final clearance given to the Canadian generic manufacturer, Apotex, to ship a triple combination AIDS therapy took place in September 2007. In May 2008, the Rwandan government awarded the tender to Apotex and finally, on September 24, 2008, the first shipment of eight million pills left the country (enough to treat 21,000 people for one year). The second shipment will leave Canada in September 2009 containing approximately another eight million doses.[1] However, Jack Kay, the Chief Operating Officer of Apotex, publicly stated that "if other critical medicines are to go to Africa in a reasonable timeframe, the Federal Government must change the CAMR Legislation. CAMR is unworkable as it now stands."[2]

In 2006, faced with rising drug costs and failed price negotiations with multinational pharmaceutical companies, the Thai government, based on the flexibilities in the TRIPS Agreement, introduced compulsory licensing for a select number of drugs for therapies related to HIV/AIDS, heart disease, and cancer. While HIV/AIDS is commonly viewed as a national emergency, the inclusion of the other drugs has generated significant controversy. The decision by the Thai government raises fascinating questions about the interpretation of TRIPS Article 31, the conditions of unauthorized use, and the debate surrounding what constitutes a "national emergency." The Thai case is further complicated, and all the more interesting, due to the Thai government's role in domestic pharmaceutical production. It is the first stern test of Article 31, and how the key actors in this debate resolve the controversies will play a significant role in determining the future legitimacy of its use.

From a policy research point of view, there is value in analyzing the rationale for introducing compulsory licensing and the success of its application in particular jurisdictions. The recent cases of Canada and Thailand provide a ripe opportunity to examine two very different regimes.

This paper examines two recent and very different examples of compulsory licensing legislation: the widely lauded Canadian regime and the controversial and possibly abusive Thai regime, both of which operate under the same WTO rules. In particular, we consider the current exceptions to the law in Canada, the status of Canadian compulsory licensing for HIV/AIDS drugs, and the many complications surrounding the program. This is then contrasted with the conditions under which Thai authorities are pursuing compulsory licenses, the outcomes of the compulsory licenses, as well as the likely impact of the Thai policy. Finally, we construct a rubric to evaluate characteristics of a successful regime. This is used to analyze the Canadian and Thai regimes and expected implications of each national policy. It is hoped that the assessment will serve as a first step toward ensuring that legitimate regimes are embraced while illegitimate ones are disallowed.

II. Background on Compulsory Licensing

Definition

The United States Trade Representative defines compulsory licensing as when "a government conditionally authorizes third parties (or the government itself) to use a patented product without the authorization of the patent holder."[3] In the context of international trade, two situations are specified in the WTO's TRIPS Agreement in which patented innovations are subject to compulsory licensing.[4] Compulsory licensing is one of the flexibilities included in Article 31 of the TRIPS Agreement to address public health problems. It is intended as an efficient and straightforward means for developing countries to improve access to needed therapies through generic competition.[5]

Purpose

As the cornerstone of innovation, patents prevent others from unlawfully using a patentee's work, though patents may also have a negative impact on further technological development in areas like medicine, software, and information technology where innovation is a cumulative and collaborative effort.[6] By their very nature, patents necessitate a tradeoff: static losses due to temporary monopoly power in exchange for dynamic gains through the contribution of knowledge to the public domain. According to a study by the Royal Study's Working Group on Intellectual Property, patenting "can encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science."[7] By their very nature, patent rights temporarily inhibit competition by restricting the production and marketing of patented innovations. While intellectual property may be seen as vital to innovation from a patentee perspective, a large literature reaching across a diversity of fields has explored the risk that strong intellectual property protection poses serious problems to developing countries by negatively impacting the availability and affordability of essential medicines.

The most recent impetus to use compulsory licensing emerged from the growing HIV/AIDS crisis, primarily in developing countries. As described by Alan Sykes,[8] the political climate was ripe for changes to TRIPS due to a number of factors. The international pharmaceutical industry was faced with a barrage of negative publicity because of its litigation against the South African government, which was then dropped in April 2001. In addition, the United States withdrew its WTO challenge to Brazil's Industrial Property Law following a compromise with Brazil on their use of compulsory licensing. Finally, the United Nations Commission on Human Rights declared access to drugs a human right.[9] As a result, significant pressure from civil society groups was instrumental in the 2001 Doha Declaration. The Declaration illuminated two provisions related to least-developed nations and countries that do not have production capacity. The key impact of the Declaration was that it clarified the flexibilities contained in the TRIPS Agreement and provided assurances to countries that they were permitted to use these flexibilities.[10] Essentially, the Doha Declaration clarified Article 31(f); it went from stating that compulsory licenses must be granted to supply the domestic market to stating that countries unable to manufacture the needed pharmaceuticals could obtain more affordable generics elsewhere if necessary. In August 2003, the TRIPS Council unanimously adopted a waiver of the restriction in TRIPS Article 31(f)[11] to allow compulsory licensing in a WTO Member to produce generic pharmaceutical products for export to eligible countries in need.[12]

Flexibilities in compulsory licensing have existed since the TRIPS Agreement took effect in January 1995. The purpose of these flexibilities is to establish a balance between making essential medicines more readily available to those who cannot afford treatments for diseases such as tuberculosis, AIDS, and malaria, while preventing the outright confiscation of patent rights. Under Article 31(b)[13] of the Agreement, a country is generally permitted to issue a compulsory license after it has made some effort to obtain authorization from the rights holder under reasonable commercial terms. However, countries do have the option to waive the negotiation with the patent holder in cases of extreme urgency or national emergency. It is important to note that the scope of the compulsory license must adhere to the purpose for which it was originally authorized and the licenses are non-assignable and non-exclusive and must be terminated when the circumstances that led to their issuance have been adequately addressed. Finally, compulsory licenses are not free: the country that issues a license must compensate the patent holder for the use of each license.[14]

Usage

At the time the TRIPS Agreement came into effect, approximately 100 countries provided for some form of compulsory licensing.[15] The requirements for use vary from country to country. For example, German patent law provided that a compulsory license may be issued in the interests of the public while Brazilian patent law allowed for it in cases of insufficient working of a patent.[16] Over time the following measures have all been used: "refusal to deal; nonworking or inadequate supply of the market; public interest; abusive and/or anticompetitive practices; government use; dependent or 'blocking' patents (on improvements to prior inventions); special product regimes, e.g., pharmaceuticals and food; licenses of right."[17]

Current Controversy

A number of characteristics make the pharmaceutical industry different from other knowledge-based sectors. For example, pharmaceutical development can be lengthy and expensive — upwards of 12 years from the time a new molecule is discovered to when it is finally available for patients. The sector is also highly regulated with a plethora of government controls that impact clinical trials, distribution, product pricing (in most markets other than the U.S.), and reimbursement. Once the effectiveness of a molecule for treating a particular disease has been established by the innovator, it is relatively easy for generic companies to rep-

licate the manufacturing process and commercialize a copy of the medicine. Given the risks associated with product development and commercialization, as well as the competitive nature of the industry, the pharmaceutical industry is highly dependent on effective intellectual property protection to protect their innovations. Although patents are considered "unambiguously the least effective of the appropriability mechanisms," the drug industry regards them as strictly more effective than alternative mechanisms.[18] Further, given the ease of replicating chemical and pharmaceutical innovations, protection is vital for the economic profitability of these firms.

A tool such as compulsory licensing, which at face value may appear to be a simple and effective means of lowering drug prices, is believed by the industry to seriously undermine the incentive for innovation.

Patent owners worldwide are keenly following the developments in places such as Thailand and Canada to see how the compulsory licensing provisions in these countries will impact public perception, national legislation, international agreements, and the global IPP system.

Although it may be reasonable to utilize compulsory licensing for national emergencies, it is important to understand why compulsory licensing is being considered as an option. An initiative is far more likely to have broad support if it aims to address a humanitarian crisis rather than one that seeks to strengthen a country's industrial policy objective. Industry is concerned that the flexibilities enshrined in TRIPS, if abused, will weaken global IPP to the point where countries such as India or China (those with significant manufacturing capacity) can begin undercutting their profitability.

The pharmaceutical industry is placed in a delicate position when countries choose to exercise Article 31 of TRIPS as it does not want to be viewed as an impediment to addressing a health care issue. Nevertheless, there is a need to distinguish legitimate compulsory licensing regimes from abusive ones. The debate enveloping the Thai case suggests that the issue is still divisive, and Article 31 continues to engender controversy, whether genuine or invented, and foster vehemently defended positions on both sides. Patent owners worldwide are keenly following the developments in places such as Thailand and Canada to see how the compulsory licensing provisions in these countries will impact public perception, national legislation, international agreements, and the global IPP system.

III. Canadian Experience

Legislative Background

Canada has a long history of compulsory licensing, and the policies related to compulsory licensing have taken a number of twists and turns throughout the years. Canada's first use of compulsory licensing began in 1923, when the Patent Act (Canada's first Patent Act came into force in 1869) was amended to permit compulsory licensing for drug patents. Compulsory licenses issued under this provision for pharmaceuticals were available only when the active ingredients were manufactured in Canada. The wording of the amendment suggests that the reasoning behind the amendment was to keep the price of medicines available in Canada low, "consistent with giving the inventor due reward for the research leading to the invention."[19] However, because the generic manufacturers operating in Canada at the time did not have the capacity to manufacture chemical ingredients, this provision was rarely used, and in the nearly 35 years from 1935 to 1969, only 22 licenses were granted.[20] According to Jerome Reichman and Catherine Hasenzahl, the number of compulsory licenses granted was even smaller: only 11 granted of 53 applications between 1935 and 1970.[21]

In 1969 government priorities changed and the Patent Act was again amended, this time to permit compulsory licenses to import raw ingredients for medicines into Canada. The purpose of the amendment in this case was to both keep the price of drugs low, as well as to foster the development of a stronger Canadian generic drug industry. Canada continued in this vein until 1987 when the "Act to Amend the Patent Act" became law. Bill C-22 was designed as an incentive for the pharmaceutical industry to invest in research and development in Canada. According to Robert M. Campbell et al.,[22] the government's rationale for Bill C-22 was fivefold: (1) to strengthen intellectual property rights; (2) to improve multilateral relations; (3) to increase high-tech economic development; (4) to regulate drug prices (through the establishment of a Patented Medicine Prices Review Board as stated in an amendment included in the Act); and (5) to provide improved health care for citizens. Bill C-22 also changed the general patent law to provide that the term of a patent will be 20 years from the date

of application filing (rather than 17 years from the date the patent was issued).

In 1991, the Director General of the General Agreement on Tariffs and Trade (GATT) completed the Draft Final Act for the conclusion of the Uruguay Round of the GATT negotiations. This text also contained the draft TRIPS agreement. It was acknowledged that the Canadian compulsory licensing regime at the time was incompatible with article 31 of the TRIPS agreement. In 1992 the text of the North American Free Trade Agreement (NAFTA) was finalized and Chapter 17 was almost identical to the provisions outlined in the TRIPS Agreement. In 1992 the Canadian government took steps to modify the Patent Act to implement the TRIPS and NAFTA provisions on intellectual property with the introduction of Bill C-91. In 1993 Bill C-91 officially became law and abolished the compulsory licensing system.

Current Canadian Compulsory Licensing Legislation

Between November 1993 and 2004, compulsory licensing was no longer allowed in Canada. The final twist on the road came with the *Jean Chretien Pledge to Africa: Access to Medicines Act* in May 2004. The Act was initiated at the urging of civil society advocates and was required for Canada to participate in the Doha export regime. At the same time, there are those who say that the impetus for the Act was purely political: that it was the swan song of a retiring Prime Minister who wanted to leave a legacy. While the Act was applauded by civil society advocates and generic drug manufacturers at its inception, significant criticisms were raised when it was put into practice and the process was revealed to be greatly flawed. Critics of the legislation (which include Apotex, the first generic manufacturer to take advantage of the Regime) suggest that there are too many unnecessary restrictions and technicalities contained within the bill. Further, the multi-stage process has been criticized for being so complex that it is almost unworkable.[23] Industry Canada (the Canadian government department responsible for fostering "a growing, competitive, knowledge-based…economy"[24]) spokespeople suggested that the bill "mistakenly assumed drug makers will seek to export drugs for humanitarian reasons, as there is room to make some money, however it does not accommodate lucrative transactions. The problem…is that generic drug makers are not charities."[25]

The stated purpose of the Act is to provide access to medicines for those living in developing countries: "Canada's Access to Medicines Regime provides a way for the world's developing and least-developed countries to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens. It is one part of the Government of Canada's broader strategy to assist countries in their struggle against HIV/AIDS, tuberculosis, malaria and other diseases."[26] The Act is the first in the world to take advantage of the flexibilities under the WTO decision in August 2003; these flexibilities allow the compulsory licensing of pharmaceutical patents in a WTO member country for the purpose of exporting lower-cost generic drugs to countries that do not have adequate capacity to make their own pharmaceuticals.

Only those countries on Canada's Access to Medicines Regime (CAMR) list which have little or no capacity to manufacture drugs and medical devices are eligible to participate in CAMR, and a compulsory license can only be requested for a drug that is on CAMR's list of eligible drugs. The compulsory license will only be granted for export — it is not intended for domestic use in Canada. It is up to the developing country to notify the WTO and the Government of Canada that they need a particular product and then to find a suitable Canadian pharmaceutical company from which to import the needed product. Unique features of the Regime include the following: (1) the fact that the Regime is also available to non-WTO countries; (2) that all drugs and devices exported under the Regime must meet the same safety, effectiveness, and quality requirements as those produced for the Canadian market; (3) Health Canada will review products intended for the Regime; (4) products exported under the Regime must have special markings, coloring, and labeling in order to distinguish them from those sold in Canada; and (5) non-governmental organizations can act as purchasers of licensed products with the permission of the importing country's government.

The Act sets out a specific procedure whereby the Canadian commissioner of Patents can issue a compulsory license to a pharmaceutical company allowing the manufacture and export of an eligible drug or medical device to an eligible importing country.

The biggest criticism of the Regime lies in the layers of bureaucracy and technicalities that it takes to work through the legislation. According to the Apotex press release announcing the end of negotiations, "Following the process it has taken Apotex over three years to get to this point where a drug can go to thousands in Africa. Apotex is the only company in Canada to have worked through the complicated CAMR process. The Generic Pharmaceutical Industry has recommended that the Federal Government simplify the process of getting urgently needed drugs to Africa."[27] Furthermore, the Government itself acknowledges that there are a number of important shortcomings to the Access

to Medicines Act. In the Industry Canada/Health Canada review of the Act, the authors recognize "that the regime could do more to address the underlying economic barriers and will undertake further analysis of this issue.... In particular, it appears that CAMR could be more explicit in allowing for the harnessing of economies of scale through the pooling of purchasing power by multiple developing countries suffering from the same public health problem."[28]

CAMR's Performance

When Jean Chretien announced the *Jean Chretien Pledge to Africa Act*, activists and civil society advocates applauded the move. However, it soon became apparent that while the spirit of the Act appeared to be in the right place, the actual logistics of the Act were cumbersome. The group Médecins Sans Frontières (MSF) highlighted many of the commonly cited shortcomings of the Act through a report issued in 2006 titled "Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable. An illustration through Canada's Jean Chretien Pledge to Africa."[29] The 8-page report highlights the Act in detail. Some of their main concerns with the Act include:

1. The Act is unnecessarily onerous (the Act contains 19 sections and over 100 clauses and subclauses);
2. The Act restricts medicines (only medicines included on the list — Schedule 1 — can be used by developing countries);
3. The Act requires unnecessary Health Canada approval (all products exported under the Act must be approved by Health Canada);
4. The Act limits drug quantity and export (a compulsory license is only granted for 2 years, and the exporter must stipulate the maximum quantity of the product that will be required);
5. The Act is a compromise (the Canadian government attempted to balance competing interests of all stakeholders).

Others, including Richard Elliott of the Canadian HIV/AIDS legal network have been equally vehement in their opposition to the Regime,[30] and in 2006, at the International AIDS conference, the Minister of Health publicly announced its intentions for speeding up the review and making necessary changes. A series of consultations and stakeholder submissions followed, as did a Parliamentary Hearing. A report was tabled in December 2007, although the Minister of Industry indicated it would be premature to bring forward an amendment to CAMR at that time. Since then civil society groups continue to pressure the government to put CAMR to rest and replace it with a more streamlined procedure that would be more likely to be used repeatedly.

While Canada was deemed to be a leader in the fight to increase access to medicines in developing countries with the initial announcement of CAMR, the prolonged negotiations and cumbersome process have led to dissatisfaction on the part of advocates and a nearly unworkable process. CAMR does not have many admirers, and the issue appears to have been abandoned by the current Conservative government under Stephen Harper. For example, the most recent release cited under the "What's New" section of the CAMR Web site is dated December 14, 2007. The current Conservative Canadian government does not view development as a high priority, which indicates that the CAMR process is likely to be left languishing in its current form, at least until the Liberals return to power.

Though far from perfect, Canada's Access to Medicines Regime is the only regime to have delivered a single drug under the post-Doha process. While one might suspect that the onerous nature of the process is responsible for the disappointing progress, the reasons behind this lack of compulsory licensing are less well understood and more complex than this single element. As noted by Amir Attaran, "[T]he European Union, Norway, Switzerland, China and South Korea (31 countries in all) also have laws permitting compulsory licensing and exporting of medicines — and none of these laws have been used either."[31] Teasing out the various factors behind the dearth of licenses has yet to be done, but the fact remains that any interest that developing nations may have in compulsory licenses remains unfulfilled.

IV. Thai Experience

Health Care and the Market for Pharmaceuticals in Thailand

Thailand has a population of 66 million and has been enjoying improvements in health and greater life expectancy, especially over the last two decades. The nation is in the midst of an epidemiological transition or backlog, facing infectious and deficiency diseases, and at the same time increasing numbers of emerging, chronic, and degenerative diseases. HIV/AIDS is a significant burden in Thailand where approximately 580,000 people are living with the virus. Arguably this number would be significantly higher without the country's AIDS program. In October 2001, the Thai government implemented universal health coverage. This was followed in October 2003, with the establishment of a policy of universal access to antiretrovirals (ARV) for AIDS patients.[32]

The Thai pharmaceutical market was valued at $1.32 billion in 2006 and is experiencing one of the fastest rates of growth in the region, approximately 6% annually.[33] Locally made products comprise the largest share of the market, amounting to 65% with imported goods making up the remaining 35%. Three categories of pharmaceutical manufacturers have a presence in Thailand: multinational corporations, 171 privately owned Thai firms, and the government-owned Thai company Government Pharmaceutical Organization (GPO).[34]

Legislative Background

With the commitment to Universal Health Insurance in October 2001, the Thai government expanded health care coverage to the population through public and private hospitals. The program, known as the "30 Baht Scheme" — which refers to the minimum fee that citizens must pay for coverage — is funded by general tax revenue and has become increasingly expensive, especially following the addition of ARV therapies.[35]

In April of 2006 Thailand's National Health Security Board established a subcommittee to implement compulsory licenses for pharmaceuticals for government use. The criteria established were the following: drugs "priced too high for the government to afford its citizens with universal access to essential medicines, listed in the National Essential Drug List, or be necessary in emergency or a situation of extreme urgency, or solve important public health problems, or help prevent and control of outbreaks, epidemics, or pandemics, or necessary to save lives."[36]

Following a coup in September 2006, the military government sought to build populist support and abolished even the minimal 30 baht fee for universal health care coverage. Then in November, the government issued a compulsory license for efavirenz (one component of a highly active antiretroviral therapy for the treatment of HIV) to the Government Pharmaceutical Organization (GPO). In January 2007, the GPO contracted with pharmaceutical company Ranbaxy to import 66,000 bottles of efavirenz. In the subsequent months, additional compulsory licenses were issued, and numerous HIV/AIDS, cancer, and cardiovascular drugs were selected for compulsory licensing. A detailed timeline of Thailand's compulsory licensing activity is described in Table 1 .

Objectives of the Thai Compulsory Licensing Program

When the Thai government issued the first compulsory licenses in late 2006 and early 2007, it claimed that its ability to provide universal health care was undermined by the high prices of the drugs essential to improving the health of the Thai population. In January 2007, when announcing the compulsory license for Abbott Laboratories' Kaletra (another drug to manage HIV), the Ministry of Health singled out the drug's high price, stating "[w]ith this high price the budget allocated from the Thai Government can only cover some patients with [Kaletra], whereas the rest has to face fatal opportunistic infections. If this ARV's formula could be produced or imported, the lower price would help [make the drug] more accessible."[37] Presently, close to 90,000 people are receiving ARV therapy in Thailand, and the cost of these drugs is obviously a significant expense for the Ministry of Health.[38] Ultimately the Thai government hopes to reduce the price of Kaletra to about 20% of Abbott's price.[39] Despite this claim, current prices have not reached this level. Moreover, the drugs available from international aid organizations have been offered at prices even lower than the government's goal.

Despite this, there are reasons to question the government's claim that the compulsory licenses are motivated by the need to safeguard public health. Thai officials point to high prices as the impetus behind the licensing decision. However, 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. In some cases, products were marked up 1,000 percent."[40] Such high markups are difficult to reconcile with a motive to lower prices. Moreover, although the pharmaceutical companies had a history of discounting medicines for Thailand, they claim that the government did not negotiate with them before issuing the compulsory licenses. In the case of efavirenz, the "government simply announced the 'public use' of the patent without discussing the matter with Merck & Co. first."[41] Though this is Merck's position, the government of Thailand denies that the compulsory license was issued without prior negotiations.[42] As expressed by the Ministry of Health, "[T]he attempt to push for prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations."[43] Clearly, price is not the only — perhaps not even the primary — motivating factor behind the issuance of the compulsory licenses.

It is then worth probing whether the decision is a supply issue. Is domestic production necessary to Thailand in order to maintain a reliable supply of the drug? Certainly this could justify the government's action and be the objective behind the compulsory licenses. However, examination of the Thai procurement rules suggests no. The sole license to manufacture the compulsorily licensed drugs was granted to the GPO.[44] The Thai government has denied private Thai manu-

Table 1
Thailand's Compulsory Licensing Timeline*

Date	Event
October 2001	Universal Coverage Scheme of Health Insurance implemented.
October 2003	Thai government establishes universal access to antiretrovirals.
April 2006	United States Trade Representative (USTR) lists Thailand on its "Special 301" Report Watch List citing weak protection for pharmaceutical test data and delays in pharmaceutical patent approvals.
April 17, 2006	The Thai government's National Health Security Board established a subcommittee to implement compulsory licenses for government use.
September 19, 2006	Bloodless military coup deposes Thai Prime Minister Thaksin Shinawatra.
November 2006	Thailand's military government eliminates the 30 baht fee for health care coverage.
November 29, 2006	Thai government issues a compulsory license for efavirenz (Merck's Stocrin) to the Government Pharmaceutical Organization (GPO), valid until December 31, 2011.
January 5, 2007	GPO contracts to import 66,000 bottles of efavirenz from India.
January 25, 2007	Thailand issues compulsory licenses for Abbott's Kaletra and Sanofi-Aventis and BMS's Plavix.
September 24, 2007	The Thai government selects additional drugs for compulsory licensing: imanitib, docetaxel, erlotinib, and letrozole.
November 2, 2007	Thai national Health Security Office announces 20 more drugs as candidates for compulsory licenses.
November 21, 2007	Novarits offers to provide Gleevec (imantinib) to Thai patients for free. (Compulsory license cancelled in early 2008.)
December 2007	New government elected.
January 25, 2008	Following failed negotiations with manufacturers, Thailand decides to issue compulsory licenses for an additional four cancer drugs. The announcement does not disclose which drugs.
February 2008	First batch of generic Kaletra delivered to state hospitals nationwide.
March 2008	New Health Minister, Mr. Chiya Sasomsup, decides to continue the previous government's policy of compulsory licensing.

**Data collected from PIJIP (2008) and Norris (2007)*

facturers procurement contracts while simultaneously claiming that universal coverage can only be assured through compulsory licenses for the multiple drugs selected.[45] An increased supply of drugs and enhanced security of a reliable supply through multiple producers does not appear to be the government's motivating objective.

While the compulsory license does not appear to be motivated by finding a reliable supply, neither does price seem to be the primary objective, since cheaper drugs are available through other channels. If price and supply security are not motivating the licensing decision, then other potential motives deserve scrutiny. It is worth noting that the Government Pharmaceutical Organization is not run as a non-profit entity, but rather as an increasingly profitable enterprise. In fact, the GPO hopes to double its 2005 revenue (10 billion baht) by 2010.[46] Furthermore, Thai government officials would like to see the GPO compete with India's generic industry and become a "regional hub for the manufacture and export of copy medicines."[47] India is currently the principle supplier of essential medicines for developing countries, exporting an estimated two-thirds of the drugs it produces.[48] Realistically, industrial policy may be more important than public health to the compulsory license strategy.

V. Compulsory License Program Design and Implementation

The preceding sections describe the compulsory licensing programs of Canada and Thailand, regimes that differ in many dimensions. In order to evaluate the legitimacy of these and other programs, it is necessary to identify the characteristics of a successful regime. This section lays out an elementary rubric that may be used to distinguish legitimate from disingenuous regimes. The subsequent section then applies this measure to the regimes of Canada and Thailand. Though these guidelines are intended to abide by the spirit and intent of the WTO rules, it is important to note that they go beyond existing rules.

Six aspects of compulsory licensing programs are considered here: Objective, Implementation, Quality, Price, Market Demand, and Evaluation. In each case guidelines are described that provide some measure of legitimacy.

Objective: The objectives of a compulsory licensing program may encompass either health policy or industrial policy goals. In the context of health objectives, enhanced access to medicines, assurance of a reliable supply and greater affordability are all important goals. Within industrial policy, important national goals may include the establishment of a domestic generic industry[49] or learning-by-doing. In light of the description compulsory licensing in cases of health emergencies, profitability is not a valid objective. No conflict of interest should be found in the implementation of the program, and the benefits should be conferred on the population rather than to industrial interests or government entities.[50]

Implementation: The necessary documentation should be streamlined and implementation should be rapid. The entire process should be transparent and easy to maneuver. As noted by F. Michael Scherer and Jayashree Watal, "The longer the issuance of compulsory licenses is delayed after patented drugs enter the marketplace, the less time licensees have to recover their start-up costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers. Thus, if compulsory licensing is to be successful, expeditious licensing procedures are necessary."[51]

Quality: Domestic manufacturers should provide consumers with quality products. The drugs should be as safe and efficacious as the patented version. The WHO's Good Manufacturing Practice Standards may provide a useful starting point for production and quality standards.

Pricing: Given that health emergencies and enhanced access to medicine are the driving forces behind compulsory licenses under Article 31, the cost savings available from the licensed versions should be passed on to consumers.

Demand: Compulsory licensing should be utilized in cases where sufficient domestic demand exists to justify the fixed costs of production, taking advantage of economies of scale in production. In addition, unauthorized use should comply in good faith with the national emergency and urgency described in Article 31b of the TRIPS Agreement. Though difficult to quantify, compulsory licenses should only be employed in cases of sufficient burden to constitute a national emergency.

Evaluation: The program should be accountable to its goals and objectives. Given the objectives described, the measures of success may include: development or growth of a domestic generics industry, the total amount of medicine delivered or disease burden alleviated, reliable provision of quality medicines, or similar measures.

VI. Evaluation of the Canadian and Thai Programs

Evaluation of Canadian Program

Access to Medicines Act

Since inception in 2004, one compulsory license has been granted to the Canadian generic firm Apotex to supply Rwanda with a combination HIV/AIDS therapy. Although the agreement was completed, the lengthy process meant that Rwanda waited years for the first shipment of Canadian-manufactured medicines. In this case, only a limited list of medicines is subject to compulsory licensing, and this list was derived from the WHO's list of Essential Medicines. Civil society activists lobbied against the inclusion of such a list as it represented a step back from an international consensus achieved with a WTO General Council Decision in 2003. Richard Elliot of the Canadian HIV/AIDS Legal Network describes the decision as follows:

> In the negotiations leading up to the Decision, several developed countries proposed to limit its scope to just addressing specific diseases or just applying to specific pharmaceutical products. These efforts were roundly condemned by civil society activists as unethical and unsound health policy, and firmly rejected by developing countries. Ultimately all WTO Members agreed that there would be no such limitations.[52]

In response to activists, the government amended its original list of 56 medicines to include all but one of the ARV drugs approved for sale in Canada at the time the legislation was enacted. To date, no other country has followed Canada's example. According to Elliot, the Act "falls short of taking full advantage of the flexibilities permitted until WTO law and also contains several unnecessary, 'TRIPS-plus' provisions that should be avoided in other jurisdictions implementing the WTO Decision to promote access to more affordable medicines for all."[53]

In order to evaluate the success of the Canadian program, it is important to recognize that since inception, only one country has applied to take advantage of this regulation and the first shipment of drugs finally left the country four years after initiating the program. The Generic Drug industry has suggested that the Act needs significant changes in order to continue with any efficiency. Jack Kay, President and COO of Apotex stated, "There is a reason no other company has tried to provide medicines under this Regime. It is too complex and has to be repeated for every request that comes in from a country. For Canada to truly be able to provide help, the regime must be changed."[54]

According to Médecins Sans Frontières, "Is it really a success? That is the question. Certainly from…an MSF perspective it's not a practical way for us as an agency to get these types of drugs from Canada."[55] Perhaps the most condemnatory evaluation of the regime comes from Amir Attaran who suggests that the regime should be discontinued completely: "Setting a naïve and ill-informed goal led to poor results. With the evident failure of Canada's law, Parliament would be wise to cut its losses and concentrate on the more concrete things it can do to help the world's poor."[56]

The government itself acknowledges that there are a number of important shortcomings to the *Access to Medicines Act*. In the Industry Canada/Health Canada review of the Act, the authors recognize "that the regime could do more to address the underlying economic barriers and will undertake further analysis of this issue…. In particular, it appears that CAMR could be more explicit in allowing for the harnessing of economies of scale through the pooling of purchasing power by multiple developing countries suffering from the same public health problem."[57]

Objective: The goal of CAMR is to provide those living in developing countries with access to less expensive, high-quality medicines. Therefore, the stated objective of the Regime is to improve the health of those receiving the drugs. The possibilities of profitability for any Canadian company are extremely low, in part because the red tape and administrative costs of the program are prohibitive.

Implementation: By all accounts, one of CAMR's main failings is the difficulty of implementation. According to Apotex, achieving shipment of the first medicines was a four-year endeavor and very complex undertaking. The process is quite transparent as the CAMR Web site holds a plethora of easy-to-read-and-understand information, and purports to provide step-by-step instructions on how to take advantage of the program.

Pricing: Apotex claims to have made the drug available to Rwanda the cost price of 39 cents per daily dose. While this is significantly cheaper than the cost of the brand product, it is more than Apotex's original price estimate of 19.5 cents. It is unclear whether the cost savings have been passed on to Rwanda's citizens.

Quality: All drugs issued under Canada's CAMR must adhere to the same regulatory standards for safety and efficacy as those drugs intended for the Canadian market. The Canadian standard for drugs is very high; therefore those countries taking advantage of CAMR can expect to receive excellent quality medicines.

Demand: There is no doubt that Rwanda needs access to safe and effective HIV/AIDS medications as "Rwandans have been hit hard by AIDS in the years following the 1994 genocide that left nearly one million dead. There are an estimated 210,000 AIDS orphans living in the small, central African nation according to the United Nations. It is one of the poorest countries in the world, and more than 80 per cent of its people live on less than $2 a day."[58] Moreover, there is near universal agreement that the AIDS pandemic is precisely the type of health emergency intended for address by the WTO rules.

Evaluation: CAMR can be viewed as a success in that safe, effective, and less expensive medicines were eventually shipped to Rwanda. However, the Regime is also cumbersome and overly burdened with administrative hurdles that make it difficult to maneuver and even unworkable. Certainly the only Canadian company to successfully navigate the red tape has indicated that they will not attempt the process again. Ultimately, the *Access to Medicines Act* may be seen as a well-intentioned attempt to use flexibilities contained within TRIPS to aid those in developing countries gain access to affordable and high quality medicines. However, given the many criticisms of the regime, coupled with the time-consuming process, one can conclude that this experiment in compulsory licensing falls short and may be vastly improved upon.

Ultimately, the *Access to Medicines Act* may be seen as a well-intentioned attempt to use flexibilities contained within TRIPS to aid those in developing countries gain access to affordable and high quality medicines. However, given the many criticisms of the regime, coupled with the time-consuming process, one can conclude that this experiment in compulsory licensing falls short and may be vastly improved upon.

Evaluation of Thai Program

Thailand's decision to issue compulsory licenses has been lauded by public health advocates and universally condemned by the pharmaceutical industry. Examination of the Thai program reveals a number of controversies surrounding the program's objectives and its implementation. Perhaps most important are the questions raised about the quality of Thailand's Government Pharmaceutical Organization's drugs. The substandard drugs produced and self-serving nature of the compulsory licenses cast doubt on the Thai government's program and the benefits conferred on the Thai people.

Objectives: To the extent that the compulsory licensing strategy satisfies industrial policy goals rather than public health objectives, the Thai program can be considered successful. Government aspirations for an increasingly profitable GPO have clearly been met. GPO earned a profit of 642 million baht in 2003 and that amount rose to 1 billion baht in 2005. "The GPO plans to double its 2005 revenue to 10 billion baht by 2010, widening the scope for profit still further."[59]

The innovative pharmaceutical industry argues that compulsory licenses reduce the incentives for future research and development on neglected diseases. This argument is admittedly weakened by the dearth of current research on these diseases. Nevertheless, *any* obstacle to research on neglected diseases should be removed to increase the likelihood of innovation in these areas. At the same time, the profits of the GPO are not being invested in research and development projects of any type. Philip Stevens notes that the GPO invested less than 0.5% of sales revenues, in contrast to the pharmaceutical industry's unaudited claim of an average of 17.5%.[60]

Quality: The action taken by the Global Fund is indicative of the quality problems plaguing the Thai program.

> The Global Fund to Fight HIV/AIDS had granted the GPO $133 million in 2003 to upgrade its plant to meet international quality standards for this drug (GPO-vir). In October 2006, the Fund withdrew the remaining monies, citing the GPO's failure to meet WHO standards. After four years of pre-testing, WHO still refused to list this drug in its pre-qualification program.[61]

The GPO's failure to meet the WHO's standards in every category attempted is suggestive of the poor quality of the GPO's products and the health risks posed to patients.

Fundamentally, no evidence of bioequivalence of the GPO-manufactured drugs exists. Substandard drugs, including those that are not bioequivalent, are both dangerous to the patient and a potential source of pathogen resistance within patient populations which may undermine an entire class of active pharmaceutical ingredients. According to Dr. Terrence Blaschke, Professor of Medicine and of Molecular Pharmacology Stanford University,

> Successful treatment of infectious diseases is the result of a complex interaction between the patient, the drug and the infectious agent. Drug concentrations that are too low can cause the therapy to fail and, equally importantly, promote the emergence of resistant forms of the infectious agent. As these can persist for years, this cause of failure can compromise the response of the patient to other medicines in the future.[62]

This is certainly happening. A 2005 investigation[63] by Thailand's Mahidol University found "GPO-vir, a copy HIV treatment GPO makes, had between 39.6% and 58% resistance in the 300 patients investigated. This result is perhaps the worst case of HIV drug resistance in the world."[64] These numbers are substantiated by a larger sample of patients as well. "About 108,000 of 500,000 people living with HIV/Aids depend on GPO-vir, the generic version of the first-line anti-retroviral therapy produced by the Government Pharmaceutical Organization. An estimated 20,000 HIV-positive people have developed resistance to the drug."[65] That is, almost a fifth of those taking GPO-vir have already developed resistance to the drug and should be on more expensive second-line therapies. While GPO-vir was inexpensive at $24/patient per month, the second-line therapies necessitated by the drug resistance come at a cost of $249/patient per month and require costly hospitalization. The cheap GPO solution will unquestionably result in greater public health problems and more expensive therapies.

Tragically, high-quality generic versions of these drugs are already available from other countries and the Global Fund offered to make them available to Thai patients. "At present, pharmaceutical producers in India can supply the same AIDS drugs for which compulsory licenses are being sought, and all of them have been either prequalified by WHO or approved by the FDA as true, bioequivalent generics."[66] This suggests that their provision would provide unwanted competition to the GPO, again pointing to industrial motives rather than public health concerns. This is substantiated by the Thai response to the Global Fund which offered to "foot Thailand's entire bill for efavirenz by purchasing a generic version of the drug from a World Health Organization-approved plant

in India. The Thai government rejected the Global Fund's offer, leaving Thai taxpayers to foot the bill for the drug's manufacture."[67]

Some of the controversy surrounding the Thai program stems from the government's primary justification that it lacks the funds for the needed drugs. This claim was made at the same time Thailand's military leaders gave themselves pay increases totaling $9 million and augmented the national defense budget by $1.1 billion, an increase of more than 30%.[68] Not surprisingly, health sector funding was simultaneously reduced by $12 million per annum.[69] Given these figures, it is difficult to believe that universal access to essential drugs is an important government priority. Moreover, such claims are undermined by Thailand's tax and tariff policies. The government collects a 10% tariff on most drug imports and maintains a 7% value-added tax on all medicines.[70]

Demand: Finally, Thailand's compulsory license program demands scrutiny for the drugs selected. Of the first three drugs targeted, Sanofi-Aventis's drug Plavix treats heart disease. While HIV/AIDS has always been considered a health emergency, the choice of Plavix has generated significant controversy. On the one hand, Roger Bate claims that "less than 1% (about 300,000) of the Thai population suffers from chronic coronary obstructive disease."[71] While Thailand's Ministry of Health notes that "fewer than 10% of the 300,000 heart disease patients in Thailand can buy Plavix. The ministry has said heart disease is Thailand's second leading cause of death, after HIV/AIDS."[72] The extent to which 300,000 patients constitutes a health emergency remains in the international limelight. The announcement of compulsory licenses for four cancer drugs further heightened the debate. The drugs were Letrozole (breast cancer), Docetaxel (breast and lung cancer), Imatinib (myeloid leukemia) and Erlotinib (lung cancer). Again, the extent of the disease burden has garnered scrutiny, given that according to the Ministry of Health, 15,000 people in Thailand suffer from lung and liver cancer.

In 2006, Thailand initiated its compulsory licensing program, setting up a government subcommittee that ultimately issued compulsory licenses for a number of HIV/AIDS, cancer, and heart disease drugs. The drugs were initially purchased from Indian manufacturers and later produced by the Thai Government Pharmaceutical Organization. While Thailand cited a lack of funds as the primary reason for the licenses, this claim has come under considerable scrutiny. In particular, critics cite the government's reduction of health sector spending, while increasing the defense budget. In addition, the poor quality of the drugs produced by the Thai GPO have contributed to the rise of resistance and amplified the cost of the Thai HIV/AIDS program as second-line antiretroviral therapies become necessary.

Moreover, the decision raises questions about the Thai interpretation of TRIPS Article 31, the conditions of unauthorized use, and the debate surrounding what constitutes a "national emergency." Given the availability of effective, off-patent alternative medicines, the compulsory license issued for Plavix® is more difficult to understand as the public health necessity the Thai government has described. The expansion of the compulsory licensing program weakens the international health community's consensus on the policy and could strip Article 31 of all future legitimacy.

Evaluation: The impact on innovative pharmaceutical companies' decisions to launch new products in Thailand will be felt more immediately. Shortly after the issuance of the compulsory licenses, in March 2007, Abbott Laboratories responded by electing not to launch any new products in Thailand, saying "Thailand has chosen to break patents on numerous medicines, ignoring the patent system. As such, we've elected not to introduce new medicines there."[73] Beyond refusing to introduce new medicines into Thailand, pharmaceutical manufactures may also reduce their investments and eliminate foreign direct investment in the region and leave Thailand.

Finally, the international response has been divided: statements of support and commendation from many public health advocacy groups and criticism and condemnation from many Western governments. Since the issuance of the compulsory licenses, Thailand was placed on the U.S. "Priority Watch List" in the Special Section 301 Report in May 2007. Admittedly there are those who argue that this is merely the U.S. government attempting to intimidate Thailand. Although the Thai program has not generated any trade consequences, Thai officials were concerned enough about this possibility to reexamine the program in March 2008.

While both the industry policy and health policy goals of the Thai program are laudable, the implementation of the program falls short. The drugs produced have been of questionable quality at best yet the program endures despite the availability of high quality generics from India and offers of drug purchases by the Global Fund. Unfortunately, current practices shed doubt on the objectives of the program and call into question the feasibility of future compulsory licensing agreements. Ultimately, it is doubtful that the cost savings that should accrue to Thai patients will materialize due to the additional costs of the necessary second-line antiretroviral therapies stemming from the rise of resistance caused by the Thai GPO-produced

drugs. Regrettably, it seems unlikely that patients in Thailand will benefit from the government's compulsory licensing program.

VII. Social Costs of Compulsory Licensing Programs

In order to thoroughly assess both the quality and value of compulsory licensing, it is essential to address the social costs that accompany its use. The calculus needed to weigh the social costs and benefits of compulsory licensing is difficult and imprecise at best. Nevertheless, accounting for what is given up via compulsory licensing and the potential long-term costs can only better inform the licensing decision and illuminate the tradeoffs in play.

Table 2
Summary of Evaluation Rubric

Measure	Canada	Thailand
Objective	To provide those living in developing countries with access to safe and affordable medicines.	Thai program satisfies industrial, rather than public health goals. The development of the domestic industry arguably comes at the cost of public health objectives. ××
Implementation	Significant difficulties encountered in implementation. Process is lengthy and cumbersome. ××	The program has generated significant international controversy. Both legal suits and trade consequences have been threatened. ××
Pricing	Drug purported to be provided at cost (39 cents per daily dose). Significant savings over innovative price.	Prices are reported to be less than those quoted by innovative firms, but quality problems with GPO-produced drugs raise concerns that the medicines are not equivalent. Moreover the government's profit motive raises suspicions that the cost savings are not being passed on to Thai patients. ××
Quality	Drugs to be shipped must meet Canadian standards for safety and efficacy.	There are serious concerns with the quality of medicines produced by the GPO. ×××
Demand	Need for AIDS drugs in Rwanda is clear.	The need for AIDS drugs is undisputed. The national emergency leading to the need for cardiovascular drugs is in question. ××
Evaluation	Despite eventual shipment of drugs from Canada to Rwanda, the process is hampered by red tape. ××	Quality concerns detract from the extent to which industrial and health policy goals have been accomplished. ××

The existing international patent system is an imperfect tool, though one that has incentivized the development of a variety of invaluable medical breakthroughs. As noted by Sykes, "[T]he information necessary to refine the system is not easy to come by — after all, what matters to the pace of research and development is its expected returns *ex ante*, and those are exceedingly difficult to observe. At best, therefore, modern patent systems provide a crude way for rewarding inventors in the face of great uncertainty about the optimal rewards in each case."[74] As such, it is difficult to predict the impact compulsory licensing will have on innovation.

A common perception is that compulsory licenses will reduce the incentive for innovation. Colleen Chien quotes one pharmaceutical industry executive who noted, "'[T]hreatening compulsory licensing…will only act as [a] disincentive to the development and marketing of new drugs.'"[75] To evaluate the validity of this statement, one must distinguish between treatments for global diseases and treatments for the diseases endemic to developing nations. For global diseases, multinational pharmaceutical companies respond to the potential profits provided by wealthy markets and consumers in industrialized countries. Accordingly, as noted by numerous studies, compulsory licensing by developing countries with small markets is likely to have a negligible impact on innovation for global diseases.[76] Alternatively, the impact on the incentives to innovate around diseases endemic to developing countries will be very different. The economic incentives to research treatments for such diseases are critically linked to pharmaceutical companies' abilities to capitalize on sales in the countries where these diseases are most prevalent. In the presence of such a strategy, it is likely that the pharmaceutical industry would respond with reduced investment into developing country disease research, opting instead to concentrate on drugs for larger markets and reduce the risk profile of their projects. In the long run, neglected diseases disappear from the research agenda.

The link between compulsory licensing and a fall in investment and reduced innovation was investigated by Chien.[77] She finds that two factors, predictability and importance, are key to determining whether innovation is impacted. The "degree to which a company can predict that a compulsory license will be taken on a patent ('predictability') and the relative importance of the markets affected by the license ('importance')" are vital to assessing how the structure and implementation of compulsory licensing impact innovation.[78] She concludes that "only those drug licenses issued predictably in significant markets are likely to harm innovation."[79] In particular, unpredictable licenses issued for known technologies will have a more limited impact than those that are predictable and potentially cover future technologies and innovations.

While compulsory licenses are invaluable when used to address health care emergencies or remove technological supply bottlenecks, developing nations run the risk of being denied future technology. In particular compulsory licensing may "obscure other possible courses of action, such as regulatory and cooperative measures, that might persuade foreign producers to invest in local production facilities with greater long-term prospects…[and] continued access to better technology over time."[80] When considering the adoption of compulsory licenses, nations must recognize that their use may discourage foreign direct investment and the transfer of advanced technologies in the future.

Overall, it is essential to consider the long-term implications of compulsory licensing. While prices may be reduced and access to medicines may be enhanced in the short-run, the future detrimental consequences may outweigh those benefits. In some cases, the mere threat of issuing a compulsory license may be sufficient to negotiate dramatically lower prices from pharmaceutical patent holders.[81] Nations must carefully assess both current and future costs and benefits in determining whether compulsory licensing is welfare enhancing. Admittedly this calculus is difficult, but developing countries must make their decisions with an eye on the long-run and some consideration of future consequences.

VIII. Conclusions

Following failed negotiations with multinational pharmaceutical firms and faced with rising pharmaceutical costs, Thailand recently began compulsorily licensing drugs for HIV/AIDS, heart disease, and cancer. Although the decision has added new fuel to the emotionally charged debate over pharmaceutical patents and health policy, compulsory licensing has been utilized for decades by a variety of countries. Regardless of stakeholder perspective, from a policy research point of view, it is essential to analyze the rationale for introducing compulsory licensing and the success of its application in particular jurisdictions. The recent cases of Canada and Thailand provide a ripe opportunity to examine two very different regimes.

Canada has a long history of compulsory licensing, and it appears that these programs have met their desired outcomes to a certain degree: there is no doubt that the program was beneficial for the generic industry. In like manner, Thailand's generic industry has also flourished as a result of their compulsory licensing program. However, the main difference lies in the fact that Thailand's generic industry directly profits

the country's coffers. Furthermore, Canada has a very strong regulatory and oversight system, which assures that the drugs produced in the country are among the safest in the world, while Thailand has exceedingly low standards, being unable to satisfy even the WHO's relatively lax standards. The direct result of this is the increased production of substandard drugs, leading to increased prevalence of drug resistant strains of AIDS within Thailand. The main drawback to Canada's system lies in its complexity. If the major flaws were addressed, then the Canadian system may well help those living in developing countries gain access to safe and affordable medicines.

There are far-reaching implications to Thailand's compulsory licensing decision as it muddies the waters of international intellectual property rights. The lack of transparency in the Thai process raises questions about adherence to the criteria set forth in Article 31 and the future functioning of the mechanism.[82] Indeed, Thailand's compulsory licensing program will have other far-reaching effects, both within that country and for the wider global innovation environment. Within Thailand, the GPO is likely to continue to reap significant profits, while the population continues to feel the negative effects of Thailand's health policy, including continued access to poor quality drugs and increasing incidence of drug-resistant strains of HIV/AIDS and other diseases. If this persists, health care costs within the country will continue to escalate as patients are forced to move to "second-line" therapies. It is, therefore, the residents of Thailand who suffer the most from this public policy initiative.

In the longer term, if pharmaceutical companies are to be believed, and compulsory licensing programs are in fact threatening the cycle of innovation to the degree discussed, then it is possible that these companies may remove neglected diseases from their research agendas. Despite this claim, it is currently difficult to find much work on neglected diseases within their research portfolios. They may choose instead to focus solely on drugs for those living in the developed world, thereby leaving the residents of less developed countries without treatment alternatives at any price. Realistically, this is exactly what is currently happening.[83] Nevertheless, creating additional obstacles to attracting research attention to neglected diseases cannot benefit developing countries and should be avoided whenever possible. For better or worse, this is the only industry (or paradigm) that has consistently discovered, researched, and developed new medicines. Patients around the world who are hoping for and depending on therapeutic advances and next-generation drugs will certainly be worse off without continued innovation.

The compulsory licensing strategy of Thailand seems ill-suited to enhancing access to medicines or increasing generic competition. Given this, a number of interesting questions remain to be answered. What are the alternatives to compulsory licensing that Thailand may utilize to ensure patients have access to safe, effective, and affordable medicines? What would happen to health outcomes in Thailand if the program, and perhaps the GPO, were abandoned? Are any of the alternatives to the traditional patent system workable in developing countries and worth pursuing? What safeguards should be instituted to guarantee that substandard medicines (such as GPO-vir produced by Thailand's Government Pharmaceutical Organization) do not reach patients in the future? In this context, these decisions are within the purview of the Thai government, but more generally, the answers to these questions will further clarify how to find the balance between public health and the protection for intellectual property rights. Such clarifications may be used to further shape and develop the rubric described above for the evaluation of compulsory licensing regimes.

Though the evidence presented here suggests that the Thai strategy is neither efficient nor efficacious, an undeniable role exists for compulsory licensing in international patent law and health care policy. Nevertheless, its future value depends on its appropriate use today. The debate surrounding the Thai case suggests that clarity is still needed. It is hoped that the suggestions presented in these pages may lessen future controversy and ease the process. The evaluation rubric outlined here may prove useful as a first-pass measure of appropriate use and a mechanism for determining whether a regime is legitimate or disingenuously designed. Thailand will continue to be a lightning rod and polarize advocates on both sides of the compulsory licensing debate. In the Thai case, it is difficult to argue that the policy benefits patients in least-developed countries and enhances access to medicines. Without safe, effective drugs, Thailand's GPO products will continue to bring about more harm than good. The lack of transparency in their compulsory licensing process as well as the controversial choices of heart disease and cancer drugs ensure that the debate surrounding the WTO's TRIPS Agreement will continue. Although compulsory licensing is a valuable component of the drive to improve access to medicines, some challenges clearly remain before use of the mechanism will be widespread.

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4. As described by Scherer and Watal:
   Article 31 allows compulsory licensing after a proposed user has been unsuccessful within a reasonable period of time in negotiating to obtain from the patent holder authorization to use the patented invention 'on reasonable commercial terms and conditions'...[While] Article 40 permits WTO member nations to take appropriate measures including compulsory licensing of patented inventions, when judicial or administrative procedures have identified conditions that constitute 'an abuse of intellectual property rights having an adverse effect on competition in the relevant market.' See F. M. Scherer and J. Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Nations," *Journal of International Economic Law* 5, no. 4 (2002): 913-939, at 914-915.
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9. *Id.*, at 8.
10. World Trade Organization, "Compulsory Licensing of Pharmaceuticals and TRIPS," Geneva, September 2006, *available at* <http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm> (last visited 12 July 2008).
11. Article 31(f) states that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." World Trade Organization, "Uruguay Round Agreement: TRIPS, Part II – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, Sections 5 and 6," Geneva, January 6, 2007, *available at* <http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm> (last visited April 7, 2009).
12. R. Elliot, "Solving the Doha Paragraph 6 Problem: The WTO Decision of 30 August 2003," *Canadian HIV/AIDS Policy & Law Review* 8, no. 3 (December 2003): 8-18, at 9.
13. Article 31(b) states:
   [S]uch use may only be 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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. See WTO, *supra* note 11.
14. Historically, royalty rates have varied greatly, from estimates of 18% in the U.K. to 4% in Canada (see J. Watal, "Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?" May 15, 2000, *available at* <http://www.cid.harvard.edu/archive/biotech/papers/discussion8.pdf> (last visited April 7, 2009.) In the minority of U.S. cases in which the royalties were established by the courts, royalties ranged from 0.2 to 3.0%. As noted by Scherer and Watal, the "choices made in industrialized nations provide ample precedent for royalty-setting on the modest side of the range of possibilities." See Scherer and Watal, *supra* note 2, at 924.
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30. See Elliott, *supra* note 12.
31. A. Attaran, "A Tragically Naïve Canadian Law for Tragically Neglected Global Health," *Canadian Medical Association Journal* 176, no.12 (April 20, 2007): 1726-1727, at 1727.
32. Program on Information Justice and Intellectual Property (PIJIP), "Timeline for Thailand's Compulsory Licenses," version 2, Washington College of Law, American University, March 2008, at 3, *available at* <http://www.wcl.american.edu/pijip/documents/timeline.pdf?rd=1> (last visited April 7, 2009).
33. *Id.*, at 4.
34. *Id.*
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36. See PIJIP, *supra* note 32, at 4.
37. Thailand, Ministry of Public Health and National Health Security Office, "The 10 Burning Questions on the Government Use of Patents on the four Anti-cancer Drugs in Thailand," National Health Security Office, February 2008, *available at* <http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf > (last visited April 10, 2009), as quoted in J. Norris, "The Unraveling of Compulsory Licenses: Evidence from Thailand and India," *International Policy Network*, May 18, 2007, at 3, *available at* <http://www.fightingdiseases.org/pdf/unravelling_of_CLs_norris.pdf> (last visited April 10, 2009).
38. P. Cawthorne, N. Ford, D. Wilson, K. Kijtiwatchakul, V. Purahong, N. Tianudom, and S. Nacapew, "Access to Drugs: The Case of Abbott in Thailand," *The Lancet Infectious Diseases*, 7, no. 6 (June 2007): 373-374, at 374.
39. F. M. Abbott and J. H. Reichman, "The DOHA Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions," *Journal of International Economic* Law 10, no. 4 (2007): 921-987, at 953.
40. D. Ten Kate, "Safe at Any Cost?" *Asia Sentinel* (Hong Kong), January 24, 2007, *available at* <http://www.asiasentinel.com/index.php?Itemid=34&id=351&option=com_content&task=view> (last visited April 7, 2009).
41. R. Steinbrook, "Thailand and the Compulsory Licensing of Efavirenz," *New England Journal of Medicine* 356, no. 6 (February 8, 2007): 544-546, at 544.
42. As noted in the September 2007 U.S. Government Accountability Office report, the U.S. Trade Representative has recognized Thailand's "ability to issue compulsory licenses subject to WTO rules and the country's domestic laws. However, it expressed concern about what it considered to be the lack of transparency exhibited in Thailand." See U.S. Government Accountability Office, *Intellectual Property: U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198, September 2007, at 49, *available at* <http://www.gao.gov/new.items/d071198.pdf> (last visited April 7, 2009). The lack of clarity surrounding whether Thailand did or did not negotiate with the patent holders perfectly exemplifies this concern.
43. V. Chokevivat, ed., Ministry of Public Health and the National Health Security Office, Thailand, "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," Sangsue Co., Ltd., Thailand, February 2007, at 6, *available at* <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> (last visited April 7, 2009).
44. P. Stevens, *Will Compulsory Licenses Improve Treatment for Patients: The Case of Thailand*, International Policy Press, London U.K., May 2007, *available at* <http://www.fightingdiseases.org/pdf/Stevens_thailand_web.pdf> (last visited April 7, 2009).
45. This decision is particularly interesting in the context of Articles 31(d) and (e) which specify that compulsory licenses without the authorization of the right holder should be non-exclusive and non-assignable. By refusing to contract with other producers and thus denying them a market, the GPO essentially becomes the only firm able to utilize the licenses.
46. See Stevens, *supra* note 44, at 5. As of July 28, 2008 the exchange rate between the Thai baht and US dollar was $1 to 33.45 baht (1 baht to $0.0298). Accordingly, 10 billion baht is about $298 million. See Federal Reserve Bank of New York, *supra* note 35.
47. *Id.* (Stevens), at 4.
48. R. Steinbrook, "Closing the Affordability Gap for Drugs in Low-Income Countries," *New England Journal of Medicine* 357, no. 20 (November 15, 2007): 1996-1999, at 1998.
49. While the establishment and growth of a domestic generics industry is considered a valid objective for the implementation of a compulsory licensing program, it is worth noting that the U.S. generics industry emerged without compulsory licensing. This may be due to the profitability of the U.S. generics market, the ease of accessing drug patent information, and the regulatory framework conferred by the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984) designed to promote generics while preserving a financial incentive for research and development.

50. Note that in the context of the objectives described here compulsory licenses could be issued for either domestic production or importation. While the requirements surrounding the phrase "predominantly for the supply of the domestic market" have yet to be resolved, many developing nations have no alternative apart from importation. Scherer and Watal make the point that during the 1970s, even Canada – with its high income and internationally renowned universities – found it necessary to import the majority of the bulk pharmaceuticals supplied under compulsory licenses (see Scherer and Watal, *supra* note 2, at 925.) If it turns out that patented pharmaceuticals distributed under a compulsory license cannot be exported as 'parallel goods' within paragraph 5(d) of the Doha Declaration, then they remain subject to article 31(f) of the TRIPS Agreement, which literally limits such exports to 49.9 per cent of the total supplies distributed under the compulsory license in the local market. Since only a small number of developing countries can manufacture technically advanced medicines, these legal impediments hamstring the ability of these countries to assist other poor countries that issue compulsory licenses in order to acquire essential medicines without possessing any local manufacturing capacity in this regard. See J. H. Reichman and C. Hasenzahl, "Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the U.S.A.," UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper no. 5, 2003, at 17.
51. *Id.* (Scherer and Watal), at 924.
52. R. Elliott, "Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export," *International Journal of Intellectual Property Management* 1, nos.1/2 (2006): 94-112, at 101.
53. *Id.*, at 94.
54. E. Gupte, "Apotex Ships Drugs under Doha License" *Managing Intellectual Property,* 28 September 2008, *available at* <http://www.managingip.com/Article/2017247/Apotex-ships-drug-under-Doha-licence.html> (last visited April 7, 2009).
55. See CBC News, *supra* note 23.
56. See Attaran, *supra* note 31, at 1727.
57. Industry Canada and Health Canada, "Report on the Statutory Review of Sections 21.01 to 21.19 of the *Patent Act*," Cat. No. Iu4-118/2007, 2007, *available at* <http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport-eng.php> (last visited 20 November 2008).
58. T. Talaga, "AIDS Drugs Fiasco a Tale of Red Tape" *Toronto Star*, August 9, 2007, *available at* <http://www.thestar.com/comment/columnists/article/244582> (last visited April 7, 2009).
59. See Stevens 2007, *supra* note 44, at 5.
60. *Id.*
61. See Norris, *supra* note 37, at 4.
62. C. Merry, R. Mairin, and T. Blaschke, "Generic Drugs for HIV/AIDS Is Good News, but Manufacturing Standards Must Be Monitored," *Financial Times*, October 6, 2003, *available at* <http://search.ft.com/ftArticle?queryText=blaschke&y=0&aje=true&x=0&id=031006001147&ct=0&nclick_check=1> (last visited April 7, 2009).
63. These results were presented at Thailand's 10th National Seminar on AIDS in Bangkok (see U.S. Centers for Disease Control and Prevention, "Thailand: HIV Drugs Losing their Power," *CDC HIV/Hepatitis/STD/TB Prevention News Update*, 2005, *available at* <http://www.thebody.com/content/treat/art25270.html> [last visited April 7, 2009]). Complete results may be found in: R. Sutthent, D. Arworn, S. Kaoriangudom, K. Chokphabulkit, P. Chaisilwatana, P. Wirachsilp, V. Thiamchai, T. Sirapraphasiri, and S. Tanprasertsuk, "HIV-1 Drug Resistance in Thailand: Before and After National Access to Antiretroviral Program," *Journal of Clinical Virology* 34, no. 4 (2005): 272-276.
64. R. Bate, "Thai-ing Pharma Down," *Wall Street Journal Asia*, February 9, 2007, *available at* <http://www.aei.org/publications/pubID.25585/pub_detail.asp> (last visited April 7, 2009).
65. A. Treerutkuarkul, "WHO Raps Compulsory Licensing Plan: Government Urged to Seek Talks with Drug Firms," *Bangkok Post*, February 2, 2007, *available at* <http://www.aegis.com/news/bp/2007/bp070201.html> (last visited April 7, 2009).
66. See Norris, *supra* note 37, at 4.
67. P. Stevens, "Thailand Violates Drug Patens for Its Own Profit," *Critical Opinion*, May 5, 2007, *available at* <http://www.criticalopinion.org/articles/17> (last visited April 7, 2009).
68. R. Bate, "Thailand and the Drug Patent Wars," *Health Policy Outlook, AEI Online*, April 4, 2007, *available at* <http://www.aei.org/publications/pubID.25890/pub_detail.asp> (last visited April 7, 2009).
69. See Stevens, *supra* note 44.
70. See Bate, *supra* 68, at 2.
71. *Id.*, at 1.
72. AFX News Limited, "Thailand to import generic version of heart drug Plavix from India," Forbes.com, August 22, 2007, *available at* <http://www.forbes.com/feeds/afx/2007/08/22/afx4043270.html> (last visited April 7, 2009).
73. T. Fuller, "Thailand Takes on Drug Industry, and May Be Winning," *International Herald Tribune*, April 11, 2007, *available at* <http://www.iht.com/articles/2007/04/11/news/pharma.php> [last visited July 12, 2008; find this article now through the *New York Times*].
74. See Sykes, *supra* note 8, at 13.
75. C. Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" *Berkeley Technology Law Journal* 18, no. 1 (2003): 3-57, at 4.
76. Although the industry claims that compulsory licensing reduces the incentive to conduct R&D in such diseases, as long as there are large emerging markets (i.e., China and India) with similar disease burdens, it is hard to imagine that the actions of Thailand will influence the industry's decision to research treatments in these disease areas.
77. See Chien, *supra* note 75.
78. *Id.*, at 5.
79. *Id.*, at 40.
80. See Reichman and Hasenzahl, *supra* note 17, at 24.
81. This strategy, however, is likely to be most successfully employed by nations with some degree of market power. The Brazilian case is noteworthy in this context. Cohen and Lybecker detail the Brazilian negotiations. See J. C. Cohen and K. M. Lybecker, "AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health," *World Economy* 28, no. 2 (Spring 2005): 211-230.
82. In a recent U.S. GAO report (*supra* note 12), Thailand's legal right to issue the compulsory licenses was reaffirmed but the lack of transparency in their process was criticized.
83. Compulsory licensing is most likely to negatively impact research on what are known as Type II diseases, those with significant developing country markets and yet a sufficient enough market in high-income countries to attract some research resources. Though explored by others, this phenomenon is exceedingly well described by Outterson. (See K. Outterson, "Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?" *American Journal of Law & Medicine* 34, nos.2-3 (2008): 279-301.) Type I diseases occur in high-income nations and the purchasing power of these markets alone can support innovation on these diseases. The majority of research is currently devoted to Type I diseases. Type III diseases primarily appear in developing nations where virtually no commercial market exists. As a consequence, few resources are dedicated to work on Type III diseases. Type II diseases create the intermediate category and innovation on these diseases attracts some resources. In some cases, high-income markets are enough to incentivize research on Type II diseases. For additional reading, please see the following: K. Outterson, "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets," *Yale Journal of Health Policy, Law, and Ethics* 5, no.1 (2005): 193-291; and K. Outterson and A. S. Kesselheim, "Market-Based Licensing for HPV Vaccines in Developing Countries," *Health Affairs* 27, no.1, (January/February 2008): 130-139.