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TRENDS IN INTERNATIONAL COMPULSORY LICENSING FOR
PHARMACEUTICALS SINCE THE INSTITUTION OF THE TRADE-RELATED
ASPECTS OF INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS (TRIPS)
AGREEMENT

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Reed F. Beall

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ABSTRACT

The Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement went into effect for World Trade Organization (WTO) members in 1995. The agreement defines minimum standards of patent protection that must eventually be observed by all signatories. TRIPS includes “compulsory licensing”, a policy that allows for states under certain conditions to permit the use of a patented innovation without the consent of the patent holder. This paper considers instances of compulsory licenses (CLs) aimed to increase access to pharmaceuticals during urgent public health scenarios. The WTO maintains no registry of CLs; therefore, this research is an effort to catalog as many CL case studies as possible since the policy’s institution and analyze them as a whole. Findings include 24 case studies involving 43 CLs in 18 nations. Results show that most CLs are issued by middle income nations such as Brazil and Thailand. Possible structural and institutional explanations are explored. The paper concludes that the policy is commonly practiced for purposes beyond its original design and that suboptimal outcomes are likely to result.

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INTRODUCTION

In June 2010, Thailand's Public Health Minister Jurin Laksanawisit announced that he and the National Health Security Office (NHSO) board would suspend patent protection on three drugs (Efavirenz, Lopinavir, and Ritonavir) used to treat HIV/AIDS. Thailand has again captured the attention of global health and intellectual property advocates alike. The country first overrode the patents of what eventually totaled seven brand name pharmaceuticals between 2006 and 2008, as it aggressively sought to expand its national health service's coverage for HIV/AIDS, cancer, and cardiovascular disease patients.¹ Many global health experts applauded Thailand's boldness and commitment to the health of its people, while other observers worried about the behavior setting an international precedent and were skeptical of the ruling party's motives so soon after the 2006 *coup d'etat*.

Thailand was not the first nation to suspend patent rights in order to attain branded antiretroviral therapies (ARVs) to better address its HIV/AIDS epidemic. Nations such as Brazil have used similar tactics in order to secure more affordable prices on ARVs.² However, what was especially unique about Thailand's actions is that it went beyond ARVs and targeted drugs for chronic illnesses.

¹ Bangkok Post (2010). The Licensing of Key Drugs. Bangkok Post. Bangkok.

² Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.

Suspending patent rights without the permission of the title holder is called a “compulsory license (CL).”³ The CL is a common feature of domestic intellectual property law.⁴ CLs allow nation states the flexibility to disregard a previous commitment to protect a patent right under unusual circumstances, such as whenever the patent constitutes a significant barrier in responding to a national emergency. During the formation of the World Trade Organization (WTO), intellectual property protection was incorporated in the founding agreements. The Trade-related Aspects of Intellectual Property Rights (TRIPS) articulated the commitment of WTO signatories to patent protection and defined the conditions under which it may be set aside. CLs’ scope of applicability, as described by TRIPS Article 31, names “national emergencies” and “other circumstances of extreme urgency” as conditions that may warrant the policy’s employment.⁵ One can imagine scenarios in which a contagious disease is spreading and killing rapidly; public authorities must take action quickly and have no time for negotiations. CLs afford states the legal maneuverability to act as such situations would demand.

At the WTO’s Doha Conference on 20 November 2001, member states reevaluated policy’s scope of applicability (the circumstances under which CLs may be

³ World Trade Organization. (2010). "Compulsory Licensing of Pharmaceuticals and TRIPS." Retrieved June 19, 2010, from http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

⁴ World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from [@1](http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf)

⁵ World Trade Organization. (2010). "TRIPS and Pharmaceutical Patents: Obligations and Exceptions." Retrieved June 20, 2010, from http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing.

invoked) and specified that “HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency.”⁶ Both TRIPS Article 31 and the Doha Declaration carry a tone of immediacy, especially when it comes to public health. One reason why Thailand’s CLs were so hotly debated was because they went beyond ARVs and licensed the generic production of branded drugs that treat cardiovascular disease and cancers.⁷ While few would argue that cardiovascular disease and cancers are legitimate public health threats, many claim that these chronic, non-communicable illnesses lack the level of urgency needed to warrant a CL.

Thailand’s employment of the CL policy is technically valid. The Doha Declaration protects a nation’s prerogative to define for itself what constitutes “circumstances of extreme urgency,”⁸ and Thailand did negotiate with the pharmaceutical firms, even though this requirement is waived during emergencies.⁹ Nevertheless, it raises the question of whether Thailand’s actions will set an international precedent for other WTO nations to use the CL policy in order to increase access to patented treatments for chronic illnesses such as cancer and heart disease. While this paper does not purport to provide concrete answers to this important long-term concern of the policy’s trajectory

⁶ World Trade Organization. (2001). "Declaration on the TRIPS Agreement and Public Health." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁷ Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

⁸ World Trade Organization. (2001). "Declaration on the TRIPS Agreement and Public Health." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁹ World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.@1.

and future effects, it attempts to provide foundational research and comprehend when and why CLs are issued at the structural and institutional levels.

The WTO maintains no comprehensive, formal registry of international CLs.¹⁰ TRIPS Article 31 does not require compulsory licensees to notify to the TRIPS Council, the body administering the agreement, of their usage of the policy. There are two conditions under which the WTO keeps record. First, the WTO posts complaints that reach the Dispute Settlement Body (DSB) on their Dispute Settlement Portal website. Currently two complaints that are relevant to pharmaceutical intellectual property protection are listed there. They were filed by Brazil¹¹ and India¹² and involve generic drugs that were held while in transit through the European Union. Neither complaint raised questions about those nations' employment of the CL policy. Second, the 30 August 2003 decision allows WTO member states without sufficient domestic production capability to import generic versions of patented drugs. Under these conditions, states should notify the TRIPS Council, and this record will be made publicly available on the website. Only one licensee, Rwanda, and its exporter, Canada, are listed there currently.¹³

¹⁰ This was confirmed by the WTO via email on 8 June 2010.

¹¹ World Trade Organization. (2010, 12 May). "Dispute Settlement: Dispute DS409: European Union and a Member State - Seizure of Generic Drugs in Transit." from http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.

¹² World Trade Organization. (2010, 11 May). "Dispute Settlement: Dispute DS408: European Union and a Member State - Seizure of Generic Drugs in Transit." from http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm.

¹³ World Trade Organization. (2010). "TRIPS and Public Health Paragraph 6 System: Notifications by importing WTO Members." Retrieved 20 June, 2010, from http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

Even while the TRIPS Council does not maintain record, WTO signatories practice international CLs for pharmaceuticals and the details of these instances are often available through public resources, the World Health Organization (WHO), the media, law journals, and in academic papers. The primary aim of this work, therefore, is to compile systematically as many CL case studies as possible and analyze them as a whole.

Chapter One of this paper provides a brief review of patents and CLs in international trade treaties. The next chapter discusses the systematic collection of the CL case studies and the results. Patterns are identified, i.e., most CL activity originates from within middle income nations, especially Thailand and Brazil, the majority of which was for ARVs between 2004-2007. Explanations for these patterns are explored. A historical analysis and sequencing of significant events illuminates reasons for many of these patterns. Next, the epidemiological transition is considered as a theoretical model that could explain why middle income nations practice CLs more often. Both analyses in Chapter Two give reason to suspect that CLs for chronic illness may become more common in the future.

Based on the suspicion that the CL policy could become a critical mechanism for middle income nations to procure affordable medications for managing chronic illness in the future, Chapter Three focuses on Thailand and other nations that have publicly entertained CLs for this purpose. Thailand stands out among nations as the most frequent and robust user of the policy. It is currently the only nation found in the case study collection to issue a CL in order to procure medications prescribed to manage chronic diseases. In hopes of better understanding what made Thailand such an outlier, Chapter

Three compares its CLs to those in the Republic of Korea, India, and the Philippines.

The comparison suggests that the political circumstances and stake—even those that have little to do with public health—may be an important reason why CLs are issued. Because the circumstances in the Thailand case studies were so unusual, Chapter Three concludes that it is unlikely that other nations would imitate the Thai CLs for chronic disease; this may contradict the implications of Chapter Two.

The final chapter discusses the possible implications and applications of the case study findings. It notes that the CL policy, as articulated in TRIPS originally, has not often been utilized. Its redefinition at Doha in 2001 and its follow-up decisions ascribed a new function to the CL policy; it has become primarily a bargaining tool for developing nations to negotiate prices on branded drugs from international pharmaceutical giants. This paper concludes that the CL policy has been retrofitted to function in a role, i.e., as a tool for development, that it was not originally designed to play and is likely to continue in this role whenever nations are moving through the transitional stages of the epidemiological transition.

CHAPTER ONE. BACKGROUND

Before continuing with the discussion of the CL case studies, this chapter provides a brief review of patents, CLs, and their place in international trade.

Intellectual Property Protection and Patents

The patent system ultimately exists to serve the state and society. Its function is to generate novel and useful innovations that will improve the quality of life. Innovators create new markets and expand human knowledge. In return, the state can award a patent or another form of intellectual property protection.¹ Therefore, intellectual property “rights” are social constructions and institutions made possible by the existence of the state and its enforcement of patent laws; in other words, patent “rights” should be understood as patent “privileges.” Nevertheless, this paper will continue to refer to patent “privileges” as “rights” because it is the terminology used in the discourse.

The average life of a patent in most developed nations has traditionally been around 17 years from the date of issue; however, it is often shorter when it comes to the pharmaceutical industry.² Drug firms tend to file a patent application as soon as a promising compound has been devised. By the time the product has been approved and is available for public consumption, there is an average about 12 years remaining before the patent’s expiration.³ This artificial monopoly or near monopoly enables the patent

¹ Sterckx, S. (2005). "Can Drug Patents be Morally Justified?" *Science and Engineering Ethics*(11): 81-92.

² Schweitzer, S. O. (2007). *Pharmaceutical Economics and Policy*. Oxford, Oxford University Press. @ 256-258

³ Grabowski, H., Vernon, J (2000). "The Distribution of Sales Revenues from Pharmaceutical Innovation." *PharmacoEconomics* **18 (Suppl 1)**: 21-32.

title holder to charge the highest price the market will bear in order to recuperate investment costs and profit.

Before awarding a patent, the state must be convinced of the following: the innovation is truly novel, rather than a simple tweak of an existing product or substance; is socially desirable, rather than morally repugnant (e.g., a society that condemns birth control would not award a patent to the inventor of a birth control pill for men); and has utility or potential utility, since the goal is to foster the useful arts, not useless ones.⁴

Patents play three functions that are mutually beneficial to the patent holder and to the state. The best-known function of patents is the “incentive function.” Drug firms argue that their profits should be thought of in terms of cost recovery and investment for future research, not rent-seeking. Pharmaceuticals require massive upfront investment. It takes an average of 10 years and about \$800 million before a drug is ready to manufacture and sell. The patent system is one mechanism that makes private investment into these endeavors viable.⁵

Another important role that patents can play is called the “signaling function.” The more patents a pharmaceutical firm owns, the more acclaim it will receive for its innovative work and potential. Investors can recognize the most promising firms by searching for those with the highest patent output. In this way, the most innovative firms

⁴ Schweitzer, S. O. (2007). Pharmaceutical Economics and Policy. Oxford, Oxford University Press.@254-255

⁵ World Health Organization (2006). Public Health, Innovation, and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health.. Geneva, World Health Organization.@19-21

are the targeted with more investment dollars and are equipped to continue to lead society to new knowledge and markets.⁶

A third recognized function of patents is the “disclosure function.” In exchange for patent protection, the state requires firms to disclose publicly the discovery that makes their novel product possible. Patents, therefore, provide a platform for disclosure without the fear that competitors will steal the idea and compete in the marketplace.

Theoretically, without mechanisms such as patents, innovators would withhold more information that others could have built upon.⁷

Compulsory Licenses

A number of situations may arise in which it is no longer in the state’s best interest to protect a patent holder’s monopoly. Suppose the innovation was discovered to be dangerous or the rights holder was not using the invention responsibly or even at all. To understand the need for CLs in the context of public health, one only need to imagine an uncooperative patent rights holder to a lifesaving vaccine during a large-scale outbreak of a deadly pandemic flu. In this unusual scenario, the state should have the prerogative to disregard its previous commitments in order to make the drug more accessible and save lives.

While situations that would warrant rescinding patent protection are uncommon, it is easy to imagine them. States need an override safeguard. CLs, therefore, are a common feature of nations’ patent laws and allow for premature competition in previously

⁶ Ibid.@19-21

⁷ Ibid.@19-21

protected markets in order to increase immediate access to the innovation and better address the public concern. The exact articulation of CL laws varies by nation.⁸ The WTO's CL policies are outlined in the TRIPS section of this chapter.

Patents are one useful and important mechanism that stimulates the massive investment necessary to develop pharmaceuticals. Contemplating the cost of drug development illuminates some of the moral aspects on this side of the debate. After investing 800 million dollars and a decade of scientists' lives into a product, pharmaceutical firms consider it tantamount to theft whenever a design is pirated and sold at a fraction of the cost, especially after they have already been promised protection by a nation's patent office. CLs are rarely put into practice, but whenever they are, a rash of noisy debates is likely to arise between those defending patent's importance for the future of medical innovation on one side and those arguing for nations' ultimate obligation to protect its citizens' health on the other.

International Trade and Intellectual Property

Intellectual property protection has been a concern in international trade for well over a century. The first major multilateral trade agreement to incorporate patent protection was the so-called "Paris Convention" in 1883. This agreement was administered by the World Intellectual Property Organization (WIPO) and obliged its signatories to afford the same protection to international patents as domestic ones,⁹ but did not demand a standard

⁸ World Health Organization (2006). Public Health, Innovation, and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva, World Health Organization.@54-55

⁹ Schweitzer, S. O. (2007). Pharmaceutical Economics and Policy. Oxford, Oxford University Press.@258-259

minimum level of protection across nations. The Stockholm Convention in 1967 amended the Paris agreements and marked the first attempt to require patent protection standards internationally. At Stockholm, the United States Trade Representative (USTR) began threatening trade sanctions upon countries where it perceived itself as losing significant investment returns due to pirated goods.¹⁰

In 1974, the US spearheaded another milestone multilateral trade agreement called the General Agreement on Trade and Tariffs (GATT). The 182 Trade Act of 1974 (Special 301) gave the USTR the power to impose unilateral trade sanctions. To this day, the United States continues to issue Special 301 reports that enact targeted trade sanctions in response to lax intellectual property protection in developing countries.¹¹

The Uruguay Round of GATT laid the foundational agreements that were to become the World Trade Organization (WTO). The WTO's primary aim is trade liberalization. TRIPS was added as an annex to GATT. Its goal was to remove intellectual property protection concerns as a barrier to trade by systematically implementing minimum patent standards among member states. TRIPS was promoted as a way to foster greater levels of global technological innovation and technology transfer that would mutually benefit all nations in the long run.¹²

¹⁰ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review 26(Summer): 385-410.@390-391

¹¹ Ibid.@391

¹² World Trade Organization. "The Agreements - Intellectual Property: Protection and Enforcement." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.

TRIPS holds “strong patent protection” as the eventual international standard. Two distinguishing features of strong patent protection are the exclusive right to sell the innovation for a term of 20 years¹³ and that both products and processes are patentable. Many developing nations’ pre-existing intellectual property laws protected patents for less than 20 years and were not applicable to processes. TRIPS outlined recommendations for incremental advances towards strong patent protection with target deadlines for those member states practicing weaker forms.¹⁴

Compulsory Licenses, Voluntary Licenses, and TRIPS

What made TRIPS unique from the previous trade agreements discussed above is that the entire body of WTO mandates were considered to be a “single undertaking”, meaning that signatories must agree to all standards in order become members. This was the first time that trade and intellectual property had been linked together so integrally. Since prospective nations could not pick-and-choose from the WTO’s policies, they were forced to weigh the prospective costs of joining against the potential benefits of increased trade. Developing nations were especially concerned that TRIPS would restrict their access to pharmaceuticals. The wording of the articles, therefore, emphatically states that the ultimate purpose of TRIPS is to cultivate greater social and economic welfare globally.

¹³ 17 years was the average global life of a patent. TRIPS called for even higher protection. Schweitzer, S. O. (2007). *Pharmaceutical Economics and Policy*. Oxford, Oxford University Press.@256

¹⁴ World Trade Organization. (2006). "TRIPS: Drug Patents, Technical Note - Pharmaceutical Patents and the TRIPS Agreement." Retrieved 20 June, 2010, from http://www.wto.int/english/tratop_e/trips_e/pharma_ato186_e.htm.

CLs were also written into the TRIPS agreement to accommodate these concerns and reflect a reasonable provision that is typical in domestic patent laws.¹⁵

TRIPS Article 31 lays out the terms and perimeters of what constitutes a valid application of the CL policy. The most salient points for pharmaceuticals are the following:

- Prior to issuing a CL, attempts must be made to negotiate with the rights holder. This requirement is waived when the level of urgency and immediacy will not allow time for negotiations, but the state must inform the rights holder of its use of the patented product without permission.
- The use of the patented material should be for domestic consumption only.
- The rights holders should be paid remuneration with the innovation's economic value in mind.
- CLs should be reserved for matters of "national emergencies", "other circumstances of extreme urgency", or "public non-commercial use."¹⁶

The first bullet refers to a preferred situation in which states will negotiate with the rights holder before issuing a CL, but this requirement is waived in emergency scenarios. These negotiations could result in price bargaining or even with the state gaining the expressed permission of the rights holder to manufacture the drug for public use--this

¹⁵ Savoie, B. (2007-2008). "Thailand's Test: Compulsory Licensing in an Era of the Epidemiological Transition." *Virginia Journal of International Law* 48(1): 211-248.@224-226

¹⁶ World Trade Organization. (2010). "TRIPS and Pharmaceutical Patents: Obligations and Exceptions." Retrieved June 20, 2010, from http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing.

arrangement is known as a “voluntary license (VL).”¹⁷ Bargaining and VLs are pharmaceutical firms’ primary method to prevent CLs. However, more aggressive firms may halt the supply of other drugs to the licensing nation or gain the advocacy of another WTO signatory that is willing to threaten retaliatory unilateral trade sanctions or file a complaint with the DSB.

The TRIPS articulation of the CL polices was designed to be general in order to allow states legal maneuverability. In order to forego negotiations with patent rights holders, the circumstances should clearly demand immediate government action. The most uncontroversial use of the 1995 TRIPS CL policy for public health emergencies would have the following elements:

- A disease that would (a) be infectious and spread easily and quickly from person-to-person, (b) kills quickly, and (c) has infected or has the potential of infecting a large number of people. A good example of such a disease would have been the avian flu (H5N1) if had it mutated into a pandemic flu. A global outbreak of such diseases are clear threats to the global public good.
- A patented drug or vaccine that would be able to (a) halt human-to-human or vector-to-human transmission, or (b) save the life of or cure the patient.
- A patent rights holder that (a) is proving unable to produce enough of the drug to meet demand, or (b) is refusing to cooperate or negotiate.

To be clear, TRIPS does not imply that these elements must to be present in order to use the policy during emergencies. The point is that the further a situation strays from

¹⁷ Ibid.

possessing these characteristics, the more questionable the application of the CL safeguards will be.

TRIPS does not mandate particular standards about what the actual announcement or format of the CLs must be, other than that the rights holder must somehow be notified. Most states already have domestic procedures in place for CLs and have one or more figures who are authorized to declare CLs under certain conditions. Therefore, for many member states, adopting the CL policy meant amending domestic protocols, rather than inventing them for the first time.¹⁸

The TRIPS Council encourages states to negotiate with each other and with firms directly; therefore, as mentioned earlier, the original articulation of the CL policy in Article 31 does not require licensees to notify the TRIPS Council.¹⁹ No complete and formal record of CL cases exists at the WTO. Nevertheless, government, media, and academic sources do discuss cases as they occur and are made known to the public. The next section of this paper is an effort to compile a list of all possible CL cases that have appeared in the media since the policy was instituted in 1995.

¹⁸ World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from [@1](http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf)

¹⁹ As mentioned in the introduction, the TRIPS Council should be notified of all cases in which nations are importing pharmaceuticals using the CL safeguards, as is stated in the 30 August 2003 Decisions. World Trade Organization. (2006). "TRIPS: Drug Patents, Technical Note - Pharmaceutical Patents and the TRIPS Agreement." Retrieved 20 June, 2010, from http://www.wto.int/english/tratop_e/trips_e/pharma_ato186_e.htm.

CHAPTER TWO. A SURVEY OF COMPULSORY LICENSING CASES FROM 1995-2010

The TRIPS Council maintains no formal and complete record of international CLs for pharmaceuticals during public health emergencies. The purpose of this chapter is to document one attempt to collect as many case studies as possible and analyze them as a whole. The purpose of collecting these cases is to better understand at a general level questions about who, what, when, where, why, and how international CLs have been put into practice. Being able to consider the cases studies as a collection provides a platform for general themes to be exposed, which may have not been otherwise obvious or certain. This chapter describes the process by which the case collection was performed, discusses the results, identifies patterns, and suggests possible explanations for those trends.

Sources and Study Methods

Initial case studies were located using web searches, e.g., Google, Google News, and Google Scholar.¹ CLs announced on government or health ministries' websites are the ideal primary source; particular effort was given to find these by using domain restricted searches. Restricted searches on websites for specific pharmaceutical firms, the Pharmaceutical Research and Manufactures of America (PhRMA), the "pharmaletter", that the "Pharma Marketletter" were also fruitful. WHO websites and documents listed

¹ The best method to compile a complete and comprehensive list of all international CLs for pharmaceuticals during emergencies for all practical purposes would be to consult legal expertise within each WTO nation. Because most nations already have procedures in place for CLs, they are likely to have a national public record in some form. Time and resources do not allow for such an endeavor at this point. Nevertheless, there are advantages to the methods used in this paper; among the most significant is that it captures case studies wherein CLs were used as a bargaining tool, but were never issued.

many cases studies.² Searches were also performed on electronic databases of academic and law journals (e.g., HeinOnline, ScienceDirect) and world news media search engines (e.g., LexisNexis, Access World News, World News Connection). International law journals proved to be one of the most valuable resources for this effort, especially in parsing out the details of individual case studies. Google Alerts were utilized and were helpful.

Another valuable resource for case collection is a website maintained by the “Consumer Project on Technology (recently been renamed “Knowledge Community International”),” a think tank directed by James Love that advocates for developing nations’ procurement for generic drugs and information technology. Love and his organization maintain a website that links to articles about instances of CLs and even to some of the official CL pronouncements. These are sorted by country, drug, and pharmaceutical firm. Love’s work on this topic has occasional mentions in academic literature as well as in publications by the WHO’s Intergovernmental Working Group’s (IGWG) on Public Health, Innovation, and Intellectual Property. Duncan Bucknell, an attorney and director of “Think IP Strategy” has also published his own case study collection.³ Still, neither Bucknell nor Love have produced a systemic survey and analysis of the case studies as a whole. This research attempts to help fill this gap.⁴

² World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

³ Bucknell, D. (2007). *Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.*

⁴ Consumer Project on Technology. "Health Care and Intellectual Property." Retrieved 22 June, 2010, from <http://www.cptech.org/ip/health/>.

Once a CL case study was located, a brief summary was created that includes the nation, the pharmaceutical firm, the disease(s) in question, the disease scenario type (this typology is defined later), the drug(s) in question, a brief synopsis of the events that transpired, the outcome of the case, and a selective bibliography. These summaries are included in the Appendix A.

Only case studies that met the following criteria were included in this study: (i) the nation was a WTO signatory; (ii) the CL was issued in order primarily to address an urgent public health matter with a generic version of a patented drug, i.e., the CL was not issued to remedy anti-competition behavior; (iii) case studies documented by three or more secondary sources were included whenever the actual CL pronouncement was unavailable⁵; (iv) the issuance of a CL was threatened or was publicly entertained by the government or a public health official.⁶

Notable Challenges in the Case Collection

Both nations and pharmaceutical firms have strong incentives to keep their negotiations with one another hidden from the public. For example, pharmaceutical firms do not want nations to know the discounts they are affording to others, since one nation's knowledge of another's discount is likely to incite demands for renegotiations. Also, nations attempting to present themselves as complying with the TRIPS agreement and promoting intellectual property rights would prefer that negotiations be kept confidential.

⁵ Five case studies that were excluded due to this criterion. These cases are included in Appendix B with the available reference(s).

⁶ James Love's website documents several of these case studies. This criterion eliminated cases in which public health authorities were being coerced by civil groups to issue a CL, but their efforts seem to have elicited no response from public officials. *Ibid.*

While great effort was spent in making the case collection sample as large as possible, it still must be regarded as an incomplete picture. Nevertheless, at this exploratory stage of research, enough facts are available and sufficient to continue with the study.

The incompleteness of the CL case study sample raises some concern about an unavoidable weakness in the study design. All of these cases appeared in the media or on the internet. The common trait among all of these cases is that they were publicized, which raises the potential for an inherent bias in the results. Perhaps instances of CLs that are kept from the public's eye would more commonly have a different outcome. This remains, however, a possibility and not a known actuality.

Another constraint is that the search was conducted exclusively in English. Expanding the publication language is likely to expand the number of CL case studies. While this problem would theoretically be mitigated by using the World News Connection (FBIS), which includes world news in translation, this search engine did not yield unique instances of CLs.

Case Outcomes

Table 2.1 and the case study summaries in Appendix A include a column entitled "Outcome." Knowing the outcome of each case proved to be more complicated than expected. On occasion, it was nearly impossible to decipher whether a CL was actually issued or just threatened. Because CLs are often a temporary measure, even when a CL seemed to have been issued, renegotiations were reinstated, a voluntary arrangement was agreed to, and the CL was rescinded. To complicate issues further, some case studies involved several drugs and the outcome for each drug was unique in some way. Due to

all of these complications, it might be wise to remove this column from the Table 2.1 entirely. The primary reason why the column has been included is to emphasize that not all of the cases listed ended in a CL or VL. The “Outcomes” column is meant to be a general reflection of the information that was available in the media at the time, rather than a hard-and-fast measurement.

In order to best address the dynamic nature of these situations and still provide a useful indicator, the following distinctions are used: For cases in which a CL was unequivocally issued, the “Outcome” column reads “CL”. Many of these cases may have eventually spawned renegotiations and may have eventually led to a voluntary arrangement, but no such eventuality was found at this time. Whenever a nation and pharmaceutical firm eventually agreed to a lower price or drug donation program in order to prevent or rescind a CL, the word “Discount” will appear in the “Outcome” column. Some of the cases marked as “Discount” did begin with a CL. “VL” is listed whenever the patent title holder authorized a government entity to produce a generic version of the product for public purposes. Whenever “CL”, “VL”, or “Discount” is listed, the nation did indeed receive a larger supply of the drug at a cheaper cost (a positive outcome) through either importing or manufacturing it domestically. The outcomes column reads “None” for cases in which a CL was publicly entertained, but was not issued and the nation did not seem to increase its access to the drug (a negative outcome). In some case studies, a bundle of CLs were pronounced simultaneously and had mixed outcomes; in these instances, the outcome mixture will be indicated. For example, the South Africa case study seems to possess all possible outcomes.

General Case Collection Results and Trends

The case study collection found 43 international CLs that were entertained by WTO signatories for pharmaceuticals to address an urgent public health concern between January 1995 and June 2010.⁷ Since many were announced simultaneously, the CLs are bundled into 25 case studies which took place in 18 different nations. CLs have been issued for some 22 unique pharmaceutical products; of which, one treats anthrax, another treats the flu (H5N1), two others treat cardiovascular disease, four treat cancers, and the remaining 14 are ARVs for HIV/AIDS. Table 2.1 summarizes the results of the CL survey, and Appendix A includes the case study summaries and includes the references for Table 2.1.

Several trends are readily apparent when the case studies are considered as a whole:

Timeframe. Even though the search for CL case studies included 15 years, over half of the cases occurred between 2004 and 2007 with fewer cases taking place before and after this timeframe. 28 of the 43 CLs (65 percent) were issued at some point within these three years.

Specific Nations. Brazil, South Africa, and Thailand stood out as the most active users of the CL safeguard. While the South Africa case study involves the largest number of drugs (8), these were wrapped up within the same incident and the country has not shown much CL activity since that time. Brazil has employed the CL policy at least four times to procure greater access to five ARV products. Thailand has utilized the CL

⁷ As is evident in the case study summaries, some CLs issued by low income nations were for all ARVs used to treat persons suffering from HIV/AIDS. These general calls for ARVs were counted as a single CL, even though it is applicable to many individual patents.

safeguards within four distinguishable case studies for an overall total of seven drugs. Of the drugs that Thailand has sought via the CL flexibility, only two are ARVs; one drug treats cardiovascular disease and the others cancers.

National Income. A significantly higher proportion of CL activity seems to be in middle income nations.⁸ Of the 18 nations included in the case study summaries, exactly half are middle income. If the number of pharmaceuticals within each case study is included, 29 of the 43 (67.44 percent) of the CLs were entertained by WTO nations classified as upper- or lower- middle income by the World Bank at that time; and of these 29, 25 (86 percent) were sought by lower-middle income countries. Brazil is the only upper-middle income nation found to have used the CL flexibilities, but has done so effectively. Figure 2.1 illustrates this clear trend.

HIV/AIDS and the disease type scenarios. The CL flexibility was observed being used to target anthrax, pandemic flu (H5N1), HIV/AIDS, a few types of cancer, and cardiovascular disease. As Table 2.2 shows, 72.09 percent of CLs (n=31) involved ARVs used to palliate HIV/AIDS. Only 9.3 percent (n=4) of the CLs were found to involve drugs for a potential outbreak of a highly infectious and lethal disease (i.e., pandemic flu and anthrax); twice as many (n=8, or 18.6 percent) of this number were entertained as an avenue to access greater quantities of drugs that treat chronic disease (i.e., heart disease and cancer).

⁸ Nations' incomes were classified using the World Bank's GNI listings for the year closest to that of the CL case study (data is available for 2000, 2005, 2007, and 2008). "Low" income is \$975 or less per capita per year; "Middle" is above \$975, but less than \$11,905 (for simplicity, this table combines the World Bank's "lower middle income" and "upper middle income"); and "High" is more than \$11,905 World Bank. (2010). "Data & Statistics: Country Classification." Retrieved 1 July, 2010, from <http://data.worldbank.org/about/country-classifications>.

These five illnesses (i.e., anthrax, pandemic flu, HIV/AIDS, cancer, and cardiovascular disease) can be subdivided in the three separate categories according to the level of immediacy demanded by the circumstances. Situations with a high level of immediacy demand rapid responses from public health officials whereas ones with a lower level of immediacy should afford the nation states more time to negotiate successfully with pharmaceutical firms. A typology has been created to classify them in Tables 2.1 and 2.2. The following reasoning is applied:

- *Type I - CLs for drugs that cure or prevent the transmission of an infectious, acute disease.* The bioterrorist-engineered anthrax scare in 2001 and the threat of pandemic flu (H5N1 avian flu) in 2005 were placed into this disease scenario. These circumstances involved diseases that had the potential to spread and killed rapidly. Because the treatment in question could cure patients, Type I scenarios are the most immediate because the more time that is spent at the negotiating table, the more lives will be lost. The public health responses must be swift under these conditions; the CL safeguards at their root for national emergencies were designed for scenarios such as these.
- *Type II - CLs for drugs that palliate an infectious, chronic disease.* CLs for ARVs is the only disease in Table 2.1 that fits into this category. It is contagious; however, the disease processes take many years to develop into a life-threatening illness. HIV/AIDS drugs are used primarily in the palliative sense. Having access to ARVs for this purpose adds years of disability to patients lives, rather than saving them entirely. ARVs, however, can be used to reduce the likelihood of transmission of the disease,

especially from mother to child during birth; this application of ARVs does add an significant level of immediacy to the situation.⁹ Time lost in negotiations and less access to ARVs could mean that more HIV-positive children are born. Nevertheless, ARVs are more commonly used to extend patients' lives and improve its quality. Type II scenarios, therefore, lack the same high level of immediacy as Type I. Because the majority of patients receiving the ARVs are not cured, nations could be said to have more of an obligation to negotiate with patent title holders.

- *Type III - CLs for drugs that manage a non-infectious, chronic illness.* This third classification of CLs includes instances in which the nation is attempting to address a chronic illness with a branded drug. CLs for heart disease and cancers have been put into this category. These scenarios demand a lower level of immediacy, relative to Type I and Type II, because these drugs neither typically cure patients nor prevent transmission. What is at stake during Type III scenarios is largely adding years of disability to older patients lives.¹⁰

⁹ De Cock, K. M. F., Mary Glenn; Mercier, Eric; de Vincenzi, Isabelle; Saba, Joseph; Hoff, Elizabeth; Alnwick, David J.; Rogers, Martha; Shaffer, Nathan (2000). "Prevention of Mother-to-Child HIV Transmission in Resource-Poor Countries: Translating Research into Policy and Practice." The Journal of the American Medical Association (JAMA) **283**(9): 1175-1182.

¹⁰ This three-part typology is meant as a rough gauge of urgency in relationship to the perception of an obligation to negotiate with pharmaceutical firms before issuing a CL. This is distinct from, but related to the WHO IGWG on Public Health, Innovation, and Intellectual Property's three-piece typology. Its typology is used to classify treatments that (i) exist, but are not widely available in low income nations; (ii) do not exist, but are present in both low and high income nations (neglected diseases); or (iii) do not exist and are present primarily in low income nations (very neglected diseases). This typology is used to gauge where research and develop (R&D) dollars are being focused, i.e., the product of most global drug R&D has low availability and pertinence in low income conditions. This point will be focused upon in the second subsection of this chapter. World Health Organization (2006). Public Health, Innovation, and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva, World Health Organization. @12-15

One might suspect that the most immediate situations would show the highest number of CLs during Type I scenarios because there is little time for negotiations and for states to consider alternatives to the CL safeguards. Following the same logic, it is initially surprising that Type I CLs are the smallest group (n=4) in Table 2.2. Whether or not there is any significance to this finding will be addressed later in this chapter.

To summarize the trends that were discovered through the case study collection, most CLs are practiced by middle income nations in order to increase access to ARVs. When both income and the disease scenario type are considered in Table 2.2, almost half (n=21, 48.84 percent) have been by middle income nations for HIV/AIDS; and the majority of these CL case studies, occurred between 2004 and 2007.

The remainder of this chapter is divided into two sections. The first will focus on understanding the reason for the spike in CLs issued internationally between 2004 and 2007. The second section discusses national income, health systems and development, and attempts to offer some explanation for why most CLs come from middle income nations. Both sections afford some clarity as to why the overwhelming majority CLs are for ARVs.

Section 2.1. Historical Explanations for Patterns in Tables 2.1 and 2.2

The historical development of the CL policy can provide a solid explanation for the spike of CLs between 2004 and 2007 and connect the dots between many of the case studies presented in Table 2.1. The CL policy's story and eventual transformation at

Doha in 2001 provides a striking illustration of how the order of events' sequence can significantly shape policy outcomes.¹¹

As developing nations began to implement the mandates that they agreed to at the Uruguay Round, they began raising major concerns and encountering unforeseen difficulties, especially vis-à-vis the HIV/AIDS epidemic in Africa. Developing nations were weary of using the CL safeguards on international pharmaceutical patents for ARVs, especially those members that lacked domestic drug production capabilities and would need to import the medications. The WTO's tethering of trade to intellectual property rights forced public officials to consider the long-term trade impacts of responding to public health needs, rather than focusing purely upon maximizing patients' quality of life. Perhaps it could be said that because HIV/AIDS was a Type II scenario (and not Type I), developing nations feared the retaliation by pharmaceutical firms, trade partners in high income nations, and intellectual property rights advocates worldwide. The "Africa Group", which is comprised of all African WTO signatories, was the most vocal and persuasive in the call for a reevaluation of the policy for in order to understand "how far their right to use [CLs] would be respected."¹²

¹¹ This subsection is in part an effort to apply sequencing as articulated by Pierson to the CL policy's development. Pierson, P. (2004). Politics in Time: History, Institutions, and Social Analysis. Princeton, Princeton University Press.

¹² World Trade Organization. (2010). "TRIPS and Pharmaceutical Patents: Obligations and Exceptions." Retrieved June 20, 2010, from http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing.

Spring 2001. South Africa

The South Africa case began in 1998 when the South African Pharmaceutical Manufacturers Association along with 40 multinational pharmaceutical giants filed a lawsuit against the government in reaction to the inception of the “Medicines and Related Substances Control Amendment Act, No. 90 of 1997”, which was designed to increase citizens’ accessibility to otherwise unaffordable drugs, on the basis that the legislation contradicted both TRIPS and the South African constitution.¹³ Boiling point was reached when Indian pharmaceutical firm Cipla entered the scene and offered to supply South Africa with generic versions of many of the ARVs in question at a fraction of the cost.¹⁴ The case received significant international media attention as the United States and the European Commission applied pressure upon South Africa to rescind the legislation. The case reached the courtroom in May of 2000; but after taking a battering in the media internationally, firms dropped the lawsuit in April 2001.¹⁵

The events in South Africa further galvanized developing nations with similar concerns about the CL policy and its applicability to the HIV/AIDS epidemic. 46 developing nations¹⁶ and some 100 civil society groups demanded for TRIPS to be re-

¹³ Hoen, E. t. (2002). "Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha." Chicago Journal of International Law: 27-46.@31-32

¹⁴ Swarms, R. L. (2001). AIDS Drug Battle Deepens in Africa. New York Times. New York.

¹⁵ Hoen, E. t. (2002). "Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha." Chicago Journal of International Law: 27-46.@31-32

¹⁶ The Hindu (2001). TRIPS: How Much Flexibility? The Hindu, FT Asia Intelligence Wire.

evaluated at Doha.¹⁷ These efforts escalated as the WTO planned to launch a series of negotiations at the ministerial level focused on development beginning in early 2000. The CL policy was added to the agenda of the Doha Round. This would be the fourth convention of WTO member states. The convention was scheduled for 14 November 2001 to discuss some 40 items within 12 themes, ranging from agriculture, to anti-dumping, to intellectual property protection and CLs for pharmaceuticals.¹⁸

Spring and Summer 2001. Brazil

Meanwhile, patents disputes in Brazil were taking form. Brazil made changes to its domestic laws in 1996 in order to be in closer compliance with TRIPS. It enacted law 9279, which heightened pharmaceutical patent protection and built-in the CL provision. However, it also enacted Article 68(5), which requires international patent holders to manufacture drugs within Brazil for a minimum of three years. Patent holders can also satisfy this requirement by making arrangements with local producers to manufacture the medications.¹⁹

The United States vehemently opposed Brazil's Article 68(5) and criticized the "local working" requirement for pharmaceutical patent protection.²⁰ The US filed a complaint

¹⁷ Millar, K. (2001). WTO Focuses on Access to Affordable Medicines for the Poor. Geneva, Agence France Presse -- English.

¹⁸ World Trade Organization. "Subjects treated under the Doha Development Agenda." Retrieved 21 June, 2010, from http://www.wto.org/english/tratop_e/dda_e/dohasubjects_e.htm.

¹⁹ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." *Suffolk Transnational Law Review* 26(Summer): 385-410.@397-398

²⁰ Ibid.@398

against Brazil with the WTO's DSB over this issue in February 2001. After sustaining substantial international negative press, the US withdrew its claim in June 2001.²¹

Matters were made worse when Brazil twice threatened to use the CL safeguards in same year. Brazil implemented a renowned HIV/AIDS program designed to provide citizens with treatments free of charge. A significant barrier to this ambitious program was the cost of patented ARVs. The first dispute was with Merck in March 2001, but the CL threat was rescinded when Merck afforded Brazil a significant discount. In August 2001, Brazil's Minister of Health Jose Serra again threatened to issue a CL after unsuccessful negotiations with Roche over the cost of the drug "Nelfinar." Renegotiations were initiated, and Roche agreed give Brazil a 40 percent discount in order to be its exclusive provider of the drug.²² While open discussions of invoking the CL safeguards had occurred in South Africa prior to Brazil, this marked the first WTO signatory to cite TRIPS Article 31 so explicitly and confidently. The US continued to criticize Brazil's behavior.²³

Autumn 2001. The US and Canadian Cases

On 18 September 2001, a mere week after the September 11th terrorist attacks, bio-engineered anthrax spores were mailed to targeted persons around the US. Many believe

²¹ Hoen, E. t. (2002). "Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha." Chicago Journal of International Law: 27-46.@32-33

²² Bjornberg, J. (2006). "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?" Northwestern Journal of International Law & Business 27(Fall).@211

²³ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review 26(Summer): 385-410.@400-402

the culprit to be US Army biological defense scientist Bruce Edwards Ivins. The first victim was Robert Stevens, a tabloid photo editor in Florida. Shortly thereafter spores were mailed to the New York Post and NBC News. The situation escalated further when Senate Majority Leader Tom Daschle and Senator Patrick J Leahy received letters. The attacks via the US Postal Service were heavily publicized, and public anxiety grew quickly. Some officials suspected Al Qaeda, Iraq, and even the Soviet Union. Bill Raub of the US Health and Human Services (HHS) said, "My fear was that this first mailing was the tip of the iceberg."²⁴

The media questioned public health officials, forcing them to consider openly what would happen in the event of mass exposure. The media's coverage drew particular attention to "Cipro", an antibiotic patented by Bayer that can be highly effective in treating anthrax. Several other drugs on the market could treat anthrax, but the media's focus was squarely upon Cipro, and it made public health officials worry about the possibility of a shortage.²⁵

Canadian officials were very troubled by the possibility of anthrax making its way across the border. The Canadian government issued a CL as a precaution and quickly began to stockpile ciproflaxin.²⁶ The Canadian CL seems to be the first instance of the policy being explicitly invoked by a high income nation.

²⁴ Shane, S. (2009). Portrait Emerges of Anthrax Suspect's Troubled Life. New York Times. New York.

²⁵ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.@403

²⁶ Bradsher, K. (2001). Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine. New York Times. New York. Curti, A. M. (2001). "The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS." American Journal of Law & Medicine **27**: 469-485.@485

Senator Charles Schumer, a democrat from New York, was interviewed about the situation. He publicly urged the Department of Health and Human Services (HHS) to do the same as Canada. Tommy Thompson, the HHS Secretary at the time, was subsequently questioned about the possibility of imitating Canada's actions. Thompson claimed that he did not possess the authority to issue a CL. Upon review, Schumer was correct—the HHS Secretary does have the authority to issue CLs during national public health crises related to national defense. President George W. Bush created this flexibility under Executive Order 13323.²⁷

Shortly after the confusion over the United States' CL policy, Thompson proceeded to negotiate a price with Bayer over large sums of Cipro to allay fears of a national shortage. A price of \$0.95 per pill for 100 million tablets was settled upon, which was a substantial reduction from the former government price of \$1.83 and a retail price between \$5.00-7.00. Bayer also donated 2 million tablets and offered the United States government the option to buy a second million at \$0.85 and a third million at \$0.75. Cipro production in the United States tripled.²⁸

Some claim that Thompson threatened a CL in order to bring about Bayer's sudden generosity,²⁹ but others detail a less aggressive and more coincidental account that

²⁷ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.@400-404

²⁸ Bradsher, K. (2001). Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine. New York Times. New York.

²⁹ Murthy, D. (2002). "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health." American University International Law Review **17**: 1299-1346.@1315

portrays him as a victim of sequential of events. Regardless of Thompson's intent, Schumer's remarks about Thompson's CL-issuing authority preceded the negotiation with Bayer; therefore, knowing that Thompson comes to the negotiating table equipped with the power to override patents, Bayer was sure to be especially accommodating. While the US never actually issued a CL, it openly examined its CL policy during a public health crisis, and the effect may have been the same.³⁰ Without knowledge of Thompson's ability to suspend patents, perhaps Bayer would have been less cooperative.

As is evident in the United States case study, the mere talk of a CL may force pharmaceutical firms to offer unusually low prices in order to maintain a semblance of their patents' protection. This negotiation tactic was loudly criticized by the United States during both the South Africa and Brazil disputes. Therefore, in the eyes of many in the international community, the United States' employment of the same tactic shortly after its decial of South Africa and Brazil appears hypocritical. The United States' apparent double standard was perfect timing to weaken its influence at the Doha Round, where the United States was expected to oppose those pushing to widen the CL policy's scope of applicability. Murthy writes, the United States' response to the anthrax situation "effectively destroyed any credibility left in the US argument that compulsory licensing for pharmaceuticals was an undesirable option to address public health crises."³¹

³⁰ Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.@407

³¹ Murthy, D. (2002). "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health." American University International Law Review **17**: 1299-1346.@1315

November 2001. The Doha Declaration: CLs Scope and Practice Widened

With these events in the background, WTO members reconvened in Doha, Qatar on 14 November 2001, only a few weeks after the events in the United States. The Doha conference was scheduled in part as a response to concerns voiced by 46 developing nations³² and some 100 civil society groups³³ about the CL policy. As mentioned previously, the Doha convention was to be one in a series of negotiations at the ministerial level focused on development issues. The convention would focus on 40 items within 12 themes, ranging from agriculture, to anti-dumping, to intellectual property protection and CLs for pharmaceuticals.³⁴ Therefore, a second policy window³⁵ opened for the WTO mandates on CLs in November 2001.

The changes and affirmations made at Doha are significant. Member states reasserted that TRIPS should not “prevent members from taking measures to protect public health.”³⁶ They also acknowledged that patent protection had functionally limited the developing world’s access to affordable pharmaceuticals and that the generic drug market in developing nations was operating with far fewer restrictions in the pre-TRIPS

³² The Hindu (2001). TRIPS: How Much Flexibility? The Hindu, FT Asia Intelligence Wire.

³³ Millar, K. (2001). WTO Focuses on Access to Affordable Medicines for the Poor. Geneva, Agence France Presse -- English.

³⁴ World Trade Organization. "Subjects treated under the Doha Development Agenda." Retrieved 21 June, 2010, from http://www.wto.org/english/tratop_e/dda_e/dohasubjects_e.htm.

³⁵ Kingdon (2003). Agendas, Alternatives, and Public Policy. New York, Addison-Wesley Educational Publications, Inc.

³⁶ World Trade Organization. (2001). "Declaration on the TRIPS Agreement and Public Health." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

environment. LDCs were given an extension on the deadlines set by TRIPS; they are not expected to comply with TRIPS until 1 January 2016.³⁷

The focus upon TRIPS impact upon the developing world was probably accelerated by the fact that many nations came to realize that--aside from the potential mark it could make on their pharmaceutical industries--the CL policy had little relevance for the developed nations; in fact, several nations actually vowed to never make use of the policy under any conditions.³⁸

A major point of discussion was TRIPS' loose definition of what circumstances ought to warrant the use of a CL. Member states reaffirmed their belief that a nation should have the prerogative to define the circumstances that warrant a public health emergency and a valid application of the CL policy within its own domestic intellectual property rights laws. The WTO refrained from moving towards a stricter definition, primarily based on the developing nations' argument that the flexible language of the TRIPS agreement was—and ought to be—the basis for the agreement, and that opinion prevailed. Therefore, the Doha agreement states that CLs can be used to address urgent public health matters such as “HIV/AIDS, tuberculosis, malaria, and other epidemics.” Rather than restricting the types of diseases and circumstances that may warrant a CL, the

³⁷ World Trade Organization. "The Doha Declaration Explained." Retrieved 23 June, 2010, from http://www.wto.int/english/tratop_e/dda_e/dohaexplained_e.htm.

³⁸ Fergusson, I. F. (2008). The WTO, Intellectual Property Rights, and the Access to Medicines Controversy. D. Foreign Affairs, and Trade Division, Congressional Research Service.@7-8

Doha agreement further blurs the definition of a public health emergency. Some nations, such as the United States, found this infuriating.³⁹

Extending the scope of the CL safeguards to include these diseases may symbolize a compromise on some important characteristics of the conditions that constitute a public emergency and a valid application of the TRIPS Article 31 safeguards as they were originally written. While malaria can be deadly, it often is not; and while HIV/AIDS will eventually cause death, patients can live years without treatment. Furthermore, as mentioned earlier, ARVs are used primarily to manage the disease, rather than to cure or interrupt transmission. In other words, Type II scenarios were recognized as a legitimate employment of the CL safeguards for some nations; whereas prior to Doha, only Type I scenarios were unquestionably warranted applications of the policy. If this characteristic is generalized, it could be argued that CLs may be applicable to other drugs that manage illness and are more palliative in nature. These admissions could justify using CLs for other diseases that are not necessarily deadly or acute, so long as the nation state considers them threatening enough to be urgent public health matters.

Another area of contention discussed at Doha was whether or not it is permissible to import and export using CLs. The 1995 TRIPS agreement is rather ambiguous on the issue, but clearly states that the CL safeguards should be considered for domestic use only. Developing member states lacking high levels of domestic pharmaceutical production capabilities argued that the CL flexibility was irrelevant to them; whenever branded pharmaceuticals were needed for a public health emergency, the only option was

³⁹ Ibid.@6-7

to import. The intention to revise this policy was agreed upon at Doha, but was not articulated into an agreement until later.

The official wording of the CL policy on importing and exporting was finished in 2003. Paragraph 6 of the Doha Declaration now reads as follows:

“...countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member State to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.”⁴⁰

The Annex of the agreement expands the eligibility of CL importing to include any nation that lacks a sufficient capacity to manufacture the pharmaceuticals domestically in order to address a national emergency. Although the Doha Declaration tolerates importing and exporting under CLs, an important caveat is that national laws still need to be aligned for it to be legal. Canada, Norway, the European Union, and India announced quickly and formally that they had already completed making these adjustments within a few short years.⁴¹

The Doha Declaration profoundly increases developing nations' pharmaceutical price negotiating power. Without the ability to produce a generic version of a branded drug domestically, some nations were at the mercy of the pharmaceutical giants as the sole legal provider of the drug. After the Doha agreement's allowance of generic importation

⁴⁰ World Trade Organization. (2003). "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of the General Council of 30 August 2003." Retrieved 23 June, 2010, from http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

⁴¹ World Trade Organization. (2005). "Chairperson's Statement, December 2005." Retrieved 23 June, 2010, from http://www.wto.org/english/news_e/news05_e/trips_319_e.htm.

under CLs, these nations could establish an alternative legal and viable pipeline to procure cheaper high-tech drugs besides buying from the patent holder, thereby giving the nation a major advantage in bargaining.

The Doha agreement, therefore, appears to be an improved version of TRIPS for developing nations in several ways. First, it affirms nations' discretion to apply the CL policy to situations that they see as warranted, including HIV/AIDS specifically. Second, Doha affirms that using CLs as a tool in pharmaceutical price negotiations is permissible. Third, Doha allows for the import and export of generic versions of branded drugs via coordinated CLs, which could improve generic drug access for nations without strong domestic pharmaceutical production capabilities. Fourth, it exempts LDCs until 2016.

These affirmations--especially regarding the use of CLs as a bargaining tool with pharmaceutical giants--and policy changes made at Doha were significant and probably would not have been possible without the events preceding it, i.e., the CL cases in South Africa, Brazil, Canada, and the United States. The policy's scope and legitimate practice was widened and its boundaries blurred. Some commentators believe this policy shift would not have been possible without the anthrax scare and recent exposure to the United States' apparent double standard.⁴² Thompson may have "inadvertently set a precedent for patent negotiating with international drug firms."⁴³

⁴² Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." *Suffolk Transnational Law Review* 26(Summer): 385-410.@406

⁴³ Ibid.@394

The 2004-2007 CL Spike

While the policy changes were conceived at the Doha in 2001, many were still under negotiation, including those relating to importing and exporting under CLs. Negotiations continued for years and are collectively referred to as “the Doha Round.” In 2003, the General Council agreed to waive paragraphs (f) and (h) of Article 31 temporarily.⁴⁴ The change was implemented and would be subject to reevaluation; the changes were made permanent on 6 December 2005.⁴⁵

During interim (2001-2003), considerable anticipation built for developing nations that were struggling to cope with the HIV/AIDS epidemic and whose national response to the disease was being held back by pharmaceutical patent obligations mandated by TRIPS. Once the Doha changes were implemented in 2003, it was not long before nations made use of the CL policy.

After three years of failing price negotiations with pharmaceutical firms, Malaysia became the first nation to invoke CL policy post-Doha and import ARVs from India. In October 2004, Indonesia invoked CLs in order to manufacture ARVs domestically after its own failed price negotiations.⁴⁶ Zambia and Mozambique also made use of the policy to license local production of generic versions of branded drugs in 2004.

⁴⁴ Germano, S. (2007). "Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries." University of Missouri-Kansas City Law Review 76: 273-294.@282

⁴⁵ Ibid.@283

⁴⁶ Ibid.@286-287

Several more CL cases occurred in 2005. In South America, Brazil again threatened a CL in June of that year when Abbott responded to its plan to produce generic versions of the branded drug “Kaletra” domestically. In the end, Abbott offered to a substantial price reduction in exchange for being the sole provider of the drug to Brazil.⁴⁷ In Africa, several nations including Eritrea announced CLs for ARVs. Those CLs that were issued by least developed nations (LDCs) are particularly interesting because such high levels of compliance to TRIPS are not required for them until the year 2016.⁴⁸ In 2006-2007, more CLs for ARVs were issued by Brazil, Indonesia, and Thailand.

The Thailand Cases and the Possible Trajectory towards CLs for Chronic Illness

The Thailand case in particular attracted a lot of international press. In late 2006 and again in early 2007, Mongkol na Songkhla, the Thai Minister of Health, issued CLs for Kaletra and Efavirenz, which are both ARVs, and Plavix, which is a blood-thinner used to manage cardiovascular disease. Many worried about the implications and repercussions of Thailand’s CL for Plavix, and these concerns were heightened even further when Thailand issued another set of CLs later in 2007 for Novartis’ Letrozole, Sanofi-Aventis’ Docetaxel, and Roche’s Erlotinib, which are used to treat varying types of cancers including those of the breast, lung, ovaries, and pancreas. Further details on the Thailand case are discussed in the Chapter Three.

⁴⁷ Bjornberg, J. (2006). "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?" *Northwestern Journal of International Law & Business* 27(Fall).@204

⁴⁸ World Trade Organization. (2006). "TRIPS: Drug Patents, Technical Note - Pharmaceutical Patents and the TRIPS Agreement." Retrieved 20 June, 2010, from http://www.wto.int/english/tratop_e/trips_e/pharma_ato186_e.htm.

The Thai CLs were controversial for several reasons. While some negotiations with the pharmaceutical firms apparently took place, the Thai CLs seemed unusually abrupt. Mongkol na Songkhla explained that he did not feel the negotiations were taken seriously enough. Perhaps the most honest response came from Suwit Wibulpolprasert, the Disease Control Senior Advisor in the Thai Ministry of Public Health, when he said: "People told us, 'It's useless to negotiate with them unless you start to announce that you want to go for compulsory licensing. Then they start to talk to you'."⁴⁹

Thailand's successful employment of the CL safeguards for cardiovascular disease and cancer drugs it marked new territory for CLs, i.e., a clear expansion in scope from Type II into Type III CLs. Fuller writes:

What is new in Thailand's case is the broader categories of drugs that the government is aiming at. . .Plavix is designed to help prevent heart attacks and strokes. The pharmaceutical industry says the spirit of the WTO rule is being violated: It should be used for national emergencies like AIDS or other fast-spreading infectious diseases, the industry argues.⁵⁰

Even after Doha widened and softened the scope of the CL policy, it maintained its emphasis upon contagious diseases with words such as "HIV/AIDS, malaria, tuberculosis, and other epidemics."⁵¹ Chronic, non-communicable diseases such as cancers and heart disease are quite different. There is, however, a very important similarity between ARVs and the drugs that Thailand sought—both are used primarily in

⁴⁹ Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

⁵⁰ Ibid.

⁵¹ World Trade Organization. (2001). "Declaration on the TRIPS Agreement and Public Health." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

a palliative sense, rather than a curative one, to manage the illness within patients who are already afflicted with the illness.

It is difficult to draw a solid distinction between using a therapy to slow the spread of cancer cells and using ARVs to slow the spread of the HIV/AIDS virus. With the palliative utility of the drugs being analogous and with the time span of the progression of HIV/AIDS with other chronic illnesses, one would be hard-pressed to argue that one palliative use is more justified than the other. There are certainly some significant dissimilarities between the two, e.g., HIV/AIDS attacks a younger age group than most cancers and cardiovascular disease, and it is infectious whereas cardiovascular disease and most cancers are not. In other words, there is burden, but not immediacy. Still, these differentiations have limited pertinence and impact since both sets of medications are primarily palliative.

What the drug firms feared in the Thailand case study, therefore, is reasonable. The characteristics that HIV/AIDS and ARVs share with chronic illness and palliative medications, respectively, could construct an ideological bridge between Type II CLs and Type III CLs. Other nations could attempt to justify using CLs for cardiovascular disease and cancers by pointing out the pertinent similarities between the palliative uses of these drugs and those of ARVs.

But Thailand wisely chose to root its defense of the CLs in something more concrete, namely, the fact that Doha empowers nations to define public health emergencies in their

own terms and that CLs are allowable for “non-commercial use.”⁵² Still, that does not mean that other nations will not capitalize on this opportunity in the future, especially now that they would not be the first country to use CLs for chronic illness.

There seemed to be significant momentum and support in the international media for Thailand, including Medecines Sans Frontieres, the Clinton Foundation, and Unaid. ⁵³ With headlines such as “Cheap Lifesaving Drugs: Thailand Leads the Way,”⁵⁴ it was not hard to believe that Thailand’s bullying of the drug firms could be the first of many blowbacks against the pharmaceutical giants in Southeast Asia. Will Thailand be the first of many nations to go beyond CLs for ARVs and get price cuts on drugs to manage chronic illnesses?

The series of these events described in this historical account connects many of the dots between CL cases and sheds light upon many of the patterns that are evident in Table 2.1 that were described at the beginning of this chapter.

Timeframe. The sequence of events also provides reasoning as to why most cases occurred between 2004 and 2007. Significant policy changes initiated at Doha, e.g., the allowance of importing under CLs, were solidified in August 2003. The time between November 2001 and August 2003 allowed for considerable anticipation to build. Nations

⁵² The Ministry of Public Health and The National Health Security Office of Thailand (2007). 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.

⁵³ Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

⁵⁴ Mehta, H. (2007). Cheap Life-saving Drugs: Thailand Shows the Way. Business Times Singapore.

insnared in unproductive negotiations awaited policy's implementation. Once the Doha policies went into effect in 2003, cases suspended in stalemates swung in favor of developing nations. In other words, there was a build up and then a release.

A build-and-release effect would also add explanation as to why the CL activity cooled after 2007. Certainly, pharmaceutical firms must have learned how to better negotiate with nations in the post-Doha environment, and this would also help explain the cooling. The tapering off of CLs between 2008 and 2010 might allay some fears that other nations would imitate Thailand's rather aggressive issuance of CLs and negotiation strategies. Still, other explanations are possible.⁵⁵

Why was the CL safeguard not used prior to the South Africa case? Judging by the fact that policy's usage spiked after the changes made at Doha as well as the dialogue during the convention, the scope of the CL policy—as defined by TRIPS in 1994—was so narrow that occasions warranting its use would arise as infrequently as diseases such as pandemic flu and bioterrorist-engineered anthrax become serious national threats. Furthermore, because the domestic constraints of the pre-Doha CL policy, Article 31 was irrelevant for all nations that lack strong domestic production capabilities and whose pharmaceutical supplies exclusively come from abroad.

Specific nations. Another explanation illuminated by this historical analysis is why Brazil stands out as one of the most frequent users of the CL policy for HIV/AIDS drugs.

⁵⁵ Perhaps this could be explained by TRIPS compliance deadlines for middle income nations, many of which were in 2006. Stricter compliance could heighten the chances that a nation would need to utilize the flexibilities. Another explanation for the tapering could be that more recent cases just have not appeared in reports yet; however, instances of CLs are likely to be recorded immediately in the media, which was monitored very closely.

Brazil implemented an ambitious program to provide its citizens with ARVs free of charge. This effort in combination with Brazil's unique legal requirement that international patent title holders must produce the product within the country for a minimum of three years in order to have patent protection certainly explains why there is frequent friction with multinational drug firms.

As mentioned earlier, the general case collection makes it clear that both Brazil and Thailand are the most active in employing the CL safeguards. The historical analysis and case summaries show that both countries were trying to expand and sustain government public health programs that provide the treatments in question to citizens at the time that the CLs were entertained. This provides one of the factors that is investigated in more depth in Chapter Three.

HIV/AIDS and the Disease Type Scenarios. The historical analysis provides some understanding as to why so many of the CLs have been issued for expensive ARVs. The HIV/AIDS epidemic was a focal point at the Doha Round and agreements were made about using the CL safeguards for this disease specifically. It is even twice mentioned in the actual Doha Declaration itself.⁵⁶

A history of CLs that details the TRIPS CL safeguards as targeting Type I scenarios, moves to Doha and Type II scenarios, and ends with Thailand practicing Type III CLs leaves one wondering if there is a logical progression towards practicing CLs in circumstances with lower levels of immediacy. This progression is visually depicted in

⁵⁶ World Trade Organization. (2001). "Declaration on the TRIPS Agreement and Public Health." Retrieved 20 June, 2010, from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

Figure 2.2. Does this mean that CLs for cancer and heart disease will become more common in the future? Or will these Thai CLs will remain anomalies?

While the tapering of CLs after 2007 provides some evidence that Thailand's Type III CLs will remain unique, it is still tempting to believe that the Thailand cases will lead to more CLs for chronic disease if the trajectory of the CL employment might be depicted as Figure 2.1. It illustrates two threads of debate since the initiation of the policy. One thread is the use of the policy for its original intended purpose (i.e., outbreaks of deadly infectious diseases). The dotted line illustrates the sporadic use of CLs under such circumstances since they arise rarely. The solid line in Figure 2.1 depicts the thread of discourse surrounding the use of the CL policy for HIV/AIDS and then of chronic diseases. It shows the increasingly large departure from the severe circumstances for which the policy was originally fashioned. What forces might be pulling movement along the solid line in Figure 2.1 towards CLs for less severe circumstances?

National Income. The historical analysis does provide some clear answers as to why most CL activity seems to be in middle income nations. The Doha convention postponed the deadline for LDCs to comply with TRIPS until 2016. This explains why few LDCs have made use of the CL flexibility. Many higher income nations made it clear at Doha that they would not make use of the CL safeguards under any conditions, ironically the United States (which may have inadvertently taken advantage of the CL policy) was one. Drug pipelines are established well enough that the CL policy, as stated at Doha, seemed unnecessary in many high income nations. This explains why fewer high income nations

use the flexibility. As stated earlier, high income nations' use of the policy will be as often as novel diseases that threaten to become widespread, deadly pandemics.

While this historical and institutional analysis has given reason for the sparse CL employment in LDCs and high income nations, it does not fully explain the relatively higher activity of middle income nations (especially lower-middle income nations). The next subsection of this chapter suggests that the forces of population aging in middle income nations and its impact upon health systems provides theoretical reasons for understanding why middle income nations might be more likely to take advantage of the CL safeguards.

Section 2.2. CLs, National Income, Disease Scenarios, and the Epidemiological Transition

As discussed in the previous section, most of the CLs in Table 2.1 were for ARVs or were employed by middle income nations. While the historical sequence of the events gives some explanation for these patterns, it does not provide a robust theoretical underpinning for why the relatively highest levels of CL activity is from middle income nations. This subsection of looks more closely at these patterns and offers the epidemiological transition as a possible underlying force that could explain the movement along “Thread 2” in Figure 2.2.

An Overview of the Epidemiological Transition Model

Figure 2.3 is a visual depiction of the epidemiological transition model.⁵⁷ Birth and death rates fluctuate at very high rates during Stage 1. The disease profile of such a

⁵⁷ McFalls, J. A. (2007). "Population: A Lively Introduction." *Population Bulletin* 62(1): 1-36.@27

population is dominated by communicable diseases, many of which are diarrheal and proliferate in regions lacking quality sanitation and clean water. While diarrheal diseases are not often deadly for adults, they can be devastating to young children. Limited access to quality prenatal healthcare and poor nutrition further contribute to a hostile environment for children under five. Under such inimical conditions, mothers must give birth to several children just to have one survive into adulthood. Therefore, the birthrates in the early stages of this model are high, yet relatively few of these children become adults. The average age of the population during this phase is consequently young and life expectancy is short.⁵⁸

Stage 2 is marked by a drop in the population's death rate. A number of factors might explain this—e.g. improvements in sanitation, water quality, vaccination programs, economic conditions, prenatal care, nutrition.⁵⁹ Changes in these areas have significant impacts on the likelihood that a child will survive its first five years of life. Children who survive beyond their fifth year often live into adulthood. Their bodies are resilient enough to recover from stresses of the communicable diseases plaguing these communities, e.g., extreme dehydration induced by cholera. The declining death rate without a corresponding decline in the birth rate will undoubtedly cause a surge in the size of the population.⁶⁰

⁵⁸ Ibid.@26

⁵⁹ Bodenheimer, T. S., Grumbach, Kevin (2009). Understanding Health Policy, McGraw Hill Lange.@130-131

⁶⁰ Pol, L. G., Thomas, Richard K (2001). The Demography of Health and Health Care. New York, Kluwer Academic/Plenum Publishers.@21-23

Stage 3 is characterized by a decline in the birth rate. Eventually families in this stage of the transition begin to have fewer children and invest more into each one of them; a body of literature exists on how and why this occurs, but will not be elaborated upon here. Whatever the explanation, a process begins to occur in which the birth rate starts to decrease. As fertility declines, there will be a lower proportion of children to a higher proportion of adults, resulting in a rising average age of the society and what is often referred to as “population aging.” Older generations begin to outnumber their predecessors and to have fewer potential caregivers and those in prime working years that can subsidize the retired.⁶¹

Stage 4 is recognized by lowered birth and death rates, relative to earlier stages in the model. The growth of the population begins to slow and the overall size might even stabilize. Natural fluctuations of birth and death rates, such as those depicted in the reader’s lower right quadrant of Figure 2.3 are to be expected. Birth rates commonly settle at a level that is slightly above that of the death rate and of “population replacement,” i.e., the number of births and deaths match at a 1:1 ratio. Most community’s size will grow slightly most years, just above the population replacement level.⁶² The average age of a Stage 4 society is often somewhere in adulthood during prime working years. Because Stage 4 populations enjoy a higher level of development

⁶¹ McFalls, J. A. (2007). "Population: A Lively Introduction." *Population Bulletin* 62(1): 1-36.

⁶² Pol, L. G., Thomas, Richard K (2001). *The Demography of Health and Health Care*. New York, Kluwer Academic/Plenum Publishers. @21-23

and long life expectancies, the most common disease-related causes of death are often dominated by chronic illnesses that are not known to be infectious.⁶³

The Contrasting Challenges for Health Systems in the Early and Later Stages of Epidemiological Transition in Connection with Communicable and Chronic Disease

Although explanations for why there is less CL activity in low and high income nations has already been discussed, the epidemiological transition model can provide a deeper theoretical explanation.

Health Systems and Challenges in Low Income Nations. Communicable diseases are generally acute and always infectious. These diseases are rampant in earlier stages of development, such as those in LDCs and low income nations. The health systems functioning under these conditions will be designed and financed to meet these challenges, given the available resources and infrastructure. If an acute, communicable disease kill its victim, it will often claim the patient within a number of days or weeks. What is so tragic and frustrating about these conditions is that curative treatments exist that can save these patients' lives, but they cannot get access to them soon enough.

The majority of these treatments appear on the WHO's "Model List of Essential Medicines." The purpose of this list is to identify the pharmaceuticals that are integral to health systems' success in conditions such as those likely in earlier stages of development, and then to concentrate on concerted global effort in making these drugs as widely accessible as possible.⁶⁴ The medications included on this list are known to be

⁶³ McFalls, J. A. (2007). "Population: A Lively Introduction." *Population Bulletin* 62(1): 1-36.

⁶⁴ World Health Organization (2010). WHO Model List of Essential Medicines. Geneva.

efficacious, as inexpensive as possible, and easy to transport and administer; most are no longer under patent or have never been patented in the developing world. In 2004, Amir Attaran found that of the 319 products on the Model List of Essential Medicines, only 17 (1.4 percent) were currently patented in the low and middle income nations worldwide. While the cost of essential medicines, might represent a barrier especially for low income nations, it is not largely because of patent protection.⁶⁵ Therefore, patent disputes and CLs are unlikely to arise from within least developed and lower income nations.

The major challenge for these health systems, then, is centered upon how to improve accessibility to existing interventions known to be effective, rather than using the latest technology to discover new ones. One often overlooked and extremely significant barrier to accessing drugs in developing settings is the weaknesses in the health system's delivery infrastructure, especially in nations that are largely rural.⁶⁶ The Rwanda CLs for ARVs is a case in point. Canada exported ARVs to Rwanda via coordinated CLs. Unfortunately, while the drugs got to Rwanda, there were substantial unforeseen challenges in getting the drugs to the patients who needed them. Africa News writes about the Rwanda CL: “. . . even if medicine were available for free, as it often is in poor nations, dysfunctional institutions and personnel ensure that the needy can't access it.”⁶⁷

⁶⁵ Attaran, A. (2004). "How Do Patents And Economic Policies Affect Access to Essential Medicines in Developing Countries?" *Health Affairs* **23**(3): 155-166.

⁶⁶ World Health Organization (2006). *Public Health, Innovation, and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*. Geneva, World Health Organization. @104

⁶⁷ Africa News (2008). Rwanda; Africa's Failing Infrastructure Renders Compulsory Licensing Pointless. *Africa News*, News Times.

Weak infrastructure not only prevents patients from getting the inexpensive medications that can save their lives, but it also contributes to them getting sick in the first place. As mentioned earlier, most communicable diseases can be contained and prevented with a full spectrum of biosocial interventions. Many believe that improving the infrastructure (e.g., water, sanitation, food, transportation, economic development) will have far greater and longer lasting impacts on the health of developing nations than healthcare itself. Of course, others are quick to point out that healthy citizens will have a greater ability to make those critical infrastructural improvements. Health and development have been recognized to be interrelated enough that gains in one area can have a positive effect in the other and vice versa. The WHO has initiated a commission to better understand this relationship.⁶⁸

Generally speaking, health systems in early stages of the epidemiological transition can be quite effective with a proportionally lower level of financial investment (relative to health systems in later stages). One reason is that treatments for communicable diseases are not only less expensive and are rarely patented, but they also tend to be curative or preventative. Patients use the medications for a fixed amount of time, and consequently, lower quantities of these drugs will have greater impacts on the public health than palliative ones. While patients might die from communicable diseases, the episodes of illness will be significantly shorter than those of elderly populations; each patient, therefore, will demand relatively fewer of the health system's resources and time.

⁶⁸ Marmont, M. (2005). "Social Determinants of Health Inequalities." *The Lancet* **365**: 1099-1104.

This is one reason that investment into health systems in low income settings can show a higher return for each dollar invested than in high income nations.⁶⁹

Health Systems and Challenges in High Income Nations. Health systems functioning in the later stages of the demographic transition face a very different set of challenges. Rather than focusing upon childhood diseases, these health systems are battling the chronic illnesses associated with elderly populations. Episodes of illness for chronic conditions, e.g., cardiovascular disease and cancer, typically take years to play out and demand more resources from health systems. Because the developed world is struggling to discover more effective ways of treating these diseases, massive amounts of research dollars are devoted to these efforts. In 2002, PhRMA estimated that the industry was working to bring some 800 new products to market that target America's aging.⁷⁰ State-of-the-art drugs will be younger, patented, and expensive. Existing medications for many chronic illnesses do not cure the patient, rather they aim to extend life, improve quality of life, or both. These medications are typically prescribed for the remainder of the patient's life in order to have the desired effect.

⁶⁹ Bodenheimer, T. S., Grumbach, Kevin (2009). Understanding Health Policy, McGraw Hill Lange.@99-109

⁷⁰The overall sum of investment into pharmaceutical research and development is not only astronomically high, but the totals have been growing consistently each year. PhARMA estimated that investment in research and development in the US was \$37 billion in 2004 and \$39.4 billion in 2005, a 6.5 percent increase in a single year. PhRMA. (2010). "R&D Investments by American's Pharmaceutical Research Companies Nears Record \$40 Billion in 2005 " Retrieved 26 June, 2010, from <http://www.phrma.org/node/303>. A study done by DiMasi *et al* that compared research and development costs with a study they conducted using data from 1987 with data from 2000. They found a substantial increase. The average pharmaceutical firm's investment into research and development had risen from \$231 million per year in 1987 to \$802 million in 2003, a 7.6 percent increase. DiMasi, J. A., Hansen, Ronald W, Grabowski, Henry G (2003). "The Price of Innovation: New Estimates of Drug Development Costs." Journal of Health Economics **22**: 151-185.@180

The upshot is that longer life expectancies are generally associated with longer episodes of illness that utilize expensive state-of-the-art technologies and with a greater dependence upon the health system over time. The return on health dollars invested will be much lower under these conditions. Even the most efficient health systems will show declining returns on investment dollars in healthcare as chronic illness prevalence increases.⁷¹ The cost of medical innovation and longer episodes of illness are just a few of several reasons (e.g., health insurance) for this phenomenon. Health systems in developed nations, therefore, are likely to be more highly financed proportionally than those in developing countries.

While there is great demand for patented drugs in the developed world, the systems to create and pay for these drugs as well as the pipelines to deliver them are relatively well established; therefore, CLs stemming from high income nations are rare. If there is a CL, one would expect it to be exclusively for Type I CL scenarios in which there is little or no time to negotiate before the health ministry must respond. Type II and III CLs have limited relevance to nations in Stage 4 of the transition because reimbursement systems to pay for branded drugs are in place.

Health Systems in Transition and CLs: An Explanation Built upon the Epidemiological Transition

Now that the differing challenges that health systems face in the beginning and end stages of the epidemiological transition have been capsulated, consider health systems in the middle stages of the model. Health systems entering the transitional stages will

⁷¹ Bodenheimer, T. S., Grumbach, Kevin (2009). Understanding Health Policy, McGraw Hill Lange.@87-98

initially be equipped for the health challenges typical of a lower level of development.

As birth and death rates decrease and population aging occurs, the nation's disease profile will begin to transform from one with a high prevalence of communicable, acute diseases to one with a higher prevalence of the chronic illnesses common among older persons.

The health system will need to adapt to the new challenges, and this will take time. Remember that population aging occurs rather rapidly because most disease-related deaths occur either in early childhood or in later in adulthood. The level of financing during transitional stages will need to increase substantially and rapidly in order to cope with the sudden burst in chronic disease prevalence. Health systems caught in the transitional stages will be especially under-financed and staffed, facing a new set of diseases that require high-tech solutions, and unable to meet the demands of a growing number of people; this pressure point should cause health systems to adapt and states to increase investment into healthcare goods and services. This will be an especially bitter transition as these health systems begin to experience the decreasing returns on healthcare investment as chronic disease prevalence rises. These demographic forces are theoretically likely to cause a financing crisis within the health system, which could naturally force substantial healthcare reform and cause these health systems to look externally and internationally for solutions. This could be one instance in which demographic forces work more quickly than social reform.

In today's globalized marketplace, transitioning nations will find pharmaceuticals that can treat the illnesses common in their aging populations, but that are priced for sale in high income nations. State-of-the-art pharmaceuticals are available, highly demanded,

and far too expensive for most transitioning nations' current healthcare expenditures. The WHO writes: "In times of economic crisis the supply of medicines is often the first component of the health-care budget to be cut."⁷² Therefore, it makes sense why middle income nations (and especially lower-middle income nations) have shown in Table 2.2 to be using the CL system the most. While all health systems could be said to be underfunded, it is the middle income nations that consistently need access to high income nations' medications and cannot afford them.⁷³ This peculiar theoretical pressure point is illustrated in Figure 2.4⁷⁴ and might offer explanatory power as to why most CL activity is in middle income nations.

If this explanation is true, then why has only Thailand been using the CL safeguards for chronic illness? Chapter Three focuses squarely upon this question. One reason might be that Type III CLs are the most controversial. Relief on the cost of any expensive medications will be especially welcome to transitioning health systems, but economic growth and trade are also particularly important during these middle stages. Since Doha names HIV/AIDS specifically as a valid use of the CL safeguards, it makes sense that middle income nations will target ARVs. If the Doha Declaration's definition

⁷²World Health Organization (2010). Essential Medicines Biennial Report 2008-2009. Geneva: 1-12.@1

⁷³The fact that some LDCs and low income nations have issued CLs only for ARVs could possibly further substantiate the notion that demographic forces are at play. Whenever lower income nations share a serious public health concern with the developed world, they may use the CL system to procure branded pharmaceuticals. This did not occur until HIV/AIDS. This is why the WHO IGWG's three-part typology that delineates diseases by their common presence between low and high income settings is especially salient to CLs.

⁷⁴Figure 2 is merely for illustrative purposes and is not meant to imply that there is a point in which there are fewer diseases (the dip wherein there is the greatest CL pressure); in fact, transitioning nations will probably show the greatest disease diversity since the illnesses of both Stages 1 and 4 will have significant presence.

of a public health emergency had included “HIV/AIDS, tuberculosis, malaria, cancer, cardiovascular disease, and other epidemics,” middle income nations would certainly target cancer and heart disease drugs. Because lower-middle income nations are the poorest nations that share many of the same health problems as developed nations, they are the most likely to effectively capitalize on flexibilities afforded to them by the international community.

The Connection to HIV/AIDS

The theoretical model depicted in Figure 2.4 also adds deeper explanation for why the most common application of the CL safeguard is for ARVs for HIV/AIDS. As mentioned previously, Type II diseases, i.e., HIV/AIDS, has many of the same characteristics that make chronic disease so troubling for health systems. ARVs are expensive, high-tech pharmaceuticals that have been initially priced for sales in high income nations and must be taken for the rest of the patients’ lives; furthermore, HIV/AIDS causes long-lasting episodes of illness and dependence upon the health system. From the standpoint of the health system, HIV/AIDS is similar to an early onset of population aging.

Not only can HIV/AIDS’ devastate the transitioning world because of its chronic features, but also because of when the disease strikes its victims. Most patients transmit and contract the disease during their sexual prime, and it will develop into a disabling illness by the time patients reach their prime-working years. Transitioning economies need to grow in order to keep up with the epidemiological transition, and HIV/AIDS could potentially stunt this growth by attacking those in the core of the economy. The

economic impact of HIV/AIDS is well-documented by scholars and does not require elaboration here, but the economic effect of HIV/AIDS is real and substantial.⁷⁵ Alex de Waal has worked out a useful theoretical narrative that details how the effects of HIV/AIDS could become so powerful that they could essentially reverse development.⁷⁶

HIV/AIDS adds financial strain upon lower-middle income nations, which already has reason to be especially starved for resource inputs. The CL policy will be especially attractive to these nations. Because Doha made CLs for HIV/AIDS acceptable, nations in transition would be particularly likely to take advantage of this legal flexibility.

The epidemiological transition offers a theoretical basis to construct an explanation for understanding some of the trends observable in Table 2.1 and 2.2. Figure 2.4 illustrates an explanation as to why most CL activity stems from middle income nations, rather than low or high income nations. It connects national income and development with the types of diseases that health systems will face. These challenges will be unique and require varying levels of investment and intervention. Nations in the transitional stages will face the health challenges of both the earlier and later stages of development simultaneously, all while the forces of population aging put particular financial strain upon them. HIV/AIDS is likely to magnify these effects. This could very well provide

⁷⁵ Dixon, S., McDonald, Scott, Roberts, Jennifer (2002). "The Impact of HIV and AIDS on Africa's Economic Development." *BMJ* **324**: 232-234. Piot, P., Bartos, Michael, Ghys, Peter D, Walker, Neff, Schwartlaender, Bernhard (2001). "The Global Impact of HIV/AIDS." *Nature* **410**.

⁷⁶ de Waal, A. (2003). "Why the HIV/AIDS Pandemic is a Structural Threat to Africa's Governance and Economic Development." *The Fletcher Forum of World Affairs* **27**(2).

one force that might push progress along the solid line in Figure 2.2 towards Type III CLs.

Other factors are certainly at work in this complicated web of confounding variables, and other theoretical explanations are possible. More research needs to be conducted before this explanation becomes more than just one plausible theory. Such research might focus upon finding a pattern of healthcare financing crises that correspond to a particular point in the epidemiological transition and nations' level of development; this could be compared with the timing of CL activity.

While the historical analysis provides contradictory clues that Type III CLs will become more common in the future, the theoretical explanations expounded in this section gives reason to suspect that CLs for drugs that treat chronic disease will become more likely in the future. Why is it then that Thailand is the only nation that has issued a Type III CL? Chapter Three focuses upon answering this question.

CHAPTER THREE. A COMPARISON OF PHARMACEUTICAL PATENT SUSPENSION IN FOUR NATIONS

Chapter Two provides some clues to suspect that CLs for chronic illness may become more likely in the future. However, thus far, Thailand was the only nation in the case study collection found to carry out a Type III CL (for five different pharmaceuticals), the most daring and controversial form of patent suspension. Korea, India, and the Philippines also appeared in the media during CL disputes for drugs that treat chronic disease, but did not issue a CL in the end. What is it about Thailand that enabled it to employ the CL policies so effectively and so many times relative to other nations? Are other nations likely to imitate Thailand's actions?

This chapter compares CL disputes in Korea, India, and the Philippines with Thailand in order to discover what other variables in addition to income might be important in shaping the outcome of these international pharmaceutical patent disputes. As Chapter Two focuses on first upon both the institutional and structural levels, this section occupies itself entirely at the institutional level. After providing a summary of each case study, each of the following facets and their impact on the outcome are considered: (i) the number of patients in question, (ii) the direct involvement of a government healthcare purchasing agency, and (iii) the potential political implications of the situation. Which of these three factors will prove to have the most powerful influence on the outcome? The meaning, method of measurement, and rationale for selecting these factors is explained in the subsequent section.

The results of the comparison are reflected in Table 3.1. The rationale behind each mark (e.g., “Low”, “High”, “Positive”, “Negative”) in Table 3.1 is explained at the end of each case study briefing included in this chapter. This comparative analysis concludes that the state’s perception of the political importance of the case is more influential in shaping the outcome than the number of patients affected or the level of state involvement in pharmaceutical purchasing. When all three of these factors listed in the header row of Table 3.1 are present, the outcome is more likely to be positive, especially when combined with the other salient structural factors such as income that were discussed in the previous chapter. The Thailand case seems to have a high presence of all factors thought to be important; perhaps it is this unusual compounding of positive variables that magnified Thailand’s capacity to be so aggressive in its CL approach. One implication of this finding is that another rash of patent overrides like the one that came out of Thailand are unlikely to become commonplace in the future because having a high presence of all factors is unusual; this contradicts the clues in Chapter Two which would lead us to suspect the opposite.

Variable Selection

Before moving to the case studies, the following section details the meaning, the rationale for selecting, and the method for measuring the presence of each of the three variables—i.e., “Factor 1 - Single or Centralized Buyer,” “Factor 2 - Number of Patients Impacted,” and “Factor 3 - Political Implications.” Table 3.1 depicts how the comparison is structured in a visual manner.

Factor 1 – Single or Centralized Buyer Health System

As mentioned in the previous chapter, Thailand and Brazil stood out as the nations that put the CL safeguards into practice the most. Both nations turned to CLs as the cost of the drugs that they needed to effectively run a state healthcare program exceeded what could be managed. Theoretically, nations with a single payer system for purchasing healthcare goods and services would be instrumental in increasing bargaining power, involvement, and investment in national drug supply. When there is a high level of demand for an expensive product, governments that are purchasing the drugs will be far more likely to seek cost containment opportunities than nations that leave pricing to be determined by the private market. Countries with a dispersed system of healthcare financing and provision will theoretically lack the intuitional power necessary to bring a CL to fruition. This factor will be measured by the overall institutional structure of each nation's healthcare finance and provision system. Public spending on healthcare as well as the percentage of citizens covered under the public system will also be considered.

Factor 2 – Number of Patients Impacted

The number of patients impacted by the proposed CL might also be an important determinant. The more patients in question, the more the situation appears to be a public health emergency. States with high numbers of affected patients will appear to be in stronger compliance with the prerequisites articulated in TRIPS and will maximize the positive impact of the CL decision. When fewer patients are in question, the states may be less likely to utilize the CL system and face a backlash from the pharmaceutical firm and trade partners. This factor will be measured by using the prevalence of the disease in

question if discussed in the literature, otherwise WHO statistics on the disease's prevalence is used. With respect to the centralized buyer variable (Factor 1), the effective number of patients impacted by a decision would essentially be the product of the number of patients affected multiplied by the proportion of those patients whose health is actually managed by the state buyer.

Factor 3 – Political Implications

The political implications of the CL in each case study is certainly the most difficult to define and quantify for comparison. This variable is intended to quantify the state's perception of potential political or economic consequences resulting from a CL decision. In other words, if the CL dispute escalates to such a level that the state's decision could significantly impact the future of the party or of the nation's institutions, then leadership is more likely to engage in more conservative decision making involving CLs.

Another consideration within this area is the level of involvement from civil society and non-governmental organizations (NGOs). The statements of international actors such as the WHO or MSF (Doctors without Borders) might impact the behavior of both the nation and the pharmaceutical firm that is engaged in patent dispute negotiations. Local NGOs, patient groups, and physicians associations might also have a significant influence.

To deal with the problem of quantifying the "political implications" factor and include both the potential influence of state and civil interests, a proxy for measurement was formulated. A critical question is asked in each case in order to simplify the issue and provide some ability to distinguish the cases. The question is "Did state authorities

or another group initiated the CL dispute?”. Further clarification is provided by assessing the consequences of the state’s decision regarding the CL. The assumption here is that when the state has a high level of stake in the outcome of the situation, it does not need to be informed by NGOs or patient groups of its precarious situation. If governments were unaware or unimpressed by the level of influence that the CL decision might have upon them, then their stake is low. Cases in which an NGO persuades the government to issue a CL can be accounted for by marking a low presence for the “political implications” factor combined with a positive outcome in Table 3.1.

The Case Studies

Korea - Case Study Briefing

The CL dispute in Korea primarily took place between 2001 and 2002 over the drug “Glivec” (the generic name is “Imatinib Mesylate”), for which the Swiss pharmaceutical giant Novartis owned the patent. Glivec is primarily prescribed for patients suffering from rather rare forms of cancer including Chronic Myeloid Leukemia (CLM) or Gastrointestinal Stromal Tumors (GIST).¹

The Korean health authorities gave Glivec orphan drug status, which was the nation’s first application of this policy.² The term “orphan diseases” refers to rare illnesses or

¹ Novartis Pharmaceuticals Corporation. (2009). "About Gleevec." Retrieved 13 August, 2009, from <http://www.gleevec.com/patient/gleevec-prescription-medication-information.jsp>

² Nam, H. S., Park, Sung Ho. (2002). "Request for Compulsory License on Behalf of People's Health Coalition for Equitable Society, Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society." Retrieved 25 June, 2010, from http://glivec.jinbo.net/Request_for_CL_Final_version.htm

ones that primarily affect impoverished nations. In the US, rare diseases are considered to be those that affect fewer than 200,000 people; there are some 5,000 of these conditions.³ When a medication is given orphan drug status, there is a special set of benefits for its producer. These benefits vary by country, but are designed to stimulate research and development for these illnesses.

Korea designed its orphan drug benefits to include priority in the drug approval application process and the allowance of the drug to be given to patients under specific conditions prior to the Korean Food and Drug Administration's (KFDA) official approval. During this pre-market window, Glivec was given to 91 Korean patients and over half of them went into remission. It was clear that Glivec was superior to current methods of treating CLM in Korea.⁴

In the spirit of the young orphan drug policy and the promising early performance of the drug, the KFDA approved Novartis' application for Glivec with a record-setting speed of only two months. The KFDA approved it, however, at the price that the patent holder requested of 25,674 *won* or about 21 US dollars per capsule. Depending on the dosage prescribed, annual cost per patient would range between 2,400-3,600 US dollars.⁵ Considering the average income per capita in Korea was estimated to be around 9,629 US

³ Novartis Pharmaceuticals Corporation. (2009). "About Gleevec." Retrieved 13 August, 2009, from <http://www.gleevec.com/patient/gleevec-prescription-medication-information.jsp>

⁴ Nam, H. S., Park, Sung Ho. (2002). "Request for Compulsory License on Behalf of People's Health Coalition for Equitable Society, Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society." Retrieved 25 June, 2010, from http://glivec.jinbo.net/Request_for_CL_Final_version.htm

⁵ Ibid.

dollars in 2000,⁶ an annual supply Glivec at full price would cost the average patient about 25 to 37 percent of their income.

Novartis applied for the drug to be covered under the national health insurance program. The Korean Health Insurance Review Agency (HIRA) determines the limits of the national health insurance plan. The HIRA commissioned an expert committee to review the drug and consider its cost and coverage. In August 2001, the HIRA announced that the national insurance coverage would indeed include Glivec, but because of its high price tag, only 70 percent of the total cost would be covered.⁷

Hoping for full coverage commensurate with the other less-effective treatments for CLM, Novartis was outraged and demanded higher coverage. The HIRA's expert committee initially refused, but eventually offered to increase coverage to 17,862 *won* (their original offer was 17,000 *won*) or about 14.90 US dollars per capsule. Novartis was dissatisfied with this slight increase.⁸

CLM patient groups were also appalled with the cost, and began demanding that Novartis reduce the price of the drug or that the Korean government issue a CL and begin distributing a generic version of Glivec. Novartis appeared to be sympathetic to these demands, but argued that the price is standard worldwide; if the firm were to reduce the price in Korea, they would be forced to follow suit and lower the price in other nations.

⁶ Kirk, D. (2001). South Korea Reports a Widening Income Advantage Over North. New York Times.

⁷ Nam, H. S., Park, Sung Ho. (2002). "Request for Compulsory License on Behalf of People's Health Coalition for Equitable Society, Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society." " Retrieved 25 June, 2010, from http://glivec.jinbo.net/Request_for_CL_Final_version.htm

⁸ Ibid.

Rather than lower the price in Korea, Novartis even considered donating 30 percent of the total supply of the drug needed in Korea or offer low income patients a 30 percent rebate.⁹

On 16 November 2001 the KFDA changed the wording of its findings during the clinical trials, stating that Glivec was most effective during the “acute aggressive” phase of the illness, which is the final of three phases in the disease’s typical progression. It is possible that this change had more to do with cost containment than medical efficacy, used to justify coverage only in more severe cases in which other treatments were proving ineffective. Some patients in the early chronic state of the disease claim that they were refused treatment. Three days later the Korean Ministry of Health and Welfare announced that the 17, 862 *won* or 14.90 US dollars per capsule price was the final decision. Infuriated, Novartis announced its final price was set at 21 US dollars per capsule worldwide and threatened to suspend supplying Korea with Glivec.¹⁰

The sudden finality and the refusal of both sides to compromise left the public confused. Some hospitals suspended Glivec prescriptions out of fear that they would be held responsible for the remaining cost left uncovered by the national insurance plan. Once this news was publicized, Novartis responded by supplying patients with Glivec free-of-charge and promised to continue doing so until the situation was clarified.¹¹

⁹ Ibid.

¹⁰ Ibid.

¹¹ Ibid.

The direction of the case from here is spotty. The price and coverage disputes continued into August 2002. Some patients still did not have access to Glivec even if they were willing to pay for the remaining cost of the drug left uncovered by the national insurance.¹² In February 2003 the price was still being hotly disputed. CLM patient groups attempted to meet with Novartis directly. Korean policy officials apparently intervened, resulting in the hospitalization of several protestors.¹³ An article by Strom and Fleischer-Black claims that in 2003 Novartis was distributing Glivec for free and encouraging patients to press the government to pay more for it.¹⁴ Moon's work mentions that the drug is now available in Korea; however, the Korean civil groups' petition for a state-issued CL was denied.¹⁵ The current state of affairs appears to be such that Glivec is being sold in Korea at full price and is only partially covered by national health insurance; Novartis Korea is supplying low income patients with the drug free of charge. It is clear that the outcome column of Table 3.1 is negative in the Korea case study.

¹² Landon, V. (2002). Pricing Dispute Leaves Patients Without Drugs. [SwissInfo.ch Swiss News Worldwide](#).

¹³ CPTech. (2003). "Korea Patients Asking for Meeting with Novartis Arrested, Hospitalized." Retrieved 23 June, 2010, from <http://www.cptech.org/ip/health/gleevec/korea-arrest.html>.

¹⁴ Strom, S., Fleischer-Black, Matt (2003). Drug Maker's Vow to Donate Cancer Medicine Falls Short. [New York Times](#). New York.

¹⁵ Moon, S. (2008). Institutions for New Product Development for Global Health: From Malaria to Mental Health and Beyond. [Institutions for Closing the Knowledge-Action Gap in Global Health](#). Cambridge, MA: Harvard Kennedy School of Government: 1-15.@12

Factor 1 – Single or Centralized Buyer Health System

Korea began offering universal coverage in 1989. The system is divided into two major branches. The National Health Insurance (NHI) currently covers around 96.3 percent of the population, and the remaining 3.7 percent are covered through the Medical Aid program.¹⁶ Because healthcare financing is centralized and largely supplied by the public, there is a “High” presence of this factor for the Korea case in Table 3.1.

Factor 2 – Number of Patients Impacted

While an exact number for CLM patients in Korea is not readily available, Glivec qualified for Korea’s new orphan drug program for rare diseases. Bearing this mind, Table 3.1 has been updated to reflect a “Low” presence for the “Number of Patients Impacted” column.

Factor 3 – Political Implications

One striking element about the Korean case is the strong activism by civil society and patient groups. Perhaps patients had a strong ability to organize precisely because the disease is fairly rare and because smaller groups may be able to organize more quickly and easily. From the time they learned about Glivec in 2000 on the internet through the eventual formal demand for a CL to be issued, the “Glivec Coalition” was an ever-present and seemingly powerful force. The coalition was a collaboration of such organizations as the CLM patient groups, the Korean Pharmacists for a Democratic Society, the

¹⁶ World Health Organization. (2005-2010). "Korea, Republic of: Health System." Retrieved 25 June, 2010, from http://www.wpro.who.int/countries/2009/kor/national_health_priorities.htm.

Association of Physicians for Humanism, the Korean Federation of Activists Fighting for Health Rights, IPLeft, and the People's Coalition for an Equitable Society.¹⁷

Still, the litmus test for the political factor is whether or not the CL discussion was initiated by the state. In this case, it is clear that the patient groups were pushing public officials for a CL. Korean public health officials only discussed the issue with patient groups and never attempted to use CLs as a negotiation tool with Novartis in a significant way. There was no clear or compelling consequence for the Korean government refusing to issue the CL. Therefore, the "Political Implications" factor's column in Table 3.1 has been marked as having a "Low" presence in this case.

India - Case Study Briefing

As in the Korean case, the CL dispute in India also centers on Novartis' Glivec, but the case is couched in a long legal context. When India joined the WTO, its intellectual property protection laws were such that processes were patentable, but not products, foods, or other elements. Therefore, so long as Indian pharmaceutical firms used processes other than the patented one, they could produce imitations of branded drugs legally. Without product patents, a rights holder's monopoly is maintained only until another firm finds a different way of deriving a bioequivalent drug.¹⁸

After becoming a WTO member state, India commenced in 1995 with a three-stage plan to amend the 1970 Indian Patent Law to include product patent protection, as was

¹⁷ Nam, H. S., Park, Sung Ho. (2002). "Request for Compulsory License on Behalf of People's Health Coalition for Equitable Society, Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society." " Retrieved 25 June, 2010, from http://glivec.jinbo.net/Request_for_CL_Final_version.htm

¹⁸ Kaur, M. (2008). "TRIPS and the Indian Patent Regime." [Social Science Research Network](#).

recommended by the TRIPS Council. The plan involved using a “mailbox” facility that received and held product patent applications until near the end of 2004; at that time, the patent office would begin reviewing applications in anticipation of the implementation of the new rules on 1 January 2005. In the meantime, patent applicants could apply for Exclusive Marketing Rights (EMR), which limits generic producers from marketing their versions of branded products in the country.¹⁹

Novartis launched its worldwide marketing of Glivec in 2001 and was awarded EMR in India by 2003. Novartis even obtained orders to halt some generic producers from marketing their versions of Glivec,²⁰ evidencing the growing recognition of the drug.

Novartis was executing an impressive drug donation program in which they were providing Glivec free-of-charge to 99 percent of the patients needing it.²¹ The level at which Novartis was donating in India was suspicious to some. It was no secret that Novartis had also filed for a product patent, and its application was among those in the “mailbox” queue to be considered once the new laws were in force.²² After having been awarded a process patent and EMR in India, the firm must have expected to be awarded a product patent as well; after all, Glivec was already patented in 40 countries, even in

¹⁹ Ibid.

²⁰ Raju, K. (2007). "The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement." Ibid.: 1-19.

²¹ Novartis Pharmaceuticals Corporation. "Glivec Patent Case in India: Fact vs. Fiction." Retrieved 25 June, 2010, from <http://www.novartis.com/downloads/about-novartis/facts-vs-fiction-india-glivec-patent-case.pdf>.

²² Raju, K. (2007). "The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement." Social Science Research Network: 1-19.

nations known for loose intellectual property protection like Russia.²³ Some would speculate that the drug donation program was actually a marketing plan, operating under the assumption that a product patent would be awarded, and the firm would commence charging for the drug from that point forward and drastically reduced its donation programming.

In late 2004 the Indian Patent Office began steadily reviewing product patent applications. The Chennai Patent Office reached a decision on the Novartis application on 25 January 2006 and announced that it was denied. The Chennai Patent Office stated that the innovation was only a slight alternation of a known substance; the innovation, therefore, did not differ significantly enough from the original and lacked the proper level of novelty to warrant a patent.²⁴

Novartis was outraged and immediately demanded an appeal, which attracted a fair amount of publicity and media involvement. Patient groups and NGOs began to voice their opinion on the topic, and misunderstandings abounded regarding the true nature of the dispute. Some groups even mistakenly thought that Glivec treats HIV/AIDS.²⁵ While the grounds for the denial are somewhat technical, the heart of the dispute can be accurately understood to be about India's new patent laws being unusually harsh on incremental innovations that would be readily accepted in other nations.

²³ David, R. (2007). Novartis Set Back In India Patent Fight Over Glivec. Forbes.

²⁴ Raju, K. (2007). "The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement." Social Science Research Network: 1-19.

²⁵ Novartis Pharmaceuticals Corporation. "Glivec Patent Case in India: Fact vs. Fiction." Retrieved 25 June, 2010, from <http://www.novartis.com/downloads/about-novartis/facts-vs-fiction-india-glivec-patent-case.pdf>.

As the appeal neared its day in court, the controversy heated up and many waited to see just how generous India's new laws would be with product patents. Many saw the decision as threatening to India's thriving generic drug industry. These speculations were confirmed when Health Minister Anbumani Ramadoss demanded that Novartis withdraw its appeal and even warned that, "India hadn't used compulsory licensing yet and 'shouldn't be pushed towards that'."²⁶ As one author from the World Markets Research Centre puts it, "This is the first instance in which the Indian political setup has reacted so strongly against the patent litigation, and points credence to the health activists' contention that a potential change in intellectual property laws would result in a dearth of essential cheap generics."²⁷ Novartis did not heed the warning and continued to press its appeal and sustained considerable criticism for doing so.²⁸

The Health Minister's threat to use a CL, however, turned out to be unnecessary. The Madras High Court upheld the original product patent denial for Glivec.²⁹ While this case did not end in a CL, it is interesting that the Health Minister postured in such a way that it was clear that India could very well utilize the CL flexibility if the High Court reversed the original ruling. To reflect India's convincing posturing that it would issue a CL if Novartis had successful appeal to the patent denial, the "CL Outcome" column of Table 3.1 has been marked as "Negative (Positive Potential)." India is clearly walking a

²⁶ David, R. (2007). Novartis Set Back In India Patent Fight Over Glivec. [Forbes](#).

²⁷ Krishnan, A. (2007). Compulsory Licensing Threat over Novartis' Gleevec Legislation Issued by Indian Health Minister. [World Markets Research Centre](#).

²⁸ Bucknell, D. (2007). Novartis' Glivec Battle with India - Patentability of Pharmaceutical Extension Patents. **2010**.

²⁹ David, R. (2007). Novartis Set Back In India Patent Fight Over Glivec. [Forbes](#).

very precarious line of trying to abide by WTO standards while protecting its generic drug industry, and it is possible that India would be willing to use CLs in order to protect it.

Factor 1 – Single or Centralized Buyer Health System

India’s health system is complex, complicated, and diverse. There are two main divisions at the federal level that oversee health governance, and many more subdivisions at the state level. India faces several challenges with outreach to rural communities in which the private sector is playing an especially important role. 75 percent of healthcare financing is generated through private means while only 25 percent is generated through public means. Of the 75 percent of private healthcare, 70 percent is bore by households and 6 percent is provided by other sources such as employers. 97 percent of private healthcare in India is paid for out-of-pocket.³⁰

The somewhat disjointed health delivery and financing system in India is reflected in its low level of centralization of public health governance. Therefore, the “Single or Centralized Buyer Health System” column in Table 3.1 has been marked as having a “Low” presence in the India case.

Factor 2 – Number of Patients Impacted

Just as in the Korea case, the types of leukemia that Glivec is used to treat are rare and data as to the actual prevalence of these diseases are not readily available. Novartis reported that it was supplying 6,700 patients with Glivec, which represented about 99 percent of the population that uses the product in India. This case is nuanced by the fact

³⁰ World Health Organization India. 11 Health Questions about the 11 SEAR Countries: 80-109.

that India's generic production is often primed for export and relevant to a far greater cohort than simply its domestic patients. However, the case is framed as a domestic matter only for rare forms of cancer. Therefore, the population in question is again relatively low. The "Number of Patients Affected" column in Table 3.1 has been marked as having a "Low" presence in the India case.

Factor 3 – Political Implications

The weight of significance that this particular case gained was impressive. Not only was the case political, but it was also important to India's legal system and economy. Once it began to be perceived as a possible precedent-setting case that could impact the drug industry, there was immediate and serious talk of utilizing the CL system. The level of engagement from civil society and patient groups, many of which misunderstood the true nature of the case, took hold only once the case became politicized. Even though a CL was never actually issued, India seemed willing to pursue it. Civil society and interest groups, however, did not need to convince the health minister of the seriousness of this case. The "Political Implications" column of Table 3.1, therefore, has been marked as having a "High" presence.

The Philippines - Case Study Briefing

The CL dispute in the Philippines is over a hypertension medication called "Norvasc" (the generic name is "amlodipine"), for which pharmaceutical giant Pfizer held patent rights. The conflict arose as the Norvasc patent neared its scheduled expiration date of June 2007. The Philippine patent law states that parallel importing is legal as soon as patents expire. The state-owned Philippine International Trading Corp

(PITC) is the nation's primary purchaser of pharmaceuticals. PITC's drug procurement budget was scheduled to be tripled in March 2007 in an effort to improve the drug stock in government-subsidized pharmacies throughout the country.³¹

In anticipation of the Norvasc patent expiration and the budget increase for drug procurement, PITC imported samples of generic versions of Norvasc from both India and Pakistan and submitted them to the Philippine Bureau of Food and Drug Administration (BFDA) for approval. PITC submitted the samples over a year prior to the Norvasc patent expiration in order to be poised to distribute cheaper versions of the drug as early as June 2007.³² The primary Indian pharmaceutical manufacture that was in line to supply the drug is coincidentally named "Dr. Reddy."³³

When Pfizer discovered this was happening, the firm filed a lawsuit on 1 March 2006 against both PITC and the BFDA for patent infringement, arguing that the Philippine officials were engaged in the "early working" of a patent.³⁴ Pfizer stated that in addition to its concerns with the rights infringement, the firm also worried about the safety and quality of the drugs that the PITC and BFDA were planning to import. Reading between the lines, CPTech attorney Judit Rius Sanjuan speculated that Pfizer's intent was to delay

³¹ Ando, G. (2007). Thai Government Expands Scope of Patent Breaking Strategy Amid Unrest in Asia, World Market Research Centre-Global Insight.

³² Datta, P. T. J. (2006). Pfizer Worried Over Parallel Import of Norvasc into the Philippines, Business Line.

³³ Ando, G. (2006). Pfizer Sues Philippine Government over Parallel Imports of Generic Norvasc, World Markets Research Centre.

³⁴ Leonard, A. (2006). Pfizer's Philippine Follies. [Salon](#).

the initiation of the parallel importing so that the firm can benefit from several more months of its monopoly.³⁵

Philippine state officials responded immediately to Pfizer and iterated that parallel imports were not to be scheduled until the patent had expired. Pfizer did not accept the explanation and continued to press its lawsuit. In mid-November 2006, patient groups that would directly benefit from the availability of a generic version of Norvasc and NGOS such as Oxfam began voicing their opinions and protesting.³⁶ It was from these groups that cries for a CL began to build.

Instead of pursuing a CL, PITC counsel found another way to deal with the situation and filed a petition to cancel the Pfizer patent. They were tipped off by a dispute over a Norvasc patent in the US earlier in the year. PITC used a similar argument, stating that the drug was not truly a novel product and that it was an obvious variation upon earlier innovations. Alberto Agra, PITC's legal counsel, said: "It is the position of government that the patent...issued was void from the beginning and therefore it should be cancelled today." If the case were decided in the PITC's favor, the Pfizer patent would be rescinded a month before its scheduled expiration.³⁷ PITC touted that this could represent a landmark case and a victory over a pharmaceutical giant; however, many wondered if it was better to wait until the patent expired naturally.³⁸

³⁵ Datta, P. T. J. (2006). Pfizer Worried Over Parallel Import of Norvasc into the Philippines, Business Line.

³⁶ Macan-Markar, M. (2006). Asian Govts Push Generic Drugs. IPS. Bangkok.

³⁷ Cerojano, T. (2007). Philippines Files Petition to Cancel Pfizer's Patent on Hypertension Drug Norvasc, Business News, Associated Press Worldstream.

³⁸ Tan, R. D. (2007). "PITC Files Landmark Patent Case against Norvasc ...even if Patent for Hypertension Drug to Expire in June." Retrieved 25 June, 2010, from http://www.pitc.gov.ph/archives/patent_case.html.

The direction of the case from this point forward has not been publicized. It is unclear if the BFDA had to wait to consider the imported generic imitations of Novarsc or whether the patent was voided. It is clear, however, that the brief time in which Philippine officials may have considered a CL was curtailed by the opportunity to rescind the patent altogether. Philippine state officials never explicitly announced that they would issue a CL, however, their aggressive engagement with Pfizer over the issue is suggestive that CLs may have been entertained had they not have found an alternative path to void the patent. To account for this contingent yet significant dynamic, the outcome column of Table 3.1 has been marked as "Negative (Positive Potential)." Further justification for this delineation will be discussed in the closing section of this chapter.

Factor 1 – Single or Centralized Buyer Health System

The Philippine health system is considered to be fairly fragmented, especially at the rural level. The nation is currently undergoing structural changes to harmonize the various private and public health providers throughout the nation. The health system is financed largely through private sources and the burden upon households to pay for care out-of-pocket is almost 50 percent, which is very high. Most care is paid for on a fee-for-service basis at hospitals, a symptom that coverage is not adequate and cost of care is a deterrent for Filipinos and preventative and health promotion programs cannot get much of a foothold. There is a nascent national health insurance program called “PhilHealth.”

The program is gaining momentum and currently covers about 74 percent of the population, but only does so with a low benefit ceiling.³⁹

While the nation's health system itself cannot be described as centralized, the PITC can be. The agency buys the overwhelming majority of pharmaceuticals for the health system. Since Pfizer's dispute was primarily with PITC, the "Single or Centralized Buyer" column of Table 3.1 has been marked as having a "High" presence in this case.

Factor 2 – Number of Patients Impacted

Cardiovascular disease is among the most common causes of death in the Philippines. In 2006, heart diseases and hypertension ranked seventh and fourth respectively among the nation's ten leading causes of death. The WHO estimated in 2003 that cardiovascular diseases accounted for 30.2 percent of all deaths in the Philippines.⁴⁰ The "Number of Patients Affected" column of Table 3.1 has been marked as having a "High" presence in case of the Philippines.

Factor 3 – Political Implications

Once this case was fully publicized, there was a large presence from NGOs like Oxfam and patient groups demanding that Pfizer remove the lawsuit or that Philippine officials invoke a CL. As there were other fronts upon which PITC could mount a battle and because the issue was primarily over how soon after a patent's expiration generics may enter the market, Philippine officials were wise to refrain from use of the CL

³⁹ World Health Organization. (2005-2010). "Philippines - Health System." Retrieved 25 June, 2010, from http://www.wpro.who.int/countries/2009/phl/national_health_priorities.htm.

⁴⁰ World Health Organization. (2005-2010). "Philippines - Health Situation and Trend." Retrieved 25 June, 2010, from http://www.wpro.who.int/countries/2009/phl/health_situation.htm.

flexibilities afforded to them by TRIPS. Protests and NGO involvement started only once the lawsuit was publicized; nevertheless, the call for a CL did not initially stem from the Philippine government, probably because it had another plan. The consequences of the CL decision does not seem to have a compelling presence either; still, it is clear that state officials seemed to relish the muscle flexing contest of legal might. The “Political Implication” column of Table 3.1 has been marked as having an “Ambiguous” presence in this case.

Thailand - Case Study Briefing

Thailand has clearly been the most active user of the CL policy. It has also been the most robust, in the sense that it has used CLs to procure less expensive drugs to treat a larger variety of diseases (i.e., HIV/AIDS, cancers, and cardiovascular diseases).

Thailand is the only nation to clearly and unequivocally issue a CL in the name of chronic illness. For the sake of brevity, and because there are multiple CL disputes that stretch from late-2006 through 2010 in Thailand, the case description in this section will be more general than the other case briefings in this chapter.

There were two surges of CLs from Thailand. The first was in late 2006 and early 2007 when Mongkol na Songkhla, the Thai Minister of Health, issued CLs for Kaletra and Efavirenz, which are both ARVs for HIV/AIDS, and Plavix, a blood-thinner used to manage cardiovascular disease. Thailand also was able to negotiate a price cut using the

threat of a CL to acquire Glivec for free,⁴¹ the same drug over which disputes took place in Korea and India.⁴²

Mongkol na Songkhla initiated the second wave of CLs later in 2007. The CLs were for Novartis' Letrozole, Sanofi-Aventis' Docetaxel, and Roche's Erlotinib, which are used to treat varying types of cancers including those of the breast, lung, ovaries, and pancreas. Mongkol na Songkhla was replaced in early 2008, however, by Chaiya Sasomsab, who threatened to rescind this second batch of CLs shortly after taking his post as the new Minister of Health. After sustaining substantial criticism from the general Thai public, international NGOs, and patient groups, Chaiya Sasomsab announced that there were major legal obstacles and that he was unable to revoke the CLs.⁴³

There is limited agreement on how and why exactly the Thai CLs happened. The dominant explanation focuses upon the military coup that occurred in 2006. The coup's new governing authorities struggled to gain the support of the general public, which questioned its legitimacy and criticized its alleged lack of concern for the needs of the poor. Pro-poor policy has played an important role in the politics of Thailand since the economic crisis of 1997, which instilled the awareness within Thais that social security and public protections from financial catastrophes are desirable for all members of society. Thailand's relatively quick recovery from the economic crisis bolstered

⁴¹ Pharma Marketletter (2008). New Thailand govt's compulsory drug licensing policy swings back and forth. [Pharma Marketletter](#).

⁴² The Nation - Thailand. (2008, 8 March). "Generic Drug Debate Intensifies." [The Nation - Thailand](#) Retrieved 25 June, 2010, from http://unitcost.fda.moph.go.th/cl/newsfile_file/newsfile_20080910044737-1.pdf.

⁴³ Shashikant, S. (2008). Compulsory Licensing of Cancer Drugs in Thailand. [Third World Network](#), TWN Info Service on Health Issues.

continued support for the enlargement of national welfare and social insurance schemes.⁴⁴ In fact, the Thai Rak Thai (TRT), which was the last ruling party before the coup, used the idea of universal healthcare coverage as a major campaign theme. It was so successful that some considered the party's view on healthcare reform to have won it the election in 2001.⁴⁵ Therefore, the most common explanation for the phenomenon is that the coup empowered the Minister of Health to issue CLs in order to win over public support and gain legitimacy in the following ways: by demonstrating its pro-poor concerns by expanding state health coverage to include more HIV/AIDS, cardiovascular disease, and cancer drugs; by challenging pharmaceutical giants and big business in the name of health and of the poor; and by invoking the flexibilities afforded by the WTO, a symbol of strategic engagement on the international scene for the good of Thai people.

The Thai Ministry of Public Health (MoPH) had been struggling to expand the coverage of its social insurance scheme and deal more effectively with Thailand's aging demographic. The MoPH was frustrated with price negotiations that had stretched out for several years with pharmaceutical giants. When the political climate changed, so could the nature of these negotiations. Perhaps the most honest and revealing statement came from Suwit Wibulprasert, Disease Control Senior Advisor in the Thai Ministry of Public Health, "People told us, 'It's useless to negotiate with them [the pharmaceutical giants] unless you start to announce that you want to go for compulsory licensing. Then

⁴⁴ International Development Research Centre (2008). Safeguarding the Health Sector in Times of Macroeconomic Instability. Trenton, Africa World Press, Inc.

⁴⁵ Pannarunothai, S., Patmasiriwat, Direk, Srithamrongsawat, Samrit (2004). "Universal Health Coverage in Thailand: Ideas for Reform and Policy Struggling." Health Policy **68**: 17-30.

they start to talk to you'.⁴⁶ The outcome column of Table 3.1 is clearly positive for the Thailand case study.

Factor 1 – Single or Centralized Buyer Health System

Thailand has a centralized health system that is primarily funded through public means. It implemented its famous “30 *Baht* Plan” in April 2002, which entitles beneficiaries to a wide range of health services for a low copayment of only 30 baht, currently valued at about 90 US cents. By 2004 the 30 *Baht* Scheme covered over 75 percent of Thais and two other social insurance schemes covered another 20 percent, leaving less than four percent of the population without public insurance.⁴⁷ These public insurance plans are financed jointly by government revenue raised through taxation, out-of-pocket payments, and mandatory contributions paid by employees and their employers to a social fund.⁴⁸ The 30 *baht* copayment does contribute a modest amount to funding the plan, but it only pays for two percent of the total cost of the program.⁴⁹

The National Health Security Office (NHSO), which was established alongside the 30 *Baht* Plan, exists autonomously from the MoPH and its role is to purchase health care and products for the country. The NHSO is intended to be a centralized purchaser that can use its discretion to buy the best care for the price regardless of agencies’ status as public

⁴⁶ Quoted in Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

⁴⁷ International Development Research Centre (2008). Safeguarding the Health Sector in Times of Macroeconomic Instability. Trenton, Africa World Press, Inc.

⁴⁸ Towse, H. (2003). "Thailand: the 30 Baht Health Plan." Student BMJ 11: 208.

⁴⁹ Pannarunothai, S., Patmasiriwat, Direk, Srithamrongsawat, Samrit (2004). "Universal Health Coverage in Thailand: Ideas for Reform and Policy Struggling." Health Policy 68: 17-30.

or private.⁵⁰ The “Single or Centralized Buyer” column of Table 3.1 has been marked to reflect having a “High” presence in the Thailand case study.

Factor 2 – Number of Patients Impacted

Thailand, like the other nations in this comparison, is undergoing a demographic transition. The nation’s disease profile is morphing from one rife with contagious diseases and high infant mortality to one dominated by the chronic diseases that plague the elderly. This is observable in the Thailand’s demographic data over the last 15 years. Chronic disease prevalence has more than doubled. Cancer, hypertension, and cardiovascular diseases are now the most common cause of mortality among Thais.⁵¹ The MoPH estimated that the second wave of CLs alone would impact an estimated 62,000 patients needing these drugs over the next five years.⁵² Due to the high prevalence of cancer and cardiovascular diseases and the bundling of CLs in the Thailand case study, the “Number of Patients Impacted” column of Table 3.1 has been marked to reflect having a “High” presence in this case.

Factor 3 – Political Implications

The political components of this case are substantial and were described in the case description. Many view the CLs as a consequence of the coup and argue that the CLs would not have happened under normal conditions. The transitional government was

⁵⁰ Ibid.

⁵¹ World Health Organization (2007). Thailand. 11 Health Questions about the 11 SEAR Countries. R. O. f. S.-E. Asia: 248-277.

⁵² The Nation - Thailand. (2008, 8 March). "Generic Drug Debate Intensifies." The Nation - Thailand Retrieved 25 June, 2010, from http://unitcost.fda.moph.go.th/cl/newsfile_file/newsfile_20080910044737-1.pdf.

seeking legitimacy and attempting to win public support by demonstrating its pro-poor politics that had become so popular in the country over the last decade. It is clear in this case that the CLs stemmed from those occupying state offices. The “Political Implications” column of Table 3.1 has been marked to reflect having a “High” presence.

The overall results of the comparison are depicted in Table 3.1. While more cases are needed to make any concrete conclusions, these results are suggestive that “Factor 3 - Political Implications” is the most influential upon the outcome of the three factors investigated.

The first factor investigated in each case was the single or centralized buyer variable. This factor was chosen because of the suspicion that arose in Chapter Two that nations intimately involved with purchasing its healthcare goods and services would have a stronger incentive to control costs, e.g., Brazil and Thailand, than nations that leave pricing to the private market. While each nation had a national healthcare purchasing agency or social insurance scheme except for India, the CL case outcome did not show a consistent pattern in Table 3.1. The Korea case reflected a high presence of this variable, but had a negative CL outcome because the national insurance program simply decided to cover less of the drug instead of forcefully demanding a lower price or access to cheaper generic alternatives. In contrast to the Korean case, both the Philippine and Thai cases had a high presence of this factor and a correspondingly positive CL outcome. The India case shows yet another pattern. It reflects a low presence of this variable and still showed a solid potential to carry out a CL for a chronic disease, if pushed. While the “Single or

Centralized Buyer” condition might better position state authorities to issue a CL and negotiate, as in the case of the Philippines and Thailand, it is not an especially weighty factor in shaping the outcome in a consistent manner when comparing these four cases.

The second variable investigated in the four case studies is the number of patients impacted factor. This factor was selected because it seems reasonable to expect that the more patients who are affected by the disease in question, the more the situation appears to be a public health emergency and warrant a CL. The cases in Thailand and the Philippines certainly had a presence of references to the high prevalence of the diseases in the respective nations, and there was a correspondingly positive or potentially positive CL outcome. Conversely, the Korea case study did not impact a large pool of patients and is combined with a negative CL outcome. These three cases show a consistent pattern of positive variable presence coupled with a positive CL outcome and vice versa; however, the India case again shows a different pattern. Despite the rare disease and low number of Indian patients impacted, there were still promising signs of India’s willingness to use the CL system. Therefore, while important in some of the cases, the number of patients impacted factor does not appear to hold a strong and consistent affect on the outcome in all cases in Table 3.1.

The “Political Implications” variable was the third factor considered in each of the four cases. It was selected because of the suspicion that when states have an added incentive or feel forced to invoke a CL, they will be more likely to do so than in cases in which improving public health is the only motive.

The Korea case was rather inconsequential politically-speaking; therefore, the government was unresponsive to public demands and even intervened on one occasion to prevent patient groups from meeting with Novartis-Korea directly. There was a low presence of the “Political Implications” factor and a negative CL outcome in Table 3.1. Conversely, an unusual set of political circumstances made for a disproportionately high presence of the political factor in the Thailand case, as was discussed in the case study’s briefing, and an unequivocally positive CL outcome (five patent disputes for chronic illness).

The Philippines case is particularly strange; the force with which both Pfizer and the Philippine state authorities reacted did not seem commensurate with what was at stake. If the case were to become precedent setting, then it is possible that the PITC would have to wait for expiration of all drug patents before applying for BFDA approval of generic equivalents. Still, it is not clear a decision in favor of Pfizer would necessarily set that precedent. Pfizer’s powerful reaction is even more difficult to understand. The pharmaceutical giants’ reputation in South East Asia were already suffering, so why risk worsening it and further polarizing drug firms and South East Asian nations for what could amount to a very small financial return? It seems that the case could have been more about the flexing of political muscle and a testing of power than anything else. If so, then politics were definitely instrumental in this case and may have resulted in a positive CL outcome, had the Philippines not found the opportunity to void the patent altogether.

Similarly, there were political and economic implications present in the India case study, even though a CL was not issued in the end. India certainly postured as though it would issue a CL if the court decided in favor of Novartis in order to protect its generic drug industry and cope with the undesirable precedent that the case could have set in India. Both the Philippines case and the India case have a presence of the political factor in Table 3.1 coupled with good potential to have a positive CL outcome.

Therefore, the answer to one of the questions raised in the introduction of this chapter regarding which factor would prove most influential within the four cases evaluated in this study appears to be “Factor 3 – Political Implications”. This variable shows the most consistent pattern in Table 3.1 of its presence in combination with a positive or potentially positive CL outcome and vice versa throughout all four cases. This conclusion is buttressed by the fact that the India case possesses good potential to issue a CL even without a strong presence of Factor 1 and 2. In other words, it seemed possible that India could have produced a positive CL outcome with only a strong presence of “Factor 3 – Political Implications” alone.

This conclusion is rather provocative. The implication is that in the case of medications that treat chronic disease, the predominant motive of the state for overriding drug patents is probably not public health, at least not exclusively. How the case is situated politically and legally certainly seems to eclipse the severity of the public health issue in predicting the likelihood of a CL for a chronic illness, regardless of whether or not the government is normally involved with national pharmaceutical purchasing. This comparative study suggests that states responding rationally to a particular set of political

and legal concerns is of equal or of greater importance than concerns about improving health when it comes to suspending patents for chronic illness. Health is an added benefit of CLs for chronic diseases, but in these cases, states' CL behavior seems to have just as much to do with politics as it does with public health.

The other question posed in the introduction of this chapter is why Thailand is such an outlier in its frequent and robust use of the CL policy. While Factor 3 appears to be the most potent variable, Factors 1 and 2 have not been totally discounted as playing a role in producing a positive outcome. Certainly, it is possible that the political implication factor could be magnified by a strong presence of a centralized national healthcare purchasing agency (Factor 1) in combination with a large number of patients affected by the decision (Factor 2). These factors, joined with the structural elements such as national income described in Chapter 2, would make a nation such as Thailand especially capable of issuing CLs. In other words, Thailand could be said to be the perfect suspect to issue CLs as it possesses the ideal constellation of all variables entertained by this paper that would make a nation capable and likely to use them.

A third concern raised in the introduction of this chapter is that Thailand would become the first of many nations to issue CLs for chronic illness. This analysis shows that a rather complex set of circumstances is required to create another situation like Thailand, and it would seem unlikely, therefore, that other nations will be able to imitate the Thai CL behavior to the same degree. This conclusion tempers the suspicion that has been entertained throughout this paper that CLs will become more common in the future for chronic illness.

CHAPTER FOUR. CONCLUSIONS, IMPLICATIONS, AND APPLICATIONS

The collection of CL case studies gathered since TRIPS' genesis shows several patterns. (i) Most of the cases occurred between 2004 and 2007 with fewer cases before and after this timeframe. (ii) Brazil and (iii) Thailand have used the CL policy the most. Brazil has used it exclusively for ARVs, while Thailand has used the policy for a variety of diseases. (iv) Significantly more CL activity seems to be in middle-income nations, rather than low- or high-income nations. (v) Most of the CLs disputes have been about branded ARVs therapies used to palliate HIV/AIDS.

These observations have some simple, yet significant implications. First, the CL policy as it was originally conceived at the Uruguay Round was not very useful at a global scale. It was seldom used prior to Doha and each of those uses was questionable. Because the policy was not applicable to most developing member states and because of the sequence of events that preceded the Doha Round, the CL policy was amended in a way that deemed it more useful at a global scale. Once the amendment made at Doha were fully instituted in August of 2003, there was a CL spike between 2004 and 2007.

A second implication of the trends observable in the CL case studies, as is shown by Table 2.2, is that most CLs have been issued by middle income nations in order to procure more ARVs at a lower cost. The theoretical discussion in Chapter Two provides both institutional and structural reasons why this phenomenon might occur. Patentable medical innovation targets diseases most common in developed nations, and many of these diseases are not the same ones that developing nations' health systems are targeting. The HIV/AIDS epidemic provides a window into understanding what happens at a global

scale when nations of all income levels share a common disease threat—technological innovation occurs most rapidly in resource rich nations and then flows through middle income nations to other middle income and low income nations. The TRIPS' agreement created a blockage in this flow. This was the state of affairs prior to TRIPS and why developing nations claimed that their access to pharmaceuticals was significantly diminished as TRIPS mandates were implemented. A major goal of TRIPS was to increase the trade of technologically innovative products; when it comes to pharmaceuticals, it initially had the opposite effect in this industry.

The severity of the blockage of developing nations' access to branded pharmaceutical innovations is only as serious as the overlap of diseases that the developing world is experiencing and the developed world is innovating for. The theoretical discussion on the epidemiological transition shows why that overlap is not typically significant. Attaran's study shows that the overwhelming majority of medications demanded by low income nations are not patented. Nevertheless, wealth and development is projected to significantly increase in the future, especially in Asia. As nations develop, their populations' illnesses will become increasingly and rapidly similar to high income nations, especially in the area of chronic diseases such as cancer and heart disease. Therefore, scenarios in which there is significant overlap in disease profiles between developed and developing nations will become more likely, especially as developing nations begin to experience population aging. Moving through the stages of this epidemiological transition is likely to cause nations to demand treatments for chronic

illness and to be forced to increase their investment into the health system. For these theoretical reasons, one might expect to see more CLs in the future for chronic illness.

A third pattern observable in the CL outcomes is that the many of case studies' outcomes for middle income countries tend to end with pharmaceutical firms offering them significant discounts and donation programs. This certainly seems to be the precedent that was set by Doha, as WTO members acknowledged the CL policy as a powerful bargaining tool. The Doha Round released some of the blockage preventing the flow of medical technology from the developed world into middle income and low income nations. The difference--relative to the pre-TRIPS state of affairs--is that member states have the incentive to bring this flow through an international legal channel; when situations become desperate, the CL safeguard is likely to be a mechanism that brings discounted products for public health into developing nations. Prior to TRIPS, flows tended to go through middle income nations with pharmaceutical production capability to low income nations; post-Doha, legal flows are likely to be channeled from high income nations directly to both middle and low income nations. While pharmaceutical firms are forced to offer greater discounts in order to be the sole provider of a particular branded drug, middle income nations are less likely to manufacture them domestically or import them from other middle income nations.

The post-Doha state of affairs is preferable to that of TRIPS as it was originally conceived because developing nations have better accessibility to badly needed high-tech drugs. While this more effectively achieves one of TRIPS goals, which is that more will have access to branded medicines, it does not stimulate technological capacity transfer

into middle and low income nations. Patent protection obligations to the WTO and irresistible discounts and donation programs will make middle income nations more likely to accept the buy-out from pharmaceutical giants than produce the drug domestically. Pharmaceutical production in middle income nations is one important way to build domestic manufacturing capabilities, especially when the drugs are in high demand and will yield research and development revenue.¹

It is easy to imagine situations in which global interests in maximizing the level of innovation while maintaining the highest levels of accessibility possible may supersede and contradict the interests of a particular pharmaceutical firm, a particular state, or both. While bystanders cannot determine whether pharmaceutical firms manage to profit despite the large discounts and donations that they give in order to prevent a CL, one must wonder what the pay off for pharmaceutical firms is. Is the motive to delay competition by the postponing the recipient nation from building its own drug production capacities? How are these discounts financially feasible? Is the pharmaceutical firm simply price-shifting, charging the ill in developed nations higher prices in order to subsidize those in developing nations?² And if Bristol Myers Squibb gives Brazil a discount, for example, is it less likely to give a discount or donation to Mozambique?

The frightening implication of Chapter Three is that nations may very well issue CLs for

¹ Correa, C. M. (2003). *Managing the Provision of Knowledge: The Design of Intellectual Property Laws. Providing Global Public Goods: Managing Globalization*. I. Kaul, Conceicao, Pedro, Le Goulven, Katell, Mendoza, Ronald U. Oxford, Oxford University Press: 410-429.

² Fuller writes that PhRMA “argues that US consumers are unfairly carrying the burden of financing research for the rest of the world. ‘Americans are effectively subsidizing other countries’ health systems through higher prices, while having fewer medicines from which to choose,’ the group said in its complaint to the U.S. government.” Fuller, T. (2007). *Thailand Takes on Drug Industry, and May Be Winning*. New York Times. New York.

reasons other than health without much regard for the impacts on research and developed in other parts of the world.

The answers to these questions certainly are a serious reminder that negotiations involving multinational corporations are not done in a vacuum. One nation's demands will impact what the firm can deliver to another. Nations with the most profitable markets will naturally be accommodated over less profitable ones. The CL system as it stands, therefore, has no intermediary entity that keeps a watchful eye on the possible externalities of negotiations during patent disputes and that advocates for the best outcome from a global prospective. While a presence from such a supranational global health governance entity such as the WHO might slow down processes during epidemics, there ought to be time when it comes to treatments for chronic disease. It is hard to imagine that the optimal global management of novel medical knowledge will arise naturally in a system that leaves national interests to play against private international corporate interests without regard to global governance. While such involvement from a global health entity is unrealistic and idealistic, the lack thereof is worth mention. Even having greater transparency in these matters, which is largely the purpose of this research, would be a step in the right direction.

Time will tell whether CLs will be a sporadic occurrence or will become commonplace for transitioning nations to access the patented medical technologies of the developed world. Either way, it is clear that the CL policy is playing a different function than the one it was originally designed for. The CL policy was created to accommodate a reasonable provision that is common in national patent laws and provides some legal

maneuverability for states during unusual and unforeseen situations. The Doha Round transformed it into a possible tool for development. This paper gives some reason to suspect that these situations will become increasingly common as nations go through the stages of the epidemiological transition. Retrofitting the CL policy in order to open channels to patented drugs for the developing world without regard to global health governance could have unintended, adverse, and certainly suboptimal long-term effects.

TABLES

Table 2.1 CL Case Study Survey

Year(s)	Nation	GNI	# of Potential CLs	Disease	Disease Scenario Type	Outcome
2001	Canada	High	1	Anthrax	Type I	Discount
2001, 2007	Brazil	Middle	2	HIV/AIDS	Type II	Discount
2001	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2005	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2005	Brazil	Middle	1	HIV/AIDS	Type II	Discount
2010	Ecuador	Middle	1	HIV/AIDS	Type II	CL
2005	Eritrea	Low	1	HIV/AIDS	Type II	CL
2005	Ghana	Low	1	HIV/AIDS	Type II	CL
2006-2007	India	Middle	1	Cancer	Type III	None
2005	Indonesia	Middle	2	HIV/AIDS	Type II	CL
2005	Korea	High	1	Pandemic flu	Type I	VL
2001-2002	Korea	High	1	Cancer	Type III	None
2003-2004	Malaysia	Middle	3	HIV/AIDS	Type II	CL
2004	Mozambique	Low	3	HIV/AIDS	Type II	CL
2004	Philippines	Middle	1	Cardiovascular disease	Type III	None
2007	Rwanda	Low	1	HIV/AIDS	Type II	CL
2001-2003	South Africa	Middle	8	HIV/AIDS	Type II	CL/VL/ Discount/None
2005	Taiwan/China	Middle	1	Pandemic flu	Type I	Discount
2006, 2010	Thailand	Middle	1	HIV/AIDS	Type II	CL
2007, 2010	Thailand	Middle	2	HIV/AIDS, Cardiovascular disease	Type II, Type III	CL
2007-2008	Thailand	Middle	1	Cancer	Type III	Discount
2007-2008	Thailand	Middle	3	Cancer	Type III	CL
2001	United States	High	1	Anthrax	Type I	Discount
2004	Zambia	Low	3	HIV/AIDS	Type II	CL
2003-2004	Zimbabwe	Low	1	HIV/AIDS	Type II	CL

**Nations' incomes were classified using the World Bank's GNI listings for the year closest to that of the CL case study (data is available for 2000, 2005, 2007, and 2008). "Low" income is \$975 or less per capita per year; "Middle" is above \$975, but less than \$11,905 (for simplicity, this table combines the World Bank's "lower middle income" and "upper middle income"); and "High" is more than \$11,905 (World Bank 2010).*

Table 2.2 CLs by Income and by Disease Type Scenario

	Type I		Type II		Type III		Total	
	#	%	#	%	#	%	#	%
Low income	0	0%	10	23.26%	0	0%	10	23.26%
Middle income	1	2.33%	21	48.84%	7	16.28%	29	67.44%
High income	3	6.98%	0	0%	1	2.33%	4	9.3%
Total	4	9.3%	31	72.09%	8	28.60%	43	100%

Table 3.1 Case Study Comparison of CLs for Chronic Illness

Nation	Factor 1 - Number of Patients Impacted	Factor 2 - Single or Centralized Buyer	Factor 3 - Political Implications	Outcome
Korea	Low	High	Low	Negative
India	Low	Low	High	Negative (Positive Potential)
Philippines	High	High	Ambiguous	Negative (Positive Potential)
Thailand	High	High	High	Positive

FIGURES

Figure 2.1 CL Case Studies by National Income and Disease Scenario

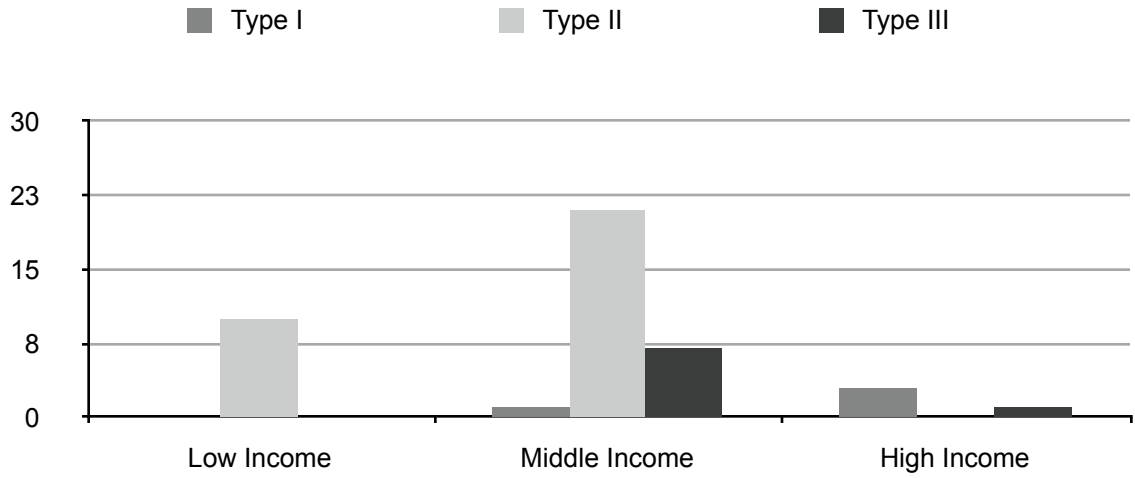


Figure 2.2 Historical Progression of CLs from TRIPS to Thailand

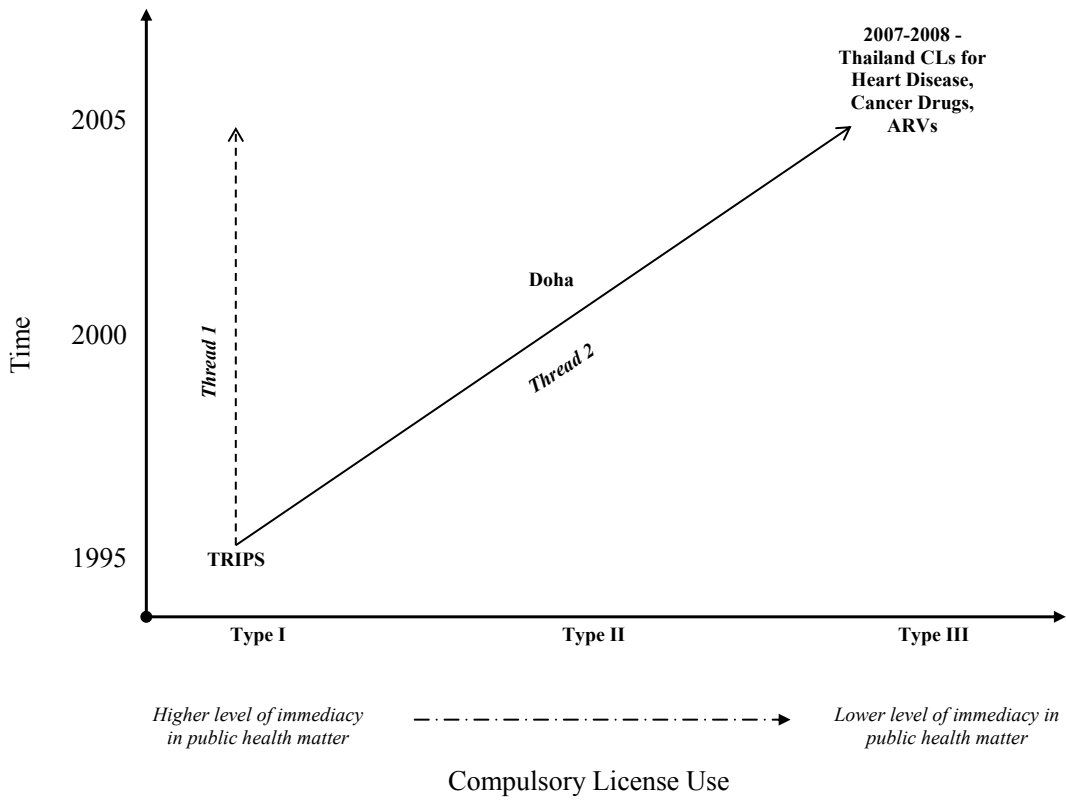
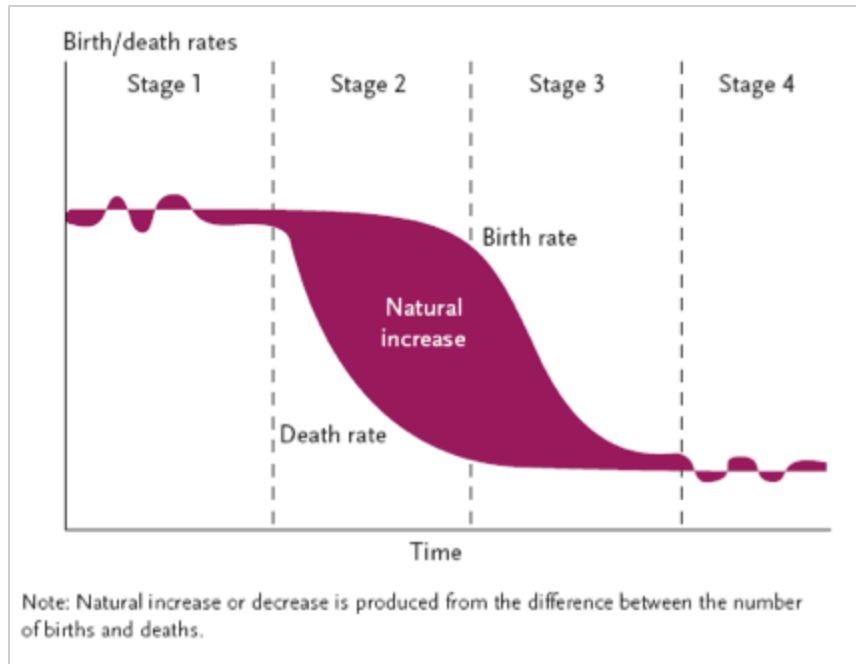
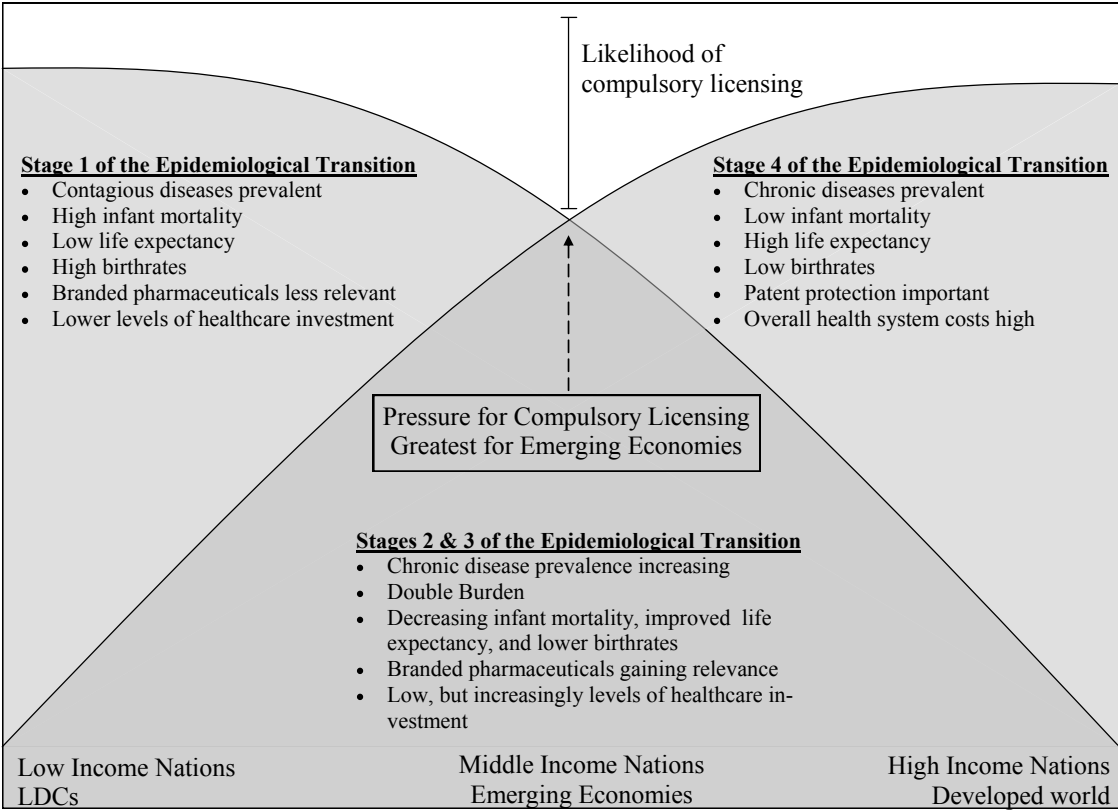


Figure 2.3 Classic Stages of the Epidemiological Transition¹



¹ McFalls, J. A. (2007). "Population: A Lively Introduction." *Population Bulletin* 62(1): 1-36. @29

Figure 2.4 The Epidemiological Transition and Pressure for CLs



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APPENDIX A. CL CASE STUDY SUMMARIES

Brazil (and Merck)

Year(s): 2001, 2007

National Income: Upper Middle

Pharmaceutical Firm(s): Merck

Drug(s): Efavirenz (STOCRIN), Indinavir

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount

Case Study Summary: Brazil initiated a program to provide ARVs to patients free of charge. "Patent-breaking threats by the Brazilian government last March prompted Merck & Company to reduce the price of two AIDS drugs, indinavir and efavirenz, by around 60 percent in Brazil" (Rich 2001). Renegotiations have happened intermittently. In May 2007, issued a CL for Efavirenz (Bjornberg 2006; Sequera 2007; Zolotaryova 2008; Merck 2009-2010).

Selective Bibliography:

Bjornberg, J. (2006). "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?" Northwestern Journal of International Law & Business 27(Fall).

Merck. (2009-2010). "Improving Access to HIV and AIDS Treatment and Care." Retrieved 29 June, 2010, from <http://www.merck.com/corporate-responsibility/access/access-hiv-aids/approach.html>.

Rich, J. L. (2001). Roche Reaches Accord on Drug with Brazil. New York Times. New York.

Sequera, V. (2007). Brazil bypasses patent on Merck's AIDS drug. Associated Press Financial Wire. Brasilia.

Zolotaryova, V. (2008). "Are we there yet? Taking TRIPS to Brazil and Expanding Access to HIV/AIDS Medication." Brooklyn Journal of International Law 33: 1099-1126.

Brazil (and Roche)

Year(s): 2001

National Income: Upper Middle

Pharmaceutical Firm(s): Roche

Drug(s): Nelfinar (Viracept)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount

Case Study Summary:

“The Swiss drug giant Roche Holding reached an agreement with Brazilian health authorities...to cut the price of the AIDS drug Viracept by a further 40 percent, putting an end to threats by the government to break the patent and produce the drug locally...Brazil's health minister, Jose Serra, said that he had begun the process of issuing a license to produce nelfinavir, as Viracept is known generically, at a state-owned laboratory called Far-Manguinhos, after saying the talks with Roche over the price of the drug had ended in deadlock...[After successful renegotiations,] Mr. Serra announced the new agreement at a news conference today in Rio de Janeiro...In an effort to reduce AIDS-related deaths, Brazil's health service provides the drug cocktails free to patients, at a cost of \$303 million last year for about 100,000 patients...” (Rich 2001).

Selective Bibliography:

Bjornberg, J. (2006). "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?" Northwestern Journal of International Law & Business 27(Fall).

Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review 26(Summer): 385-410.

Rich, J. L. (2001). Roche Reaches Accord on Drug with Brazil. New York Times. New York.

Reuters News Agency (2001). Brazil Plans to Ignore Patent on AIDS Drug. Reuters. Rio de Janeiro.

Brazil (and Abbott)

Year(s): 2005

National Income: Upper Middle

Pharmaceutical Firm(s): Abbott

Drug(s): Kaletra (lopinavir + ritonavir)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount

Case Study Summary: “In June 2005, Brazil's Health Ministry threatened to infringe the patent on Kaletra, an anti-AIDS medication owned and developed by Abbott Laboratories; Brazil said that it would produce a generic version of the drug in government laboratories unless Abbott agreed to lower the price or voluntarily grant patent rights to the Brazilian government...in justifying its position, the health ministry asserted that the price of Kaletra ‘previous to the agreement was so high that it endangered the sustainability of Brazil's AIDS program’” (Bjornberg 2006). “Brazil's Health Minister Humberto Costa said last week that his ministry was issuing a compulsory license order for the Kaletra antiretroviral (ARV) drug on the Sao Paulo office of Illinois-based Abbott Laboratories Inc...Under the compulsory license, the first-ever issued by Brazil in a long-running battle over pricing between several developing countries and multinational companies, the price would be slashed from \$1.17 a pill to 68 cents” (Reuters News Agency 2005).

Selective Bibliography:

- Bjornberg, J. (2006). "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?" Northwestern Journal of International Law & Business 27(Fall).
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- Sequera, V. (2005). Brazil expects U.S. AIDS drug makers to comply with demands. Associated Press Worldstream. Brasilia.

Brazil (and Gilead)

Year(s): 2005-2006

National Income: Upper Middle

Pharmaceutical Firm(s): Gilead

Drug(s): Tenofovir

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount

Case Study Summary: “Brazil requested Merck & Co. Inc., Abbot Laboratories Inc. and Gilead Sciences Inc. to grant "voluntary licensing" of drug technology so it can keep its much-copied AIDS program afloat, the health ministry said. Brazil imports the four drugs used in its free, combination antiretroviral drug treatment. It wants to make copies and pay royalties. The products in question are Merck's efavirenz, Abbott's lopinavir and ritonavir, and Gilead's tenofovir. "We expect to cut by half what we currently pay," the ministry's health control secretary, Jarbas Barbosa, said in a statement on the request sent on Monday. Brazil has often threatened to break drug patents unless foreign manufacturers slash costs” (Reuters News Agency 2005). Gilead reports that in May 2006, the firm afforded Brazil a 50 percent discount (Gilead 2007).

Selective Bibliography:

Gilead. (2007, 27 February). "Form 10-K: Annual Report which Provides a Comprehensive Overview of the Company for the Past Year." from [@22](http://www.gilead.com/pdf/GILEADSCIENCESI10K.pdf)

Reuters News Agency (2005). Brazil takes step toward breaking AIDS patents. Reuters Health Medical News. Brasilia.

Sequera, V. (2005). Brazil expects U.S. AIDS drug makers to comply with demands. Associated Press Worldstream. Brasilia.

Canada

Year(s): 2001

National Income: High

Pharmaceutical Firm(s): Bayer

Drug(s): Cipro (ciproflaxin)

Disease: Anthrax

Disease Scenario Type: Type I

Outcome(s): Discount

Case Study Summary: Canada issued a CL as a precaution during the 2001 anthrax attacks. After a CL was announced, price negotiations between Canada and Bayer commenced. This case is discussed in more detail in Chapter Two.

Selective Bibliography:

Bradsher, K. (2001). Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine. New York Times. New York.

Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.

Harmon, A., Pear, Robert (2001). Canada Overrides Patent for Cipro to Treat Anthrax. New York Times. New York.

Ecuador

Year(s): 2010

National Income: Lower Middle

Pharmaceutical Firm: Abbott

Drug: Kaletra

Disease: HIV/AIDS

Disease Type Scenario: Type II

Outcome: CL

Case Study Summary: “Ecuador granted its first compulsory license for a patented pharmaceutical since declaring last year that it would utilize international rules allowing it to do so. The compulsory license was granted for ritonavir, an antiretroviral drug, on 14 April to Eskegroup SA, the local distributor for Cipla, an Indian generic pharmaceutical producer, according to Andrés Ycaza Mantilla, head of the Ecuadorean intellectual property office (IEPI). The owner of the patent is Abbott Laboratories, a US pharmaceutical manufacturer. Eskegroup will pay royalties to Abbott for using the license under the term of the compulsory license. The compulsory license has been granted for the time that was left on the patent, until 30 November 2014” (Saez 2010).

Selective Bibliography:

Claux, D. (2010). Kaletra's Compulsory License Divides Opinion in Ecuador. World Markets Research Center.

Saez, C. (2010). "Ecuador Grants First Compulsory License, For HIV/AIDS Drug." Retrieved 29 June, 2010, from <http://www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hiv-aids-drug/>.

Valdivieso, J. (2009). Ecuador to make cheap versions of patented drugs. Associated Press Financial Wire. Quito.

Eritrea

Year(s): 2005

National Income: Low (least developed country status)

Pharmaceutical Firm(s): Various

Drug(s): All ARVs

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On June 5, 2005, the Minister of Health issued a compulsory license for for importation into Eritrea of generic HIV-AIDS medicines” (CPTech). This was a general call for call ARVs.

Selective Bibliography:

CPTech. "Examples of Health-Related Compulsory Licenses." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/cl/recent-examples.html>.

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

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Ghana

Year(s): 2005

National Income: Low

Pharmaceutical Firm(s): All ARVs to treat persons suffering from HIV/AIDS

Drug(s): ARVs

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On October 26 2005, the Minister of Health issued a government use compulsory license for importation into Ghana of generic HIV-AIDS medicines” (CPTech).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

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Panafrican News Agency (PANA) (2006). Ghana Announces Arrival of More ARVs as Patients Picket. Accra.

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India

Year(s): 2006-2007

National Income: Lower Middle

Pharmaceutical Firm(s): Novartis

Drug(s): Gleevec

Disease: Cancer (leukemia, stromal tumors)

Disease Scenario Type: Type III

Outcome(s): None

Case Study Summary: Case described in some detail in Chapter Three. India threatened to issue a CL after unproductive patent disputes with Novartis.

Selective Bibliography:

David, R. (2007). Novartis Set Back In India Patent Fight Over Glivec. Forbes.

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Raju, K. (2007). "The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement." Social Science Research Network: 1-19.

Indonesia

Year(s): 2005

National Income: Lower Middle

Pharmaceutical Firm(s): Boehringer Ingelheim

Drug(s): Lamivudine and nevirapine

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On 5 October 2004, a presidential decree was issued in Indonesia authorizing the Minister of Health to appoint a manufacturer to exploit patents on lamivudine and nevirapine on behalf of the government. The decree specifies a royalty rate of 0.5% of the net (generic) sales price. The authorization lasts for seven years (nevirapine) and eight years (lamivudine), i.e. for the remaining patent term” (World Health Organization 2008).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

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Korea (and Roche)

Year(s): 2005

National Income: High

Pharmaceutical Firm(s): Roche

Drug(s): Tamiflu

Disease: Avian flu (H5N1), Pandemic flu

Disease Scenario Type: Type I

Outcome(s): VL

Case Study Summary: “The South Korea Food and Drug Administration (SKFDA) has announced that it will consider side-stepping international intellectual property (IP) laws to produce generic Tamiflu (oseltamivir; Roche (Switzerland)), in order to ensure that the country is protected in the event of an outbreak of avian influenza (bird flu). The agency has indicated that, if necessary, it would manufacture the drug even in the absence of the patent holder. Yonhap reports that an SKFDA official has taken 'legal steps', consulting various experts to determine if exceptions to international IP laws are valid in this situation. The agency is also assessing whether or not any local pharmaceutical companies are capable of producing oseltamivir” (Ando 2005). ““Roche sent us an official letter a couple of days ago, saying that it would sublicense Tamiflu production to any Korean company that can produce it in sufficient quantities,’ Young-chan, director of the Korea Food and Drug Administration (KFDA), told our reporter Wednesday...The KFAD has already asked local pharmaceutical companies whether they are able to produce it or not and whether they are willing to produce the drug jointly with Roche," he said, adding that no application has yet been submitted”” (Korea Times 2005).

Selective Bibliography:

Ando, G. (2005). Generic Tamiflu Becomes a Possibility in South Korea. World Markets Research Centre.

Korea Times (2005). Health Regulator Seeks to Produce Bird Flu Drug. Korea Times.

Korea Times (2005). Local Firm to Produce Bird Flu Drug with Roche. Korea Times.

Korea (and Novartis)

Year(s): 2001-2002

National Income: High

Pharmaceutical Firm(s): Novartis

Drug(s): Gleevec

Disease: Cancer (leukemia, stromal tumors)

Disease Scenario Type: Type III

Outcome(s): None

Case Study Summary: Discussed in some detail in Chapter Three. Despite rallying by patient and civil groups, Korea rejects application for Compulsory License of Novartis' Gleevec. Government did negotiate and got discounts, but it is not clear that it was done via the contemplation of issuing a CL.

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

CPTech. "Examples of Health-Related Compulsory Licenses." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/cl/recent-examples.html>.

Landon, V. (2002). Pricing Dispute Leaves Patients Without Drugs. SwissInfo.ch Swiss News Worldwide.

Nam, H. S., Park, Sung Ho. (2002). "Request for Compulsory License on Behalf of People's Health Coalition for Equitable Society, Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society." " Retrieved 25 June, 2010, from http://glivec.jinbo.net/Request_for_CL_Final_version.htm

Malaysia

Year(s): 2003-2004

National Income: Upper Middle

Pharmaceutical Firm(s): Bristol-Myers Squibb, GlaxoSmithKline

Drug(s): Didanosine, Zidovudine, Lamivudine + Zidovudine

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On 29 October 2003, however, the authorization for the exploitation of a patented invention on behalf of the government...was issued. It allowed a local company to import didanosine tablets, zidovudine tablets and a fixed-dose combination (FDC) of didanosine+zidovudine from a generic manufacturer in India...The authorization was valid for two years. It required that the medicines be labelled with the words ‘Ministry of Health Malaysia’ and imposed several other conditions, including a maximum price and a requirement that royalties be paid to the patent holder(s). The MoH offered the patent holders 4% royalties. The patent holders however showed little interest in accepting or negotiating the proposed remuneration...Following the government use authorization, the patent holders reportedly reduced their prices by 50-80%” (World Health Organization 2008).

Selective Bibliography:

Germano, S. (2007). "Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries." University of Missouri-Kansas City Law Review 76: 273-294.

Minister of Domestic Trade and Comer Affairs Malaysia. (2003). "Authorisation for exploitation of patented invention in Malaysia." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/c/malaysia/arv-license.html>.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

Mozambique

Year(s): 2004

National Income: Low (least developed country status)

Pharmaceutical Firm(s): GlaxoSmithKline, Boehringer Ingelheim

Drug(s): Lamivudine, Stavudine, Nevirapine

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “The Mozambican government has become the first in Africa to issue a compulsory license for the local manufacture of generic versions of patented HIV/AIDS drugs, in line with the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. The licence is understood to have been signed on 5 April [2004] this year, and was granted to domestic generics outfit Pharco Mozambique LDA. The company will manufacture fixed-dose combination therapies (comprising lamivudine, stavudine and nevirapine) under the brand Pharcovir 30 and Pharcovir 40. Pharco will pay royalties of 20% of revenue from the products...The government's licence justifies its decision on the grounds that the manufacturers of branded anti-retrovirals (GlaxoSmithKline, lamivudine; Bristol-Myers Squibb, stavudine; and Boehringer Ingelheim, nevirapine) failed to produce their own fixed-dose combination” (Dummett 2004).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

CPTech. "Examples of Health-Related Compulsory Licenses." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/cl/recent-examples.html>.

Dummett, H. (2004). Government Issues HIV/AIDS Compulsory License. World Markets Research Centre.

Namburete, S. (2004). "COMPULSORY LICENCE no. 01/MIC/04." Retrieved 30 June, 2010, from <http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>.

The Philippines

Year(s): 2004

National Income: Lower Middle

Pharmaceutical Firm(s): Pfizer

Drug(s): Norvasc

Disease: Cardiovascular disease

Disease Scenario Type: Type III

Outcome(s): None

Case Study Summary: This case is discussed in some detail in Chapter Three. Pfizer filed a lawsuit against the PITC, the Philippine governmental agency that supplies many of the nation's drugs, for the early working of a patent. PITC had applied for approval for a generic version of the branded drug in anticipation of expiration in the same year. In response, Philippine officials threatened to use the CL TRIPS flexibilities.

Selective Bibliography:

Ando, G. (2006). Pfizer Sues Philippine Government over Parallel Imports of Generic Norvasc, World Markets Research Centre.

Datta, P. T. J. (2006). Pfizer Worried Over Parallel Import of Norvasc into the Philippines, Business Line.

Leonard, A. (2006). Pfizer's Philippine Follies. Salon.

Tan, R. D. (2007). "PITC Files Landmark Patent Case against Norvasc ... even if Patent for Hypertension Drug to Expire in June." Retrieved 25 June, 2010, from http://www.pitc.gov.ph/archives/patent_case.html.

Rwanda

Year(s): 2007

National Income: Low (least developed country status)

Pharmaceutical Firm(s): Apotex (Canadian generic supplier)

Drug(s): FDC (Lamivudine, Nevirapine, Zidovudine)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “In July 2007, Rwanda notified the WTO secretariat of its intention to import 260 000 packs of a FDC of zidovudine+ lamivudine+nevirapine from Apotex, a generic manufacturer in Canada. This is the first attempt to make use of this system. The notification states that Rwanda reserves the right to modify the quantity as necessary. It furthermore states that Rwanda will make use of its right, as a least-developed country, not to enforce any patent rights that may have been granted with regard to this product. Following this request, the Canadian Commissioner of Patents granted, in September 2007, a CL to Apotex, allowing Apotex to manufacture the concerned product exclusively for export to Rwanda. This CL is valid for a period of two years” (World Health Organization 2008).

Selective Bibliography:

Africa News (2008). Rwanda; Africa's Failing Infrastructure Renders Compulsory Licensing Pointless. Africa News, News Times.

Feldman, J. (2009). "Compulsory Licenses: The Dangers behind the Current Practice." Journal of International Business and Law **8**(Spring): 137-167.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

World Trade Organization. (2010). "TRIPS and Public Health Paragraph 6 System: Notifications by importing WTO Members." Retrieved 20 June, 2010, from http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

South Africa

Year(s): 2001-2003

National Income: Lower Middle

Pharmaceutical Firm(s): CIPLA (India generic supplier), various patent title holders

Drug(s): Nevirapine, Lamivudine, Zidovudine, Stavudine, Didanosine, Efavirenz, Indinavir, and Abacavir.

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount/VL/none

Case Study Summary: This case is discussed in some depth in Chapter Two. A long battle between many pharmaceutical giants and the nation began in the late 1990s and came to a head in 2001 and was eventually dropped. Talk of using the CL safeguards, however, continued and gained momentum when “on March 7, 2001, Indian pharmaceutical manufacturer CIPLA formally requested the South African Department of Trade and Industry to issue compulsory licenses to patents on the following HIV drugs: nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir and abacavir” (CPTech). Other anti-trust CLs were practice in 2002-2003.

Selective Bibliography:

Block, R. (2001). Cipla Sidesteps South African Fight With a Bid to Offer Generic Drugs. Wall Street Journal. Johannesburg.

Hoen, E. t. (2002). "Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way From Seattle to Doha." Chicago Journal of International Law: 27-46.

Swarms, R. L. (2001). AIDS Drug Battle Deepens in Africa. New York Times. New York.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

Taiwan/China

Year(s): 2005

National Income: Lower Middle

Pharmaceutical Firm(s): Roche

Drug(s): Tamiflu

Disease: Pandemic flu, Avian flu (H5N1)

Disease Scenario Type: Type I

Outcome(s): Discount

Case Study Summary: Taiwan considers itself on the front lines of a potential bird flu pandemic...Unsure that Roche would be able to live up to its promise to provide enough Tamiflu to cover a sufficient percentage of Taiwan's population, Taiwan decided to plunge ahead. In November 2005, Taiwan's government issued a license to allow local companies to manufacture generic versions of Tamiflu -- the only drug in the world considered effective in combatting the effects of bird flu...[Taiwan amended] its patent laws to allow the export of its generics to other nations” (Leonard 2006).

Selective Bibliography:

Leonard, A. (2006). Adventures with Tamiflu: Is Taiwan Throwing Down the Big Gauntlet at Big Pharma? [Salon](#).

Nag, A. D. (2007). "The Bird Flu and the Invoking of TRIPS Article 31 "National Emergency" Exception." [Syracuse Journal of International Law and Commerce](#) **34**: 689-713.

Roche. (2005). "Media Release: Roche confirms ability to supply pandemic Tamiflu to the people of Taiwan." Retrieved 29 June, 2010, from <http://www.roche.com/med-cor-2005-11-25>.

Thailand (and Merck)

Year(s): 2006, 2010

National Income: Lower Middle

Pharmaceutical Firm(s): Merck

Drug(s): Efavirenz (ARV)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “Thailand issued its first CL in November 2006, for efavirenz. About two months later, the first consignment of generic efavirenz was imported from India, at half the original price...Generic efavirenz [was] being imported...initially. Meanwhile national companies have started preparations for local production” (World Health Organization 2008). This CL was renewed in 2010.

Selective Bibliography:

Bangkok Post (2010). The Licensing of Key Drugs. Bankok Post. Bangkok.

Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

Thepharmaletter (2010). Compulsory licensing for two AIDS drugs extended by Thailand health authority. Thepharmaletter.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

The Ministry of Public Health and The National Health Security Office of Thailand (2007). 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.

Thailand (and Abbott, Sanofi-Aventis)

Year(s): 2007, 2010

National Income: Lower Middle

Pharmaceutical Firm(s): Abbott, Sanofi-Aventis

Drug(s): Kaletra (ARV), Plavix (heart disease)

Disease: HIV/AIDS, cardiovascular disease,

Disease Scenario Type: Type II/Type III

Outcome(s): CL

Case Study Summary: “In January 2007, two more CLs were issued, for lopinavir/ritonavir [Kaltera] and for a cardiovascular drug, clopidogrel [Plavix]. This was the first time a developing country used compulsory licensing in relation to a non-communicable disease. Thailand’s actions were widely reported in national and international media, and drew mixed reactions. Notably the inclusion of a cardiovascular drug generated controversy. One of the affected companies [Abbott] withdrew seven pending applications for registration of new drugs in Thailand” (World Health Organization 2008). The Kaletra CL was renewed in June 2010 (Bangkok Post 2010). Thailand has entertained CLs for Abbott’s Aluvia (lopinavir/ritonavir) (Pharma Marketletter 2008).

Selective Bibliography:

Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

Savoie, B. (2007-2008). "Thailand's Test: Compulsory Licensing in an Era of the Epidemiological Transition." Virginia Journal of International Law **48**(1): 211-248.

The Ministry of Public Health and The National Health Security Office of Thailand (2007). 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.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

Thailand (and Novartis)

Year(s): 2007-2008

National Income: Lower Middle

Pharmaceutical Firm(s): Novartis

Drug(s): Gleevic

Disease: Cancer (leukemia, stromal tumors)

Disease Scenario Type: Type III

Outcome(s): Discount

Case Study Summary: “The Swiss drug company Novartis offered an effective 75 percent price reduction this week in its leukemia medicine, Glivec, after Thai officials said they were studying a compulsory license on the drug, which would have allowed the government to produce it in its own factories and distribute it on a nonprofit basis” (Fuller 2007). This CL has been considered intermittently throughout the Thailand saga; however, Novartis seemed to prevent the CL by always offering greater discounts. Later in 2007, Novartis arranged to provide the drug to Thailand for free (Agence French Presse -- English 2007).

Selective Bibliography:

Agence French Presse -- English (2007). Thailand may get cancer drug free from Novartis. Agence French Presse -- English. Bangkok.

Fuller, T. (2007). Thailand Takes on Drug Industry, and May Be Winning. New York Times. New York.

Pharma Marketletter (2008). New Thailand govt's compulsory drug licensing policy swings back and forth. Pharma Marketletter.

Thai Press Reports (2007). Thailand Compulsory Licensing to Expand to Cancer Drugs. Thai Press Reports.

Thailand (and Novartis, Sanofi-Aventis, Roche)

Year(s): 2007-2008

National Income: Lower Middle

Pharmaceutical Firm(s): Novartis, Sanofi-Aventis, Roche

Drug(s): Femara (letrozole), Taxotere (docetaxel), Tarceva (erlotinib)

Disease: Cancers (Femara is used primarily to treat breast cancer; Taxotere and Tarceva are used primarily for lung cancer)

Disease Scenario Type: Type III

Outcome(s): CLs

Case Study Summary: This case study is described in Chapter Three. The Thai Minister of Health, Mongkol na Songkhla initiated the second wave of CLs later in 2007. The CLs were for Novartis' Letrozole, Sanofi-Aventis' Docetaxel, and Roche Erlotinib, which are used to treat varying types of cancers including those of the breast, lung, ovaries, and pancreas. Mongkol na Songkhla was replaced in early 2008, however, by Chaiya Sasomsab, who threatened to rescind this second batch of CLs shortly after taking his post as the new Minister of Health. After sustaining substantial criticism from the general Thai public, international NGOs, and patient groups, Chaiya Sasomsab announced that there were major legal obstacles and that he was unable to revoke the CLs.

Selective Bibliography:

Pharma Marketletter (2008). New Thailand govt's compulsory drug licensing policy swings back and forth. Pharma Marketletter.

Sajirawattanakul, D. (2008). "Drug-licensing revision should be ready by April." Retrieved 30 June, 2010, from http://unitcost.fda.moph.go.th/cl/news_detail.php?id=868&type=5.

The Nation - Thailand. (2008, 8 March). "Generic Drug Debate Intensifies." The Nation - Thailand Retrieved 25 June, 2010, from http://unitcost.fda.moph.go.th/cl/newsfile_file/newsfile_20080910044737-1.pdf.

Thai Press Reports (2007). Thailand Compulsory Licensing to Expand to Cancer Drugs. Thai Press Reports.

United States

Year(s): 2001

National Income: High

Pharmaceutical Firm(s): Bayer

Drug(s): Cipro

Disease: Anthrax

Disease Scenario Type: Type I

Outcome(s): Discount

Case Study Summary: See Chapter Two for more detailed account. The United States examined its CL policy after bioterrorist-engineered anthrax spores were mailed to political and news entities around the country. The nation began to fear a shortage of Cipro and the Secretary of the Health and Human Services preceded to negotiated with the patent title holder. A substantial discount was agreed upon.

Selective Bibliography:

Curti, A. M. (2001). "The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS." American Journal of Law & Medicine **27**: 469-485.

Ferrone, J. D. (2003). "Compulsory Licensing during Public Health Crises: Bioterrorisms Mark on Global Pharmaceutical Patent Protection." Suffolk Transnational Law Review **26**(Summer): 385-410.

Murthy, D. (2002). "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health." American University International Law Review **17**: 1299-1346.

Zambia

Year(s): 2004

National Income: Low (least developed country status)

Pharmaceutical Firm(s): Boehringer-Ingelheim, Bristol-Myers Squibb

Drug(s): Lamivudine, Stavudine, and Nevirapine

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On 29 September 2004, Zambia issued a CL to allow a domestic company to manufacture a FDC of lamivudine, stavudine, and nevirapine. The CL prohibits export, and specifies that the total amount of royalties payable to the patent holder(s) shall not exceed 2.5% of the turnover of the product” (World Health Organization 2008).

Selective Bibliography:

Chilrpamushi, D. M. (2004). "Notice of Issuance of Compulsory License." Retrieved 30 June, 2010, from <http://www.cptech.org/ip/health/c/zambia/zambia-bms09302004.html>.

Patel, D. K. (2004). "Compulsory License No. CL 01/2004." Retrieved 30 June, 2010, from <http://www.cptech.org/ip/health/c/zambia/zcl.html>.

The Times of Zambia (2004). Company Granted License to make ARVs Locally.

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

Zimbabwe

Year(s): 2003

National Income: Low

Pharmaceutical Firm(s): Varichem Pharmaceuticals Ltd (local generic manufacturer)

Drug(s): Any ARV used to treat persons suffering from HIV/AIDS

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On 8 April 2003, Zimbabwe issued a CL for all HIV and AIDS- related medicines. The license was issued after a period of emergency on HIV/ AIDS was declared. The CL allows a local company, Varichem Pharmaceuticals Ltd, to produce ARVs or HIV/AIDS-related medicines during the emergency period. The license requires the company to supply three quarters of its production to state-owned health institutions and specifies that the medicines produced under the license will be subject to price controls. Varichem reportedly launched its first ARV in Zimbabwe in October 2003, and has since launched several other ARVs. It supplies to both the government and private sector” (World Health Organization 2008). “In 2003, the period of emergency was extended by five years [expiring in] until 31 December 2008” (Bucknell 2007).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. Mondaq Business Briefing.

CPTech. "Examples of Health-Related Compulsory Licenses." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/cl/recent-examples.html>.

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World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.

**APPENDIX B. CL CASE STUDIES WITH INSUFFICIENT REFERENCES
Brazil (and Bristol Myers Squibb)**

Year(s): 2003

National Income: Upper Middle

Pharmaceutical Firm(s): Bristol Myers Squibb

Drug(s): Reyataz (atazanavir sulfate)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): Discount

Case Study Summary: “Following lengthy negotiations, the Brazilian government has reached agreement with US drug-maker Bristol-Myers Squibb (BMS) to purchase its new protease inhibitor Reyataz (atazanavir sulfate) at a hugely discounted price. The agreement makes Reyataz, a drug used in combination with other anti-retroviral drugs (ARVs) for the treatment of HIV/AIDS, available to the Brazilian government at a unit price of US\$3.25, a 76.4% discount on the current market price of US\$13.80. Brazil, famous for its successful drug price negotiations, said this latest discount was the largest it had ever obtained from a multinational drug-maker. The Ministry of Health estimates that the discount will translate into a yearly saving of R\$191m (US\$65m). Brazil spends over R\$500m (US\$170.2m) a year on procuring AIDS drugs...the deal with BMS increases the pressure on the other three pharmaceutical companies to follow suit, while the threat of compulsory licenses made earlier by the Brazilian Ministry of Health has also upped the stakes” (Sturm 2003).

Selective Bibliography:

Sturm, T. (2003). Brazil Negotiates Substantial ARV Discount from BMS. World Markets Research Centre.

Cameroon

Year(s): 2005

National Income: Low

Pharmaceutical Firm(s): ?

Drug(s): Nevirapine (Brand name Viramune), Lamivudine (Brand name 3TC), and Fixed dose combinations of Lamivudine and Zidovudine (Brand name Combivir)

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On January 2005, the nonprofit corporation Essential Inventions requested the Minister of Public Health to grant a government use/ex officio compulsory license of the patents relevant for importation, manufacture or sale of generic versions of the following medicines used in the treatment of HIV/AIDS: Nevirapine (Brand name Viramune) Lamivudine (Brand name 3TC) Fixed dose combinations of Lamivudine and Zidovudine (Brand name Combivir)” (CPTech).

Selective Bibliography:

CPTech. "Examples of Health-Related Compulsory Licenses." Retrieved 29 June, 2010, from <http://www.cptech.org/ip/health/cl/recent-examples.html#Cameroon>.

Guinea

Year(s): 2005

National Income: Low

Pharmaceutical Firm(s): Various

Drug(s): ARVs

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “On 18 April 2005 Guinea issues compulsory licenses for importation on patents on drugs to treat HIV-AIDS” (Bucknell 2007).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. [Mondaq Business Briefing](#).

Indonesia

Year(s): 2007

National Income: Lower Middle

Pharmaceutical Firm(s): Merck

Drug(s): Efavirenz

Disease: HIV/AIDS

Disease Scenario Type: Type II

Outcome(s): CL

Case Study Summary: “In March 2007, the decree was amended to include efavirenz. The decree was issued –and amended– in a low key manner, and does not appear to have attracted any criticism” (World Health Organization 2008).

Selective Bibliography:

Bucknell, D. (2007). Worldwide: The Global IP Scorecard For Pharma & Biotech Compulsory Licenses. [Mondaq Business Briefing](#).

World Health Organization. (2008). "Briefing Note: Access to Medicines: Countries Experiences in Using TRIPS Safeguards." Retrieved June 19, 2010, from http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf.