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# Compulsory Licenses: Damaging Firm Value in the Short Run?

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# Compulsory Licenses: Damaging Firm Value in the Short Term?

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**I) Introduction:**

Ever since their creation over 500 years ago, patents have mostly existed to provide incentives for innovation. In the modern era, a patent rewards an inventor for his invention if it meets the criteria of being new, useful, and non-obvious. If these criteria are all satisfied, the government can grant a temporary monopoly to the inventor. This temporary monopoly aims to adequately remunerate the inventor for the invention. While there may be an overall societal increase in welfare as a result of the invention, during the life of the patent, the producer captures much of the increase. Reflecting the common economic view on patents, F.M. Scherer states that they "confer social gains by making innovations profitable, and by stimulating innovators to carry their cost – reducing efforts further, but they impose social losses by requiring consumers to wait longer for the competitive fall in prices" (Scherer, 1977). Often, it is only after the expiration of the patent that the consumer reaps much of the benefit of the innovation.

The existence of patents has not tended to be contentious, with it being widely accepted that patents serve as a blunt tool to promote innovation. But this comes at the cost of dampening the welfare of both competitors and consumers, as described above. This loss to consumers and competition has been accepted as a necessary cost to stimulate innovation.

Scherer lays out the issue of optimal patent protection clearly, stating that the goal "of patent policy is to strike a balance: enough protection to sustain a desired flow of innovations, but not superfluous protection in view of alternate incentives for innovation and the social burdens monopoly power imposes" (Scherer, 1977). While his

conclusion does capture well the problems associated with the patent system as a whole, it inadequately captures the social problems associated with monopoly power on pharmaceuticals more specifically.

When a new drug hits the market, it means better options for those who can afford the new drug. However, the monopoly makes the new product both expensive and scarce. Therefore, when individuals are unable to pay monopoly costs associated with the new drug, the social cost is that they are left with lower quality drugs (or no drugs at all). Since they are unable to pay for the higher quality medication, these individuals have worse health outcomes than the individuals who can afford to pay. On a moral and a social level, this outcome is neither optimal nor desirable. However, if the patent system were not in place, the lack of incentives to innovate could mean no new drugs in the market at all. This would mean reduced outcome for all. So, in principle, if there was some system where the patent system was in place but also allowed for specific cases of voiding the patents for patient use in epidemics, that would be the most beneficial for citizens while also keeping the drug companies' incentive to innovate. Historically, many nations have hesitated to patent pharmaceuticals because that did not align with the best interests of the developing nation (Boulet, 2000). The lack of pharmaceutical patents has, however, grown increasingly rare in a more global patent landscape that has created international minimum standards for patent protection.

Attempting to balance social responsibility and monopoly incentives highlights the patent system's inability to deal with situational ethics. While the current patent systems are well functioning for almost all industries, the ethics surrounding pharmaceutical patents are far more serious than for other industries. The problem

faced is to choose between reducing patent protection, which may be a disincentive to innovate, or not reducing protection and allowing individuals to suffer. In this regard, traditional patent law is silent. Compulsory licenses, which are granted by a government to allow someone else to produce the patented product or process without the consent of the patent owner (WTO-1, 2006), attempt to find a solution to the public health problem while still allowing patents on pharmaceuticals. Hopefully these licenses perfectly balance the need for strong international patent systems while still providing drugs to those who need them in times of emergency.

The problems surrounding patents, essential medicines, and compulsory licenses are exacerbated as the economy becomes more global and wealth discrepancies become magnified. With the larger wealth gaps and a pharmaceutical pricing structure unfavorable to the developing world, whole populations are priced out of the market. These larger gaps in welfare serve to highlight the need for solutions to the patent problems surrounding pharmaceuticals, since pricing groups of people out of the market is a sub-optimal outcome socially.

In the sections that follow, I will discuss first the history of patents to provide a base of understanding for the modern patent system. Second, I will lay out the modern international patent legislation, especially the legislation and guidelines in place for compulsory licenses. Next, I will explain previous research on compulsory licenses and describe event studies before advancing to my own research.

The aim of my thesis is to assess whether the announcement of a compulsory license has a short-term effect on the market capitalization of the firm whose drug is licensed. Previous research, as discussed in my literature review, has examined the

effects of compulsory licenses on R&D expenditure and the effects of an issuance on the country. However, the question of whether issuing a compulsory license affects pharmaceutical company market capitalization change has not been empirically studied. Answering this question will allow us to learn whether shareholders view announcements of these licenses and a negative, positive, or irrelevant through use of an event study methodology. The investigation and results of this research will help paint a more complete picture surrounding compulsory licenses and their impact on firms. In the end, the results were overwhelmingly insignificant, underscoring the need for policy reexamination toward these compulsory licenses.

Historically, companies have viewed compulsory license as a bad outcome, penalizing countries that use and abuse the compulsory license system. The results suggest that companies should perhaps not be so worried or care so much about compulsory licenses. Hopefully these results will catalyze a change in outlook toward compulsory licenses.

## II) Background:

### *A) Patent History:*

Prior to the Venetian Patent Statute, passed on March 19th, 1474 by the Venetian Legislature, patents served more as a tool for monopoly enforcement and for the benefit of the Venetian state and less as incentives for innovation (Nard, 2006). Prior to this statute, the granting of patents was not common practice. In his 1964 book titled "Genesis of American Patent and Copyright Law," Bruce Willis Bugbee found 13 patents issued between 1416 and 1472 (Bugbee, 1967). Before the statute, patents functioned to grant a monopoly for individuals on resources rather than to grant the control of

their inventions to inventors. At least half of those patents issued before 1474 were monopolies to mineral companies to eliminate competition. These monopolies were justified by the state because of the "heavy expenses required for the works, and the benefits flowing to the Republic"(Mandich, 1948). While these patents worked for both the benefit of the patent recipient and the state, they did not encourage innovation nor reward it.

The Venetian Patent Legislation of 1474 was the first example of a patent system with similar scope and limitations to our modern system. In its simplest form, the early patent legislation sought to encourage technological advancement by issuing private grants (patents). The legislation laid out that "by the authority of the council, every person who shall build any new and ingenious device in this City, not previously made in our Commonwealth [would have monopoly rights over the invention] for the term of 10 years"(Mandich, 1948).

While the intellectual property system and legislation has expanded significantly since the 15th century, it is evident how well Venetian legislation has served as the framework for later patent systems. First, it mentions explicitly the building of "new and ingenious" inventions. This emphasis is also found in the modern patent criteria of both new and non-obviousness. Secondly, the statute allocates to inventors a monopoly over their invention for 10 years. While the time allotted has changed in the modern era, we still subscribe to a system that grants a temporary monopoly as remuneration for ideas and R&D expenditures. Comparing the Venetian system to our modern system, it is clear how the Venetian statute provided a scaffold for modern patent law.

Using the Venetian Patent Statute as a framework, many nations and states followed suit and built their own domestic patent systems. Since the patent system was still in its infancy, it was susceptible to abuse by both the state and individuals and interpreted in ways that allowed the ever-increasing abuse. Abuses eventually grew to the point where counter legislation was needed, such as the Statute of Monopolies in England in 1623 (Machlup, 1958). This statute forbade the granting of broader patents such as "exclusive rights to trade" except to individuals who were the "first and true inventor" (Machlup, 1958). Given the emphasis placed upon the "first and true inventor," we can deduce that the use of patents within England previously was not in a manner consistent with the Venetian Statute. Rather, it was more similar to the use of patents within Venice before 1474, granting monopolies and as a means to raise money for the crown.

Other domestic patent law systems used the Venetian foundation to create patent laws for rewarding of innovation, as well. Even the US Constitution (1787) addressed patents, stating that congress has the power "to promote the Progress of Science and useful Arts, by securing the limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"(Machlup, 1958). Patent laws were progressively more detailed and complete than the original Statute of 1474. However, as markets became more global, there was a need to create international patent rights; these were first enacted during the Paris Convention for the Protection of Industrial Property in 1883. Eight countries initially ratified the Paris Convention in 1883, with another eight ratifying it before 1900 (WIPO).

The Paris Convention was catalyzed by the ever-increasing global nature of markets and by events such as the World's Fair and inventors exhibitions. During the 1870's, the Austro-Hungarian Empire aimed to host a national inventors exhibition, however the proposed event was met with serious concern by the international inventors' community (Sell, 2001). Individuals were worried that their inventions would be stolen since no international legislation existed regarding patents. In the end, the empire passed a temporary bill allowing protection of international intellectual property to encourage participation.

While the protection resolved issues in the short term, this inventors' exhibition initiated the debate and conversation surrounding international patent protection. In the end, the Paris Convention was similar to the Venetian patent system but with an additional stipulation. Since this patent system was on an international scale, individuals could get a patent in a particular country and, theoretically, not utilize it and block progress within that country. Because of that, an agreement was reached where "foreign patents [were required to] be worked in order to be valid"(Murphy, 1994). This stipulation was not included in domestic documents, since it would have been foolish to patent a product and not utilize it in the only market where it was patented. With the addition of this clause, the potential for abuse of the international patent landscape was mitigated.

Additionally, the Paris Convention and legislation of 1883 was the first instance of compulsory license discussion on the international stage. The license legislation was enacted to "respond to anti-competitive, non-working or blocking behavior or cases of 'public need'"(Boscheck, 2012). While this definition is very broad and non-specific, it

still serves as one of the first, and certainly most famous, examples of the beginning of compulsory licenses. Finally, it clearly lays out the intention for compulsory licenses to be a checks and balances sort of measure.

With the framework provided by the Paris Convention in mind, the next several intellectual property (IP) iterations continued to alter the patent system, but international adoption of patent protection was incredibly different across countries. This is especially true when comparing countries with different levels of development. While some nations subscribed to the legislation put forth by the Paris Convention, others had created their own systems, additional legislation, or avoided patent legislation all together. All of that changed, however, with the implementation of the TRIPS agreement.

*B) Modern Patent Landscape: The TRIPs Agreement and more*

The biggest change to the modern patent landscape occurred with the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organization (WTO) in 1995. Like the Paris Convention, many considered the TRIPS agreement to be a response to technological changes and the need for a more robust governance regime (May, 2006). Among other broad sweeping reforms, it required all members of the WTO to begin to unify their patent protection so that it was homogenous across all member nations. For example, the agreement required all members to recognize the legitimacy of product patents, which are patents on inventions. Before TRIPS, many nations, especially developing nations, only recognized process patents, which are simply patents on methods of production. For example, if a company creates a new compound, under a product patent

system, they have complete rights over the compounds use. If, however, it was patented in a process patent system, they only have monopoly rights over the specific synthesis they used, not the actual compound. This disregard for product patents meant that pharmaceutical innovations and new drug compounds were not patentable; only the steps of formulation were patentable. The lack of product patent protection had meant a decrease in drug price and an increase in availability, along with a disincentive to innovate for firms looking to enter that market space.

As domestic patent landscapes became more homogeneous, companies were more likely to enter into more markets with greater confidence. This confidence stems from the patent landscape becoming more protective. The TRIPS agreement was, as one article puts it "a product of non-state actors whose comparative advantage lay in innovation rather than imitation"(Sell, 2001). This highlights the essential argument, by opponents, that TRIPS was set up to favor those already in power within the international patent landscape. Since all countries had to alter (not immediately) their intellectual property rights (IPRs) to stronger patent protection brought forth by the developed world, suddenly certain developing nations had less ability to produce drugs legally and cheaply for their population. This occurred since products that were unpatented previously became protected with the inclusion of product patents. While there was no grandfathering of old patent systems, countries have had varying timelines to change their systems based on levels of development. The developing nations had until 2005 to change their laws to the standards put forth by TRIPS, and least developed nations have been granted until 2016 to change the laws as they regard pharmaceutical patent (WTO-2). While eventually the leveling and raising of minimum

of patent protection standards could help developing world industries such as pharmaceuticals, the short run effect was a reduction in access and an increase in the price of medication, which did not benefit developing nations.

Since most of the legislation surrounding TRIPS benefitted firms that already had strong patent protection, compulsory licenses were deemed a necessary tool for both the benefit of developing nations and a compromise to give them more incentive to agree and sign. The TRIPS agreement laid out the vague criteria for when a patent could be broken. It states that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health" (Article 27.2) This sentence, while written with clear intention, is not clarified anywhere within TRIPS so it leaves itself open to interpretation. For instance, while the intention may be understandable, nowhere in the agreement is it explained what constitutes the protection of *ordre public* or morality. Additionally, what constitutes commercial exploitation is also not explained. This article of TRIPS, while dealt with more explicitly in the next section of the paper, was a serious point of contention when written due to its vague nature and potentially serious opportunity for abuse.

In the aftermath of the signing of TRIPS, non-governmental organizations such as Medecins sans Frontieres (MSF) had multiple issues with the TRIPS agreement as it pertained to global health. The MSF argued that increased patent protection would cause higher drug prices. These higher prices would price developing nations out of the market, lower sources of high quality drugs which developing nations had been relying on, along with a loss of jobs for those formerly working in the pharmaceutical industry

in the developing country. Individuals and nations who were pro TRIPS touted a potential increase in the availability of new essential medicines in a developing world market place, but there can be a difference between theoretically available and actually accessible medicines. In the developing world "the drugs will remain out of reach to people in developing countries because of high prices. As a result, the access gap between developed and developing countries will widen" (Hoen, 2002) Examining the pattern of R&D expenditures in the aftermath of TRIPS, the increased standards were still not be enough to incentivize R&D for maladies that most affect the developing world (Kyle & McGahan, 2012). Therefore, after implementing TRIPS, the developing world was forced to grant patents and accept sharp price increases on drugs which they formerly had access to, without significant increase in the R&D expenditure for tropical diseases (Correa, 2002).

Although the concerns laid out by MSF were legitimate and serious, no immediate legal challenges arose, most likely due to the lag allowed for updating IPRs to the standard set by TRIPS. In fact, it took until 1998 for there to be a legal conflict surrounding access to medicine. In 1998, the South African government passed a law called the Medicines and Related Substances Control Amendment Act that was aimed at increasing availability of affordable medicines. Issues such as off-patent legislation, transparent pricing schemes and parallel importation were all discussed in the act (Hoen, 2002). All of these issues aimed to increase access to drugs, especially HIV drugs, which were desperately needed. Pharmaceutical companies, along with the backing of their home governments, wanted this legislation repealed given that it would be detrimental to their business. By the time the large pharmaceutical companies and the

developed nations dropped their lawsuit, it was clear that "the flexibilities of TRIPS and their use for public health purposes needed clarification to ensure that developing countries could use its provisions without the threat of legal or political challenge"(Hoen, 2002).

In the South African example, the government needed AIDS medication to combat what was clearly an epidemic that would continue to grow, with 20% of all pregnant South African mothers infected with HIV at the time of the legal battle. Even though this situation fit the criteria of article 27.2 of TRIPS, the fact that large corporate players still attempted to stifle the dissemination of cheap drugs made it clear that the vague wording and explanation within TRIPS needed to be clarified.

Because of conflicts surrounding the execution of country rights within TRIPS, there was a need for less ambiguous legislation, which was first remedied by the Doha Declaration. The Doha Declaration, ratified by the WTO in November 2001, clarified the TRIPS agreement as it relates to compulsory licensing and other methods of reducing the price of drugs in national emergencies. Paragraph 4 of the Doha Declaration states "we agree that the TRIPS agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." When considering the previous legal battle in South Africa surrounding access to medication, this paragraph aims to explain the WTO's stance on compulsory licenses as a tool to counter threats to and remedy hazards to public health. Building upon paragraph 4,

paragraph 5b states that, “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Taken together, these define more clearly the clause within TRIPS surrounding compulsory licenses. It is worth noting, additionally, that the term compulsory license was never in fact used within the TRIPS agreement, however it was explicitly used within the Doha Declaration (Oh, 2006). All in all, the Doha Declaration aimed to clarify any ambiguity within the TRIPS agreement and represented a legislative response to the conflict that occurred in places like South Africa in the aftermath of TRIPS.

Originally, the TRIPS agreement stated that all drugs affected by compulsory licenses must be manufactured within the country itself and not imported to the country, however this changed with The Doha Declaration and the amendment 31bis to the TRIPS agreement. The new guidelines from the Doha Declaration called the rule requiring domestic production into question, stating that this rule could prevent effective use of the compulsory license if a country couldn’t domestically manufacture the drug. They called for an “expeditious solution to this problem.” Eventually, the issue of manufacturing domestically was cut out of the requirements for a compulsory license. In the end “WTO members agreed to relax the domestic production rule in the context of essential medicines by permitting the manufacture and export of products from a non [compulsory license country] to a [compulsory license country]” (R. C. C. Bird, Daniel R. , 2008). This relaxation of rules surrounding production was also laid out in the amendment to TRIPS within article 31*bis*.

Ratified on December 6th, 2005, article 31*bis* allowed and explained the circumstances in which developed nations were allowed to issue compulsory licenses to

their generic manufacturers to produce and export medications to developing nations. As laid out in her book entitled "Intellectual Property and Health Technologies," Joanna Brougher explains that in order to allow the importation of drugs through a compulsory license, multiple criteria must be met by both the importing and exporting nations. The importing nation must submit a notification to the TRIPS council that specifies which drug is needed, how much of it, and that they intend to issue a compulsory license (Brougher, 2014). In turn, the exporting nation must issue a compulsory license that gives them the right to produce and export to the importing nation, and they may only produce enough to satisfy the importing country's demand. This change directly affected drug availability and alleviated many of the problems facing developing nations that lacked the production capability to manufacture their essential medicines domestically.

While this amendment is understandable as a short run solution, it also has potential negative consequences in the long term when considering the effect of compulsory licenses on incentives to invest in manufacturing and other industies. If a country in question can outsource production versus creating some domestically, it is less likely to invest in domestic manufacturing. The relaxing of the requirement for domestic manufacturing should perhaps have been lagged, not removed, in order to create more positive outcomes overall.

While it is understood that increased patent protection due to TRIPS favors established companies in developed nations due to increased patent protection, compulsory licenses may be the one area where developing nations won a victory during the creation of the TRIPS agreement. Inclusion of compulsory licenses gave the

developing nations a bargaining chip during discussions and negotiations with developed nations and their drug companies surrounding drug prices and drug access. Many authors also acknowledge the importance of these licenses for public health. Colleen Chien explains the rationale behind the inclusion of compulsory licenses, stating that "drugs are too important to patent and leave vulnerable to monopoly abuses"(Chien, 2003). As much as compulsory licenses are deemed a necessary tool, the worry remains that given increased costs and risks associated with drug development, pharmaceuticals are especially at risk of compulsory license and that they may seriously hurt innovation.

The primary benefit gained from the existence of compulsory licenses may not even be the licenses themselves. Rather, the threat of the licenses can incentivize companies to give voluntary reductions in price (called here a voluntary license). This compromise of a voluntary license allows drug companies to retain control over their intellectual property, which is paramount, while still allowing a reduction in price for the countries in need. Control of their own intellectual property allows pharmaceutical companies to better avoid misuse and abuse of their patent. With a voluntary license, a company can better control the flow of the drug, its use, its re-export to other countries, its quality, etc. When a compulsory license is issued, the company loses control over all of these aspects, which is a bad outcome for the company. While the threat of the compulsory license is not needed when the company is willing to negotiate fully on matters of pricing, the threat is invaluable when dealing with companies who may be "initially unwilling to negotiate prices to a level that a country can afford" (Savoie, 2007).

Understanding that a voluntary license is a more positive outcome for both parties, under most circumstances, countries are required to negotiate for a voluntary license prior to issuing a compulsory license. This means that, no matter how many compulsory licenses we actually see in the market, the impact that they have had is far greater. For example, the threat of a compulsory license has been successfully used by Brazil to negotiate lower prices from multiple pharmaceutical companies (Feldman, 2009). While the rest of this thesis discusses and deals with compulsory licenses, it is important to remember that merely examining the licenses themselves does not capture a huge positive benefit from the threat of the licenses.

Returning to compulsory licenses, Chien established that the effect that a compulsory license has on innovation and R&D expenditure could be explained by examining both predictability of the compulsory license and importance of the market in which the license was issued. Predictability can be defined as the degree to which a company can anticipate the coming compulsory license. In 1977, Scherer postulated that unpredictable compulsory licenses do not harm innovation (Scherer, 1977). The rationale behind this argument is that if a compulsory license cannot be predicted, then it will not factor into a company's analysis of potential returns when considering R&D programs. If, however, the licenses are predictable, companies may factor the likelihood of a license into the decision making process (Chien, 2003). When Chien describes the importance of the compulsory license, she means the importance of the domestic market in which the compulsory license is issued. If a country, which normally contributes negligibly to the total revenue for a drug, issues a compulsory license, it has a completely different effect than if a country with a significant portion of the global

market issues the license. In combination, if a country that is expected to have a very high percent of the global market is also very likely to issue a compulsory license, that will considerably change a company's incentives to innovate, therefore fundamentally changing their cost-benefit analysis and maybe changing which projects they fund. While it would almost never happen, an example like this almost occurred when the United States threatened to issue a compulsory license for Ciprofloxacin in the aftermath of the terrorist attacks on September 11th.

Beyond the predictability and importance of the compulsory license to firms, we will be well served to discuss different disease types and how the threat of a compulsory license may significantly change a company's incentive to innovate. Leading NGOs and medical providers have categorized diseases into three main categories: type I, type II, and type III. Type I diseases are diseases where the vast majority of the market is in the developed world as opposed to the developing world (diabetes), and the disease burden in the developing world is less than three times that of the developed world. A type II disease is a disease where the majority of individuals that have the disease live in the developing world, however some individuals in the developed world also contract the disease (Dengue). Type II diseases have between three and 35 times the disease burden in the developing world as the developed. Finally, a type III disease is a disease almost exclusively affecting the developing world and practically non-existent in the developed world (Malaria). These diseases have a total burden between 35 and 1000 times larger in the developing world as the developed world (WHO, 2012). Theorists predict and history shows that most compulsory licenses are issued by developing nations, which is an unsurprising result,

given that those nations have the least access to medications. Given all this background information, we can hypothesize the effect for each disease type.

**III) Literature Review:**

*A) Predicting Impact*

While the impact of the license on the short-term value of a firm has not been studied, other research has been done to assess other impacts of the license. First, trying to ascertain the impact of a license on drug sales has been theorized. Using the framework from above, if a drug for a type I disease gets a compulsory license issued by a developing nation, one can expect the overall revenue of the drug company who owns the drug to be unaffected because the revenue from the drug will be almost entirely in the developed world (Reichman, 2009). Similarly, for a type II disease, although it may have a bit more of a deleterious effect on the financial outlook of the drug, the developing markets are still less critical than the developed markets. However, for type III diseases, where the revenue is coming almost exclusively from the developing world, the issuance of a compulsory license would, theoretically, have a significant deleterious effect on the outlook of drug sales worldwide (whether those drugs get made in the first place is a different discussion).

*B) Who Issues Them:*

Adding to the literature on compulsory license issuance, Beall and Kuhn from University of Denver's School of International Studies, decided to examine what types of countries were actually issuing the compulsory licenses for patented pharmaceuticals. They hypothesized that even when a compulsory license was issued, the lower income countries (LIC) would lack the production capability, distribution networks, and buying

power to efficiently and effectively utilize the compulsory license (Beall & Kuhn, 2012). By combing through as many databases as possible, they found 13 issued compulsory licenses to examine in their analysis. They found that there were more compulsory license issued by upper middle-income countries (UMIC) than LICs.

This result highlights potential inefficiencies in the compulsory license system due to their underutilization by LICs. It stands to reason that the countries that could benefit most are the countries that have the lowest levels of health and health care (LICs). However, the smaller number of licenses issued in LICs indicates that, although they need the compulsory licenses the most, they are not issuing them. The authors speculate that this has to do with issues of production. Even though most of the licenses examined came after TRIPS article 31bis that allowed for import of compulsory licensed drugs, the lack of LIC countries means compulsory licenses are not being utilized to their full potential.

*C) Incentives to Innovate:*

Whether compulsory licenses change or harm incentives to innovate has also been studied. Colleen Chien looked at six cases of compulsory license in her analysis, four of which she describes as "sporadic," while the other two were the result of a merger, which makes them irrelevant to this thesis. Calling them sporadic means that they could not be predicted at all (harkening back to the importance of predictability). Not surprisingly, the four licenses that she deemed sporadic did not cause a drop in R&D expenditure in the therapeutic area of the license. Chien echoes the argument highlighting the difference between compulsory licenses issued for a global disease versus a developing world disease. Even though Chien does not find a statistically

significant result in her analysis, she does acknowledge that the disincentives to innovate may not be captured in the analysis if research was never undertaken to begin with (Chien, 2003). While this underscores why compulsory licenses may do more harm to developing nations than can be quantified, this does not capture the entire picture, since they may bring additional bargaining power. Overall, an unclear picture may arise of compulsory licenses in which the true benefits and costs of the licenses are unknown.

*D) FDI Impact:*

The issuance of a compulsory license by a developing nation may also come with other negative consequences like divestment by large multinational pharmaceutical companies. This can be assessed by the change in total foreign direct investment (FDI) into a country. FDI is the flow of people, capital, and technology from one country to another. In the pharmaceutical industry, FDI is usually the acquisition or production of subsidiaries in the host country(R. C. C. Bird, Daniel R. , 2008). FDI has been used in the past as a metric to judge confidence in the host nation. A significant portion of pharmaceutical companies' worry comes about due to the potential for compulsory license mishandling and very high transaction costs for both companies and nations. If a country is likely to enter into a compulsory license, it may be in the multinational firm's best interest to avoid ventures into that country and seek a more friendly business environment rather than deal with the constant threat of a license and the high legal costs if they do come to fruition (Bird, 2009). Additionally, manufacturers tasked with production of the compulsory licensed drug may take advantage of the license and attempt to generate profit rather than alleviate the epidemic through low cost

medication. For example, the Washington Post in 2002 reported that "Nearly $18 million worth of reduced-price HIV drugs intended for impoverished Africans have been intercepted by profiteers and shipped back to Europe to be sold at marked-up price" (HST, 2002). While this number is not large for the bottom line of a pharmaceutical company, parallel imports / arbitrages have the potential to eat away significantly at the earnings potential of a drug and also harm the intended beneficiaries of the drug. Due to parallel imports, there is the potential for extreme negative consequences of a compulsory license for the multinational entities (MNEs) profits even if the issuing nation is a negligible market, especially since the company itself cannot control the distribution during a compulsory license.

Egypt is an example of what can happen when a country seemingly oversteps their bounds with respect to a compulsory license and then suffers significant negative consequences. Egypt has, historically, been in favor of the use of compulsory licensing for drugs, although perhaps for questionable reasons (Aziz, 2003). It has cited reasons including that the current price of the drug is too high, and it does not meet demand. As unfortunate as this may be, the drug price being too high for a non-essential medication is not in itself enough to warrant the issuance of a compulsory license under the Doha declaration. Egypt's issuance of a compulsory license on Viagra in 2002 illustrates this perfectly. While some may argue this medication is of the utmost importance, it is difficult to believe that Egypt was suffering so severely, or so much worse than the rest of the world, as to warrant considering it a public health issue. Although "local pharmaceutical manufacturers [accused] the Egyptian Ministry of Health of exploiting Egypt's poor by granting Pfizer the exclusive right to sell Viagra within Egypt's

borders," that is not enough reason to grant a compulsory license (R. C. Bird, 2009). The issuance of the license exemplifies the potential misuse of the compulsory license system. This license was granted because of political pressure applied by small pharmaceutical companies within Egypt, not by individuals looking out for the public health of Egyptian citizens. Additionally, the argument made for the compulsory license was a financial one, and not an essential medicine one, which does not constitute a reason for a compulsory license under TRIPS and the Doha Declaration.

Multinational corporations met the issuance of a compulsory license by Egypt first with harsh criticism, then with action. Their action was catalyzed by their lack of faith in Egypt's intellectual property laws. This was highlighted when Egyptian representatives to pharmaceuticals were informed that their weak patent landscape had cost them over $300 million of investment into their pharmaceutical sector (Aziz, 2003). While the Viagra license exemplifies the potential for abuse, the weak patent landscape had already been hurting Egypt's economy significantly. The amount of foreign direct investment into Egypt declined from about $950 million dollars in 1987 to $425 million in 2002 (R. C. C. Bird, Daniel R. , 2008). While the authors' conclusion does seem a little ambitious and one-dimensional given Egypt's tumultuous political scene, it is clear that when used and misused, the issuance of a compulsory license can have strong negative consequences on the non-generic pharmaceutical sector of a nation.

While Egypt is a good example of the potential impacts of compulsory license misuse on foreign direct investment, other nations have dealt with similar issues as well. In the time immediately following TRIPS, the Argentine Senate forced through

legislation which enacted patent law inconsistent with TRIPS, causing a reduction in trust from MNE's (R. C. Bird, 2009). For example, upon filing an appeal against a compulsory license, the license would not be suspended immediately. Rather, the patent office would wait for the ruling of the court (R. C. Bird, 2009) to require the suspension of the license. This allowed for imitation to occur easier, causing serious revenue loss for MNE's. In the period after this new Argentine legislation, countries such as Germany and Sweden actively voiced concern and stated that the lack of IPR was the central concern of business owners considering entering into Argentina (R. C. Bird, 2009).

Overall, it has been shown that the issuance of a compulsory license has the potential to cause severe negative consequences to the issuing nation. There is not much information about how the license affects the value of the company that the license was issued against. I will address this by examining how the value of a firm does or does not change after the announcement of a compulsory license.

*E) Event Studies:*

In order to ascertain the impact of the license, I employ an event study methodology in this thesis. The goal of any event study is to calculate and test the impact of specific value changing moments on a firm's stock price by calculating the expected return over a period and comparing it to actual return. In modern corporate finance, event studies are used to study the effect of events such as dividend announcements, earnings, mergers, capital expenditures, and new issues of stocks (Ross, 2010). Because compulsory license announcements often come as a surprise

announcement, this event study methodology is perfectly suited for the needs of this thesis.

Sporadically used since the 1930's, event studies entered the main stream in the 1960's, with two seminal papers by Ball and Brown (1968) and Fama et al. (1969) (Corrado, 2011). In fact, well over 500 papers using the event study methodology have been published between 1974 and 2000 in 5 of the large economics journals (Kothari, 2004). This number shows the wide use and acceptance of event studies as a viable methodology. In pharmaceuticals more specifically, extensive research has been done with event studies. They have been used to answer questions in the pharmaceutical space such as long term value creation (Tomovic, 2012), the value of alliances and joint ventures (Campart, 2007), and the impact of transforming domestic patent systems from process to product patents (Kawaura & La Croix, 1995). While the event study has been employed to answer many questions in the pharmaceutical space, it has never been used before to answer the question posed in this thesis: what is the short-term impact on firm value of the announcement of a compulsory license? Before employing an event study, however, it is first necessary to specify which country to take data from, which model to use, the length of time to study, and which tests to run.

Rather than an event study methodology, I could have used the difference-in-differences (DID) methodology. This also looks at the change in a treatment group versus a control group. This is also an extremely common framework, which would have worked for this analysis. However, these two methodologies are so close, and the fact that the expected change for the stock price should be reflected quickly versus for

looking for impact over time, means that the event study is as well, if not better, suited for this research than a DID analysis.

*F) Choosing the Reference Country:*

Before gathering data, I first had to decide which market's data to use, since many of the licenses were occurring in developing nations. Obviously, if the license issued was in a country without a stock exchange, it was easy to justify using the data from the US as a proxy. However, it was not as clear a decision when dealing with larger countries such as Brazil. In event study research involving multinational corporations or subsidiaries, the market used is chosen in one of three ways (Gu & Reed, 2013). First, you can use the firm's home market. Second, you can use the market with the highest volume. Finally, you can use the US as a proxy. In the end, using Gu & Reed's rationale, the US was chosen for analysis since the US satisfies two if not all three of those criteria set out in their paper. In the end, no matter where the license was issued, data from the NYSE or NASDAQ was used.

*G) Return Generating Models:*

In order to successfully complete an event study, one needs an accurate way to model expected performance of a stock during the period following the compulsory license (called the event window). While some may argue that this is the wrong period to study, and the compulsory license effect would be noticed more when earnings are released, there are far more pieces of information being learned during an earnings announcement, thereby diluting the impact of the license. So, the event window with the period including the announcement better reflects the impact of just the license.

In order to calculate the expected return of a stock over a given period, we create a model of the stock's performance in the previous time frame to help us estimate. This model is called a return-generating model and is critical to the event study.

The three accepted forms of the return generating model are the market-adjusted return model, the mean-adjusted return model, and the risk adjusted return model (Fernando, 11/25/2009). The market-adjusted return model is the crudest estimation model, stating that the expected return of the security during the event window is equal to the market return on that day. This essentially states that every stock has an expected return on day t equal to the market on day t and that the firm has absolutely no impact at all. See equation below:

$$E(R_{it}) = \beta_i R_{mt}$$

Where $E(R_{it})$ is the expected return of firm *i* on day *t*, $R_{mt}$ is the return of the market on day *t*, and $\beta_i$ is modifier to relate the two. This equation is even more constrained than it first appears, since this model forces $\beta_i$ value to be equal to one. While this leads to a simple analysis, it seems oversimplifying and removes any information about the past performance of the firm from the analysis. In pilot simulations and practice, this may lead to "somewhat inflated [effect] compared with the other two models" (Fernando, 11/25/2009).

Fernando's comment translates to a high potential for a type I error. A type I error is, in simple terms, the probability of a false positive, which should be avoided if possible. So, in order to avoid a false rejection of the null hypothesis, the market-adjusted model is not used.

Compared with the market-adjusted return model, the mean adjusted return model does attempt to make the analysis more directed, however it still does not quite have the accuracy of the risk-adjusted return model. In the mean-adjusted model, the expected performance of the company is equal to the average performance of the company in the window leading up to the event (the event window), shown the in the equation below:

$$E(R_{it}) = \alpha_i$$

Here the $\alpha_i$ is a constant equal to the average daily return of the stock during the estimation window. While this model does account for the firm's performance in the period leading up, it does not account for the market's effect on firm performance at all. Just as the market-adjusted return model was incomplete for not including any firm performance information, we can describe this model as incomplete for not including any information about market performance. This would leave the analysis open to huge gaps. Imagine if, halfway through the event window, there was the beginning of an economic downturn. That would not be captured when examining purely company data and would lead to incomplete analysis. For this reason, the market-adjusted return model was not chosen for this study.

Finally, the risk-adjusted return model accounts for both the previous company performance and the market performance, remedying the issues discussed earlier. Using the equation

$$E(R_{it}) = \alpha_i + \beta_i R_{mt}$$

where $R_{it}$ is the firm's performance and $R_{mt}$ is the market performance, we can estimate an α and a β, which are the slope and intercept of the line we are predicting, for the

period prior to the license. This allows me to calculate an expected performance given what happens in the market in the event window. Additionally, this model is preferable because it results in smaller variances of abnormal returns (Strong, 1992). In the end this model was chosen since, of the three models shown above, this is the most accurate since it accounts for the market and the firm, not just one or the other.

*H) Length of Event Window:*

The event window, as discussed previously, is the period immediately following the event (in this case the compulsory license). Some research has focused on the length of time best suited for an event window. In some cases, long event windows of over a year are required. However, those have a surfeit of problems which arise, such as other events causing shocks, different market outlooks, etc (Kothari, 2004). For the purposes of this study, a long event window would be entirely unnecessary. I assume in this research that the effect of a compulsory license will be seen in the days or weeks following the issuance of the license. In a similarly designed study focusing on the analysis of pharmaceutical alliances and joint ventures on stock price, a 21 day period was used as the event window (which, when it comes to this analysis, means 15 trading days) (Campart, 2007). Additionally, within the paper it is noted that, while three weeks was used "an event window of 3 days would suffice here, for all the reaction of the investors is concentrated with these 3 days" (Campart, 2007). However, it struck me that many of these announcements may be made at the end of the day. So, in order to account for this possibility, one day was added to the event windows for both the three and fifteen trading day windows. Given all of this input, event windows of four days and sixteen days were both chosen, in order to assess the impact of the compulsory licenses.

*I) Statistical Tests:*

Finally, after calculating the cumulative abnormal return (CAR), it is necessary to establish which statistical tests to use. Making the assumption that the CARs are normally distributed, first the data will be run with a parametric *t* test. Many authors, such as Fernando, employ the *t*-test to test significance across all samples. Some authors have argued for and concluded that, even if a dataset is non-normally distributed, the *t* -test is still an appropriate test (Dyckman, Philbrick, & Stephan, 1984). However, not all share their belief. Since our data is across multiple time periods, companies, and diseases, there is no reason to assume that the data is normally distributed so the Wilcoxon-signed rank test is also utilized. Serving as a non-parametric alternative to the *t* -test for event studies, the Wilcoxon is often used in tandem with a normal student *t* -test (Tomovic, 2012), (Akbar, 2010). The Wilcoxon test assesse whether two sets of data are statistically different. Here, the two sets of data are the calculated *t* -stats for each example and zero. The null hypothesis for the Wilcoxon test is that the median difference between the pairs of values is zero. If we fail to reject that hypothesis, then we are unable to say that the two data sets are different, meaning that the calculated *t* -stats are not different from zero. Ranking absolute values of the t-stats from largest to smallest, the test then assesses whether there is a statistically significant difference in the two data sets. Since the use of these tests in tandem is both common and standard practice, this thesis also employs the use of these two tests.

**IV) Methods:**

Event studies calculate the "abnormal return" for a stock on a given day and test whether this abnormal return is statistically different from the expected return for the day given the performance of the market. In order to successfully calculate this, the following equation is used:

$$AR_{it} = R_{it} - E(R_{it}|R_{mt}) \quad (1)$$

Where $AR_{it}$ is the abnormal return for firm *i* on the event day, $R_{it}$ is the return for firm *i* on the day *t* of the event window, and $E(R_{it}|R_{mt})$ is the expected return of firm *i* given the market return for day *t*.

In order to calculate the $E(R_{it}|R_{mt})$ term, we must first establish how the firm's stock fares compared with the market. We do this by examining the time before the event, called the estimation window. Using the risk-adjusted market model, the following regression is used:

$$R_{it} = \alpha_i + \beta_i R_{mt} + \varepsilon_{it} \quad (2)$$

Using this regression with each firm's returns in the days preceding the event and the market return allows the calculation of the $E(R_{it}|R_{mt})$ term with only the market return for day t. Combining equations (1) and (2), we can rewrite the equation for abnormal returns as:

$$AR_{it} = R_{it} - \hat{\alpha}_i - \hat{\beta}_i R_{mt} \quad (3)$$

Therefore, now that we have established how to calculate the abnormal return for day t, the normal distribution will appear as follows:

$$AR_{it} \sim N(0, \sigma^2(AR_{it})) \quad (4)$$

Before going further, it is necessary to examine the variance of the abnormal return for the normal distribution. From Mackinlay's review of event studies (MacKinlay, 1997), the variance of the abnormal return is written as:

$$\sigma^2(AR_{it}) = \sigma^2_{\varepsilon_{it}} + \frac{1}{L_1}\left[1 + \frac{(R_{mt} - \hat{\mu}_m)^2}{\hat{\sigma}^2_m}\right] \quad (5)$$

Where $L_1$ is the length, in days, of the estimation window, and $\hat{\sigma}^2_m$ is the variance of the market. However, as long as the estimation window is sufficiently large, the $\frac{1}{L_1}$ term will cause the entire second term to vanish. For this paper, a 150 day estimation window will be utilized (so $L_1 = 150$), as that has previously been shown to be more than sufficient (MacKinlay, 1997). That therefore reduces the variance of the abnormal return to just the $\sigma^2(AR_{it}) = \sigma^2_{\varepsilon_{it}}$, which is the variance of the error term $var(\varepsilon_{it}) = \sigma^2_{\varepsilon_{it}}$ which we saw in equation (2).

Using the abnormal return for a single day does not provide enough information to be able to assess the abnormal returns associated with a single event. As discussed earlier, the length of the event window was rationalized both by the standard practice (15 days post event) and by the assessment Campart et al. had of their own data which helped me conclude that a four-day event window post event was sufficient. This requires the abnormal returns be transformed into a cumulative abnormal return, denoted as CAR:

$$CAR_i(\tau_1, \tau_2) = \sum_{\tau=\tau_1}^{\tau_2} AR_{it} \quad (6)$$

Where $\tau_1$ is the first day of the event window and $\tau_2$ is the final date of the event window. Similarly to the single day abnormal return variance, for large estimation period the variance is:

$$\sigma_i^2(\tau_1, \tau_2) = (\tau_2 - \tau_1 + 1)\left(\sigma_{\varepsilon_i}^2\right) \quad (7)$$

It is necessary to use $\tau_2 - \tau_1 + 1$ since $\tau_1$ is equal to zero. If we did not add 1 then the variance of the CAR would be underestimated. With equations (6) and (7), we can therefore state that the normal distribution for the cumulative abnormal returns is as follows:

$$CAR_i(\tau_1, \tau_2) \sim N(0, \sigma^2(\tau_1, \tau_2)) \quad (8)$$

Given a null hypothesis that compulsory licenses do not significantly affect the stock price, we can use the above equation to test the null hypothesis assuming the distribution is normal. Additionally, since we do not have any prior notions on what, if any, effect the license will have, we will utilize a two-tailed test. Stated explicitly, the null hypothesis is that there will be no significant effect of a compulsory license on company stock price or trading volume.

**V) Data:**

Using the event study methodology outlined above, and the recommendations outlined as well, the data requirements are clear. First, in order to sufficiently calculate the firm return given the market return during the event window, 150 days of estimation window data is required. For this, the firm in question, along with a large stock index (the S&P 500), and an index with a pharmaceutical focus (the NYSE ARCA Pharmaceutical Index) are required. Regressions will be run comparing both the cumulative abnormal returns compared to the S&P, and compared to the pharmaceutical index. For the event window, sixteen days of data are required. Once again, that data will be of the company in question, the S&P 500, and the pharmaceutical index described above.

Additionally, I also decided to gather the volume data for both the firms and the S&P index. Using this information, an additional test with event study methodology can be run to ascertain whether there was a statistically significant trading volume difference caused by the event. Similarly to the stock price analysis, this will also be a two-tailed test.

To ascertain the dates of the licenses, it was necessary to draw on multiple sources. While Beall and Kuhn found 13 verified compulsory licenses in 11 nations (Beall & Kuhn, 2012), other sources have stated much higher numbers of compulsory licenses. For this analysis, news outlets such as the Wall Street Journal were scoured and search engines used to verify Beall and Kuhn's information and ascertain exact dates of those licenses, and others as well. In the end, data for 24 companies was gathered. Although more compulsory licenses have been issued, the firm was either private (Boehringer Ingelheim) or was not listed on the NYSE at the time of the license (Roche).

**VI) Results:**

First, each compulsory license episode was tested for significance using the methods shown above. Each company stock price was tested in six ways. First, using a four-day event window, the firm's stock price return was tested against the pharmaceutical index return (drg), the S&P index market price return (SP), and finally against the S&P market volume (SP_V). Then, the same regressions were run, but instead of an event window of four day, it was a sixteen-day window. From there, the aggregated *t* -statistics were then tested to see if there was any predictable effect of the licenses. By testing the aggregate I can then speak about the expected impact of a

license, if any exist. It would not just be enough to talk about individual cases, since that would be essentially anecdotal.

*A) Four Day Event Window:*

First, the shorter event window data was used, given Campart's comments surrounding the lack of a longer event window. The overall results for the short event window are shown below in Table 1.

For each event, the *t* -statistic associated with the cumulative abnormal return is shown. This *t* -stat shown is the *t* -stat associated with the CAR calculated using the drug index (drg), the S&P (SP) or the S&P volume (SP_V). If the *t* -stat is significant, that means that the CAR is statistically different from zero, which was shown in equation 8 (pg. 32). Table 1 also shows how many of those *t* -statistics were positively significant, insignificant, and negatively significant. Finally, the statistical probabilities for both the *t* -test and the Wilcoxon rank-signed test are shown below, which both used the *t* -stats as their data.

The associated *t* statistic is shown for each event when compared with the drug index, the market price, and market volume (see appendix for information on each event). Looking at the summary of those 24 events for the short time period, when compared with the drug index, ten were insignificant, while four were significantly positive and ten were significantly negative. First off, the fact that almost half of the data points showed no significance underscores that companies may be more worried than they need to be.

| Event_ID | t-stats using 4 day drug index | t-stats using 4 day S&P | t-stats using 4 day S&P Volume |
|---|---|---|---|
| 1 | -0.32 | 0.02 | 1.52 |
| 2 | -0.72 | -0.74 | 1.46 |
| 3 | 0.92 | 3.05# | 2.46# |
| 4 | -3.34$ | -2.25$ | 0.39 |
| 5 | -10.08$ | -9.12$ | -4.01$ |
| 6 | -6.02$ | -5.40$ | 0.51 |
| 7 | 2.90# | 5.59# | -0.48 |
| 8 | -2.12$ | -0.76 | 2.14# |
| 9 | -8.48$ | -6.74$ | 2.48# |
| 10 | 3.08# | 2.18# | -0.18 |
| 11 | -0.10 | 1.26 | -0.43 |
| 12 | 0.15 | 3.17# | 1.08 |
| 13 | -1.45 | 0.26 | 0.17 |
| 14 | -0.10 | -1.00 | 6.98# |
| 15 | 4.37# | 3.36# | -1.55 |
| 16 | 0.53 | 1.27 | -2.39$ |
| 17 | -0.95 | 5.25# | -0.35 |
| 18 | 0.68 | 0.19 | 0.17 |
| 19 | -3.08$ | -0.58 | -1.76 |
| 20 | -2.44$ | -1.40 | 0.30 |
| 21 | -2.40$ | 1.05 | -3.97$ |
| 22 | 4.22# | 6.89# | -0.60 |
| 23 | -3.82$ | -1.47 | 1.34 |
| 24 | -11.74$ | -9.87$ | -3.97$ |
| **Tstat_positive (*t*>1.96)#** | 4 | 7 | 4 |
| **insignificant** | 10 | 12 | 16 |
| **Tstat_negative (*t*<-1.96)$** | 10 | 5 | 4 |
| **T_test of t-stats** | .0580* | 0.7819 | 0.9121 |
| **Wilcoxon of t-stats** | .0865* | 0.909 | 0.9544 |
| ***=Significant to the 10% level** | | | |

Table 1: Overall results for *t*-stats, *t*-test, and Wilcoxon signed Rank test when using shorter (4 day) event window period

While this was true, the tests ran with the drug index as the market did prove to be significant to the 10% level. Additionally, testing the *t* -statistics of the drug index event study with the non-parametric Wilcoxon signed-rank test also come out to be statistically significant to the 10% level. All in all, both the *t* -test and the Wilcoxon show a weak significance for the data in this particular case. This was, however, the only time when either the *t* -test or Wilcoxon showed any significance.

When examining the *t* -statistics associated with the market price and market volume, we find even more of the events being insignificant. For the market price, twelve were insignificant, while seven were significantly positive and five were significantly negative. For the volume analysis, sixteen of the twenty-four were insignificant, four positive, and four negative. Not surprisingly, when running these calculated values through both a parametric student *t* -test and Wilcoxon signed-rank test, they come out showing that compulsory license issuance has no statistically significant effect on the value of the firm in question.

Looking at these data with a four-day event window, we find that the effect of the compulsory license on company stock price seems to be significant only when compared with the drug index, and not with the S&P. That being said, it still does not illuminate to us the circumstances that make a license positively, negatively, or insignificantly impactful.

*B) Sixteen Day Event Window:*

Although I tested the four-day event window because of Campart's suggestion, I also used an event window that extended 3 weeks post event (so 16 trading days), since that is standard

| Event_ID | t-stats using 16 day drug index | t-stats using 16 day S&P | t-stats using 16 day S&P Volume |
|---|---|---|---|
| 1 | -17.95$ | -20.74$ | -3.07$ |
| 2 | -11.17$ | -21.10$ | -4.39$ |
| 3 | 0.41 | -2.71$ | 6.05# |
| 4 | -2.91$ | 4.59# | 2.97# |
| 5 | -14.20$ | -11.37$ | 2.61# |
| 6 | -30.76$ | -33.14$ | -3.74$ |
| 7 | 12.46# | 20.94# | -3.18$ |
| 8 | -1.52 | -23.75$ | 8.33# |
| 9 | -14.87$ | -20.34$ | 5.43# |
| 10 | 3.39# | -10.68$ | -2.30$ |
| 11 | 7.61# | 1.79 | 2.20# |
| 12 | 5.81# | 7.63# | -0.24 |
| 13 | 30.21# | 34.03# | -10.67$ |
| 14 | 1.63 | -9.30$ | 10.00# |
| 15 | -2.94$ | -12.56$ | 4.68# |
| 16 | -3.31$ | -21.99$ | -13.24$ |
| 17 | 0.33 | 12.03# | -1.51 |
| 18 | 12.55# | 17.62# | -7.44$ |
| 19 | -10.93$ | 10.86# | -0.13 |
| 20 | -5.24$ | 15.34# | -6.84$ |
| 21 | 15.75# | 20.80# | 2.07# |
| 22 | 7.45# | 11.34# | 0.73 |
| 23 | 4.80# | 11.05# | 8.36# |
| 24 | -19.54$ | -13.02$ | 1.29 |
| **Tstat_positive (*t*>1.96)#** | 9 | 11 | 10 |
| **insignificant** | 4 | 1 | 5 |
| **Tstat_negative (*t*<-1.96)$** | 11 | 12 | 9 |
| **T_test of t-stats** | 0.615 | 0.710 | 0.944 |
| **Wilcoxon of t-stats** | 0.689 | 0.627 | 1.00 |

Table 2: Overall results for *t*-stats, *t*-test, and Wilcoxon signed Rank test when using longer (16 day) event window period

procedure for event studies. Set up similarly to Table 1, all the results and information pertinent to the research is highlighted below in Table 2.

Once again, the *t*-statistics are shown with respect to the drug index, the market price, and the market volume. The striking differences in values here is evident when compared with the four-day event window. While 11, 13, and 17 of the events were insignificant with a four-day window, here it is only four, one, and five. There exist two explanations. It takes the market a while to digest and fully analyze the effect of the compulsory license, so this longer event window offers to us a better idea of what effect they might have. The other possibility is that other material events are taking place for these companies and that the results we are seeing do not have to do with the license so much as other factors, which is elaborated on in the discussion.

The statistical tests provide no evidence to reject the null hypothesis that there is something statistically impactful occurring. Using all three sets of data, it appears that a compulsory license announcement has no statistically significant effect on firm value, regardless of whether we use the drug index or S&P price, or on volume traded.
A similar lack of significance is noted when examining the data through the Wilcoxon test as well. None of them proved to be significant at all, culminating in the volume test with sixteen-day event window actually having a probability of exactly 1.00. Whether looking at the data with the *t*-test or the Wilcoxon, it is clear neither stock price nor trading volume shows any significant effect due to compulsory licenses.

**VII) Discussion:**

In this thesis I aimed to test whether the issuance of a compulsory license had a statistically significant effect on company stock price. As outlined above, the only case

with significance was the four-day event window, when using the drug index. When considering that all other tests run found no significance, it is reasonable to state that these licenses have no significant affect on firm value. Since using the larger event window removes any significance, we see that what significance might've existed gets muddled and overtaken by the normal proceedings of the market. Thus, I conclude that I cannot reject the null hypothesis that the announcement of a compulsory license does not have a short-term effect on the market capitalization of the firm whose drug is licensed.

That is not to say that every case is insignificant. As explained above, we find almost all the cases having either a positive or negative effect with the longer window, but it appears to be evenly split and therefore, unpredictable.

When first establishing that short and long event windows would be used, it was justified with Sandy Campart's paper on the impact of partnership announcements. In her paper, as quoted previously, she describes that a three-day window would have captured most of the effect of the license. However, in this thesis, this did not occur, given that the findings are very different when using the two event windows. The possible explanation is twofold. First, the market could viscerally react to negative news. This could explain the negative result found for the short window with the drug index. If any of these announcements are viewed positively, those could take longer to digest and react to. Additionally, there could be other things clouding the longer event window, which are discussed below.

*A) Finding Significance:*

I want to address a phenomenon I see with the data, which I call finding significance. As previously pointed out, more of the results are insignificant with the short event window than with the long event window. I believe that it is both plausible and reasonable to assert that the higher number of cases with significance after sixteen days is not caused by the compulsory license announcement. Much of this assertion depends on whether or not you believe that it would take more than a few days for the market to adjust to the license. While a three-week event window may be necessary for things such as complex mergers, a simple license on one drug in one country does not seem to be particularly complicated news. Additionally, I believe that some of these firms do not even consider the licenses to be material information. I say this given the difficulty that I had in finding the compulsory license announcements. In many cases, no mention of compulsory licenses could be found on company websites, even in press releases. This illustrates to me that these firms do not think that the license is important enough to even inform their investors about. Investors often learn about a compulsory license through other news sources. With this in mind, I find it very difficult to imagine that the effect of the license is so difficult to ascertain that it takes weeks. Rather, the license is digested quickly and then other factors cause the effects within the three-week window.

Additionally, my conclusion stems from the fact that the results are significant in both directions (positive and negative). If all the licenses were moving in one direction after 3 weeks, then I would argue that the licenses were finally understood and reflected in the market. However, this is not the case, and there are roughly as many

positive as negative results in the longer window. For the drug index comparison, nine of the twenty-four are positively significant, while eleven of the twenty-four are negatively significant. For the S&P price comparison, eleven are positively significant, while twelve are negatively significant. Finally, for the market volume, ten are positively significant while nine are negatively significant. From this, it is clear that companies are about as likely to have a better than expected outcome compared with a worse than expected outcome. I believe this result shows that other events (positive or negative) are occurring, thereby impacting and diluting the effect of the license. Additionally, it could also just be strong random noise, however that does seem to be a stretch since such a long estimation window was used. In summary, I expect that something else is going on here other than the compulsory licenses.

*B) Clustering:*

The potential issue of clustering arises a few of times in these data. Clustering occurs when the company data may impact the data collected for the market index. This may cause a deflation in the index, therefore under-estimating the abnormal return. While most of these examples are single company, single drug licenses, this is not always the case. In some cases, drugs are licensed which have active pharmaceutical ingredients from multiple companies, and who share profits as well. Additionally, there is one case when Indonesia licensed multiple drugs at the same time. While these cases of multiple drugs at once should have no effect on the S&P, there may be an effect on the drug index. For the Indonesia example, while Gilead Sciences and Abbott Laboratories are not on the index, GlaxoSmithKline and Bristol Meyers Squibb both are. That being said, there are 27 companies on the pharmaceutical index, so the effect is far from

substantial. While this only occurs a few times, it could have caused some dampening of the overall effect when using the drug index as reference. Attached in the appendix is the current company used in the index.

*C) Further Research:*

These results raise the question about what, if anything, determines the effect of the licenses. Further research into the companies who reacted well and poorly is required. Possible explanations include HIV versus non-HIV licenses, acute versus chronic illnesses, the development level of the country, the type of illness that gets a drug compulsory license (type I,II, or III), the company whose drug gets licensed, etc. These questions harken back to Colleen Chien's discussion of both the predictability and importance of the market. For HIV drugs, since so many have been licensed, perhaps the market had already taken into account the possibility of the license. Similarly, by looking at the markets in questions, we can further examine what makes a market 'important' and whether that is the determining factor in the impact of the license. In addition the development level of the country, the potential for leakage of drugs into cash markets, and corruption may play a role as well. Perhaps by identifying those cases and factors that cause a negative effect, companies can be more open to compulsory licenses that do not fit that bill and therefore will not negatively impact company stock price.

**VII) Interviews:**

In addition to doing my own research and economic analysis, I wanted to discuss compulsory licenses with key opinion leaders to gain insight into the pharmaceutical side. I conducted two interviews in the time after my results were complete. First, I

interviewed an individual (in this thesis referred to as Ryan) who had previously served as CEO of a biotech company. Second, I interviewed an individual (in this thesis referred to as Paul) who has served as legal counsel for major pharmaceutical companies for much of their career. The basic questions I asked them are reproduced in the appendix.

*A) Opinions:*

As individuals who had first hand experience in the field since TRIPS and other legislation, I was curious to ask how and to what extent that their opinions on compulsory licenses have changed over the last 20 years. Ryan noted that the fear has certainly lessened given the fact that "practice suggests that compulsory licenses aren't used very often" and that this outcome is nowhere near as detrimental as "compared with the known and unknown at the beginning of the establishment of the compulsory licenses." Paul echoed this sentiment, describing that "the nightmare scenario where everything was going to be compulsory licensed hasn't played out over the past 20 years" It appears that my inclination that these licenses have not had a doomsday effect is echoed throughout the industry. This signals a large change in industry sentiment since compulsory licenses inclusion in TRIPS in 1995 and potentially also opens the door for more targeted use without retaliation.

Although both did acknowledge that the hysteria twenty years ago was misplaced, they both expressed a cautious attitude toward compulsory licenses. Paul commented that, no matter how many had been issued, "if you're a company that has a threat of compulsory licensing to your property you're going to be worried about it." This seems a reasonable point since it is never a good business move to have another party with access to your IP without your having any legal recourse. Ryan similarly

cautioned about the use of compulsory licenses, but he focused more on the risk of leakage, "the concern that I would have is if, as a result of a compulsory license, there was an increase in export from that country so the cheaper products flooded the market." This was touched upon earlier as a huge potential negative effect of the licenses, and that fear still holds, even though to this point it really hasn't been shown to occur. With both of these opinions, it is clear that individuals within the industry are still concerned about the impact of the licenses.

Additionally, I asked Paul about the Beall and Kuhn result pertaining to who was issuing compulsory licenses. While I was first surprised by the result, he was not at all. He explained that in these lower / upper middle income countries "you're going to have huge populations who can't afford the medicine. And you're going to have a situation too where there's not really government funding to provide it." In essence, even though the countries look more developed on paper, the individuals who are most likely to be suffering from diseases and illness may not have any more capacity to purchase them than people in the least developed countries. He sees developing nations using them as much as a tool to help drive down health costs as anything else. While this viewpoint is advantageous for the developing nations, it does sound like a thin line between misuse and abuse and using them to lower western rates on drugs.

Finally, when asked about what other hurdles exist to getting drugs to those who need them, Paul was quick to point out issues surrounding regulatory approval. In each country there are different rules and regulations in order to get drug approved. In this model of regulatory approval, a lot of these countries are not worth attempting to get IP in given the high cost of studies. However, if there was a homogenizing of regulatory

steps, this could lead to huge increases in access. That way, "if you have approval in the US or Europe, perhaps you could get automatic approval in the rest of the world." This would work unbelievably well to increase the number of medications available for people in the developing world. While there could and would still be issues surrounding pricing, at least enough new medications would be in the market to facilitate price reduction and increase quality of patient outcomes.

**IX) Conclusion:**

Before conducting my own analysis in this thesis, I laid out the fear and worry from companies about the potential for abuse and misuse of the compulsory licenses. While this fear may still exist, the data does provide evidence that the compulsory licenses do not have a predictable effect on firm value in the short run. While they are significant to the ten percent level in the four-day event window in one set of data, that significance is lost for the longer event window. Although more research must be undertaken to establish under what circumstances a license may be beneficial or detrimental to firm value, it is clear now that the mere issuance of a license is not enough to cause a predictable effect, either positive or negative.

This result hopefully will join the other research on compulsory licenses to aid in decisions surrounding them and inform opinions. For example, it is clear that a company should not view any threat of a compulsory license as a negative to their valuation. Similarly, countries should understand that the licenses do cause significant negative effect in some cases, in addition to positives in others. If the circumstances can be understood, compulsory licenses could be more effectively used to increase healthcare outcomes across the globe, without causing a significant negative effect to

firm value. After all, that is the intended purpose of these licenses. In fact, no research has yet been undertaken to assess the impact of a license on public health and health outcomes. While this question seems straightforward, it still has not been empirically studied.

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**Appendix:**

A) Information regarding each compulsory license studied, including company, country, and date.

| Event Number | Country | Company | Date |
|---|---|---|---|
| 1 | Indonesia | Gilead | 9/3/12 |
| 2 | Indonesia | Abbott | 9/3/12 |
| 3 | Ecuador | GSK | 11/12/12 |
| 4 | Ecuador | Abbott | 4/24/10 |
| 5 | Ghana | GSK | 10/26/05 |
| 6 | Israel | Biogen | 10/9/95 |
| 7 | Thailand | Sanofi | 1/25/07 |
| 8 | Malaysia | BMS | 10/29/03 |
| 9 | Mozambique | GSK | 4/5/04 |
| 10 | Mozambique | BMS | 4/5/04 |
| 11 | Rwanda | GSK | 6/20/07 |
| 12 | India | Bayer | 3/12/12 |
| 13 | Brazil | Abbott | 6/24/05 |
| 14 | Indonesia | Merck | 9/3/12 |
| 15 | Indonesia | GSK | 9/3/12 |
| 16 | Malaysia | GSK | 10/29/03 |
| 17 | Indonesia | GSK | 10/5/04 |
| 18 | Italy | Merck | 6/15/05 |
| 19 | Zambia | GSK | 9/21/04 |
| 20 | Zambia | BMS | 9/21/04 |
| 21 | Thailand | Merck | 11/29/06 |
| 22 | Argentina | Roche | 10/18/05 |
| 23 | Thailand | Abbott | 1/25/07 |
| 24 | Thailand | BMS | 1/25/07 |

B) Standard questions asked to both Paul and Ryan in my interviews:

- Since the compulsory licenses represent end of the negotiation process, I would love to hear more about the process leading up to the issuance of a CL. What are the criteria on your end to allow a drug to go to compulsory licensing (assuming a country really does attempt to negotiate)? Does it have to do with size of the market? Sales of the drug? What are the criteria do you / would you consider when allowing a drug to be CL'ed or to offer extremely steep discounts in the form of a Voluntary license?

- Do you see compulsory licenses to be a last-resort? Do you think countries see them the same way?

- How do you think the feeling about compulsory licenses has changed in the last 20 years?

- Following up on question 3, Since the TRIPs agreement there have been somewhere in the 30 license range. Do you think this shows that they have had less effect or impact than first feared?

- Are there other, potentially more effective, mechanisms you can think of than a CL to remedy the issue of access without losing patent right?

C) Components of NYSE ARCA index for pharmaceuticals (^DRG) on 5/4/15

| Ticker | Name |
|---|---|
| ABBV | AbbVie Inc. |
| ABT | Abbott Laboratories |
| ACT | Actavis plc |
| ALKS | Alkermes plc |
| AZN | AstraZeneca PLC |
| BMY | Bristol-Myers Squibb Company |
| ENDP | Endo International plc |
| GSK | GlaxoSmithKline plc |
| HSP | Hospira Inc. |
| JAZZ | Jazz Pharmaceuticals |
| JNJ | Johnson & Johnson |
| LLY | Eli Lilly and Company |
| MNK | Mallinckrodt plc |
| MRK | Merck and Co. Inc. |
| MYL | Mylan N.V. |
| NVO | Novo Nordisk A/S |
| NVS | Novartis AG |
| PFE | Pfizer Inc. |
| PRGO | Perrigo Company plc |
| RDY | Dr. Reddy's Laboratories Ltd. |
| SHPG | Shire plc |
| SNY | Sanofi |
| TARO | Taro Pharmaceutical Industries Ltd. |
| TEVA | Teva Pharmaceutical Industries Limited |
| VRX.TO | Valeant Pharmaceuticals International, Inc. |
| ZTS | Zoetis Inc. |