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# Compulsory licensing in the TRIPS agreement

*A study of long-run effects on innovation and foreign direct  
investments*

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## **Abstract**

The aim of this thesis is to provide an insight into the potential effects that follow the use of compulsory licensing in developing countries. Compulsory licensing is implemented in World Trade Organization's agreement of trade related aspects of intellectual property rights (TRIPS) and attempts to strike a balance between creating access to existing drugs and promoting the research and development of new ones. Pharmaceutical patent holders argue that this measure will reduce their incentive to provide the world with future needed drugs. Humanitarian organizations along with the developing world underline the importance of compulsory licensing as a measure to secure life-saving medicines to people who otherwise would not afford them. Thus, depending on whose perspective one takes, compulsory licensing could be viewed as either a harmful or beneficial policy measure. One might also see possible effects on the level of innovation within the countries that use the compulsory license, as the license may provide knowledge transfer that motivates innovation. A negative effect, however, could be possible sanctions in foreign direct investments as a response to the use of compulsory licensing. The amount of empirical literature trying to investigate these effects is scarce. Most compulsory licenses issued through the TRIPS agreement are on HIV/AIDS drugs. Further, there is a possibility that depending on different characteristics of the country issuing the compulsory license, the effects on innovation and foreign direct investments may vary. Such characteristics could be national policies in the country, importance of their market for the rights holder and characteristics belonging to the patented drug. These characteristics should be considered implemented in future research.

## Preface

When I was 19 years old, I got the opportunity to stay in Mali in West Africa for 5 months. By working at a health care centre and talking to workers in non-profit organizations, I was made aware of the importance of access to generic drugs for the people who stayed there. By taking the course INB427, Globalization and Integration at NHH the spring 2012, I was introduced to the TRIPS agreement and how this legal global arrangement relates to patent protection of drugs. This motivated me to learn more about the economic aspect related to distribution of drugs in the developing world.

By working on this paper, I have expanded my knowledge on how the pharmaceutical business works, especially in relation to global protection of intellectual property rights. It has been challenging to times, but most of all I believe it has been rewarding. I would like to thank my supervisor Ragnhild Balsvik for important guidance. Also, thanks to Lina and Thorild for understanding and support along the way.

Helga M. Beyer

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## Table of contents

<b>ABSTRACT</b> .....	<b>2</b>
<b>PREFACE</b> .....	<b>3</b>
<b>1. INTRODUCTION</b> .....	<b>5</b>
<b>2. THE TRIPS AGREEMENT</b> .....	<b>7</b>
2.1 MAIN OBJECTIVES AND CONTENTS .....	7
2.2 TRIPS AND THE CASE OF PHARMACEUTICALS .....	9
2.2.1 <i>Patents</i> .....	9
2.2.2 <i>Compulsory licensing</i> .....	11
<b>3. THE DEVELOPMENT IN THE USE OF COMPULSORY LICENSING</b> .....	<b>13</b>
<b>4. PATENTS</b> .....	<b>16</b>
4.1 EFFECTS FROM ENFORCED PATENT RIGHTS.....	17
4.1.1 <i>Innovation</i> .....	19
4.1.2 <i>Foreign direct investments</i> .....	21
<b>5. COMPULSORY LICENSING</b> .....	<b>23</b>
5.1 A THEORETICAL JUSTIFICATION .....	24
5.2 EFFECTS ON INNOVATION FOR THE PATENT HOLDER .....	26
5.3 EFFECTS ON INNOVATION FOR THE LICENSEE .....	28
5.4 EFFECTS ON FOREIGN DIRECT INVESTMENTS .....	29
5.5 EFFECTS ON PRICES .....	31
<b>6. INDONESIA: ARE THE IMPLICATIONS APPLICABLE?</b> .....	<b>33</b>
6.1 THE INDONESIAN PHARMACEUTICAL INDUSTRY .....	33
6.2 COMPULSORY LICENSES .....	35
6.3 INNOVATION AND SPILLOVER EFFECTS FOR INDONESIA.....	37
6.4 FOREIGN DIRECT INVESTMENTS AND TRADE SANCTIONS IN INDONESIA .....	39
6.5 THE FOREIGN LICENSORS INCENTIVE TO INNOVATE.....	41
<b>7. CONCLUDING REMARKS</b> .....	<b>44</b>
<b>8. REFERENCES</b> .....	<b>46</b>

# 1. Introduction

Several non-profit organizations argue that access to life-saving medication in the developing world is not sufficient. In some cases, such drugs are not accessible at all while in other situations drug prices are not at an affordable level leading many consumers untreated. The World Health Organization (WHO) claims that add-ons by wholesalers, distributors and retailers plus government taxes and duties result in the unaffordability of the medication in many countries (Cameron et al., 2008). Another explanation for these high prices is the patent award. The patent award gives the producer the sole right to provide the medication. These exclusive rights have the purpose to secure the costs of research and development (R&D) for the inventor and further more serve as a dynamic measure, by motivating future inventions. The importance of developing new medication to combat diseases is clearly important, however, problems do arise in the use of patents on medication. One problem is that patents have the function of locking out competition. Through monopoly rights, the patent holder may charge an unaffordable price for consumers in developing countries. According to Subramanian (2004), analytical models predict that introducing patents on medication lead to an increase in price between 25-50 %.

The dynamics of patent protection creates a dilemma. On the one hand it causes a static loss today for consumers through high prices. On the other hand, by securing the inventor his costs of inventing, the world and consumers will have access to medicines in the future that otherwise would not exist. Whether the dynamic gain from intellectual property rights outweighs the consumer loss in the short run is unclear (Goldberg, 2010). Many experts agree that there is no clear-cut answer. The TRIPS (Trade Related aspects of Intellectual Property Rights) agreement attempts to balance this issue by implementing provisions of intellectual property rights that members of World Trade Organization (WTO) are obliged to follow. The agreement also includes two measures specially related to drugs. When high prices on drugs are caused by patents, member states may apply the policy measures of parallel import or compulsory licensing. Parallel import is the import of goods into a country without the permission of the intellectual property rights holder (WTO, 2013). The latter gives the opportunity to import a product from another market, for example where it is sold at a lower price, and resell it in the home market at a lower price than the original price in the home market.

Compulsory licensing is “when a government allows someone else to produce the patented product or process without the consent of the patent owner” (WTO, 2006). Compulsory licensing allows a country to either produce or import a copied version of the patented drug (generic drug) without the fear of sanctions being imposed. In return, the patent holder receives an adequate remuneration. Since the policy measure was implemented in the TRIPS agreement, many governments have applied it (Beall & Kuhn, 2012). Frequent users are middle-income countries like Brazil and Thailand.

Actors in the pharmaceutical industry view compulsory licensing as an intellectual property denial harming their industry and reducing their incentives to do R&D (ChemistryWorld, 2013). Others claim that compulsory licensing could possibly lead to withdrawal of foreign direct investments (FDI) since the pharmaceutical actor is demotivated to invest and share knowledge with a country issuing compulsory licenses (Bird & Cahoy, 2008). A positive effect in addition to decreased prices for developing countries is that the use of compulsory licensing may bring cumulative innovation (Moser & Voena, 2012). As knowledge is transferred by the use of compulsory licensing, it will create opportunities of innovation. The purpose of this paper is to give an overview of the use of compulsory licensing and further review the theory and empirical literature on the above-mentioned effects of the policy measure. Further, these effects will be assessed using the case of Indonesia and their application of compulsory licensing.

To start off I have provided an explanation of the TRIPS agreement in chapter 2. By presenting the trends of compulsory licensing and explaining some aspects of the pharmaceutical market in developing countries it could be easier to understand the effects from compulsory licenses. Therefore, chapter 3 gives an overview of the use of compulsory licensing since the implementation of the policy measure in the TRIPS agreement. Chapter 4 presents basic theory on predicted effects of patent enforcement and some empirical literature that supports this theory. This is important as we see that effects of compulsory licensing are connected to the effects of patents. Chapter 5 provides a theoretical rationale supporting the use of compulsory licensing and further presents empirical literature and theoretical models on the effects of compulsory licensing. In chapter 6, the predicted effects will be assessed based on Indonesia’s use of compulsory licensing. Finally, chapter 7 summarizes the results in order to evaluate whether the use of compulsory licensing in the TRIPS agreement hamper the inventors ability to innovate, lowers FDI for the issuing country or increases their innovation.

## 2. The TRIPS agreement

WTO's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was signed and implemented on January 1<sup>st</sup>, 1995 with the establishment of WTO (Hoekman et al., 2002). The agreement contributes to a worldwide strengthening of protection of intellectual property by setting down a minimum standard of different related regulations (Ashish & Nigam, 2008). The starting point of the agreement goes back to the eighth round of negotiations in GATT, the Uruguay Round (1986-1994). Before the establishment of WTO in 1995, GATT was the multilateral instrument governing international trade (Ashish & Nigam, 2008). The Uruguay round resulted in the establishment of WTO in 1995. WTO's objective is to implement and monitor a common institutional framework that applies to all its member states. The agreements cover goods, services and intellectual property, where the TRIPS agreement gives provisions for intellectual property rights.

In the development of the TRIPS agreement, several difficulties arose, especially concerning North-South relations. The differences in protection of intellectual property rights in the countries have made it difficult to come to an agreement. Southern countries tend to have weaker protection of intellectual property rights that benefit them since they are able to copy products more easily. At the same time most rights owners belong to Northern countries, the developed part of the world, who wish for a better worldwide protection of intellectual property rights. It has been difficult to balance the economic interests of these two players (Hoekman et al., 2002). Throughout the years from 1995, adjustments have been made in order to clarify several ambiguities in the TRIPS agreement.

### 2.1 Main objectives and contents

The TRIPS agreement aims to balance the incentive to invent future inventions and creations and the objective of allowing people to use existing inventions and creations (WTO, 2006). The agreement stems from disagreements in how to handle counterfeit goods, as the enforcement of intellectual property rights differ between countries (WTO, 2013). The TRIPS agreement strikes a three-way balance. First, a high level of intellectual property rights encourages inventions and creators since they can expect to earn future benefits, which again provide social and technological gains (WTO, 2006). Second, the manner in which the agreement has been developed makes it possible to fulfil social goals. WTO uses the

example of disclosure, where the patent has to be available for others to study while the patent is being protected. This contributes to technological transfer and progress as well as others to be ready with the product when the patent expires. Third, the agreement provides flexibility so that the governments are free to fine-tune the protection in order to meet social goals. This especially relates to the use of patents where governments may make exemptions of intellectual property rights in the case of national emergencies, anti-competitive practices or if the rights-holder does not supply the invention.

The key provisions in the TRIPS agreement consists of five different areas, general provisions and principles, transitional arrangements, dispute settlement, enforcement, and standards. The most important features of the agreement are the last three. General provisions and principles give direction through basic principles such as non-discrimination between domestic and foreign intellectual property rights-holders (Hoekman, Mattoo, & English, 2002). The provisions also contain general rules on acquiring and maintaining intellectual property rights. The TRIPS agreement gives a minimum standard that member countries need to follow. Through the agreement, countries are allowed to implement stricter measures by national law that may lead to higher levels of intellectual property rights, implying that a fully harmonization of global laws in intellectual property rights are unlikely (ibid). Transitional arrangements give developing countries the right to use longer time implementing different policies compared to developed nations. The transition period has been extended two times for least developed countries and is reasoned by “their special requirements, their economic, financial and administrative constraints, and the need for flexibility so that they can create a viable technological base” (WTO, 2013). In June 2013, WTO chose to extend the transition period until 1 July 2021.

Enforcement relates to domestic procedures and remedies for the enforcement of intellectual property rights (Hoekman et al., 2002). Member countries have to apply this set of minimum rules in order for intellectual property rights holders to be able to enforce their rights. Amongst others, the procedures provide detailed provisions on administrative and civil procedures and remedies, special requirements for border measures and criminal procedures. In the case of disputes between member countries, dispute settlements consist of procedures that actors need to follow. Finally, the standards relate to minimum set of standard of protection that one expects each member country to apply. The standards define “the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection” (WTO, 2013). The standards are important as it



deals with most of the forms of IP: copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits and undisclosed information. The pharmaceutical industry has been one very important industry where you find conflicting views and problems in the interpretation of the TRIPS agreement. These problems often relates to North-South dilemmas.

## 2.2 TRIPS and the case of pharmaceuticals

Developing countries (south) backed by non-profit organizations, asked for reforms during the ministerial meetings after the foundation of the TRIPS agreement (Hoekman et al., 2002). These issues relate to the demand for clarifications of what flexibility developing countries have in order to protect public health. The ministerial meeting in 2001 resulted in the Doha declaration and was an important meeting in order to secure developing countries access to generic drugs. The changes coming from this meeting is explained from compulsory licenses and will be presented later on. First, the TRIPS agreement's explanation of patent protection needs to be presented.

### 2.2.1 Patents

WTO defines patents as a mean that “provides the patent owner with the legal right to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions” (WTO, 2006, p. 2). Patents in the pharmaceutical industry are important of several reasons (Timmermanns & Hutadjulu, 2000). First, R&D expenditures are very high in the pharmaceutical sector. The R&D expenditures of the pharmaceutical industry are reported to be four point five times greater than that of the chemical industry (IFPMA, 2012). Second, when registering the patent, there is a requirement of disclosure. Third, it is relatively easy to copy a drug and therefore a patent helps to protect the invention. Fourth, a patent gives the rights-holder the ability to charge a higher price than realized in the case of free competition. These higher profits cover the costs of R&D. Pharmaceutical companies urged for negotiations of global enforcement of intellectual property rights during the Uruguay round (WTO, 2006). These negotiations resulted in the TRIPS agreement. This indicates that intellectual property protection is important in the medical industry.

Member countries of WTO need to follow several general obligations for pharmaceutical patents. Article 27 in the TRIPS agreement states that patents should be “available for any invention, whether products or processes, in all fields or technology without discrimination, subject to the normal test of novelty, inventiveness and industrial applicability” (WTO, 2013). Further, the patent has to last for a minimum of 20 years. Other general obligations relates to non-discrimination, which means that countries cannot discriminate between different fields of technology, between the place of invention, and whether products are imported or locally produced. There are also several criteria’s for a patent to be approved. It has to be new (novelty), it has to be an “inventive step”, and it must have “industrial applicability” (ibid). The objective of disclosure means that the applicant has to describe the invention in the application. The government is required to ask for details of the invention and they may even require the applicant to reveal the best method to carry out the invention. The TRIPS provisions also include eligibility for patenting, giving reasons for when governments may refuse patents. Finally, it exist research exceptions that gives provisions about when and how a country may use a patented invention for research in order to understand the invention more fully. Further, this part of the agreement gives the opportunity for producers of generic drugs to obtain a market approval of a patented drug in advance of its patent expiry. Consequently, the generic producer is ready to enter the market as soon as the patent expires. This provision is sometimes called the Bolar provision.

Industrialized countries argue that the unified patent protection will have three main effects for developing countries (Timmermanns & Hutadjulu, 2000). It will lead to increased initiatives of FDI, promote the transfer of technology, as well as promoting local R&D. Developing countries, however, have during the negotiations been dwelling in their willingness of enforcing domestic intellectual property rights, mostly due to the fact that pharmaceutical production primarily is situated in the industrialized part of the world. Clearly, it is different stakeholders with belonging differing views on the effects of enforcement of intellectual property rights. One stakeholder is the innovative pharmaceutical industry and their view that global trade is dependent of patent protection and other forms of intellectual property protection in order for the world to access new medicines (ibid). A second stakeholder is the developing countries and their national pharmaceutical producers that fears that enforcement of intellectual property rights will make the gap of knowledge between them and the producers of knowledge (who often are situated in developing countries) even bigger. The bargaining power could also shift more in the hands of the patent

holder, making it more difficult to negotiate suitable prices for the developing world (ibid). A third stakeholder is the consumers who worry about the affordability and access to essential drugs. The patent cause higher prices on the drug and this will lessen access for consumers not affording the drugs. The TRIPS agreement includes flexibilities that member states may use in order to protect public health (WTO, 2006). One of these flexibilities is compulsory licensing.

### **2.2.2 Compulsory licensing**

“Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner” (WTO, 2006, p. 4). The policy measure may apply to patents in any field but is mostly associated with pharmaceuticals. The goal is to try to strike a balance between promoting access to existing drugs and promoting research and development into new ones (ibid). This flexibility has always existed in the TRIPS agreement, but the Doha declaration in 2001 clarified and enhanced the measure. These clarifications were needed due to some nations being unsure on how to interpret the measures, as well as “how far their right to use the flexibilities would be respected” (WTO, 2006, p. 5).

The reasons for why countries are allowed to use compulsory licensing are not stated in the TRIPS agreement. It is up to each country to decide the grounds in national law. In most circumstances, the grounds include public health reasons (ibid). In order to protect the legitimate interests of the patent holder several conditions need to be fulfilled in order to use a compulsory license. Article 31b says that a company or person applying must have first attempted, unsuccessfully, to obtain a voluntary license from the right holder on reasonable commercial terms. However, for “national emergencies”, or “other circumstances of national urgency”, or “public non-commercial use”, or “anti-competitive practices” there is no need for an attempt of voluntary licensing. Another condition is that an adequate remuneration must be paid to the patent holder. The remuneration needs to be in accordance with the “circumstances of each case, taking into account the economic value of the authorization” (WTO, 2006). The production of the good shall also predominantly be for the supply of the domestic market. However, countries may also apply for compulsory licensing of import of generic produced drugs. This was the main enforcement coming from the Doha ministerial conference in 2001. It gives countries lacking capacity to produce pharmaceuticals themselves the opportunity to access generic versions from elsewhere.

Through the provision of compulsory licensing, the hope is to signal to the patent owner that in case of misuse of monopoly power, it is possible for a third party to make use of the invention (Timmermanns & Hutadjulu, 2000). The opponents of compulsory licensing emphasize that there exist negative effects from issuing compulsory licenses that outweighs the positive effects arising from lower prices. One problem relates to the quality and the skills of the local producer to reproduce the same drug in a safe and effective manner. In addition, they argue that the measure often is used for industrial policy instead of promoting cheaper drugs. They also argue that less research funds will be conducted in the areas subject to compulsory licensing policies (ibid).

Until now, we have seen that the TRIPS agreement tries to balance the interests of developing and developed countries in the global enforcement of intellectual property rights. However, it exist different opinions of what effects the policy measure of compulsory licensing will spur. In order to look for such effects a natural first step would be to look at the development in the use of compulsory licenses.

### **3. The development in the use of compulsory licensing**

Before looking into the theoretical and empirical literature discussing predicted effects from compulsory licensing, it is necessary to look at the degree in which the policy measure has been used. This chapter will also contribute with some clarifications and explanations about certain legal aspects before presenting the development in the use of compulsory licensing. The policy measure of compulsory licensing is also implemented by law, individually by several countries, amongst others USA (Chien, 2003). Therefore, the possibilities of using compulsory licensing have existed on national levels even before it was implemented in the TRIPS agreement. The focus in this paper however, is effects from use of compulsory licensing as implemented in the TRIPS agreement.

Even though the TRIPS agreement was implemented almost 20 years ago and seems to unify intellectual property rights across borders, the laws differ between countries (Harris & Thomas, 2013). India is very relevant to discuss in this relation. When a company wants to issue a patent they need to apply for it in each country they want it to be valid. Shortly explained, India has own laws for how and what patents to approve (Murthi, 2009). This makes them equipped to produce generic versions of drugs that in some cases are patented by rights holder in other countries. One recent example of how this apply in practice is the case of Novartis (Novartis, 2012). Novartis is a large pharmaceutical company who wanted one of their cancer drugs to be patented in India. However, Indian law has denied the patent, making India able to produce generic versions of the drug, making them able to provide poorer part of the world with cheaper generic versions of branded medicines. Amongst others, it is estimated that India dominate the antiretroviral market accounting for around 80% of annual purchase volumes, where developing countries are the main clients (Waning et al., 2010). Antiretroviral drugs are drugs used in the treatment of HIV/AIDS. India is a member of the WTO, and by the end of the transition period, they have to implement the universal agreement on intellectual property rights. Many health organisations argue that this will hinder many people in least developed countries to access cheap antiretroviral treatment in the future. India is therefore an important actor in providing the developing world with needed medication. The generic drugs that India provides are not necessarily patented but in some cases, they are. If the drug is patented the country who wants to import the drug needs to issue a compulsory license.

From a database analysis of trends in compulsory licensing, Beall & Kuhn (2012) finds that low-income countries are not using compulsory licensing in the same degree as middle-income countries. In their analysis, they investigate how the trends in the use of compulsory licensing have evolved since 1995 through June 2011. In order to be included in the analysis the episodes of compulsory licensing had to be issued by a WTO member state as well as being supported by the local government or public officials. Further, the reasoning of each case had to be justified by public health reasons. Following, an explanation of the trends and overview of compulsory licensing episodes is presented.

Table 6.1 shows the development in the use of compulsory licenses since 2001. The table is extended from Beall and Kuhns (2012) analysis with the episodes that have found place after June 2011. The trends however still remains in the pattern pointed out by Beall & Kuhn. As we see, most of the compulsory licenses count for drugs treating HIV/AIDS, followed by drugs treating cancer (ibid). Further, the outcome is not always an actual issuance of a compulsory license. In some cases, it results in voluntary licenses (VL) and discounts negotiated with the rights holders. Voluntary licenses means that the rights holder voluntarily negotiates the grounds for the license and in such incidents maybe even more specific information about the patent is revealed. This transfer of knowledge could ensure a better quality on the generic drug than in the case of a compulsory license (IFPMA, 2012). In regards to the income group, Beall & Kuhn establish that most compulsory licenses are issued by countries defined as middle-income countries (UMIC and LMIC) by the World Bank. Least developed countries (LDC) and low-income countries (LIC) has a rather low share

The development in the use of the compulsory licenses is important to remember as we now move over to basic theory and empirical literature on patents and compulsory licensing.

<b>Year</b>	<b>Country/market</b>	<b>Income level</b>	<b>Drug Area</b>	<b>Outcome</b>
<b>2001</b>	Brazil	UMIC	HIV/AIDS (3)*	Discount
<b>2001</b>	Canada	HIC	Communicable disease	Discount
<b>2001-2003</b>	South-Africa	UMIC	HIV/AIDS (8)	VL/Discount/none
<b>2001</b>	United States	HIC	Communicable disease	Discount
<b>2002</b>	Egypt	LIC	Erectyle disfunction	CL
<b>2003-2004</b>	Malaysia	UMIC	HIV/AIDS (3)	CL
<b>2003</b>	Brazil	UMIC	HIV/AIDS	Discount
<b>2003</b>	Zimbabwe	LIC	All HIV/AIDS	CL
<b>2004</b>	Mozambique	LDC	HIV/AIDS (3)	CL
<b>2004</b>	Zambia	LDC	HIV/AIDS (3)	CL
<b>2005</b>	Argentina	UMIC	Pandemic flu	VL
<b>2005</b>	Brazil	UMIC	HIV/AIDS (2)	Discount
<b>2005</b>	Ghana	LIC	All HIV/AIDS	CL
<b>2004</b>	Indonesia	LIC	HIV/AIDS (2)	CL
<b>2005</b>	Taiwan	HIC	Pandemic flu	VL
<b>2005-2006</b>	Argentina	UMIC	Pandemic flu	VL
<b>2005-2009</b>	Brazil	UMIC	HIV/AIDS (2)	Discount
<b>2006-2007</b>	India	LIC	Cancer	None
<b>2006-2007</b>	Thailand	UMIC	HIV/AIDS (2)	CL
<b>2007</b>	Brazil	UMIC	HIV/AIDS	CL
<b>2007</b>	Thailand	UMIC	Cardiovascular disease	CL
<b>2007</b>	Rwanda	LDC	HIV/AIDS	CL
<b>2007-2008</b>	Thailand	UMIC	Cancer	Discount
<b>2007-2008</b>	Thailand	UMIC	Cancer (3)	CL
<b>2010</b>	Ecuador	UMIC	HIV/AIDS	CL
<b>2010</b>	India	LMIC	Cancer	Patent revocation
<b>2012</b>	India	LMIC	Cancer	CL
<b>2012</b>	Indonesia	LMIC	Hepatitis	Patent revocation
<b>2012</b>	India	LMIC	Cancer (2)	Patent revocation/allows generic
<b>2012</b>	Ecuador	LIC	HIV/AIDS	CL
<b>2012</b>	Indonesia	LMIC	HIV/AIDS, Hepatitis	CL
<b>2013</b>	India	LMIC	Cancer	CL initiated

\*if more than one drug, stated in ()

*Table 1.1: Incidents of compulsory licenses since 2001( (IMS consulting Group, 2013), (Beall & Kuhn, 2012))*

## 4. Patents

A patent is an exclusive right given to the inventor preventing others from using the invention. Several theories exist to explain the existence of patents (Mazzoleni & Nelson, 1998). The most promoted aspect is that patents promote invention, often called the invention-inducement theory. Other theories are the disclosure theory, the development and commercialization theory, and the prospect development theory.

The invention-inducement theory is a traditional economic explanation of why we need patents. The theory states that we need patents in order to increase the supply of useful inventions since perfect competition is not an optimal mechanism covering expenditures of R&D for innovators (ibid). The theory relates to the aspect of knowledge. Knowledge has the characteristic of being non-rival, which means that once it is released others may apply it without extra expenditures on R&D, possibly causing market failure and disincentive to invent (Encaoua, Guellec, & Martinez, 2006). Therefore, in order to encourage innovation public intervention is needed so that the will to continue inventing is sustained. The assumption is that with higher levels of patent protection more innovation will occur. Therefore the patent has a social purpose by providing the society with inventions that otherwise would not exist.

The disclosure theory assumes that patent protection encourages firms to disclose their invention (Mazzoleni & Nelson, 1998). The disclosure provides other actors the opportunity to use the knowledge or technical aspect that further could lead to new inventions. In absence of patent protection, a patent holder would have no other option than try to maintain secrecy (Scherer F. M., 1980). However, the patent enhances the incentive to share knowledge, and consequently the rights holder could earn more profit from his invention by for example developing it in cooperation with other actors. Therefore, this theory puts an important aspect on how a patent might help to improve rewards of inventing (Mazzoleni & Nelson, 1998). The disclosure may also widen the possibility of cooperation in cases where the inventor lacks the knowledge of developing the invention. When national law demands disclosure in exchange for the patent award, the patent serves both a public and private good effect (Dressler, 2011). The private good effect is that the patent protects the invention from others to use it, while the underlying knowledge of the invention is made public, creating a public good.



The development and commercialization theory may seem identical to the investment-inducement theory (Mazzoleni & Nelson, 1998). However, the development and disclosure theory focuses on the timing of when the patent is granted. If the patent is granted early in the process of inventing, it serves as a guarantee for the inventor by assuring him that the expenditures of R&D are covered in the case of a successful outcome. This may induce a positive development process. A patent may also motivate the patent holder to seek finances in the capital market. To fund money in the capital market could be crucial for a small company in order to overcome large costs from the development process of their invention, and further to reach the market (ibid).

The prospect theory builds on the rationale that an invention creates possibilities for “follow-on” inventions in the same category (ibid). In order for this development process to evolve properly, a broad patent to control it is needed. In absence of a broad patent that control the development on the invention, many actors will try to race for the same target thus leading to “over-fishing in the prospect pond” (Mazzoleni & Nelson, 1998, p. 1042). The mentioned term means that as the actors compete towards the same target, they will use a wasteful amount of recourses. A broad patent would therefore hinder wasteful research of the prospect. However, from the view of some theorists, a broad patent could also serve as a hinder for inventors, who are able to find solutions that the rights holder does not see. Therefore it arise social costs from this view since the broad patent could hinder possible future inventions.

## 4.1 Effects from patent rights

As we have seen, the patent is introduced in order for the society to enjoy benefits from innovation. A basic assumption is that the need in the society of inventions is higher than the incentive to innovate (Dressler, 2011). By introducing patent protection the society would benefit more since the patent induce innovation. The patent holder is enabled to control the invention and earn proper profit from it, which covers the costs of developing the product. The proper profits comes from the granted monopoly right, and do bring other economic effects. A basic monopoly model can demonstrate these effects.

In the cases where patent protection creates monopoly, the patent owner may charge a higher price than in a competitive market (Goldberg, 2010). The price in the market will be the one that maximizes the monopoly owner’s profit on production (Deardoff, 1992). This will result

in a higher price and lower quantity sold than if the invention worked in a fully competitive environment. The monopoly model (figure 4.1) assumes linear demand and constant marginal costs. The quantity produced in the situation of monopoly,  $q^m$ , is lower than in the competitive setting, and the price,  $p^m$ , is situated between the parameter,  $a$ , in the demand function and the marginal cost parameter,  $p^c=c$ . For the patent owner, the profit,  $\pi^m$ , is now about half of the consumer surplus you find in a fully competitive setting. This transfer from the consumer to the monopolist comes from the increase in price that the consumer has to pay due to the monopolistic market. The deadweight loss,  $L$ , reduces the optimal consumer surplus, and appears due to quantity given up by the consumers not able to buy the product. In relation to medication, it means that there is a share of the consumers left untreated since they are not able to pay the higher price, and this is the main concern for developing countries (ibid). The total social surplus is clearly reduced from the competitive setting. The reduction in the consumer surplus accounts for most of this reduction.

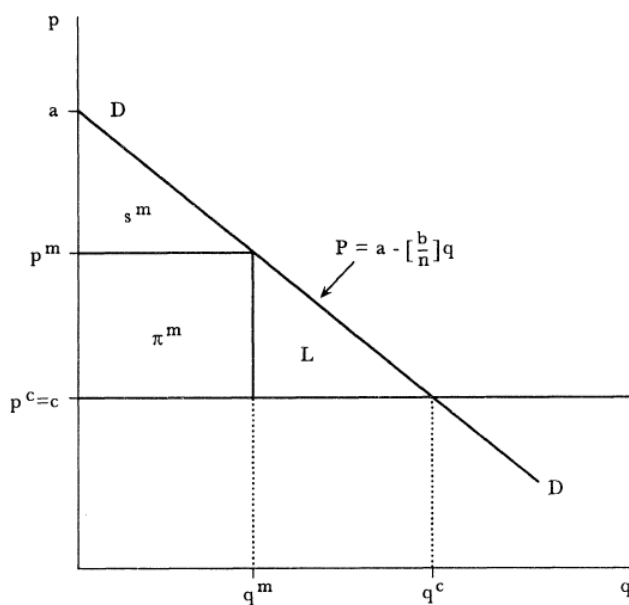


Figure 4.1: welfare effects of monopoly pricing in a single market (Deardoff, 1992, p. 37)

For the patent owner, the remuneration is the monopoly profit,  $\pi^m$ , which is supposed to weigh with the outlays of developing the invention. This provides security so that the patent owner has an incentive to continue doing research and develop new products (ibid). This dynamic effect is the main rationale supporting patent rights (Mazzoleni & Nelson, 1998). The theory assumes higher positive effects for the inventor than the negative welfare effects from the monopoly rights. Further the patent protection has the aim to serve the society as a

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whole. The producers get protection and their R&D costs covered, while the users get access to goods that without the patent protection would not been developed. However, as explained in the basic model above, negative costs appear as well. The monopoly leads to social costs and misallocation of resources that do not appear in a fully competitive setting (Scherer F. M., 1980).

What happens when extending the model above to a multiple country world? If countries were symmetric, the situation of extending intellectual property rights across borders would not be a problem and we could use the same analysis as in the one country model above (Goldberg, 2010). However, the reality is that countries differ in characteristics like skill endowments, technical know-how and domestic market. Therefore, different implications on welfare might appear depending on the characteristics of each country when introducing patent rights (ibid). This is why many researchers have developed models and theories in order to investigate how welfare effects might differ depending on these differences. This topic often relates to north-south dilemmas, as developing countries (south) tend to have quite different characteristics than industrialized countries (north). Both theories of why we should harmonize intellectual property rights in the world and the opposite exist in the literature (ibid). As Helpman (1993) underlines, the theoretical research done on the topic of effects of patent enforcement cannot alone answer the question of whether enforcement of patent rights is desirable. It is rather a helpful instrument to identify which channels present what effects from the policy measure. Further, empirical work might help providing answer for which assumptions it is important to consider in a model (Goldberg, 2010). Following, important aspects from theory and empirical literature concerning patent enforcement and its interaction with innovation and FDI will be presented.

### **4.1.1 Innovation**

The argument for why we should harmonize intellectual property rights across borders builds on the rationale of the invention-inducement theory. In absence of a patent the inventor will lose incentive to invent due to uncovered costs of R&D. The consumer loses in the long run, since the absence of a patent could lower the future access to new developed medicines (Helpman, 1993). It is however questioned whether enforcement of patent rights in a small country induce any extra decisive innovation as most of the global market already covers the product with a patent (Deardoff, 1992). Assuming that most innovation appears in the developed world, covering more of the world with patent protection will provide diminishing

returns on the incentive to innovate. This further implies that as more actors introduce patent protection, the gain from generating innovations will not be large enough to outweigh the static loss from introducing monopoly pricing on existing inventions (ibid).

It is a complex matter to find out whether enforced intellectual property rights in developing countries spurs the right amount of positive welfare effects to justify its use (Deardoff, 1992). This requires a welfare analysis and several models have been developed in order to analyse the aspects mentioned above. Deardoff (1992) calculates how the welfare effect changes through decomposing it into the elements of terms of trade, production composition, available products and intertemporal allocation of consumption. His dynamic model concludes that south loses from tightening the intellectual property rights in their countries. In the absence of FDI, the terms of trade moves towards the north and the manufacturing of the product also changes to this part of the world. The manufacturing costs are higher in north and therefore bring higher prices for the south. This consequently brings higher losses for the south. The model introduces innovation as an endogenous factor meaning that innovation in the north is responsive to the introduction of higher levels of intellectual property rights in south. In the short run, the response is that innovation increases which lead to a higher contribution of available products. The welfare gain from the increased pace of available products consequently is positive in the short run. The long run aspect however shows contrary results. The pace of introducing new products declines in the long run and results in negative welfare effects for the south. The reasoning for this is that the temporarily increase in innovation will not be sufficient to compensate the south for their losses (ibid). Deardoff (1992, p. 49) expresses it in the best manner: "As more and more of the world is already covered by patent protection, the extra market that can be covered, and hence the extra invention that can be stimulated by patent protection still further, becomes smaller".

Deardoff predicts that the positive dynamic effect from innovation is diminishing in scale when enforcing patent rights in developing countries (ibid). As earlier mentioned, compulsory licenses are predicted to break the dynamic effect of patents that create welfare gains. However, Deardoff predicts that the gains are diminishing in the long run. Could it therefore be justifiable to use compulsory licenses in developing countries? Enforcement of intellectual property and analysing welfare gains from it is not the main focus in this thesis, and this question will not be investigated further. However, it is important to remember for later that it could seem as the action of one developing country plays a marginal role in affecting the effects from innovation.

### 4.1.2 Foreign direct investments

Foreign direct investments appear when the production, distribution or other activities of a company is controlled by a foreign actor (Moosa, 2002). It is assumed that FDI is a main source providing developing countries access to new technologies. Further, this could provide growth for the host country by increasing capital accumulation. Spillover effects may also arise from FDI if knowledge transferred to the local subsidiary leaks out to the host country. Channels serving spillover effects could be technical assistance to suppliers and customers, export behaviour and managerial practices. Whether FDI causes positive spillover effects is highly discussed and the predictions are rather mixed (ibid). Following, empirical literature showing positive effects is presented. Sjøholm and Okamoto (2005) examine productivity growth in Indonesia. Their analysis shows that depending on the degree of competition in a country the spillover effects may vary. If the competition is strong this may impact the choice of what technology the multinational company (MNC) choose to transfer through FDI, which further leads to higher spillovers. Arnold and Javorcik (2009) find that the productivity in Indonesian manufacturing plants possibly improve when a foreign company acquires it. The improvements in productivity are explained by increased investment outlays, employment, and wages as the foreign firm is restructuring the plant. The analysis also predicts that foreign acquisitions tend to integrate the acquired plant better in the global economy through increased exports and imports.

Industries depend on securement of intellectual property rights when transferring technology and inventions across borders as they do not want to be imitated (Kashcheeva, 2013). A positive aspect for the developing country introducing patent rights will therefore be that they become more attractive as an investment environment and market (Lanjouw, 1997). In relation to medication, this could provide the local market with more suitable drugs since facilities are located closer to the market (ibid).

When measuring welfare effects in developing countries from increased patent protection, the degree in which the country relies on FDI seems to affect the results (Kashcheeva, 2013). Kashcheeva includes FDI in her study in order to investigate the global effect of higher levels of intellectual property rights on growth. She determines how depending on the level of FDI into a country the effects of higher levels of intellectual property rights on growth might differ. FDI is assumed to positively affect the growth in the model. Further, it is expected that the receiving country of FDI experience a loss when they enforce intellectual

property rights, as they are not able to imitate products. Therefore, the positive effects on growth from increased FDI are compared to the negative welfare effects stemming from less imitation as they enforce intellectual property rights. She also includes the costs the receiving country of FDI must pay to acquire knowledge from the foreign partner. The results shows that “a 10% point increase in a country’s ratio of FDI to GDP leads to an approximately 3% point increase in growth and that a one standard deviation increase in intellectual property rights is associated with a 1% increase in growth” (Kashcheeva, 2013, p. 717). It seems as at the highest levels of FDI, a more lax policy of intellectual property rights increase the growth rate. This study supports earlier empirical findings that enforcement of intellectual property rights stimulates industrial development (ibid). Further, as the author underlines, it shows that it is important to include FDI inflows in welfare analysis when evaluating total welfare effects from enforced intellectual property rights in developing countries. However, different country characteristics may lead to different welfare effects (ibid). The phase of development in which the country is situated could be a determining factor. At the same time, the effects of intellectual property rights could be different depending on the industry and firm in which the FDI flows are aggregated.

Summed up, the results above are important to bear in mind as we can see that the effects from higher levels of intellectual property rights are ambiguous and could very well depend on the ratio of FDI in the country restructuring their policies. Different benefits and disadvantages are predicted to arise. The loss of being able to imitate a product and increased costs in acquiring knowledge could be possible disadvantages. The benefits may arise from possible increased FDI that it is assumed leads to higher productivity and spillover effects for the host country. These aspects are important to remember when moving over to the review of effects from compulsory licensing.

## 5. Compulsory licensing

Compulsory licensing has the objective to counteract the social costs that consumers experience in a monopoly market by “increasing competitive supply and reduce prices” (Scherer & Watal, 2002, p. 929). Some patent models that are developed by researchers include the mechanism of compulsory licensing in order to optimize the use of patents. Tandon (1982) proposes the notion of royalty rates that optimally trade off the negative incentive effects of licensing with the positive consumer price effects. His model builds on the basic single country model and the theory implies that compulsory licensing may lead to increased welfare.

This model has two dimensions, first to set an optimal patent life and second to set an optimal royalty rate charged to otherwise unrestricted licensees (Kaufer, 1989). The innovator is able to charge a royalty rate, but it is constrained by a policy maker putting the rate below the optimal rate the patent holder would charge. The price of the product is therefore less than optimal set by the inventor, and this lessens the deadweight loss. By increasing the patent life, Tandon shows that the incentive to innovate is sustained. Bond and Saggi (2012, p. 10) express that “Tandon’s definition of compulsory licensing differs from that applied by the WTO”. Tandon lets countries use compulsory licenses regardless of adaptations made by the patent holder, so that the supply of potential licensees yields a perfect competitive industry equilibrium. The theoretical view on how compulsory licensing works by WTO is rather that a license is issued in the circumstances when the patent holder does not agree on terms like voluntary licensing. At the same time, the royalty rate tends to be lower compared to Tandon’s results of an optimal royalty rate. The aspect of patent life is not explained further here, however it is an aspect that has contributed to several theories of determining the optimal life of a patent in order to induce innovation.

In many ways, compulsory licensing is a measure implemented to improve welfare, but put towards the classic theory of patents, many argue that it could seem to destroy the basic patent mechanisms explained earlier. In the cases where economists have tried to explain compulsory licensing, they often have relied on the Tandon model. However, this model assumes a fully competitive setting with linear demand. If the demand is not linear, the effects for consumers may be different (Flynn et al. 2009). This could further give theoretical implications that may justify the use of compulsory licensing.

## 5.1 A theoretical justification

In the article "an economic justification for open access to essential medicines" (2009), Flynn et al. theoretically explains how the deadweight losses could be even worse for developing countries experiencing patents on medicines. An important characteristic that relates to the theory of compulsory licensing is the characteristics of demand in a country. The demand curve and its shape most likely differ between developing and developed countries that in turn has implications on deadweight losses. The degree of elasticity in the demand curve contributes to these differences. Scherer (1980) also supports this theoretical explanation of social costs from patents, underlining that that the demand for medication often is inelastic.

Starting with the earlier introduced model of monopoly in a single country, the shape and slope of the demand curve will have impact on the pricing strategy for the monopolist (ibid). A factor contributing to the slope of the demand curve is the elasticity of demand, whether the curve has elements of convexity or concavity. The convex part of a curve, which is flatter horizontally, indicates a high sensibility to price changes. If there is a small increase in price, the consumers in this part of the curve will easily give up their purchase. On the concave side, you find a higher willingness to pay a higher price for the product. In the pharmaceutical market, the demand is often inelastic (concave) over a considerable price range (Scherer F. M., *The economics of the patent system*, 1980). In the situation of monopoly, the result would be that the patent owner could charge a high price, highly exceeding their production costs creating even higher social losses for the people with lower willingness to pay. Low-income countries are usually less willing to pay a high price for medication and therefore more sensible to price changes. Goldberg (2010) shows that the pharmaceutical producer in a market with highly convex demand curves focuses on serving the convex part of the market charging high prices. The convex share of the demand does not react heavily on large price increases leading to small losses in demand when increasing prices. This results in a large share of the market being unable to afford the product leading to substantial larger deadweight losses than in the case of perfect straight linear demand.

As the monopolist will target its price towards the steep end of the demand curve, this leads to a price around 4 times bigger than in the case of a linear demand curve (Flynn et al. , 2009, p. 5) (figure 5.1). The deadweight loss is almost the same as the profit for the monopolist. In the situation linear demand, the deadweight loss is around half of the profit.



Further, a demand curve could help us understand this aspect. It has the form of  $p = 1 - q^n$ , where  $p \in (0,1)$ . When the demand curve becomes more convex, meaning that  $n$  decreases, the ratio of deadweight loss to profit increases. Flynn et al. underlines that it is not possible to generalize the degree of convexity in a real world picture, however, the general principal applies. If the degree of convexity increases, the monopolist will try to serve a smaller segment of the market, which leads to larger deadweight losses.

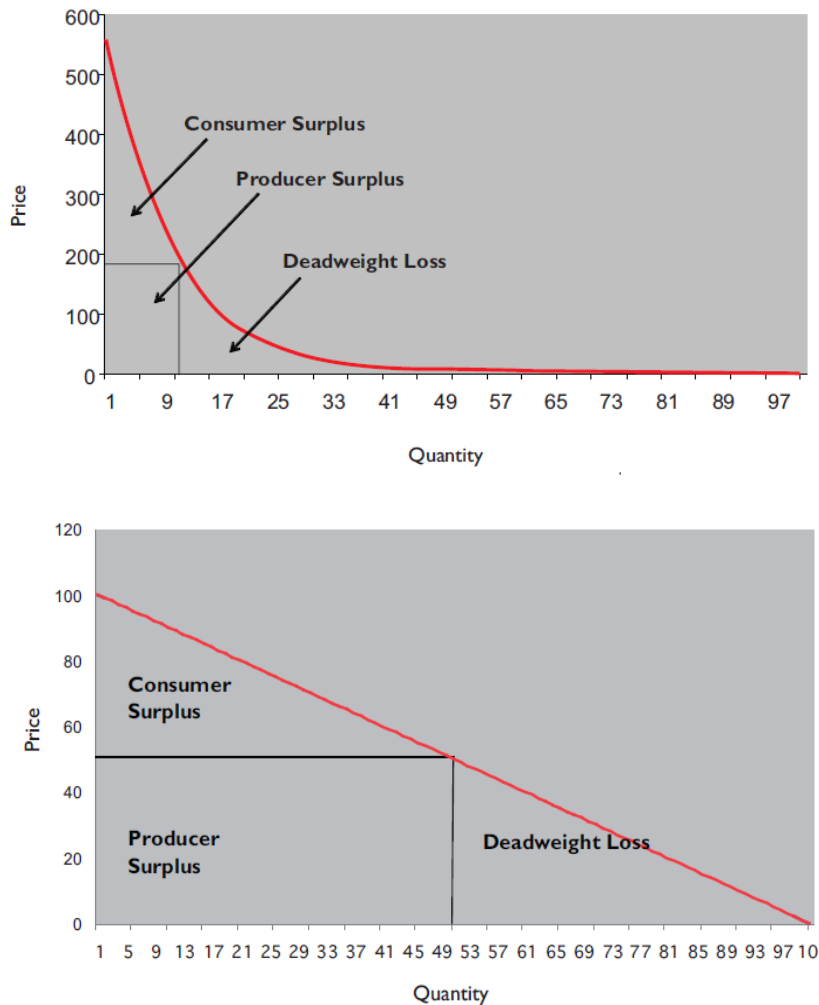


Figure 5.1: Convex versus straight demand curve (Flynn et al. , 2009, p. 4 & 5)

This theoretical explanation shows that by using compulsory licenses, which is assumed to decrease prices, a larger share of the population will have access to the drug. This will increase the welfare gain for developing countries as it is argued that their demand curve is convex. As we see, the static immediate gain from a compulsory license is decreased prices and more people affording the drug. The long run effect is that more people survive from diseases as they could access the drugs more easily. Other long run effects are also assumed

arriving from the use of compulsory licenses. Some relates to the effects on innovation, both for the patent holder (licensor) as well as the company granted the compulsory license (licensee). Another effect is what potentially could happen to FDI in the country using the compulsory license.

## 5.2 Effects on innovation for the patent holder

Chien (2003) supports the view that compulsory licenses do not decrease the incentive to innovate for the patent holder. She looks at six episodes of compulsory licensing that were issued in the 1980s and 1990s by the Department of Justice in the United States. The use of compulsory licensing is a policy measure implemented by US law and is mostly used to counteract anti-competitive behaviour. In order to determine whether the compulsory licenses led to a decline in innovation for the patent holders, Chien looks at each company and their R&D therapeutic segment that is exposed to the compulsory license. The actual decline in innovation was measured by counting patents issued in the aftermath of the licensing. Further, it was predicted that two factors contribute to decline in innovation; the predictability and importance of the compulsory licenses. The predictability relates to the degree in which the company can predict that a patent is licensed. "Unpredictable licenses that cover only existing technologies are more limited in scope than those that are predictable and cover future inventions" (Chien, 2003, p. 872). If a compulsory license comes unanticipated and late in the development process of the product (predictable), it might be too late for the patent holder to change its course. In earlier stages of the development process, it is argued that the patent holder more easily may put off incentive activity or R&D efforts until the license has expired (unpredictable). Therefore, when a compulsory license is unpredictable, it is less chance that it will affect the company negatively. When the patent is at a late stage in its development, it is assumed to impact innovation in a larger extent. The importance of a compulsory license relates to the relative importance of the market struck by the license. The importance is defined as high if the market the compulsory license is targeted towards is a part of the main target market of the patent holder. Then the two actors have to share market. The hypothesis states that if the license is predictable and significant the innovation decrease.

Chien decides the significance of the license by defining at which stage in the development process the patent is placed. It is assumed that with more mature technology incorporated in

the patent the licensor has a higher competitive position in the market. Therefore, when the technology of the product is in a later stage of its development, this affects the business of the patent holder more than if the patent is in an earlier stage. The predictability of the patent is decided by looking at each case and the amount of future innovation the license possibly could cover. In the four cases where the licenses are defined as unpredictable, it is seen no decline in innovation. In the two other cases where the licenses are defined as predictable, the impact on innovation is a bit more ambiguous. One of the cases predicts a decline in innovation from the predictable license.

To measure if there had been a decline in innovation, Chien looks at patent applications filed by each licensor during the license period. In five of the cases, it appears to be no decline in R&D activity subject to the compulsory license. However, it is difficult to know if the activity in R&D during the license period is regarded as “normal” activity as there is lack of a proper comparison of the activity to a control group or previous activity. The explanations of unchanged effort in R&D are based on continued R&D actions in the area and specific surrounding conditions to each case. Further, it is most likely not controlled for other factors that also may have affected their R&D activity in aftermath of the license. Government support could for example be one of many factors which may have contributed to maintain their R&D activity and counteracted a possible negative effect from the compulsory licenses.

Scherer (1977) conducted a statistical analysis of the effects that compulsory licenses might have on R&D. His data are collected from 1977, when the US Federal Trade Commission made thousands of patents available. He analyses whether this had a negative impact on the patent holder's incentive to innovate. The study includes 700 companies affected differently by compulsory licenses, and compares their outlays of R&D expenditures. By calculating the R&D ratios over sales Scherer concludes that companies exposed to compulsory licenses actually spent more on R&D than companies that were not exposed in the same industry. However, this study also failed to compare these ratios to previous years of expenditures, making it difficult to determine whether the compulsory licensing led to a shift in R&D ratios by the companies being involved.

Regardless whether the paper of Chien indicates any proper empirical results from the effects of compulsory license on innovation, it highlights some important considerations that need to be considered in an analysis. It relates to where the patent is placed in its stage of development when exposed to a compulsory license, as well as the importance of the market.

As earlier mentioned, most compulsory licenses in the TRIPS agreement are on HIV/AIDS medications. How do the measures of Chien relate to the use of compulsory licensing of these drugs? Further, could it be possible that the limited scope the pharmaceutical area represents of the total R&D expenditures for a patent holding company leads to no significantly change in their incentive to innovate?

### 5.3 Effects on innovation for the licensee

The empirical literature in regards to the effects of compulsory licensing on the country using the license is scarce, just as for the previous section. The rationale is that when using compulsory licenses it could spur effects like learning by doing as well as create cumulative innovation (Moser & Voena, 2012). Moser and Voena investigates the effects of compulsory licensing on patent activity in US through the “enemy act”. In 1917, the US congress allowed domestic firms to access patents, mostly belonging to foreign producers, in the circumstances where the product contributed to the war effort. The paper investigates how use of compulsory licensing affects the issuance of patents by companies in the business of organic chemistry. They compare annual changes in patents for chemical inventions. It compares annual patents over different groups depending on the degree they had the possibility to issue licenses. By comparing different groups depending on the degree they were affected, it makes it possible to control for other factors that could have encouraged innovation. Such factors could for example be improvements in education and scientific training, or tariff barriers to protect the industry. Since all subclasses in the study were affected by such factors, but a small part of them by compulsory licensing, it makes it possible to compare the subgroups that were “treated” with a compulsory license to those that were not.

The study consists of 669 owned patents that where licensed to one or more of 326 American companies. The results show that companies producing on a compulsory license, on average increased their innovation between 15 to 30 percent. The regressions further shows that the innovation increases with the number and the novelty of the patents. It means that when the number of patents available for a licensee in a subclass in the industry is higher, it contributes to more innovation. In addition, the fewer years since the patent were issued, the more it has a positive effect on innovation. The study further investigates the timing of these effects and concludes that it took several years before the effects were showing. Since it

takes time to learn and materialize the knowledge, the effects were at its highest significant level eight to nine years after the patents were available for the licensees. These results indicate that domestic firms benefit from compulsory licensing through increased innovation. It is believed that the firm through “learning by doing” develops their skills and capabilities to invent by themselves.

Moser and Voena (2012) further points out that India could be an interesting country to investigate as they have developed a competitive industry in producing generic drugs. However, other countries that use the measure of compulsory licensing by the TRIPS agreement are quite different from India, and issue licenses in a quite different manner. Bond and Saggi (2012) imply two reasons for why the results of Moser and Voena are not applicable for low-income countries issuing compulsory licenses. Since the issuance of such licenses often includes just a few drugs and production methods, the transfer of knowledge is not sufficient to spur additional innovation. In addition, they find it hard to believe that in the cases where compulsory licenses do lead to large amount of technology transfer, the receiving country has the suitable knowledge and technological facilities to exploit the transfer in a beneficial way. This result in the question of whether the use of compulsory licenses in the TRIPS agreement spurs any additional innovation for a licensee situated in a developing country. Is it possible to find implications of whether the use of compulsory licenses through the TRIPS agreement may contribute to development of local pharmaceutical industry in developing countries?

## 5.4 Effects on foreign direct investments

A highly discussed topic is the retaliatory measures a country issuing compulsory licenses could meet from the country where the patent holding pharmaceutical company is based (Shahnawaz, 2012). Such retaliatory measures could influence the inflows of FDI to the licensing country. It is argued that developing countries in fear of retaliatory measures will be reluctant to issue a compulsory license, as they want to secure FDI inflows and trade from the rights holding country.

Several considerations arise in the discussion of whether compulsory licenses affect the inflow of FDI. In order to look at the economic effects of compulsory licensing on FDI, Bird and Cahoy (2008) underlines that the relationship between FDI and compulsory licensing may vary dependent on the country’s different income levels and investment attraction

levels. They believe that the susceptibility of middle developing countries to FDI losses when using compulsory licenses could be important. By using Brazil and Egypt as examples, the authors try to underline that depending on different capabilities in ability to resist political pressure the impact on FDI may vary. Both these countries are defined as middle-developed countries. However, the ability of Brazil to use other methods in advance of the final decision of compulsory licensing may have contributed to not decreasing their FDI inflows in the pharmaceutical industry. As an example, Brazil uses compulsory licenses only when negotiations for discounts have failed. This strong political capability of negotiating could be difficult to find in smaller developing countries. Therefore it could be difficult to apply the same model of Brazil on other developing countries. Brazil also has a well-developed pharmaceutical industry, which could make them better equipped to resist pressure from foreign actors (*ibid*).

Looking closer at least developed countries, it is argued that issuing a compulsory license will not affect their FDI inflows, as they are too small and not lucrative enough to affect a FDI decision (*ibid*). For middle-income countries however, the effects on FDI may be more apparent. By developing a game theory model, Bird and Cahoy tries to conceptualize the importance of collective action by least developed countries when issuing compulsory licenses. The game, which is non-cooperative, assumes that each player acts in a way that maximizes own profit. The benefits from imposing a compulsory license are modelled, as well as the negative impact of loss in FDI. This model consequently assumes that the use of a compulsory license will lead to equal reductions in FDI inflows. In this situation, the optimal will be not to issue compulsory license.

The assumption above assumes equal negative effects on FDI inflows for least developing countries. It is difficult to know whether this is true. This would require an investigation of whether reductions in FDI appear and how much it possibly could be when issuing licenses. On the other hand, this is possibly not the right place to start, as the fear of sanctions in FDI leads to no attempt in using a compulsory license at all. Shahnawaz (2012) claims by using Thailand as an example, that in order to minimize welfare loss from a disease, determinants contributing to the country's income will affect the timing and decision of a compulsory license. If international trade is an important determinant for the revenue of a country, "the risk of retaliatory action serves as a deterrent to issuing a compulsory license" (Shahnawaz, 2012, p. 14). In an analysis of the trends in compulsory licensing after the Doha declaration, Beall & Keall (2012) finds that most licenses are issued by middle-income countries. They

stress the fact that the goal with the Doha declarations was to increase access to drugs for developing countries and that this is not seen in practice. One reason of little use by developing countries could therefore be the fear of sanctions, but it exist other possible explanations too. Least developed countries have other rules and methods to access drugs (Beall & Kuhn, 2012). As earlier described, the transition period in the TRIPS agreement allows them to implement intellectual property rights in a slower pace than other member countries. Therefore, the comparability across country income categories could be biased. Another reason could be that they easily can access HIV/AIDS medication by other mechanisms, like importing generic drugs from India since they also may produce generic drugs until the transition period in the TRIPS agreement has expired.

As earlier presented the enforcement of patent rights may lead to a higher levels of FDI to the country and lead to positive spillover effects. Is it possible that compulsory licenses implemented by the TRIPS agreement could work in the opposite way, making pharmaceutical companies unwilling to invest in the respective country and therefore hinder positive spillover effects? Further, is it possible that restrictions in FDI depend on FDI levels flowing into the country when issuing the license?

## 5.5 Effects on prices

As mentioned the main goal of compulsory licensing in the TRIPS agreement is to decrease prices and increase competition. This is done in order to increase access to patented drugs and at the same time compensate the patent owner for the loss of intellectual property rights (with the royalty rate). It is therefore natural to look at whether the measure actually decreases prices on drugs, increasing the welfare for the consumers. Medicines sans frontiers (MSF) each year report the development in prices of antiretroviral drugs. The World Health organization (WHO) also conducts analyses of prices and the results from the two organizations are similar. Introduction of generic competition leads to a decreased prices benefitting consumers in developing countries. As we saw in the presentation of development in use of compulsory licenses, compulsory licenses are mostly used in the production of antiretroviral drugs. Following, I will look at one specific patented antiretroviral and look at the development in the respective price published by MSF and WHO.

Efavirenz is an antiretroviral drug in which it has been issued compulsory licenses on in several countries, amongst others in Thailand (2006), Brazil (2007) and Indonesia (2012) (Medicines Sans Frontiers, 2013). The company Merck filed for the basic patent on the drug in 1993. It expired in August 2013. However, it exist modified versions of the drug that are patented by the company until 2018. In the beginning, the compulsory licenses issued by Thailand and Brazil applied for import of generic version from India. Later in time, each of the countries allowed a local producer to supply the drug. Amongst many other antiretrovirals (more than 20), MSF reports the development in the price of Efavirenz. To gather information about prices MSF has sent questionnaires to each of the different producers. In the analysis, only generic producers that are quality-assured by US-FDA or WHO prequalifications are included. Other unqualified versions do also exist but is not included in the analysis of MSF. For the drug efavirenz it exists nine generic producers in which are included in the analysis. MSF reports that since 2002 the unit price per tablet (of 600 mg) of the originator brand has decreased by 32% while the cheapest generic version has decreased by almost 92% (figure 5.5). Figure 5.5 shows the development in the prices by the lowest price quoted for developing countries since 2001.

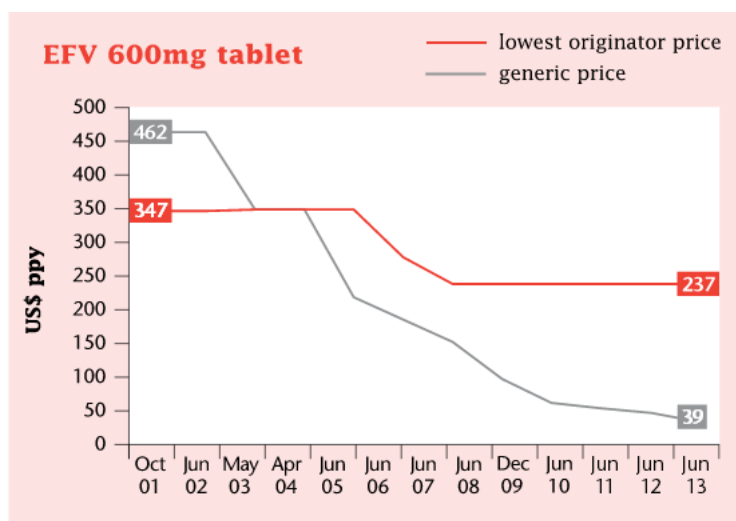


Figure 5.5: Development in price of EFV 600 mg tablet (MSF, 2013, p. 28)

This is just one example showing the difference in prices between an original brand and a generic one. The overall trend in the report of MSF is that in the cases where generic competition is present, the price of the drug tends to be lower than the price from the original producer. This accounts for several of the drugs in which developing countries has frequently issued compulsory licenses on (ibid).



## 6. Indonesia: are the implications applicable?

In order to evaluate the implications presented in the previous chapters of effects from compulsory licenses, I am going to look at Indonesia and their use of compulsory licensing. Several important aspects have contributed to the choice of Indonesia. First, Indonesia has issued several compulsory licenses, starting already in 2004. This could give the opportunity to look at possible effects that have arrived over time. Second, Indonesia is an actor who has the ability to produce generic medicines themselves. Third, the World Bank defines them as a lower middle-income country (The World Bank, 2013). Therefore, it is a possibility that their structure in governance and pharmaceutical industry is not that strong as larger generic actors like Brazil, Egypt and India. Empirical research on these larger actors clearly is important for the dynamics of issuing compulsory licensing, however as stressed several times through the literature review, the long-run effects from compulsory licensing on welfare could very well depend on each country's characteristics. Therefore, it could be interesting to see how the implications from the literature review apply in a country as Indonesia with its belonging characteristics. Fourth and last, all the licenses that Indonesia has issued are on HIV/AIDS drugs, which fit well with the ongoing trend of compulsory licenses.

### 6.1 The Indonesian pharmaceutical industry

The population in Indonesia is the largest in South East Asia and the world's fourth largest (MarketLine, 2012). The country has also been one of the fastest growing economies the last years. Their strong growth complimented by political stability makes them one of the South East Asia's strongest economies. The economic growth has contributed to reduce poverty but inequality has increased. The share of middle class is however increasing, and therefore Indonesia serves as a potential market for many foreign providers of consumer goods (Rastogi, Tamboto, Tong, & Sinburimsit, 2013). This also counts for foreign pharmaceutical actors.

The pharmaceutical sector in Indonesia is the largest in South East Asia and domestic estimated sale of pharmaceuticals is assumed to increase with the years (Table 6.1) (Economic Intelligence Unit, 2013). As of today, they represent the largest pharmaceutical market in South-east Asia and the predicted growth in sales makes them remain in that

position. Estimates also predict an increase in the drug prices, with the increase in prices of imported raw materials. About 95% of the raw materials are imported to the Indonesian generic industry. The Indonesian government play an important role in the decision of prices and puts requirement on local producers to maintain low prices on their drugs. In some incidences it is reported that this lessen the willingness for pharmaceuticals to supply the local market. Further, the ministry of Health encourages to the use of generic domestic produced drugs. Consequently, during the last years, there has been a shift in use, from import of branded products to own produced generic versions. This also contributes to build upon the domestic industry (ibid).

Pharmaceutical sales	2008 <sup>a</sup>	2009 <sup>a</sup>	2010 <sup>b</sup>	2011 <sup>b</sup>	2012 <sup>b</sup>	2013 <sup>c</sup>	2014 <sup>c</sup>	2015 <sup>c</sup>	2016 <sup>c</sup>	2017 <sup>c</sup>
Pharmaceutical sales (US\$ m)	4,439	4,808	5,936	6,800	7,334	8,088	8,955	10,070	11,262	12,333

<sup>a</sup> Actual, <sup>b</sup> Economist Intelligence Unit estimates, <sup>c</sup> Economist Intelligence Unit forecasts.

Source: The Economist Intelligence Unit.

*Table 6.1: Estimated sales of pharmaceuticals (Economic Intelligence Unit, 2013)*

It exist about 200 domestic pharmaceutical companies in Indonesia, and they supply about 70% of the local market (ibid). The largest Indonesian manufacturer Kalbe Pharma holds 15% of the market share (Gross, 2013). Most companies are small and unable to do research due to lack of finances (Economic Intelligence Unit, 2013). They rather produce through licenses agreed with foreign companies. This is a popular way for foreign pharmaceutical companies to enter the market. The global pharmaceutical company Pfizer, who has an 11% local market share in the Indonesian pharmacy market, decided in 2012 to expand their operations (The Jakarta Post, 2012). They invested in factor capacity to lift the local market share in the generic market. Such investments done by the world's largest research-based pharmaceutical company could indicate that generic production rather is the focus foreign owned companies in Indonesia (Chun chi, Zhang, & Breed, 2013). In regards to foreign firms, the Indonesian government has imposed policy measures to strengthen the local pharmaceutical industry. If a foreign firm wants to enter the Indonesian market with a product, they have to either manufacture locally or cooperate with a local manufacturer that holds equity of at least 25%. One exemption is patented products and products that cannot be manufactured in Indonesia (Gross, 2013). The local requirement appears to be an obstacle for foreign companies willing to invest in Indonesia. Novartis, a large international actor, express that the requirement of ownership could hinder them in opening wanted R&D facilities in Indonesia (ibid). Today it operates about 35 foreign companies in Indonesia, who

holds the remaining 30% of the market share. During 2012, Indonesia broke a new record in FDI realization as it increased with 26 percent (The Jakarta Post, 2013). Of total investments in Indonesia, FDI counts for 70 percent. The FDI in the pharmaceutical sector counted for 11,3 percent of total FDI in 2012, standing as the third most important sector. The table shows that FDI in the chemical and pharmaceutical sector have increased gradually since 2010 (Indonesia Investment Coordinating Board, 2013).

	2010	2011	2012	2013*
FDI	793,4	1467,4	2769,8	2561,6

\*Realized numbers the three first quarters of 2013

*Table 6.2: Value of FDI in the Chemical and Pharmaceutical Sector in Million US\$ (Indonesia Investment Coordinating Board, 2013)*

## 6.2 Compulsory licenses

Indonesia has issued compulsory licenses three times. In 2004, the government issued licenses on production of two HIV/AIDS medicines, lamivudine and nevirapine (Love, 2005). These patents expired in 2011 and 2012 and the royalty rate to the rights holders were at 0.5% of the net selling value. The local production was delegated to PT Kimia Farma, a state owned company. In 2007, Indonesia renewed the compulsory licenses on the two drugs lamivudine and nevirapine plus adding a license on the HIV/AIDS drug efavirenz. In September 2012, the government announced that they were going to issue compulsory license on seven HIV/AIDS and hepatitis B medicines in the urgent need to control these diseases (Khor, 2012). This episode serves as one of the most significant incidents of compulsory licensing due to the amount of drugs included (IRIN, 2013). As we see (table 6.3), most of the issued licenses includes HIV/AIDS drugs, which also tends to be the pattern for other countries issuing compulsory licenses (Beall & Kuhn, 2012). The table under lists the compulsory licenses issued in Indonesia since 2004. It also includes other countries using compulsory licensing on the patent as well as other approved generic producers.

Year	Drug	Patent holding company	Patent expire	Other countries	Number of generic approved producers*	Expansions?
2004 and 2007	Nevirapine (HIV/AIDS)	Boehringer Ingelheim	2010	Mozambique (2004), Zambia (2004)	9	Hemihydrate form (2018), extended formulation (2028)
2004 and 2007	Lamivudine (HIV/AIDS)	Biochem Pharma Inc	2010	Mozambique (2004), Zambia (2004), Ecuador (2012)	9	
2007 and 2012	Efavirenz (HIV/AIDS)	Merck & Co. , Inc	2013	Brazil (2007), Thailand (2007),	9	
2012	Abacavir (HIV/AIDS)	Glaxo Group Limited	2018	**	7	2016 (in Europe), 2018 ( in USA)
2012	Didanosine (HIV/AIDS)	Bristol-Myers Squibb Company	2018			
2012	Combination Lopinavir and Ritonavir (HIV/AIDS)	Abbott Laboratories	2018	Thailand (sanctions) (2007),	4	
2012	Tenofovir (HIV/AIDS, hepatitis B)	Gilead Sciences, Inc.	2018		6	
2012	Combination of Tenofovir and Emtricitablne, Combination of Tenofovir, Emtricitablne and Efavirenz (HIV/AIDS, hepatitis B)	Gilead Sciences Inc.	2024/ 2026		4 / 6	

\*As of May 2013 by US FDA or WHO prequalifications, OBS: not necessarily enacted by compulsory licenses

\*\*February 2013 Medicines Patent Pool and patent holder agreed on a voluntary license agreement for 118 countries

*Table 6.3: use of compulsory licenses in Indonesia ( (Public Citizen, 2013) (Khor, 2012), (Love J. P., 2007))*

### 6.3 Innovation and spillover effects for Indonesia

Are there any implications that Indonesian compulsory licenses has contributed to development of the local pharmaceutical industry? An important aspect to remember is the focus on generic competition in Indonesia. As earlier mentioned the Indonesian government supports generic competition rather than encourages innovation. Indonesia spends little funds on R&D, and in 2011, Indonesia got only seven patents approved in total in the American market (MarketLine, 2012). This is quite few compared to Malaysia and Thailand who respectively got 161 and 53 patents the same year (ibid). The total amount of patents approved domestically for each of the mentioned countries are to be found in the database of the World Bank (figure 6.4). The diagram shows that Indonesia issues almost half of the amount of patents than Thailand and Malaysia. To measure whether the license of the drug nevirapine and lamivudine in 2004 spurred more patent issuances by the generic companies would therefore most likely be meaningless, as it seem that Indonesia compared to similar countries do not issue many patents. Another reasonable way to look for increase in innovation could be to look at how the production in the specific segment of HIV/AIDS medicines has evolved since the first license. Has it led to any internal development in the companies of their capability to produce of HIV/AIDS drugs? A natural way to investigate this could be to count new introductions of generics in the aftermath of the start-up of the two above-mentioned drugs.

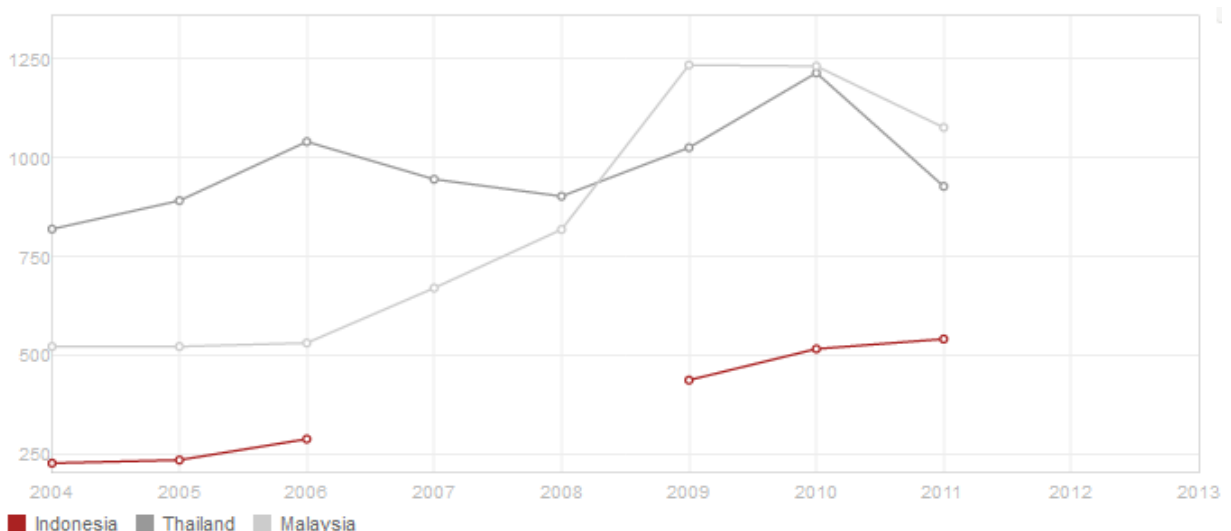


Figure 6.4: Patents issued in total in Indonesia compared to Thailand and Malaysia (The World Bank, 2013)

Kimia Farma was the first company to produce the licensed drugs, nevirapine and lamivudine in 2004. It had capability to produce and was interested in providing the drugs in 2004. Kimia Farma is a state-owned company and is one of Indonesia's major pharmaceutical companies (Sipahutar, 2012). It has been difficult to find any evidence of whether this opportunity of production has served as a spin-off for the production of other antiretroviral drugs in Indonesia. It is expected that Kimia Farma also will produce the drugs that were licensed in 2012 (IRIN, 2013). This could indicate that they have the expertise the government believe is needed in order to produce generic versions, and that there has been no room for spillovers of the production to other Indonesian companies. From this information, it seems as the transfer of knowledge from the licenses may not have spurred any additional innovation or know-how for the domestic industry. The earlier mentioned argument from Bond and Saggi (2012) comes handy in trying to explain this matter. The transfer of the knowledge has not sufficient in spurring any additional innovation or know-how. However, it most likely has contributed to strengthen Indonesia as a generic producer of drugs.

As explained, the focus of the Indonesian government is to nurture their local generic pharmaceutical business so that their citizens may access inexpensive drugs (Economic Intelligence Unit, 2013). By allowing a company to produce the generic drug, they fulfil their goal of providing cheaper drugs to the people. To measure whether a growth in product assortment is caused by the compulsory license could therefore be difficult as the company is state owned and probably receive government support. Separating the factors affecting product extensions in this analysis is therefore hard. At the same, the access to needed data is limited. If having access to the data, a suggestion could be to look at the Indonesian pharmaceutical sector and separate the effects in an empirical analysis. Important to remember in such an analysis is the importance of including all factors that may have contributed to the Indonesian pharmaceutical growth. Specially, it is important to include other political measures than compulsory licensing as we see that Indonesia do have several tools in hand in order to build up their local industry.

Another aspect to remember in relation to innovation is that the patents on the two drugs licensed in 2004 were both expiring in 2010. Is it possible that with the matureness of the patent, less innovation is possible for the licensee? If the patent is insignificant for future product development, the license consequently would not lead to any further effects for Kimia's product development and innovation. For the drug nevirapine, the licensor,

Boehringer Ingelheim, has issued several voluntary licenses. One way to interpret this action is that since the patent is no longer important for the patent holder, as it do not provide opportunities for further monopoly rights they are more willing to negotiate voluntary licenses. As MSF (2013) reports, Boehringer Ingelheim in 2004 and 2007 signed voluntary license agreements, which today counts for 78 least developed countries, low-income countries and sub Saharan countries. At the same time, it could be interpreted as a strategic action from the rights holder, making them able to control the market more easy. This is discussed more under the implications of effects on the licensors incentive to innovate.

## 6.4 Foreign direct investments and trade sanctions in Indonesia

In this chapter, the focus is whether the issuance of compulsory licenses in the TRIPS agreement may have made MNCs unwilling to do FDI. Are there any indications in the case of Indonesia that it has harmed trade or selection of drugs? Could the degree in which Indonesia is dependent on FDI contribute to explain the possible results?

Examples from other countries show that large pharmaceutical companies have reacted by withdrawing investments or products in the respective countries or they have lobbied their own government in order to protect their industry (Correa, 2011). Thailand is a country where you find several examples on how the patent holding company has reacted in order to oppose the compulsory license. Thailand tried to issue a compulsory license on the HIV/AIDS drug efavirenz in 2007. The patent holding company Merck responded in several ways by lowering prices on the drug and made an effort to lobby their US government. By lobbying, the outcome is often that the lobbied government puts pressure on the licensing country to withdraw the license. Another example is that the patent holder withdraws products from the licensing country (ibid). Thailand met repercussions from the patent holding company Abbott when issuing a compulsory license on the HIV/AIDS drug Kaletra in 2007 (Schuettler, 2007). As a protest, Abbott cancelled plans launching new drugs in Thailand. Abbott stated themselves that Thailand had broken the patent system several times and that Abbott's best solution was to cancel launches of seven new medicines. The drugs included new HIV/AIDS versions as well as other drugs treating kidney diseases and high blood pressure etc. (ibid).

India has experienced sanctions by companies withdrawing investments in relation to patents. India's generic industry is protected by an own domestic law. When India according to domestic law refused a patent application on a cancer drug from the Swiss company Novartis, the company responded by cancelling expansions of R&D centres in India (Gill, 2007). This case however does not relate to the use of compulsory licensing in the TRIPS agreement. Nevertheless, it illustrates how a domestic law of intellectual property rights may hinder investments. The big pharmaceutical industry claims that compulsory licenses do lead to the same effects as poor intellectual property rights, and maybe one could expect episodes of sanctions in FDI due to compulsory licenses as well (ChemistryWorld, 2013).

In Indonesia, it is difficult to find similar examples of sanctions in FDI or trade as a consequence from their compulsory licenses. It could be several potential explanations for why Indonesia has not experienced any negative side effects in FDI or trade. Following, some of these are going to be discussed. First, as mentioned before, their large population and growing share of middleclass serves as a potential future market for investors. Second, other existing policies in Indonesia may serve greater obstacles for foreign pharmaceutical actors than what a compulsory license constitutes. The earlier mentioned ownership requirement by Indonesian law is an example. Third, the same drugs that Indonesia has issued compulsory licenses on are licensed in other countries as well (table 6.3).

Big pharmaceutical companies operating in Indonesia seem to have increased their appearance in the market rather than withdrawing operations. It is done by both entering the market with new products as well as increasing FDI. As explained earlier Pfizer invested in an expansion in 2012. Another example is Merck who in 2012 opened a \$21 million packaging plant in Indonesia (Gross, 2013). They expect their annual sales in Indonesia to go up 13-18 percent in 2013. Further, the numbers of FDI has increased with the years (table 6.2) and this could indicate that Indonesia is experiencing a growth in willingness to invest in their pharmaceutical sector. Foreign pharmaceutical companies see Indonesia as an upcoming market and the best strategic choice for them would therefore be to invest. To react by withdrawing FDI in such a case would therefore not be the best strategic choice. It could seem as foreign companies value their future earnings and possibilities higher than the possible benefits they achieve by reacting with hostile actions towards a compulsory license. The fact that Indonesia is such a big country with a large potential market is a benefit not many other low income countries are in possession of. This shows restrictions in FDI could very well depend on characteristics of a country, in this case the future potential market of



Indonesia. Further, it could imply that the actions from patent holding companies most likely depend on what is most strategically wise to do.

Indonesia is also a special case through their ownership requirements that put pressure on the FDI partner to cooperate and share practices. An argument for why they do not experience sanctions could therefore be that affected partners who operate in the country already have made a lot of effort to settle down their businesses. This effort may have been more time consuming than compared to settling down in other countries. To withdraw investments in aftermath of being affected by a compulsory license would therefore induce even more costs and seem unreasonable. Another reason for why it could seem unreasonable to act hostile towards Indonesia is that the drugs are also licensed in other countries. As their monopoly rights have already been violated, maybe their loss from one more country issuing the license will not harm their company in a significant way.

## 6.5 The foreign licensors incentive to innovate

What are the implications for the foreign pharmaceutical companies affected by the compulsory licenses in Indonesia? The question that arised from the literature review was whether the pharmaceutical area as well as the use of compulsory licenses of HIV/AIDS drugs is too little in the big pond of medicines to affect the innovators R&D activities. Further, it is to be questioned whether developing countries and their significance in the market as a whole will make any difference to the licensor when introducing compulsory licenses. In the literature review, we saw that the scope of the future possibilities of development for the patent possibly could affect the innovation. How do these measures relate to the patents on HIV/AIDS drugs, and are they applicable?

Statistics predicts that around half a million people are living with HIV in Indonesia and every 25 minutes one person is infected (UNICEF Indonesia, 2012). On a global scale in 2012, it is estimated that in total around 35 million people live with HIV (UNAIDS, 2013). Does the potential market share in Indonesia play a important role for the income to a patent holding company providing HIV/AIDS drugs? Probably the Indonesian market is important considering they are the fourth largest country in the world. Thailand does probably also serve as an important potential market for pharmaceutical providers of antiretroviral drugs. The share of the world in which India provides with generic medication probably is also an important market share for big pharma. The earlier mentioned protests from patent holding

companies towards these two countries could therefore signal that they see it as a threat to their innovation when a significant share of their market is affected. Indonesia however, seems to not have experienced any protests. Could the specifics of the drugs that Indonesia has licensed help explaining the lack of protests? As table 6.3 shows, the two producers of nevirapine and lamivudine both issued licenses to other countries as well in 2004. The remaining time on the patented drug nevirapine was not very long as it expired in 2010. The extended version patented until 2028, is for a version of the drug that you only have to take once a day compared to the other version, taken twice a day (Medicines Sans Frontiers, 2013). It could indicate that the future possibility for the patent to spur innovation and monopoly profit for the patent holding company present. In such an incident, there would be no point for the patent holding company to protest against compulsory licenses on the drug. This could also be why Boehringer Ingelheim, the patent holding company, was so willing to negotiate voluntary licenses in advance of the expiry, to secure their markets and be better prepared for generic competition.

MSF are in the opinion of that pharmaceutical companies grant voluntary licenses to control more of the market (Medicines Sans Frontiers, 2013). Amongst others the transparency of these agreements are claimed to be low, as there is no openness of what the deals include between the right holding company and the licensing country. In this way, the right holding company manages to have more control than through a compulsory license. They could for example arrange settlements that include more cooperation and possibilities for partnerships (ibid). At the same time, the company maintains some control by settling down restrictions for whom the license count and which companies are allowed to produce the drug. Many middle-income countries are locked out of voluntary licenses deals. The market share in which they endow for the patent holding companies could be a reason for the lockouts from the voluntary licenses (ibid). The patent holders are not willing to share knowledge with countries that has a pharmaceutical industry that are capable to produce the drugs in a large scale.

The act of sharing knowledge through a voluntary license with only least developing countries could therefore indicate that the market share these countries make up is not significant for the company's profit. Further, it may be unlikely that compulsory licenses from small countries negatively influence their future R&D activities in the HIV/AIDS area. The size of the companies involved could also support this argument. Meaning that all the other patented products they provide still will give them profits that could induce innovation.

The amount of R&D funding spent on HIV/AIDS drugs of the total R&D spending internal in the company could contribute to clarify this. If assuming that the HIV/AIDS share is low, the impact on the company's R&D efforts might be low. In order to obtain such numbers one would have to have access to each company's figures, which is hard to obtain.

The effects from issuing licenses on other groups of drugs could give other implications. For the future, there is a possibility that a new trend in compulsory licensing will involve compulsory licenses on medicines treating cancer (often referred to as oncology) (IMS consulting Group, 2013). Cancer is one of the main diseases causing deaths besides HIV/AIDS in developing countries. If the incidents of compulsory licenses escalate and widens in scope of types of drugs, the implications for the licensor could be seen in a greater extent than until now. This could be the reason for why pharmaceutical companies rather negotiate for other solutions than compulsory licenses. By avoiding compulsory licenses they could be able to protect the scope of the market possibly affected from generic production.

## 7. Concluding remarks

The purpose of this thesis was to discuss positive and negative effects of compulsory licensing in the TRIPS agreement, on both the patent holder and the country issuing the license. The theory and empirical literature has provided an overview of predicted effects compulsory licensing might have on innovation for the licensor and the licensee, and on FDI over time. The effects on prices have also been presented. By looking at Indonesia and its use of compulsory licensing, I have discussed whether there are seen any identifiable effects as predicted by the theory and empirical literature. This has been necessary since the use of compulsory licensing through the TRIPS agreement is not similar to earlier use in which earlier empirical work bases on.

In terms of price, compulsory licensing introduces competition that has shown to decrease prices. This is beneficial for people in in developing countries who otherwise could not afford the medication. In regards to the innovators incentive to innovate, there seems to be contributors in literature stressing the point that there are seen no negative effects from compulsory licensing. However, the empirical literature on this effect is scarce weakening the validity of this point. In the case of Indonesia it may seem as if their use of compulsory licenses has not affected the patent holder's incentives to innovate, even though the Indonesian market most likely represents a fairly market share for the patent holding pharmaceutical companies. The remaining time left on the patent's specifics in this case could possibly provide an explaining of this. Since the patent expires in short time, the introduction to generic competition might not represent any significant loss for the rights holder. However, as mentioned, other implications may arrive if the use of compulsory licensing expands to other drug classes as well if the time remaining on the patent is longer.

When looking at the countries that use compulsory licensing, in my case Indonesia, it seems as if they have not experienced any significant growth in their capability of inventing new antiretroviral drugs. Whether this is due to the limited amount of knowledge transferred from the compulsory license is difficult to determine. Another proposed explanation could be that the Indonesian government encourages domestic generic production rather than motivating development of new drugs. This could serve as an example of how compulsory licensing could affect local innovation differently depending on the country using it and it's characteristics. Characteristics of the country that might play a role in this could for instance

be local policies, market characteristics and the countries level of development. The effects on FDI as a result of compulsory might also vary dependent on country specific characteristics. Even though there exists indications that other countries experience negative effects on FDI and trade, there is a lack of evidence of this in the case of Indonesia. Indonesia's role as a future potential market for big pharmaceutical companies could provide an explanation of this.

This study shows that there is a lack of empirical research on the effects of the use of compulsory licensing when it is applied according to the TRIPS agreement. There are many opinions of negative and positive effects, however, few based on empirical research. In my opinion this is quite striking. Suggestions for future research could be to investigate effects from compulsory licensing, especially on FDI. Could the effects on FDI vary according to country specific characteristics? Results from such an analysis could possibly be important in the future development of policy measures with the aim to balance the interests of developing countries and the developed world. An additional important aspect is how the type of drugs and their importance for the licensors R&D activities could impact their incentive to innovate if it is exposed to a compulsory license. A proper empirical analysis that includes this aspect on the innovators incentive to innovate could be useful.

As a final remark, it is important to mention the aspects that have not been included in this thesis. Long run effects of compulsory licensing could for instance possibly be quality of the drugs produced as well as the size of the royalty rate paid to the licensor. I hope however that this review can contribute to providing information of elements important to include in future research on the use of compulsory licensing.

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