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TRIPS and medicines – Prices, Availability and Health: The effect on India, Thailand, South Africa and Brazil

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Abstract: This thesis investigates the TRIPS-agreement signed by all members of the World Trade Organization and how it has affected the price and availability on medicines, and in extension its overall effect on health. This was investigated by conducting four case studies of India, Thailand, South Africa and Brazil. It was found that prices had been affected by TRIPS due to the extension of patent term in India and Brazil, delaying generic manufacturing and that compulsory licensing though permitted under the agreement held consequences, as seen in the cases of Thailand and South Africa. Availability in turn had not increased as indicated by studies of groups of essential medicines in any of the case studies, but appeared restricted by both high prices and other factors. In extension this meant added difficulties in affording and procuring medicines which meant negative effects on public health.

Key words: Patents, TRIPS, Medicines, Developing countries

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1. Introduction

Intellectual property rights that are global and valid in several countries and continents are relatively new to the world. Trade Related aspects of Intellectual Property Rights (from now on “TRIPS”) is the largest global attempt ever, and has received a lot of criticism from Non-Government Organizations (from now on “NGOs”) and developing countries. TRIPS is an agreement signed by the 159 members of the World Trade Organization (from now on “WTO”) reached in negotiation of the 1995 Uruguay round, which regulates intellectual property protection. That TRIPS encompasses patentability of medicines, biological resources and life forms among other things has been critiqued for resulting in large social costs. Unaffordable essential medicines for the poor are one example of conflicting social costs and economic benefits: the social benefit of curing the ill is confronted with the need of pharmaceutical companies to regain funds spent on R&D (Khor, 2002).

This thesis will deal with an adjacent subject to the much covered subject of economic growth, namely patents, innovation and development. More specifically medical patents and how the strengthening of intellectual property rights (“IPR”) have come to influence prices and availability of medicines, as well as public health, in developing countries. As such it can be said that this paper will mainly rely on two literatures in a quest to answer the research question: literature and studies on the effects of patents and literature covering the effects of TRIPS on prices and availability of medicines. The strand of literature that covers patent effects on innovation and growth is widely diverse in its theories and findings. Although innovation can be found as a key component in both older and newer models, there are differing opinions on how to best foster and encourage it. Critics of patents lean against models such as Justin Lin’s “Flying geese”-model in arguing that imitation is key to the achieving of economic growth and development in developing countries. Others like Thurow (1997) argue that an unrestricted access to the innovations of others would deter from innovation. The nature of knowledge makes it a public, unrivalrous, good which by definition carries market failures of failing to provide such goods. To ensure that there are incentives to invest and engage in innovation patents have been developed, which allow innovators to charge above the marginal cost of production and thereby profit from their inventions. (Thurow, 1997)

This thesis aims at investigating the impact of pharmaceutical patents on price, availability of medicines and overall effects on public health by looking at the impact of TRIPS on India, Thailand, South Africa and Brazil. No such complete study considering several parallel cases when looking at medicine prices, availability and public health has been conducted previously, and as such it is hoped that this effort should shed additional light on the merits and demerits of TRIPS. Previous studies have often focused on just one country or one effect for a shorter period of time, thereby not giving much of a comprehensive overview of overall effects. The focus also differs from many other studies on patent effects which consider the needs of major companies in terms of protection to motivate and spur innovation (Mazzoleni, Nelson, 1998).

1.1 Aim and justification

There is a large ongoing debate on the merits and costs of stricter implementation of global IPR, especially in connection to developing countries of the world. Supporters of stricter IPR are of the opinion that IPR don't primarily serve developed countries and large corporations, but are instead of great benefit to small inventors and society as a means of information sharing. Opponents of IPR argue the social costs arising in developing countries as greater than patent holders' economic benefit, meaning a need for restrictions on patentable items and maximum patent term duration (McDonald, 2002). In this paper the heated debate of IPR is brought to its edge by considering medicines, which is a central example of a large number of patents and arguably large social costs. By investigating changes in medicine price, availability and public health after the strengthening of IPR through TRIPS this paper aims to investigate some of the effects of TRIPS. In achieving its aim and answering the research questions this paper will encompass a brief section on the history of patents, as well as some explanatory sections on key concepts and organizations such as TRIPS, the WTO, essential medicines and The World Health Organization (WHO). The thesis will make use of four case studies on the countries India, Thailand, South Africa and Brazil.

Question 1:

How has TRIPS affected the price levels of medicines in the chosen case studies?

Question 2:

How has TRIPS affected the access to essential medicines in the chosen case studies?

Question 3:

To what extent is the implementation of IPR agreements such as TRIPS likely to have affected public health according to economic theory in the chosen case studies?

2. Background

2.1 History of patents

In some European countries the practice of issuing patents date back to the 14th century. Historically patents have been offered as an incentive for inventing, a possibility predominantly available in industrialised and developed countries, and less so in developing countries. This can be understood through considering the potential benefits which a nation stands to gain from granting patents. The inventor and the nation may use patents to gain cutting edge by preventing others from using the invention (Moser, 2013). However, developing countries haven't always respected patents. Just as innovation is perceived as integral in staying at the technology frontier, so is imitation seen as a means for developing countries to approach the technology frontier and thereby improve economic growth and development. There are many historical examples of international patent disputes spanning from 19th century piracy of British literary works in the US to modern pirated Harry Potter-novels in China. Practices of patent infringement and piracy are not limited to literary works, but counterfeit medicines have also been notorious. Developing countries' interest in respecting patents has historically tended to increase as they begin to develop technologies and inventions worth patenting. Another reason for developing countries to strengthen their IPR has been after international pressure from developed countries (Mihm, 2007). Attempts to capture the pattern of innovation and imitation have been made, such as in "the Flying geese model" proposed by Justin Lin, chief economist of the World Bank. Lin (2011) argues that economic development, defined as a continuous industrial and technological upgrading, is achievable by all countries pursuing their comparative advantage and emulating the successful processes of others by benefitting from a so-called latecomer advantage. This process is often referred to as "the Flying geese"-model, due to the development pattern of countries resembling the shape of flying geese. The majority of developed countries have developed by using government intervention and market mechanisms to replicate the techniques and growth strategies used by others. This captures the reason behind the reluctance of developing countries to implement strict IPR in early stages of development as this hinders them from drawing advantage of the latecomer advantage as a means of pursuing growth and development (Lin, 2011).

Patent agreements like TRIPS that are valid in several countries across multiple continents are relatively new to the world. This is especially true for patents on medicines, a commodity which several, both developed and developing, countries have purposely neglected to include in patent laws until recently. Examples of developed countries include Finland which began to permit medical patents in 1995, Italy in 1978 and Japan in 1976 (Jain, 2013). This shows that changes in patent laws are still continuous. Recent demands for increased patentability have for instance come from software and biotech companies (Mazzoleni, Nelson, 1998). As new fields of inventions have arisen and gained ground in world markets, together with increased global trade, the need for patents have increased, thereby driving changes in patent law. Not only has the point in time at which patent laws were introduced varied over time and among countries, but also the duration of patents. This makes it apparent that the relatively uniform modern patent laws enforced by the WTO are a new phenomenon (Moser, 2013).

Modern patents are usually valid 20 years. Patents can either be filed domestically, regionally or internationally, depending on the type of innovation and what is deemed most suitable. The cost for filing will vary depending on where the patent is filed; domestic patents are often cheaper than an international patent that applies in all member countries of the WTO. For a patent to be granted it is usually required for the invention to be non-obvious, of use and new (de Laat, 2005). This is more precisely put in Article 27 of the TRIPS-agreement which states that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. While the patent is valid the invention described is protected from copying or usage by others than the patent holder or any licensees. For medicines, this translates to mean prevention of produced (cheaper) generic brands (World Trade Organization, 1995). In the application for a patent the invention needs to be specified and described. There are primarily two reasons for this: to avoid confusion in the event of patent conflicts and to ensure that the underlying knowledge becomes publicly available. The patent holder’s temporary monopoly is in theory compensated for by making the knowledge publically available once the patent expires, thereby ensuring that the knowledge befalls society. This can for instance mean facilitating the production of generic medicines since the patented medicine has been fully disclosed in the patent and is thereby easy to replicate once the patent on the chemical compound expires. (de Laat, 2005).

The need for patents within the pharmaceutical industry has been argued as especially great by economists such as Kingston (2001). As the intellectual property of medicines can be captured in a formula and the formula takes comparatively little effort to unveil once the product has been released to the market, it is hard to protect by mere secrecy. The barriers for imitation are fairly low, and if the medicine proves useful in treatment, then the potential profits are large. The large amount of funding required for reaching a final product made clear that patents were required in order for companies to regain their investments in R&D (Kingston, 2001). Patenting of medicines usually occurs when the chemical and possibly valuable compounds have been synthesized, applications have been discovered and the processes for manufacturing have been developed. Studies have shown that about 80 percent of all pharmaceutical products and 43 percent of all processes are patented. Depending on findings of previous studies, the average length, or time lag, between the filing of a patent and the commercial launch of the medicine is 11-12 years (Sternitzke, 2010).

2.2 The World Trade Organization

The World Trade Organization (WTO) is an organization consisting of 159 countries that have agreed to work towards free trade. WTO was founded in 1994 based on the old General Agreement on Tariffs and Trade (GATT), which had filled similar functions since 1947. WTO meant an expansion of GATT into new areas relevant to trade, such as IPR, foreign investments and trade in services. According to WTO rules all members have to ensure that domestic laws are in accordance with WTO agreements, meaning that agreements such as TRIPS must be adhered to. For reasons discussed below TRIPS has attracted loud criticism from various actors and member countries (Fasan, 2012).

2.2.1 TRIPS

The TRIPS-agreement (Trade Related Aspects of Intellectual Property) reached in the 1995 Uruguay round of trade negotiations has meant stricter IPR for many WTO members, especially developing countries. New categories of commodities covered by TRIPS include medicines, biological resources and life forms. Article 7 in the agreement describes that the hope behind efforts to create a uniform level of intellectual property rights is that it should facilitate the transfer of technology and serve to further increase the incentives for investing in innovation (World Trade Organization, 1995). TRIPS is the most extensive and far-reaching agreement of IPR in history, and the long term goal of the WTO is to see these standards implemented globally (Supakankunti, et. al., 2001). Article 27 of the TRIPS-agreement specifies that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” However, members are permitted to exclude diagnostic methods, surgical techniques, plants and animals that aren’t micro-organisms from patenting to mention some of the possible exceptions (World Trade Organization, 1995). Pharmaceutical product patents have long been exempted from patent law by several developing countries for humanitarian and public health reasons (Abbott and Reichman, 2007). Once TRIPS was agreed upon such countries were given a time period during which they were permitted to adjust and alter their patent laws in accordance to TRIPS (World Trade Organization, 1995).

Many feared that this change in patent laws on medicines would lead to large changes in the market for medicines. Critics such as Supakankunti et. al. (2001) talked of increased prices as a consequence of decreased competition, fewer medicines available to the poor, and negative overall public health effects as final consequence. TRIPS was also speculated as possibly resulting in less foreign direct investment (from now on “FDI”) and research and production of medicines in developing countries; in other words a higher concentration of advanced technologies to developed countries. This can result in a skewed perspective on which areas of research need attention and funding, as well as a lower degree of technology transfers (Supakankunti, et. al., 2001). Recent studies conducted after the implementation of TRIPS, specific in their grading of IPR strength, have shown that there is a statistically significant positive effect of strong IPR on FDI. This effect wasn’t found in all industries, but was significant to the pharmaceutical industry (Halydier, 2012).

Complaints voiced from developing countries regarding the social costs that might arise from the inability to afford treatments against epidemics (such as HIV/AIDS, malaria, tuberculosis) resulted in alterations made to TRIPS commonly referred to as the Doha declaration. The Doha declaration allowed for the ability to issue compulsory licenses for medicines refused to be supplied at a reasonable price by patent holders, or in cases of national emergency. The conditions that need be met for such grants to be possible are specified in Article 31, “Other Use Without Authorization of the Right [Patent] Holder”, of the TRIPS-agreement. If the necessary preconditions are met then governments are entitled to issue compulsory licences entitling domestic producers (or third-party producers in lack of a domestic industry) to produce the medicines needed to treat the epidemic for which the patent holder would be duly compensated (World Trade Organization, 1995). The permitting of compulsory licences and

other safe guards of public health are referred to as “TRIPS flexibilities”. The flexibilities are meant to protect public health (Collins-Chase, 2008). Those countries accused of failing to comply with TRIPS will be tried under the WTO dispute settlement system, and if found guilty WTO procedure-sanctions may be enacted (Suprakankunti, et. al., 2001).

However, compulsory licences have shown not to be as efficient as intended in solving for unreasonable prices or in other times of need. A report conducted by the United Nations in 2001 showed that developing countries refrain from or hesitate to file for compulsory licences out of fear of the repercussions from developed countries (United Nations, 2002). That such reservations may not be unwarranted have been illustrated in instances of issued compulsory licences, such as for the drug Kaletra in Thailand. The pharmaceutical company Abbott which held the patent responded by withdrawing all its patent applications for the Thai market, as well as by refraining from introducing an improved version of Kaletra at a later stage. Moreover Thailand was also placed on the so-called “priority watch list” meant to shame countries (Jain, 2013).

Article 1 of the TRIPS-agreement states that countries are at a liberty to introduce stricter IPR than those under TRIPS, as TRIPS only sets minimum requirements for IPR (World Trade Organization, 1995). The US as a country which exports great amounts of intellectual property has been trying to negotiate bilateral agreements that mean stricter IPR than under TRIPS. These IPR go under the name “TRIPS Plus”. Such negotiations regarding intellectual property protection have been held with both Thailand and South Africa and would mean protection of intellectual property that surpasses the requirements of TRIPS by far. This has caused several legal commentators such as Collins-Chase to warn against what possible consequences entering such treaties would have for the public health and development. In light of possible negative consequences it is of importance that alterations in IPR are carefully scrutinized with regard to social cost before being implemented (Collins-Chase, 2008).

2.3 WHO: Essential medicines

The World Health Organization (WHO) is concerned with health and part of the United Nations system. WHO works with forming the research agenda on health. It also sets goals for how public health can be improved, means of achieving these goals and surveys health trends (World Health Organization, 2014b). WHO published its first list of essential medicines consisting of 186 medicines in 1977. At the time the publishing was acknowledged as bringing attention to the problem of high medicine prices and poor availability of essential medicines in many developing countries. Since its first publishing the list has attracted attention and critique from many actors. The pharmaceutical industry has argued it too restrictive and NGOs have critiqued the list for lacking transparency in its decision process. Since its first publishing the amount of medicines included on the list has more than doubled (Laing, et. al., 2003). The structure of the list itself has also undergone changes. Up until 2001 low price was one of the requirements for medicines to be included on the list. This meant that many medicines under patent protection, like antiretroviral drugs (ARV-drugs), were excluded from the list in spite of their great importance to treatments. Modern versions of the list have also been altered to include details on decisions regarding included and excluded medicines to increase transparency (Ford, 2004). Investigations have been conducted by the

WHO on how prices of medicines on the list of essential medicines have varied. However, as criteria for the list have varied and such investigations haven't been conducted regularly for a consistent group of countries, regions or medicines meaning that these investigations offer little insight to general trends and effects (World Health Organization, 2014a).

The WHO has recommended that all countries compose lists of essential medicines. This recommendation has been made in light of strives in developing countries to expand the coverage of health insurance. The list is supposed to act as a means to estimate and minimize the total costs of medicines provided under the health insurance policy, as well as attract attention and focus to important medical subjects. Although health insurances may vary among countries, as will be illustrated in the case studies, the costliness of treatment is naturally of interest to both individuals and governments. If a treatment is very expensive and needed by a large share of the population, it may be difficult for governments to afford. Lists of essential medicines enable countries to clearly observe the share of patented medicines in their total medicine expenditure. The share of patented medicines in expenditure may be large in spite of the fact that patented medicines are often few in relation to the amount of generic (un-branded) medicines. Only four percent of the essential medicines in Mexico were under patent protection in 2012, but represented 56 percent of the total cost of medicines within the public sector (Gómez-Dántes et. al., 2012). Comparisons of national lists of essential medicines to the WHO list of essential medicines have shown that national lists tend to include fewer medicines. Such differences can be understood through natural differences in diseases when comparing different countries and continents, but also through the fact that national lists tend to be updated more sparsely which can mean a time lag for newer medicines (Laing, et. al., 2003).

3. Theoretical framework

3.1 The nature of knowledge: Why are patents needed?

The nature of patents and knowledge places them within the category of public goods. Knowledge generated from innovation and R&D is a public good in the sense that it is impossible to prevent others from using, since it is nonrivalrous, thereby creating a free rider problem. This makes it difficult for producers and investors to regain investments and charge prices reflecting the cost of R&D. The nonrivalrous nature of public goods often results in an unwillingness to provide such goods and market failures (Encaoua, et. al., 2006). Patents provide a solution by protecting the intellectual property of inventors. Thereby patents can be seen as a government policy designed to stimulate private investments (Courvisanos, 2009). Patents grant the inventor a temporary monopoly, usually for 20 years, during which time the inventor can charge a price higher than the marginal cost of production. In exchange the patent applicant must disclose the information behind the patent, which enables imitation and further improvements once the patent has expired. Many great innovations have arisen from improvements made to older innovations, as can be seen in examples of improvements made to pharmaceutical drugs such as insulin and anti-clotting drugs (Scotchmer, 1991). In this context patents provide a solution to market failures in the sense of providing incentives for investments in innovation and aiding in technology transfer and the spreading of information. However, apart from the solving of problems described above patents also come with inherent problems, such as through the creation of inefficiencies and poorly specified, too broad, patents (Yamabhai, 2012). Thereby the balance between too little protection (meaning a feared low innovation and a slow pace of technological development) and too much protection (meaning a unnecessarily large deadweight burden) is of importance, but difficult, to find (Encaoua, et. al., 2006).

3.2 Patents and inefficiencies: The Coase theorem

The inefficiencies that might arise as a consequence of negative externalities in connection to property rights have been widely covered in economic models. One such model is the Coase theorem, which states that given zero or negligible transactions costs the matter of who is in possession of a property right is irrelevant as bargaining will lead to a satisfactory solution to all involved parties. Externalities arise as a consequence on non-excludability, to which patents provide a solution. When everything is owned the problem of externalities is resolved: in the example of a polluted river the pollution may be prevented if someone holds the right to do so. If a public good is internalised in a group with a set amount of members, then these members will negotiate agreements that set the amount of externality at the optimal level for all parties, given low transaction costs and a possibility to bargain. Agreements such as TRIPS regarding IPR could be seen as such an attempt to limit the level of externality. (Harris, 1990)

3.3 The downside of patents

The negative aspects connected to intellectual property rights is not limited to the inefficiencies brought by the establishment of monopoly power, but also to the hindering of information diffusion and spreading, thus the downside of patents is twofold (Encaoua, et. al.,

2006). Critics such as McDonald (2002) have argued that patents are primarily a legal document, and that patent lawyers try their utmost to only include the information needed to defend the patent, which often means that it is not specific enough to allow for imitation once the patent has expired. Thereby the holders of patents can be argued as cheating society from the rewards promised at the expiration date of the patent (McDonald, 2002). Mazzoleni and Nelson (1998) point to that innovation has long been the driving motor behind industrialisation of developed countries, such as the US and Britain, in a time when patent laws weren't as extensive as presently. This makes it wrong of developed countries to place such high demands on IPR compliance on developing countries. Where social costs provide grounds for doing so it is key to impose softer IPR, such as in developing countries, with medicines being one example (Mazzoleni, Nelson, 1998). This might also increase the gap between developed and developing countries as prominent economists such as Stiglitz (2008) have theorized that the gap stems from disparities in information, and not just resources. This might make global patent agreements such as TRIPS harmful to development in the sense that they hinder the spreading and diffusion of information which is necessary in order to promote growth and development in developing countries. This matter has become of increasing importance in a modern society which is highly centred on information and knowledge (Stiglitz, 2008). This phenomenon is not limited to developing countries, but can be seen in developed countries such as the United States as well. In the US after the patent of a medicine expires its price drops on average by 60 percent given the competition of one generic producer, with 10 competitors the price drops by 29 percent (Oliviera, et. al. 2004).

The problem with a global system of IPR is of course that it is difficult to set a standard of IPR that is suitable to everyone. The system of IPR most suitable to industrialised developed countries such as the US might not be the same as the optimal system for IPR to the developing country of Ecuador. Although the need for medicines of the ill, perhaps terminally so, in developing countries may be great these patients simply can't afford to pay that which is asked for medicines. Thereby these patients make a group of potential consumers that attract very little interest from pharmaceutical companies in terms of future research attentions (Stiglitz, 2008). That which primarily concerns patents in connection to public health is the need to find a balance between economic profits and social costs. Not in the least since the right to medical treatment is listed and mentioned as a basic human right and included in the millennium goals (Gupta et. al., 2013). Other critics such as Gupta (2004) have voiced concern regarding the impact increased patent protection will have on the markets of generic medicines. Not the least will this mean a decreased pressure on more efficient and innovative production processes, but also mean no price competition as the patent holder will be able to charge monopolistic profits for the minimum 20-year duration of the patent (Gupta, 2004). This is argued necessary for innovation to occur, but contradictory to neo-classical models in which goods should be priced according to their marginal cost (McDonald, 2002).

3.4 The merits of patents

Since knowledge has no marginal cost and production costs are comparatively low, it would be difficult to make profits on medicines without some kind of protection of intellectual

property. The traditional view of patents as described by many economists is that while patents may have a market-distorting effect, they are at times a necessary incentive and protection for innovation to take place. However, this being said there are diverging opinions regarding the overall effect of patents on economic growth. The prevailing modern view, as is reflected in regulations and trade agreements, is that patents are of benefit to economic growth since they encourage innovation. Without patents the small possibility of being able to financially benefit from innovations would deter innovators from investing in innovation. This view has led to a general movement towards stricter patent regulations and a wider approval of patents worldwide. The TRIPS-agreement can be seen as an integral part of this work, but there are also other efforts directed towards broadening the acknowledgement of patents internationally (Moser, 2013). It is believed by some that the patent system will have many long-term benefits, such as a stimulation of R&D that might otherwise be considered too risky from the viewpoint that the investments made might be difficult to recoup. The introduction of patents in developing countries is hoped to mean an increased focus on medicines relevant to common tropical diseases such as malaria and tuberculosis and also HIV/AIDS. Patent protection will increase the probability of being able to profit from such research (Gupta, 2004).

Such hopes are placed on the long-term effect of TRIPS on the Indian pharmaceutical industry. Barnes (2003) has argued that since the Indian patent act for pharmaceutical products has been so weak historically, there has been little incentive for Indian pharmaceutical companies to engage in R&D. There is a slight need to invest in research to discover own medicines when the freeriding on the discoveries of others is relatively cheaper and carries such large potential markets. This can also be argued as having contributed to the comparatively little attention that has been devoted to diseases mainly afflicting developing countries. Had Indian pharmaceutical companies engaged in more own research, then perhaps these efforts could have been placed within areas more relevant to developing countries, unlike pharmaceutical companies in developed countries. While it may be justified to argue the difficulties for most developing countries to engage in such research, the situation for India with its large pharmaceutical sector is arguably different from most other developing nations (Barnes, 2003).

3.5 Are patents really necessary?

Schumpeter had another theory connected to innovation and monopolies that is commonly referred to as Schumpeterian competition. The theory behind this notion is that innovation results in temporary monopolies. As inventors try to replace each other's inventions to gain monopoly Schumpeterian competition arises. This results in a kind of intense competition (Tang, 2006). However, critics like Stiglitz (2008) argue that the concept of a temporary nature of monopolies that Schumpeter refers to is flawed. Monopolies are rarely temporary, but have often proved to be long-lasting in nature, both from information withholding, but also through the creation of IPR and patents. Stiglitz exemplifies this by mentioning possible network externalities and costs connected to switching, as can be seen in the monopoly power gained by Microsoft within software (Stiglitz, 2008). Moreover, several studies, as one conducted by Tang (2006) on firms in Canada, have failed to find a strong connection among

monopolies between competition and innovation, which would indicate that Schumpeter's theory proves lacking in relation to reality (Tang, 2006).

Economists such as Moser (2013) and Allen (1983) have suggested patents to be redundant to innovation and economic growth based on studies of economic history proving that both economic growth, and industrialization, is processes achievable without the protections of patents. In a paper investigating the effect of patents on innovation in a historical context Moser (2013) found that historically the bulk of innovation has occurred outside of the patent system. (Moser, 2013). Historical evidence indicates that innovation has frequently arisen as a consequence of knowledge sharing outside the patent system. Allen (1983) observed this phenomenon when studying the 19th century iron and steel industry in Britain and denoted it "collective innovation". Many of the important discoveries to productivity growth within the industry were made by various individuals who didn't file patents for their discoveries. Allen concludes that under the 19th century and the then prevailing circumstances collective innovation was perhaps the most important source of inventions, since it allowed for cumulative advancement (Allen, 1983). Moser (2013) has also made use of historical data from exhibits on innovation and prizes awarded for best innovation to compare inventions from countries with and without patent legislation. When considering the period 1851-1876 the investigation revealed a large amount of high-quality innovations coming from countries without patent legislation. This is concurring with the line of theory that emphasizes that technological advancement is shaping patent law and driving the increased possibility to patent, as opposed to patents encouraging and fostering innovation. In this sense it is of utmost importance not to grant too broad patents, which could thereby hinder or deter from further innovation, both within and outside the established patent laws (Moser, 2013).

3.6 Alternatives to patenting

Not all research is motivated by promises of profit, as is illustrated in open source coding, but research can be driven by many other reasons perhaps unrelated to profits which then makes intellectual property protection redundant in terms of motivation. This being said, the need for funding research is still important. In response to the argument that the protection of intellectual property is necessary in order to motivate and spur investments in research and innovation it has been argued that there are other ways to receive funding that might make such demands redundant. Examples of other means of financing include government funding and university research. That such research should be of importance is illustrated in many examples of inventions that have grown to be of importance over history. The fact is that not all of these have fallen under the protection offered by IPR, as is illustrated in the recent movement within software towards open source coding. This illustrates that monopoly on intellectual property may neither be necessary nor the most efficient way to protect and spur innovation (Encaoua, et. al., 2006).

Among those who suggest that the patent system is ill-equipped in its design to achieve the objectives of increased innovation and development there have been suggestions of other means to incentivize innovation. One such suggestion proposed by Stiglitz (2008) would be to offer prizes to anyone that would come up with an innovation living up to a predetermined set of objectives. This could be a vaccine for malaria for instance, and is an idea which has been

used in the past to encourage work to find mechanical chimney sweeps for instance. Among the benefits listed for such an innovation encouragement system are a smaller need for advertising and that it would have less of a distortionary effect than creating temporary monopolies (Stiglitz, 2008).

4. Methodology and data

4.1 Research design

In answering the research question case study-methodology will be used to investigate how TRIPS has affected price and availability of essential medicines in India, Thailand, South Africa and Brazil. Case study-methodology has been chosen in order to get a more detailed view on prices and availability of essential medicines, and in extension the public health situations of the chosen countries have been affected by TRIPS. Systems for both health care providing and patent law have varied in the studied countries which makes a qualitative study more appropriate, since this enables accounting for such differences in the analysis. In answering the research question the paper strives to use information relating to the subject on several different levels, and subcomponents of the four cases of India, Thailand, South Africa and Brazil to give a full understanding. The analysis of the information obtained will be guided by the theory discussed in the theoretical framework. However, there are also limits and weaknesses connected to using case study methodology. Commonly mentioned problems of case study methodology include a possible lack of internal and external validity and possible difficulties to reproduce the study. However, depending on the structure of the case study many problems can be mitigated (Saunders et. al., 2012). Another factor which makes case study-methodology necessary to the paper is the need to consider both the phenomenon of medical patents as such, as well as the context within which medical patents are introduced, since the context is thought to hold valuable explanatory value (De Vaus, 2011).

Possible threats to internal validity arise from other factors than the key variables of interest influencing the outcome. However, an idiographic structure which focuses on a set of particular factors or events and thereby tries to develop an understanding or explanation of the case is commonly considered as sufficient to avoid the problem of lacking internal validity. Problems of lacking external validity are often considered large in connection to case studies. This means that there is no basis provided by case studies upon which generalizations can be made. The findings of the case cannot with confidence be considered as being representative of a broad group of other cases, primarily due to the number of cases being too small to make findings statistically significant. In the context of this thesis it means that the findings on effects of TRIPS on medicine prices, availability and public health cannot be used to draw conclusions of the effects of TRIPS in other countries. Therefore it is of utmost importance to be careful in making generalizations. As this study includes countries with differing patent legislation prior to TRIPS, differing disease burdens and differing initial approaches to TRIPS, the need for cases with different conditions can be argued as having been satisfied (De Vaus, 2011).

India, Thailand, South Africa and Brazil have been chosen as case studies out of countries having implemented TRIPS, and include information on their general health profile, previous patent legislation, changes in medicine prices and medicine availability. Medicines discussed in case studies are all included on WHO's list of essential medicines. The case studies will be contrasted with each other to detect any alterations in medicine prices and availability, and if this appears related to changes in public health. Public health will be commented upon by

putting what is found regarding prices and availability of medicines in the studied countries in relation to their respective disease burdens.

4.2 Sources

Obtaining reliable information is of great importance to any study, and not the least for case studies. Therefore all papers and data sources have been evaluated carefully. The paper has mainly used published papers on innovation, patents and TRIPS in establishing the previous research section and theoretical framework. In order to be able to answer the three research questions case studies of the four chosen countries (India, Thailand, South Africa and Brazil) were used. All of the chosen papers and case studies were published in well-renowned papers and are therefore deemed as trustworthy. The data obtained from this will be completed by information and data from WHO, which is regarded as a prominent institution thought trustworthy. If there is any relevant critique or questions to materials used this will be mentioned. This will establish a fundamental understanding of essential medicines and what importance this might carry for developing countries.

4.3 Limitations

This thesis will not consider all aggregated types of patents. As this is a paper of a limited format it will only consider the TRIPS-agreement and patents on medicines since this is that which primarily relevant to the subject and the research questions. Therefore no general answer regarding whether or not patents as a whole are beneficial to innovation, development and economic growth will be offered.

5. Cases

5.1 India

5.1.1 General health and the health system in India

India spent 4.05 percent of its GDP on health care in 2012. This corresponds to \$61.4 per capita (World Health Organization, 2014c). India faces a large disease burden of both non-communicable afflictions with expensive treatments, such as diabetes, cancer and heart disease and communicable diseases such as AIDS (Yip and Mahal, 2008). Close to the regional average of 169 people per 100 000 in India suffered from HIV in 2013. 1523 people out of every 100 000 got infected with malaria in 2013, which is slightly above the regional (South East Asian) average of 1462, but lower than the global average of 3752 people per 100 000. The Indian population also suffers from pneumonia, dengue fever, tuberculosis, some of which are difficult to treat due to being medicine resistant. Factors which contribute to the spreading of the diseases in India are poor drinking water and poor hygiene, something which mainly affects people living in poor and rural areas (World Health Organization, 2014d). There are large differences in health within the Indian population that vary depending on gender, education, caste, wealth and geography. This can be seen in large differences in life expectancy between Indian regions. In the region of Madhya Pradesh life expectancy is 56 years, whereas in Kerala life expectancy is 74 years (Balarajan, 2011).

Under the Indian constitution public health is a responsibility of the states, therefore the states are expected to provide the bulk of the funding of public health services. Public health care in India is available free of charge or offered to a nominal charge to those in need of medical attention. This being said there are often added out of pocket expenditures. Added expenditures which may arise include cost of medicine treatments, medical (laboratory) tests and hospitalization costs. This has led to claims that the government should seek to increase its funding by for instance establishing health insurance programs. Moreover, the public health system in India is considered to be of poor quality due to lacks in financing, quality- and access- problems (lacking essential medicines and supplies). This has been pointed to as one of the contributing factors of the large financial burden placed on Indian households in need of medical attention. Investigations of the Indian health providing system have shown that those who can afford it prefer to seek care in the private health system. Many households are unable to afford full or partial insurance that would cover medical expenses (Ellis, et. al. 2000).

In 2008 only 15 percent of the Indian population was reported as having any type of health insurance, mainly through their employer (Yip and Mahal, 2008). By 2011 the share of population covered by health insurance was reported to have dropped to 10 percent (Balarajan, 2011). Although the possibility of private health insurance became available in 1999, only about 1 percent of the Indian population had used this opportunity by 2008. This means that the bulk of the Indian population will have to pay for added expenditures out of their own pocket. India has committed to spending more money on health care to alleviate the monetary problems of the rural and poor population, and to address its disease burden. One such action directed towards achieving this goal is the governments' establishment of a

heavily subsidized voluntary health insurance system for the poor introduced in 2003. However, enrollment in the insurance policy has been low (Yip and Mahal, 2008). Investigations into health expenditures of the Indian population have shown that in 2004-2005 about 39 million people in India fell into poverty as a consequence of medical expenditures, not taking into account those already under the poverty line (Balarajan, 2011).

5.1.2 Indian patent law prior to TRIPS

Prior to the implementation of TRIPS India did not permit patents on pharmaceutical products. The Indian decision on denying patents on medicines was made in the 1970 Patent Act, a law which still permitted patents on manufacturing processes, but prohibited patents on the medicines themselves. The removal of patent protection led to a thriving production of cheaper generic medicines and labelled India as pharmacy of the developing world according to organizations such as Médecins sans Frontières (Chaudhuri, 2012).

The decision made regarding TRIPS in the 1994 GATT-round meant that India as a WTO member would have to alter its practices regarding patents on medicines. These changes would have to be completed by 2005, which still meant a near ten years later than most other countries that agreed to comply with TRIPS. Exceptions on the starting date of TRIPS were made for countries that did not recognize pharmaceutical patents prior to TRIPS, so as to offer a transition period. This meant that pharmaceutical companies in India could continue to manufacture generic copies of medicines until 2005. Such generic imitations could also be exported and sold to other places in the world, most notably resulting in the famous pirate-pill story of HIV-blocking drugs sold to African countries (Kotwani, 2013). In 2004, right before the Indian implementation of TRIPS, India was supplying 22 percent of the generic medicines of the world (Jain, 2013). Once the implementation of TRIPS in 2005 had been ruled upon India established a mailbox for patent applications. The mailbox was designed to work as a transitional measure in the years 1995-2004 in which patents applications would be received and stored up until the date when TRIPS was introduced to Indian patent law (Chadhuri, et. al. 2010). The changes on the 1st of January 2005 concretely meant an extended patent term (from 7 to 20 years), the possibility to patent medicines as well as micro-organisms (and not just production processes) (Jain, 2013).

The new Indian patent law still permits generic companies to produce and export generic medicines to the least developed countries of the world (where the introduction of TRIPS has postponed until 2016) and includes what according to legal commentators is “the most extensive provisions on compulsory licensing” among countries with TRIPS (Mueller, 2007, p.542). Although India has included some safeguards to protect public health in its new patent legislation, such as strict laws on patentability (affecting the possibility of secondary patents getting approved among other things), the amount of patents granted on essential medicines have led critical voices from the UN to argue that these safeguards appear insufficient and aren't employed fully (Chadhuri, et. al. 2010).

5.1.3 Prices of medicines

Many Indian pharmaceutical firms specialized in reverse-engineering medicines invented in other foreign markets. Since reverse-engineering is less costly than R&D conducted the result

has been far less expensive Indian medicines (Gupta, 2004). The impact of the large Indian generic industry can be seen in studies which have shown that prior to the introduction of TRIPS the price difference when comparing branded medicines to generic medicines could be as large as 90 percent. As prices of medicines drop substantially as a patent expires and generically produced versions become available, it is interesting to investigate how TRIPS has affected this process (Gupta et. al., 2013). As a consequence of the removal of the patent restriction and expiring patents on several prominent patented medicines MNCs began to have a greater interest in the market for generic medicines as well. This presented itself through the takeover of several Indian firms and partner agreements signed with Indian firms. Fewer actors and producers in the pharmaceutical market meant a decreased competition which in itself is likely to contribute to increased prices (Chaudhuri, 2012).

The applications in India's so-called mailbox were made available to the public on the 1st of January 2005 when the Indian Patent Office began processing its patent applications. This revealed that many of the filed applications were in fact secondary patent applications, meaning a patent application which covers ancillary features of an existing patent used to delay the manufacturing of generic medicines. This meant that the opening of India's mailbox brought on lengthy legal proceedings between generic manufacturers and Multinational corporations (from now on "MNCs"). Examples of such medicines include Roche's anti-cancer drug Tarceva and Gilead's anti-HIV drug Viread. Such actions speak against the self-professed will of large pharmaceutical companies to work towards increased medicine affordability among the poor in developed countries, since these lawsuits (even if eventually not won) have complicated the manufacturing and selling of cheaper generic medicines (Chadhuri, et. al. 2010). Novartis filed a patent for its drug Gleevec (or Glivec) which treats leukemia in 2006. The branded drug is sold at \$26 000 dollars per yearly treatment, contrasting with the generic version sold for about \$2600, which is unaffordable to many Indians. Novartis' patent filing for Gleevec was rejected, on the grounds of it counting as "evergreening", a practice among pharmaceutical companies to make minor improvements to drugs with expiring patents and then file for a new patent. Such a patent application will only be granted in the case of a substantial improvement in efficiency, though what constitutes a substantial improvement is not defined by the law (Mueller, 2007).

A study conducted by Chaudhuri (2012) which aimed to investigate the effect TRIPS, and the increased amount of multinational companies and monopolies, have had on Indian prices on medicines revealed that prices have indeed increased since 2005. The in the words of the author "exorbitant prices" are mainly to be found within treatments for life threatening diseases, such as cancer. The author points to the similarities this bears to the state of the Indian medicine market prior to the abolishment of patent protection on medicines in the 1970's (Chaudhuri, 2012, p.53). An investigation of price changes of a group of medicines on the list of essential medicines comparing 1996 to 2006, just after the implementation of TRIPS in India, show that in that period the prices went up by 15 percent (accounting for inflation). This goes to illustrate that TRIPS is unlikely to have made essential medicines more affordable in India. Especially since only 30 percent of the Indian population could

afford modern medicines in 1993, prior to the implementation of TRIPS, in spite of medicine prices in India being among the lowest in the world (Balarajan, 2011).

5.1.4 Availability of medicines

An econometric analysis using product sales data from market research firms such as IMS Health Inc. to investigate the availability of new medicines in countries around the world found that new medicines were less likely to be found in developing countries with historically weak IPR, such as Brazil and India, than in developed countries with more secure IPR, such as Germany, even after the implementation of TRIPS. Using Spain as a base country the group of investigated essential medicines were only 35 percent as likely to be patented and sold in India despite its TRIPS compliance. The explanation for this might lie in studies which have found that market exclusivity in India is difficult to obtain, even after the implementation of TRIPS. In a studied sample of newly introduced drugs on the Indian market more than 70 percent were manufactured by two producers or more, implying up to 70 percent chance of there being a generic version. In an econometric study of how many new medicines were introduced into developing markets it was found that less than two thirds of the new medicines in the sample were available on the Indian market. Though this means a cost of consumers due to a loss of cutting-edge medicines, it could be argued as being compensated for by lower prices of generic drugs (Berndt, et. al., 2011).

Bird (2009) has also pointed to high Indian tariffs on imported pharmaceuticals as a barrier to receiving essential medicines. Indian tariffs on pharmaceutical imports are currently at 55 percent, as a protectionist measure directed towards protecting and fostering India's pharmaceutical industry. In the new era of TRIPS this can mean significant added costs to medicines that are under patent protection and imported from other countries. It has been estimated that if China, Brazil, India and Nigeria lowered their current high tariffs on imported medicines, then half of the world's population would get a much improved access to essential medicines. This can of course be disputed by stating that the imported patented medicines are usually too expensive to begin with, but naturally matters aren't improved by high tariffs (Bird, 2009).

5.1.5 Competition

A study conducted by the UN to investigate the pharmaceutical market in India five years after the implementation of TRIPS showed that the market had undergone some change since the changes in patent law were made. The new policy-environment led to increased collaboration between Indian pharmaceutical companies and international MNCs, as well as mergers and acquisitions. This has meant decreased competition in the market, to the detriment of consumers. The study also offered evidence that disproved the hope of TRIPS resulting in an increased R&D-focus of Indian pharmaceutical companies in tropical diseases relevant to developing countries, but neglected by pharmaceutical companies of the developed countries. Although R&D expenditure increased under the investigated period among firms with heavy R&D expenditure (37 out of a total 166 firms) from 3.89 percent in 2001 to 8.35 percent in 2006, most of this research was devoted to developing generic medicines of expired patents and establishing them in the markets of developed countries and new medicines with more lucrative markets. The study concluded that even after TRIPS the strength of the Indian

pharmaceutical market lies within the manufacturing and export of generic medicines. The remaining firms showed a near constant of 1 percent of budgets being spent on R&D under the investigated period (Chadhuri, et. al. 2010).

5.2 Thailand

5.2.1 The health system and general health in Thailand

Thailand spent 3.93 percent of its GDP on health care in 2012, or \$215.1 per capita (World Health Organization, 2014c). 663 people per 100 000 in Thailand suffered from HIV in 2013, which is well above the regional (South East Asian) average of 185, and also places Thailand above the global average of 511. In contrast only 205 people out of every 100 000 got infected with malaria in 2013, well below the regional average of 1462. Aside from problems of infectious diseases such as AIDS, diarrhea, malaria and tuberculosis the Thai population also suffers from non-communicable diseases such as cancer, respiratory diseases and asthma. 12 percent of all deaths in Thailand in 2010 were from cancer, whereas communicable diseases held a 17 percent share of all deaths (World Health Organization, 2014e).

Thailand has had a system of universal health care in place since October 2001 (Tangcharoensathien, et. al. 2002). Prior to this there were large inequalities reported among rural and urban areas, as well as between rich and poor citizens. The previous system was financed by user fees (about 20 percent), tax money and public and private third party payers. The old Thai system of health insurance was organized to protected groups of people. There was also the possibility of purchasing a private health insurance which partially or fully reimbursed medical costs (Pannarunothai and Mills, 1997). These measures only covered about 70 percent of the Thai population (more or less partially), which meant that approximately 30 percent were left completely without insurance coverage. A universal health insurance was introduced in 2001, which meant that the entire Thai population was covered. The new insurance was funded by general tax revenue and a fixed payment of 30 Baht per visit to the hospital (Tangcharoensathien, et. al. 2002). The drugs prescribed under the insurance policy were limited to those on a national list and some treatments for chronic diseases and other high-cost treatments were subject to price ceilings, meaning among other things no entitlement to ARV-drugs for AIDS-patients. The new rule in Thailand after the military coup in 2006 chose to remove the 30 Baht fee and make the insurance free of charge instead (Hughes and Leethongdee, 2007).

5.2.2 Thai patent law prior to TRIPS

Reports written by NGOs such as Médecins sans Frontières point to a long history of trade pressures being placed on Thailand to implement stricter protection on intellectual property, such as through threats to implement sanctions on prominent Thai export commodities like jewelry, and wood. These pressures have led to early implementation of many IPR as can be seen in the establishment of pharmaceutical process patents in 1979, pharmaceutical product patents in 1995 and restricted possibilities on compulsory licenses placed in 1998 (Collins-Chase, 2008).

5.2.3 Prices

Thailand's compliance with TRIPS increased its budgetary expenses of providing medicines to a new total of 10 percent of its total government budget. In 2007 this motivated the Thai government to issue three compulsory licenses against medicines patented by MNCs: against Abbott for its drug Kaletra, against Merck for its drug Efavirenz (both Kaletra and Efavirenz are ARV-drugs) and Sanofi-Aventis for its drug Plavix (which is used for coronary disease treatments). The licenses were issued for generic imports from India. Before its issuing of compulsory licenses the Thai government had attempted long negotiations with the mentioned pharmaceutical companies for price reductions, but to no avail. At the time of the issuing of a compulsory license for Efavirenz Merck's price was almost double that of the Indian generic version, and Thailand expected to achieve a 20 percent price reduction for its generic imports of Kaletra. As a response to this action Abbott chose to withdraw all of its pending patent applications for the Thai market (Abbott and Reichman, 2007).

That strong patent protection has influenced the price of medicines in Thailand is illustrated in many examples of drugs that have been on the market with few or no substitutes, thereby resulting in high prices. The drug Fluconazole used to treat HIV patients is among the medicines listed on WHO's list of essential medicines. Up until 1998 the patent for Fluconazole was held by Pfizer, which thereby possessed monopoly rights to sell Fluconazole on the Thai market. When Pfizer's patent expired in 1998 the price of Fluconazole dropped by about 98 percent, thereby illustrating the effect an introduction of competition can have on prices. (Ford, 2004) A comparison of the present price of Fluconazole in Thailand and Kenya (where it is under patent protection) reveals stark contrasts in price. A daily dose in 2008 of Fluconazole costs 70 cents in Thailand, whereas the same daily dose costs 20 dollars in Kenya. This illustrates what difference in price generics can mean (Collins-Chase, 2008).

5.2.4 Availability

Thailand is one of the countries that have tried to implement the option to issue compulsory licenses for production of medicines often mentioned in connection to TRIPS as a possible safeguard of health. In the period 2006-2007 Thailand issued two compulsory licenses for the manufacturing of two medicines aimed at treating patients with AIDS. Although the licenses were in accordance with TRIPS this still held repercussions for Thailand, both from the pharmaceutical industry and from other countries. Abbott, the pharmaceutical company which held the patent for one of the medicines, Kaletra, responded by withdrawing all its products that were awaiting patent approval in Thailand and has withheld registration of any new medications since. This includes an improved version of Kaletra, the drug for which a compulsory license was issued. Another consequence of the Thai compulsory licensing was that Thailand was placed on a so-called "priority watch list" meant to shame the countries listed by the US trade representative (Jain, 2013). The acting of the Thai government has also been strongly criticized by the industry chamber of commerce. However, after some initial confusion the official stance of the EU was in support of Thailand's actions, in spite of a letter sent from European Trade Commissioner Peter Mandelson with veiled threats of economic reprisal. The Thai government responded to the action taken against it by stating that it would

bring any wrongfully imposed sanctions to the WTO dispute settlement (Abbott and Reichman, 2007).

5.3 South Africa

5.3.1 The health system and general health in South Africa

South Africa spent 8.79 percent of its GDP on health care in 2012 or in per capita figures \$644.6 (World Health Organization, 2014c). 11 589 people out of every 100 000 in South Africa are infected with HIV, an estimated 6.4 million in total. This makes HIV the heaviest of South Africa's disease burdens. The regional (African) average of people suffering from HIV is 2774 per 100 000, and the global average is 511, which puts the large South African share into perspective. South Africa also has a higher than average amount of people suffering from tuberculosis, 857 per 100 000, which is above the regional average of 303 and the global average of 169. 67 percent out of all deaths in South Africa in 2010 were from communicable diseases. Other figures interesting to note are the 3 percent share of total deaths from diabetes and the 7 percent share represented by deaths from cancer (World Health Organization, 2014f). The health profile of South Africa shows that infectious diseases predominately affect the poor, whereas chronic diseases affect rich and poor alike. The rich of South Africa can be said as having completed the epidemiological transition, whereas the poor still suffer from many pathologies of both communicable and non-communicable kind (Sanders and Chopra, 2006).

Estimations have found that in South Africa alone the lives of over 200 000 AIDS infected could be spared per year given access to antiretrovirals (ARVs). The cost of treatment for those suffering from AIDS is high – in South Africa a treatment consisting of three ARV medicines yearly costs \$2000 in the private sector and \$750 in the public sector. This is unaffordable to many, since the median yearly income in South Africa is \$1000. Such statistics illustrate the importance of increasing competition to reduce prices and permitting manufacturing of generic drugs. Introducing even stricter protection of intellectual property would be a step in the wrong direction if the goal is to decrease medicine prices, increase access to essential drugs and improve public health and life expectancy (Collins-Chase, 2008).

When Nelson Mandela came to power in 1994 he started to execute major changes to the health policies in South Africa aimed at improving public health, such as making health care for pregnant women and children younger than six free of charge. In 1997 the government produced a “White paper on the transformation of the health system in South Africa” aimed at creating a unified, single health system for all through directives. Health policy in South Africa is developed on a national basis and then adapted so as to fit regional needs. However, such change proved difficult given existing regulations and the state of public health in South Africa with an escalating crisis of AIDS. This meant a delay until 2003 before the propositions were turned into law (Whiteside, 2014). In spite of great ambitions of creating an equal health system for all it was shown that the per capita health investment of the South African government declined by 14.1 percent between 1995 and 2002, with an annual increase in health expenditure by 0.3 percent between 1998 and 2002. There were also great

gaps in resource distribution among richer and poorer districts, where the districts showing the greatest deprivation levels got the least resources (Sanders and Chopra, 2006). Only a smaller share of government health expenditure actually befalls public health care and the poor, as can be seen in the fact that in 2012 44 percent of health expenditure was spent on the 16 percent of population with private health insurance (Whiteside, 2014). Human resources have also transitioned in favor of the private sector, with a shift from 40 percent of physicians caring for patients with health insurance in 1975 to 66 percent in 2004. This shows a trend even after 1994 towards growth of the private medical sector and a strong trend for medical practitioners to work in the private sector (Benatar, 2004).

5.3.2 South African patent law prior to TRIPS

Prior to TRIPS the Patent Act of 1978 and the Intellectual Property Laws governed patents in South Africa. Patents on pharmaceutical products were permitted, but the law gave the government great flexibility in compulsory licensing opportunities (International Intellectual Property Institute, 2000). The South African attitude towards TRIPS has to be considered within the context of the state of the nation in the time around 1995. At this point in time, the early 1990's, South Africa was on its path towards trying to remove the remnants of its apartheid regime. Trade liberalization was perceived as something positive to the future development of the nation, and a welcome end to the years of trade isolation as a consequence of some nations choosing to use their trade power to boycott the apartheid regime. According to many commentators this meant a more positive attitude towards some of the changes proposed by the WTO at the time, since they were perceived as means to help in abolishing apartheid, but this also meant a less negative attitude towards TRIPS than in other developing countries, most notably India and Brazil as they represent two of the four chosen countries (Klug, 2012).

5.3.3 Prices

Historically generic manufacturers haven't had a large market in South Africa. This is mainly due to the structure of the pharmaceutical market and its division during the time of apartheid. Private markets represented the largest value for pharmaceutical companies, as can be seen in the fact that 80 percent of South Africa's total health expenditure was found in private markets in the early markets 1990's. This changed after the fall of apartheid once the government decided to increase the quality of public care and make it available to everyone at low cost, meaning struggles in affording medicines (Klug, 2012).

South Africa has also had its confrontations over medicine prices with pharmaceutical manufacturers and companies. One such debate was held as early after the implementation of TRIPS as in 1999 when South Africa tried to negotiate a compulsory license for the US government funded medicine AZT. AZT is an ARV-drug meant for HIV patients and was sorely needed by the South African population at a time when the AIDS infected increased at a great speed. The US government refused to negotiate price levels on AZT, which made it very difficult to afford for South Africa. A monthly supply of AZT would in 1999 have cost each patient \$240 per month, in contrast to the generic Indian produced version which cost \$48 dollars per month. At the time given the amount of patients in need of the medicine and the intention of the South African government to distribute the medicine free of charge a cost

of \$240 per monthly treatment for each patient was simply too great for the South African budget. In reaction to this South Africa protested against the unwillingness of the US government to reduce the price of AZT, which led to a heated debate over R&D expenditure for medicines, and the need for companies to recoup sunk costs (Bond, 1999).

5.3.4 Availability

As a result to its inability to afford providing ill with medicines South Africa tried to pass an amendment to its patent law which soon became contested. The 1997 Amendment Act authorized the South African Minister of Health to issue compulsory licenses for parallel imports of generic medicines from third party countries. As mentioned above this led to much heated debate among other countries and in the pharmaceutical industry, arguing that the amendment failed to comply with the South African constitution and TRIPS and threats of various repercussions, but the legal battle was eventually won by South Africa (Kongolo, 2001). However, in spite of this the damage can in many ways be seen as having been done to the health of many South Africans. During the two years of the battle over South Africa's desire to file for compulsory licenses its program for ARV distribution hung in the air. In this time patients already infected with HIV could have been provided with medication and further attempts to curb the spread of the disease could have been made. This being said the denial of top government officials that HIV causes AIDS is popularly attributed as the largest reason why South Africa's share of population suffering from AIDS is presently among the largest in the world (Bird, 2009).

It has been argued that the weak infrastructure and poor education of South Africa would have made it difficult to distribute medicines even if patent laws had made cheaper generic medicines readily available. Thereby it is a bit simplistic to blame pharmaceutical companies and patents for the AIDS crisis in South Africa and other developing countries (Barnes, 2003). Other official reports such as the International Intellectual Property Institute support Barnes in arguing that poor infrastructure (which complicates storing medicines, administering medicines and testing of patients) is a large problem in both South Africa and other Sub-Saharan African countries, which means that any problems in availability of medicines can hardly be completely assigned to TRIPS. This being said, there is also a broad agreement that patents have had an influence on availability (International Intellectual Property Institute, 2000).

5.4 Brazil

5.4.1 The health system and general health in Brazil

Brazil spent 9.31 percent of its GDP on health care in 2012. This corresponds to \$1056.5 per capita (World Health Organization, 2014c). In 2012 158 out of every 100 000 in Brazil were infected with malaria. This is slightly above the regional average (WHO's Americas region) of 139, but below the global average. Most of the malaria cases in Brazil were reported from the regions of the Amazonas, making it a regional problem. Prevalence of tuberculosis (59 out of every 100 000) is also slightly above the regional average of 40 per 100 000 (World Health Organization, 2014g). An estimated 730 000 people with AIDS live in Brazil, out of which only about 190 100 are being treated with ARV-drugs. A national STI (Sexually transmitted

infection)-program for AIDS was established in 1996. This program guaranteed free treatment to HIV/AIDS-patients funded by the government through the Brazilian Ministry of Health, and has been reported to have decreased the mortality of AIDS patients by about half (Emilio, 2011).

Brazil has been brought forward as a model example among countries that deal with AIDS and in their dealing of other diseases that are preventable through vaccination. However, in other areas, such as in dealing with the problems of Dengue fever, Brazil has had very little success in its control efforts. Nevertheless, the improvements made in public health can be seen through a 20 percent decline in deaths from non-communicable diseases between 1996 and 2007. The decline stems mainly from a decrease in number of deaths from chronic respiratory diseases (such as asthma) accompanied by decreased smoking rates, and reduced cardiovascular diseases. Other non-communicable diseases such as neuropsychiatric diseases, diabetes and obesity have increased, that are often more ascribed to increased welfare and developed countries. It is important to note that Brazil, as one of the countries with the largest income inequalities of the world, also suffers from social, ethnic and geographical differences in disease afflictions. The regions of the southeast and south are wealthier than the regions north and northeast (Victora, et. al., 2011).

Brazil has a history as a military dictatorship from 1964 to 1985, and upon the return to democracy there was a strong social movement promoting a reformed health sector. This led to a Unified Health System (SUS) being introduced into the new 1988 constitution. A comprehensive universal health insurance was introduced and funded by taxes and social contributions (like social security payments). This system has been in place and providing the Brazilian population with free health care on primary, secondary and tertiary levels since 1989 (Victora, et. al., 2011).

5.4.2 Brazilian patent law prior to TRIPS

Brazil has a long patent history and introduced its first patent law in 1890, earlier than many other developing countries of the world. However, this law did not involve pharmaceutical patents. This meant that Brazil, like India, was given a transition period until 2005 before it had to implement the TRIPS-agreement (Flanagan and Whiteman, 2006). Unlike India, Brazil made the highly criticized decision not to exercise this right after considerable trade pressures, including a proposed 100 percent tariff on all Brazilian exports from the US. Therefore Brazil introduced a new patent law in 1996 that was in accordance with TRIPS, despite its heavy protesting against TRIPS. This can be seen in stand taken by the Brazilian government that public health should not have to be “subordinate to abuses of economic power” at a conference arranged by the WHO and UN on AIDS in June 2000. Brazil did however exercise its right to include a robust compulsory licensing plan, meaning for instance that in case a patent holder fails to use the patent for manufacturing or exploitation within three years’ time of the patent’s issuing the government has the possibility to issue a nonexclusive compulsory license (Viana, 2002, p.311).

5.4.3 Prices

Brazil lost almost all its production capacity of Active Pharmaceutical Ingredients as a consequence of the compliance with TRIPS, meaning a great increase in imports and price of pharmaceutical products. As an integral part of Brazil's applauded universal public access policy to support all citizens with ARV-medicines Brazil relied on its system of public manufacturing facilities to provide affordable ARV-drugs. As a consequence of TRIPS and increased resistance in patients against treatment with first-line ARV-drugs a need for new second-line ARV-drugs arose. However, second-line and other important ARV-drugs were patented by MNCs and couldn't be produced in Brazil without infringing on those patents. This meant a new cost of medicines which by far surpassed the original cost of domestic production, or imports, of generic ARV-drugs, and subsequently meant a strain on the public health expenditure budget. This led the Brazilian government to make use of its possibility to threaten pharmaceutical companies with the issuing of compulsory licenses (Abbott and Reichman, 2007).

In 2007 Brazil issued compulsory licenses for ARV- medicines, such as for the patented products Kaletra ("Lopinavir") held by Abbott and Merck's Efavirenz to be produced by a Brazilian manufacturer. Efavirenz is an ARV-treatment used in treating 75 000 of Brazil's 200 000 patients. Merck had made an offer to willingly lower its price of Efavirenz from \$580 to \$400 dollars per patient; however this was still significantly more expensive than importing a generic version from India at a cost of \$165 dollars per patient and year. Further the companies holding the patents in question were asked to transfer their technology to domestic Brazilian producers so as to enable domestic production, but all refused. After threats from the Brazilian minister of health of breaking patents the pharmaceutical companies eventually caved. This meant for instance that Abbott agreed to lower the price of Kaletra by 46 percent and provide it free of charge to parts of the AIDS-infected in Brazil (163 000 out of 600 000 carriers of the virus). The compromise meant that the price of Kaletra sunk from \$1.17 to 63 cents per pill and Abbott got to keep its patent for Kaletra. This made the Brazilian policy to supply HIV medicines free of charge to those in need more affordable for the government. It was also estimated that the issuing of a compulsory license on Efavirenz saved the Brazilian government an approximate \$30 million per year. However, worries were voiced that the negotiation tactics may be damaging for Brazil's reputation among pharmaceutical companies and led to a decreased will to launch products in the future (Emilio, 2011).

5.4.4 Availability

The same econometric analysis described in the section in India using product sales data from market research firms such as IMS Health Inc. to investigate the availability of new medicines in countries around the world was conducted for Brazil. The study found that new medicines were less likely to be found in developing countries with historically weak IPR, such as Brazil and India, than in developed countries with more secure IPR, such as Germany, even after the implementation of TRIPS. By using Spain as a base country the group of investigated essential medicines was only 23 percent as likely to be patented and sold in Brazil as in Spain, despite its TRIPS compliance. In contrast the average medicine was 60 percent more likely to be available in Germany, which indicates that Spain is not the country with highest

availability either. In Brazil it was a significantly more likely that the average patented medicine would have zero sellers, fewer than two-thirds of the essential drugs included in the sample were sold in Brazil, which means a great loss in available cutting-edge medical products offered to consumers in Brazil, implying that there might be a welfare loss (Berndt, et. al., 2011).

5.4.5 Competition

The Brazilian pharmaceutical industry predominately caters for the domestic market, in contrast to the Indian pharmaceutical industry which has a large share of exports and a positive trade balance in pharmaceutical products. No Brazilian firms have taken steps to conducting R&D and increasing their own innovation, but have rather stayed focused on the generic segment. Brazilian pharmaceutical markets hold 80 percent of the domestic market share of generic medicines. In the post-TRIPS period this has resulted in a large trade deficit in medicines of nearly three billion dollars (Schüren, 2013).

6. Findings

6.1 Medicine prices

After the implementation of TRIPS there is clear evidence of growing financial pressure from high medicine prices on the health budget of governments in developing countries. This is not in the least illustrated in the issuing of compulsory licenses in Thailand and the threat of issuing compulsory licenses in Brazil (Abbott and Reichman, 2007). Although compulsory licenses have been proposed as a possible solution to the problem of high medicine prices in times of acute need, compulsory licenses haven't lived up to those expectations in practice, as was illustrated in the Thai issuing of compulsory licenses for ARV-medicines. The right to do so is clearly stated in the TRIPS agreement, but nevertheless it held negative consequences for Thailand as seen in the withholding of new medicines by the affected pharmaceutical company. (Jain, 2013) When discussing ARV-medicines it is also important to take note that different diseases carry different costs. While malaria and tuberculosis are curable, HIV is not. Tuberculosis requires frequent medical attention for about 6-9 months (longer if the tuberculosis is drug resistant), but eventually the patient is expected to recover. Treatment of HIV/AIDS patients is lifelong, and also means frequent medical attention and expensive (often patented) medicines, which makes it a completely different challenge in terms of affordability for both patients and governments. In attempts to increase affordability this might mean more directed efforts depending on the disease (Cleary, et. al., 2013).

From the studied cases of India, Thailand, South Africa and Brazil it has been found that TRIPS has affected prices, not in the least in the sense of prolonging (or introducing in the case of Thailand and India) patent term, and thereby delaying the time at which generic production can begin. Although pharmaceutical companies boast of their policies towards helping developing countries in fighting disease burdens through lowering their medicine prices, proof of this has been sparse. Instead the response to price negotiations has been cool, as seen in the cases of Brazil and Thailand, and the response to compulsory licenses has been lacking in understanding and approval. (Collins-Chase, 2008) If MNCs were to charge affordable prices for their patented medicines in developing countries, then access to essential medicines need not be negatively affected, however this has not been observed in the case studies. Although other factors may influence the price of medicines, such as high import tariffs, the impact of prolonged patent terms is hard to neglect. Thereby it can be said based on the case studies that TRIPS has increased the price levels of medicines in India, Thailand, South Africa and Brazil, in spite of active efforts from the studied countries to minimize the damage done to their health budgets by negotiation, issuing compulsory licenses and carefully phrased laws. (Klug, 2012)

6.2 Availability of medicines

Although it was shown above that prices of medicines have increased, this need not mean that the overall availability of medicines has decreased. In theory the stricter patent laws can be attributed to have led to more patent applications of new medicines, which can perhaps compensate for the increased price levels. However this has been disproved in a study conducted by Berndt on medicine availability in countries with a history of weak patent laws

on pharmaceutical products. An econometric analysis using product sales data from market research firms such as IMS Health Inc. to investigate the availability of new medicines in countries around the world found that new medicines were less likely to be found in developing countries with historically weak IPR, such as Brazil and India, than in developed countries with more secure IPR, such as Germany, even after the implementation of TRIPS. This was exemplified in the two case studies by numbers illustrating the difference in availability using Spain as a base country. This would indicate that old habits die hard, and that the introduction of TRIPS might not have brought the effect of having increased the will of pharmaceutical companies to patent drugs in developing countries yet. (Berndt, et. al., 2011)

Since the two factors influencing the anticipated profits on a new drug: market size and patent protection, the small loopholes created by the Indian government after implementing TRIPS may partially be working against it. Although the Indian market is large, thereby increasing the probability of a drug being launched, its patent protection is still weaker than many other countries with TRIPS. Therefore pharmaceutical companies may still hesitate in deciding to file for patents and launching their new drugs in India. Patent protection is primarily relevant to the first entrant to a market, the innovator (or licensee) since it shelters from competition thereby increasing their incentive to introduce the new product on the market. When the fixed costs of entry (product testing) are smaller than the profits anticipated, then new firms will enter the market (Berndt, et. al., 2011).

There are also other factors than increased price that can be found contributing to poor medicine availability. This was shown in the case of South Africa, where Barnes (2003) has pointed to the poor infrastructure and its negative impact of medicine availability. Poor education of human capital, few doctors in rural areas, low ability to properly store and distribute medicines are all factors which contribute to the poor availability of medicines in South Africa. This does not mean that the high prices of patented medicines are unimportant, but it does mean that an over focus on medicine prices as a determinant of availability might be dangerous, since low prices alone aren't sufficient in solving for problems of availability. Therefore the findings on availability of medicines after TRIPS are somewhat mixed, but for the cases of India, Thailand and Brazil there are clear indicators that the availability of medicines has decreased. Both econometric studies indicate that old lax patent laws still have an impact as shown in studies of India and Brazil, and from the retaliation of pharmaceutical companies after the issuing of compulsory licenses as was shown in the case of Thailand. Thereby the overall effect on availability of medicines after TRIPS can be seen as largely negative, but perhaps not the sole determinant of availability as illustrated in South Africa. Economists such as Barnes have pointed to the poor infrastructure in many developing countries, such as South Africa, that complicate the distribution of medicines in rural areas. This is a relevant remark for many developing countries and a matter which should be addressed, but for some reasons patents, IPR and monopolies are that which has attracted the most attention of NGOs and other critics (Barnes, 2003).

6.3 Public health

The generic production of ARV-drugs in Brazil under its policy to distribute ARV-drugs free of charge to all its citizens infected with AIDS was initiated in 1997. The result of this policy was enough to break the development of the disease as theorized by health experts. Instead of 1.2 million being infected by 1999 as was estimated in 1979, the development had by then been halted and returned to the level of infected on 1995. However, the policy has been costly to the Brazilian government, and might have been difficult to accomplish had Brazil not had the capacity to initiate large scale production of generic medicines itself. (International Intellectual Property Institute, 2000) This, and other similar policies introduced in the other studied countries, was complicated by the introduction of TRIPS due to the limitations it set on generic manufacturing among other things. Brazil struggled in being able to afford the second-line ARV-drugs it needed, and faced great opposition when trying to use its prerogative to issue compulsory licenses. (Emilio, 2011) Brazil eventually managed to negotiate price reductions, but in the cases of Thailand and South Africa solutions didn't come as easily. Thailand eventually had to issue a compulsory license, and South Africa faced a prolonged law suit during which time many HIV patients had time to die. (Kongolo, 2001) Thereby it can be said that though TRIPS includes some flexibilities to protect public health, these flexibilities appear difficult to implement in practice. Thereby the externalities that arise from the monopoly rights defined in TRIPS cannot be seen as minimized according to the Coase theorem. Perhaps this might be due to unequal bargaining power among developed and developing countries, but in either way it appears that the created externalities are large. Thereby the overall effect of TRIPS on public health appears negative, in opposition to some of the economic theory studied. (Harris, 1990)

7. Conclusion

Based on evidence found in theories, models and the studied case studies it has become clear that the issue of medical patents has raised a lot of emotions and given reason to much heated discussions and debates as to what the ramifications of such legislative action might be. The case studies give support for the warnings heeded by critics, since they indicate that prices have gone up and access to essential medicines has decreased. This is supported by instances such as the choice of pharmaceutical companies not to register new medicines in Thailand as a punishment for its enforcement of compulsory licences in the past. This would indicate that the words of warning regarding stricter regulations for medical patents should be taken seriously, since there is a possibility that the consequences of such acting may indeed be severe. However, it should also be kept in mind that the TRIPS-agreement is a fairly young agreement and that its long term effects have yet to be revealed.

Many of the economists cited, such as Stiglitz (2008), have stated that there is a fine line between too much and too little intellectual property protection, and that the same degree of protection might not be optimal to all countries. Since tens of millions of people die yearly from diseases that are treatable by existing cures, out of inability to afford them, this line appears not to have been found. (Bird, 2009) One possible solution to the problem of expensive medicines as proposed by Khor is that TRIPS could be amended to exempt essential medicines listed from patentability. (Khor, 2002) As TRIPS is still a relatively new agreement it is yet to see how its effects unfold and what they might be in a long term perspective.

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