Pharmaceutical Patents, Hindering the Healing Process

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**Introduction**

Rights in the context of ownership are a seemingly simple idea recognized around the world as a system that works. However, this system can only benefit the producer rather than benefiting both the producer and the receiver. This stagnant receiving of benefits is especially true in the sector of intellectual property rights when the receiver is a developing country. Developing countries face obstacles when trying to reach stability in both fiscal expansion and the well being of their societies. One of these obstacles is the strict patent and copyright law, which harms the poorest countries as these laws impose higher prices on medicines, and other commodities making them harder to obtain. Thus, this obstacle makes development more difficult as the countries do not have the money to pay for the medicines, which results in constituents not having access to vital medicines and therapies. Intellectual property rights on pharmaceutical drugs make it harder for developing countries to gain access to affordable medicines. Development becomes harder to achieve if a country cannot acquire the basic medical care for its population, as rampant disease can cause crippling effects on a society. The intellectual property rights that drive up prices on pharmaceutical drugs are protected in international trade as several organizations were created to ensure the rights are constantly upheld through laws, and standards of practices. In order to fight the adverse effects of intellectual property rights, like higher prices on essential goods, the International Commission on Intellectual Property Rights was formed in 2001 with the purpose of making developed countries and organizations, like the World Trade Organization and the World Intellectual Property Organization, think about the developing countries plight of reaching development when issuing new international intellectual property laws. As intellectual property rights of pharmaceutical drugs continue to impose an obstacle to development, solutions are needed to ensure fair access to much needed medicines that benefit both the developing and developed countries.

**Key Concepts and Key Players**

Intellectual property rights are a crucial way to protect one’s work and initiatives, as the formation and implementation of this legal issue is a complex process. To be able to define the term intellectual property rights each individual word needs to be broken down and assessed to achieve the goal of conveying how intellectual property rights work. The idea of property is an important factor in the term as it sets the requirement of what constitutes the protected or not. The word property means, in relation to this term, “the item owned considered in relation to the bundle of rights, liberties, powers, liabilities, and regulations that surround the item and constitute ownership” (Wreen, 2010, pg. 433). While property defines what is being protected, the idea of rights in the term is considered to be the most important as “the essence of ownership is a bundle of rights, assigned to the owner, and regarding use of and access to the item itself” (Wreen, 2010, pg.434). Rights enable the holder to sell, change, destroy, manage, protect from unwanted use or exploitation, or prevent unsolicited alterations to the property in question. The rights indicate ownership of the property. As intellect is not something that can be defined as a physical entity, intellectual property is “ownership without anything owned” (Wreen, 2010, pg. 440). With the ideas of property and rights defined, the entire term needs to be classified.

                   Law identifies intellectual property rights as patents, copyrights, trademarks, and trade secrets. The role of intellectual property rights, especially regarding the practices of patents and copyrights, is to protect current innovations while simultaneously stimulating new innovations. A copyright protects literary, artistic, and musical works. Trademarks include any word, name symbol, or device, or any combination, used or intended to be used in commerce to identify and distinguish the goods of one manufacturer from others and indicate the source of the goods. Information that has value because it is not generally known and is the subject of efforts to keep it secret is a trade secret. This type of intellectual property rights has a protection that does not expire as long as the owner makes reasonable efforts to keep the information secret. In regarding the main focus of the paper, pharmaceutical drugs’ patents, the intellectual property rights that will be looked at in further detailed are patents. According to the World Intellectual Property Organization (WIPO) a patent is “an exclusive right granted for an invention, which a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem” (WIPO). To be able to secure a patent, a patent application needs to be filed that gives a detailed explanation of the item the creator wishes to be patented. Once the application has been filed, a national patent office or a regional office, like the European Patent Office, reviews the requests, and makes the decision to grant or not grant the patent. To obtain an international patent by using one application, WIPO created the Patent Cooperation Treaty (PCT), which will allow the individual states to review the patent request, and individually grant the patent in the states (WIPO).

In order to protect intellectual property rights in international trade, trade laws are created and enforced. Governing international organizations have been created to legislate and ensure these trade laws are protected throughout the world. In 1995, the World Trade Organization (WTO) replaced the General Agreement on Tariffs and Trade (GATT) to deal with the regulation of trade between countries, create trade agreements, and resolve any trade disputes between member countries. Currently there are 153 countries in the WTO, accounting for over ninety-five percent of the world’s trade, and is made up of a governing conference, a general council, and a director-general. A protecting agency of intellectual property rights in international trade is an agreement called the Trade-Related aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was created in 1994 by the General Agreement on Tariffs and Trade to fight “piracy and counterfeit and technological protectionism realigning labour divisions of Northern innovations and their market in the South” (Manion, 2005, pg. 79). The Agreement serves as a set of standards that regulate intellectual property rights as they are applied in trade agreements between member countries of the WTO. In 2001, a new trade agreement was developed to lower trade barriers around the world to try to stimulate global trade. This new trade agreement is called the Doha Development Round or the Doha Development Agenda, and was issued by the WTO. While the underlying mission of the Doha Development Round is to promote fair trade between developed and developing countries, in 2008 criticism began to circulate as allegations were made that this agreement enforced trade rules that hindered chances of development. Though the Doha Development Round has been criticized for not protecting, in a sense, the developing countries this agreement is currently in affect and helps set the standards of global trade.

The World Intellectual Property Organization (WIPO) was created in 1967 as an agency of the United Nations. The goal of WIPO is to protect intellectual property rights around the world through the use of nine strategic goals that help keep the agency current, and the gives the agency the ability to respond to issues and problems that surround the “evolving external environment” (WIPO).There are currently one hundred and eighty-four states that are members of WIPO, in which each member state receives one vote to reach a consensus in each decision. With each organization, trade agreement, and agency the global trade system is highly monitored with many different rules and regulations to abide by, which each participating member state in agreement.

Since these organizations and agreements have been developed criticism has surrounding them as their policies can be described as unfair towards developing countries. One of the agreements that have received quite a bit of criticism is the TRIPS Agreement in the critique that is not beneficial to developing countries trying to gain access to affordable medicines. The TRIPS Agreement provides a compulsory licensing provision which sets the prices of medications through trying to standardize intellectual property laws around the world. In a proposed method to eliminate this compulsory licensing a tiered-pricing scheme would help lower prices of medicines universally, and more specifically the price of HIV/AIDS drugs. A tiered-pricing scheme on pharmaceutical drugs would allow countries with lower resources to buy drugs at a much lower price than other countries. A working example of a tiered-pricing scheme is the system adopted by the European Community to help lower pharmaceutical prices. While a tiered-pricing system will help lower the prices of vital medicines, like HIV/AIDS drugs, it will not ultimately fix the problem, but will be a step in the right direction (Watson, 2009, pg. 143-159).

**Intellectual Property Rights In Developing Countries**

While intellectual property rights have traditionally helped businesses grow as they receive income from the profits of the rights they own, generally the benefits generated from them are not seen in developing countries. Traditionally the idea of forcing developing countries to strengthen their national intellectual property rights was created by developed countries to gain additional profits to help spur economic growth in those developing countries. However, this notion is criticized as the socio-economic benefits of strengthening intellectual property rights in developing countries have not been significantly documented. According to Emmanuel Hassan and his colleagues, intellectual property rights affect the growth in developing countries in five different aspects: foreign direct investment, trade, innovation, public health, and genetic resources and traditional knowledge. Foreign direct investment is an important factor in economic growth for a country as it allows for “access to foreign markets and benefit from reverse technology transfer” (Hassan et al, 2010, pg.3). The relationship between intellectual property rights and foreign direct investment in developing countries has been a growing field for scholarly literature over the past two decades.  Strong intellectual property rights can reduce foreign direct investment in developing countries as they can “increase the market power of multinationals in developing countries, giving them incentives to increase the price of their products and to decrease their investment and sales abroad” (Hassan et al, 2010, pg. 9). This increase in price of the product can also lead to an incentive to for foreign firms to “decrease their exports to developing countries” as a direct result of strengthening intellectual property rights” (Hassan et al, 2010, pg. 15). The United Nations Conference on Trade and Development in 2004 stated that international trade is extremely important in economic growth in developing countries as it can be used as way to combat poverty. However, the rate of importing needed goods is exponential higher than the rate of exporting for developing countries, which causes a financial problem as the countries do not have the money to pay for needed imported goods. Many economists argue that the rules governing the recent multilateral and bilateral agreements in international trade are unfair to developing countries as “the majority of gains from trade are accrued to developed countries” (Hassan et al, 2010, pg. 10).

Innovation follows the same path as direct foreign investment and trade in the notion that strengthening intellectual property rights will hinder innovation in developing countries. Strong intellectual property rights can increase costs of needed technology to compete with foreign innovations, and “can encourage the dissemination of free technical information in the economy” (Hassan et al, 2010, pg. 22). The relationship between public health and intellectual property rights deals directly with the patents that are held on pharmaceutical drugs. Developing countries have to rely on exports of pharmaceutical drugs from countries, usually developed countries, where there are strong intellectual property rights. Strong intellectual property thwarts generic competition, which usual provides a lower price on the needed pharmaceuticals, as generic pharmaceutical drug companies do have the resources to produce the same quality of drug as the major pharmaceutical companies. Strong intellectual property rights also decreases compulsory licensing, as generic competition must be introduced for this price control practice to happen, as it is generic companies that hold the compulsory licenses.

By having ways to decreasing pharmaceutical prices deferred by stronger intellectual property rights, the public health of developing countries decreases as the countries cannot afford to purchase the much needed medicines for their populations. The affects of stronger intellectual property rights with genetic resources and traditional knowledge of developing countries will hinder the access to and use of these resources in developing countries. With these five aspects in mind, easing intellectual property rights, especially patent law with respect to public health, around the world would help aid poor nations while they are trying to develop.

Strict patent and copyrights laws are harming poor countries, as the laws can impose higher prices on medicines and other commodities, making them harder to obtain, and thus making development more difficult. The International Commission on Intellectual Property Rights wants developed nations, the World Trade Organization, and the World Intellectual Property Organization to think about developing nations and their plight to become developed nations into account when issuing new international intellectual property laws. The International Commission on Intellectual Property Rights was created in 2001 by the British government to research how intellectual property rights can be used to help developing nations rather than exploiting the nations for money. In order to conduct its research, the Commission consulted with over six hundred companies, groups, organizations, government agencies, and universities in Brazil, Belgium, China, Germany, India, Kenya, Switzerland, the United Kingdom, and the United States. The Commission also takes into consideration that developing countries may not know how to create intellectual property laws that will in turn help them support development as well as keep to international standards of the laws, and thus has created suggestions as to how these countries can better their understandings of international intellectual property laws. These suggestions include specific tax breaks, and lowering pharmaceutical drug prices. In 2006, the TRIPS Agreement stated that all member countries must provide standards of protection on all intellectual property and all member countries must follow these standards. The Commission’s research into intellectual property rights has spurred other Commissions to convene over the relationship between intellectual property and developing countries (Weise, 2002 pg.7).

In response to the British’s government’s International Commission on Intellectual Property Rights in 2001, the World Health Organization (WHO) produced its own report in Geneva in 2006 called the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). This report reviews the roles of existing research and development efforts, the role of intellectual property in stimulating innovation, and to encourage research and developing for new medicines for diseases that mainly affect developing countries. The report focused mainly on intellectual property in regards to pharmaceuticals. According to the report intellectual property is “irrelevant in stimulating innovation in developing countries where markets have limited purchasing power” (Hoen, 2006, pg. 421). This report concluded that if developing countries agree to bilateral trade agreements such as TRIPS Agreement, then it could hamper or delay access to generic medicines. The report analyzed medical innovation in three components: discovery, development, and delivery. To rectify the problems the report found with intellectual property in developing countries the Commission recommended the “WHO develop a global plan of action to secure enhanced and sustainable funding for developing affordable and accessible products that address diseases that disproportionately affect developing countries” (Hoen, 2006, pg. 422). In order to complete this global plan of action the Commission suggested that the WHO should continue to watch the impact of intellectual property on new products in relation to accessibility to medicines. The Commission also recommended that health technologies should be adapted to suit the needs of the people in developing countries. To help prevent future diseases in developing countries the report stated that innovation and access to medicines are the ways to solve this problem (Hoen, 2006, pg.421-423).

While the Commission reported these findings in 2006 plausible solutions have yet to be reached as the Commission appealed its reports to pharmaceutical companies. The Commission wanted pharmaceutical companies to be responsible for not filing patent applications in developing countries so the availability of generic versions could flourish in those areas to diminish the high prices of medicines. The Commission also wanted pharmaceutical companies to grant voluntary licenses of medicines that already have patents in order for the generic option to be available in developing countries. While the solutions the Commission have set out for pharmaceutical companies, these attempts are in vain as these same companies are the ones who have been lobbying for the TRIPS Agreement for three decades. This futile attempt was officially knocked down when the International Federation of Pharmaceutical Manufactures’ Association published a statement saying the industry is “rejecting any calls for weakening of the intellectual property systems” (Hoens, 2006 pg. 422). Though the pharmaceutical industry did not adhere to the possible solutions the message of the CIPIH was released before the World Health Assembly, and thus set up a possible reason of debate about intellectual property and access to medicines in developing countries. The Commission’s research into intellectual property rights injunction with benefiting developing countries portrays a relationship between intellectual property rights and human rights (Hoens, 2006, pg. 421-423).

**Intellectual Property Rights and Human Rights**

The relationship between intellectual property rights and human rights is a murky one as scholars have debated both sides of argument; some claiming that these rights do in fact harm human rights and others stating that intellectual property rights are human rights. To begin discussing this argument the controversial idea that intellectual property rights are human rights needs to be explored. Those who argue for this side of the debate are manly businessmen who believe that these rights fight piracy, as those who tend to steal others’ hard work and recognition take away the human rights of the creators. By stating that intellectual property rights are human rights the argument makes the claim that it “mobilize[s] power resources in favor of a new uniform international property regime that could coerce developing countries into compliance” (Heins, 2008, pg. 218). As this side of the debate tackles the business side of intellectual property rights, the argument that the rights take away from human rights deals more with the social and health ramifications. To better understand this plea, the example of AIDS epidemic serves to illustrate how a specific intellectual property right, patents on medicines, can harm many people and thus take away their human right of health and wellness. The awareness of the increase of HIV/AIDS medicines due to intellectual property rights began in the mid-1990s, when consumer activists and aid agencies concluded that “the granting of product patents for pharmaceuticals, the ban of parallel imports of cheaper generic substitutes for patented AIDS drugs, and the avoidable death of people living with the virus” (Heins, 2008, pg. 225). The stance that intellectual property rights harms human rights is clear, and the Campaign for Access to Essential Medicines was created. The example of not being able to provide essential HIV/AIDS medication to a sick population portrays how intellectual property rights harm human rights. Scholars and businessmen remark that intellectual property rights are human rights in the notion that they protect one’s endeavors, but the fact that intellectual property rights, such as patents on pharmaceuticals, can take a person’s human right of health and ultimately right of life away makes a fiscal reward seem insignificant.

**Findings and Possible Solutions**

While the ethics between intellectual property rights and human rights seem easy to distinguish, pharmaceutical companies are more interested in the question of ownership and the role of patents in pharmaceutical drugs, especially in the field of research and development. In the field of research and development in pharmaceutical drugs there are both private and public sectors, in which the public sector is involved in more of the discovery of new drugs and then license their discoveries to the private sector to manufacture and sell the drugs. With public and private sectors investing a lot of capital into this field of research and development, acquiring and enforcing patents are extremely important. Currently patents are mainly used to protect pharmaceutical-related inventions. By applying patents to pharmaceutical-related inventions it “deprives society of the benefits that the widespread use and dissemination of basic scientific ideas could generate” (Correa, 2004, pg.785). This use of patents lead to innovations in the pharmaceutical business revolving around the process of making improvements to existing drugs, and the realization of using those existing drugs in different ways. Thus, these innovations are used to secure market exclusivity when the original patents expire, and new patents are needed. For example, from 1989 to 2000 the United States’ Food and Drug Administration (FDA) awarded one thousand thirty-five new pharmaceutical drug applications, of which a third of these applications involved products that are already available with improvements with new active ingredients. The other sixty-five percent of those applications presented products that contained existing active ingredients that are already found in products that were currently available at the time. By applying new patents to existing products that have been slightly modified, the private sector of research and development are hindering the chances for new innovations that could help fight diseases and viruses (Correa, 2004, pg.784-787).

As well as using new patents to continue market exclusively, large firms are using patents to defer new competitors. This offensive approach to the use of patents to defer new competitors can be broken down into four strategies: blanketing, fencing, surrounding, and flooding. Blanketing is a strategy that large firms use that “mimes every step in a manufacturing process with patents claiming minor modifications” (Correa, 2004, pg. 785). The offensive strategy called fencing involves acquiring patents to block any innovation in the field of research and development. The third strategy, surrounding, is used to create less important patents that surround the central or important patent of a product to protect the important patent after it expires. The final offensive strategy used by large firms to retain their patents and control over a particular section of the pharmaceutical business, is flooding. Flooding is used to acquire “many patents on minor or incremental variations on technology developed by another company” (Correa, 2004, pg 785). These offensive strategies are forms of anti-competitive practices to create dominance over the international pharmaceutical drug business, thus blocking generic companies from entering the market.

Patents are important in the research and development sector of pharmaceutical drugs as they can be used to promote new innovations, however they can also be used to diffuse competition. Pharmaceutical patents restrict competition, and the marking of generic competition, and thus developing countries need to design and implement their own patents laws to create competition which in turns leads to better access to vital medicines. Developing countries need to look into how these patents are granted and the exact laws surrounding these patents, in order to avoid being accused of abusing existing patents. The patent system currently focuses on creating patents for the developing process of pharmaceuticals which hinders the creation of competing medicines more than the patents held on new medicines (Correa, 2004, pg. 784-787).

As new technologies further the integration of the world’s economy globalization becomes involved in almost every aspect of international trade. With globalization, countries like China and India have gained recent economic windfalls, which forces developed countries like the United States and the United Kingdom and organizations like the World Trade Organization and the World Intellectual Property Organization to tighten their trade and intellectual property rights regulations. The economies of India and China are dependent on developed countries as they provide much needed trade business. However, the trade that occurs between India, China, and the West does not always conform to the trade and intellectual property rights regulations set down by the World Trade Organization and the World Intellectual Property Organization, as India and China are not currently bound by these laws. Thus, India and China do not have to abide by laws when they produce the traded goods; however the countries have to follow the laws when importing goods from other countries that do follow these regulations. With this inconsistency, intellectual property rights can be used against a developing nation to benefit a developed nation in the terms that a developed nation does not have to pay high prices for goods, but imposes high prices on goods the nations are exporting to developing nations (Wutherlin, 2009, pg. 399-413).

As intellectual property rights affect trade in developing countries like India and China, patents and economic policies are affecting access to essential medicines in developing countries. According to study done by Amir Attaran in 2004, there are three steps to understanding how patents affect the ability of acquiring medicines in developing countries. These three steps are to compile a list of medicines that are considered by the medical world as essential, identify those medicines that had a patent in 2003, and to talk to pharmaceutical and patent companies to see how these essential medicines were patented in developing countries. The essential medicines were described as vital pertained from the World Health Organization, and of that list three hundred nineteen were eligible for this study. Attaran’s study looked at sixty-five countries which comprised all of Africa, Brazil, China, India, Russia, Indonesia, and Mexico, which makes up about two-thirds of the world’s population. The results of Attaran’s study were that only a few essential medicines had patents in developing countries, which in turn results in pharmaceutical companies not manufacturing those medicines in those particular countries as they do not want to lose their patents. Another factor Attaran noticed in his study was that pharmaceutical companies are not seeking out patents in the smallest and poorest of countries as the revenue received on these patents would not be economically worthwhile. The final result of this study was the realization that even though only a few essential medicines are patented in developing countries, the vital ingredient in most of these medicines does have patents, and thus effectively block the generic, cheaper versions of medicines from obtaining patents. As a solution, Attaran suggests that having flexible patent laws in developing countries to be able to provide essential medicines. This study illustrates an explanation as to why pharmaceutical companies are not producing medicines in developing countries which could help alleviate the high prices on importing medicines (Attaran, 2004, pg. 155-166).

To analyze how the patents of pharmaceutical drugs work in the pharmaceutical business, an examination of how intellectual property rights in China work was conducted in the first half of 2010. To examine the relationship between intellectual property rights and China’s pharmaceutical business, China’s intellectual property rights protection system needs to be analyzed. On August 23rd, 1982 China enacted its “Trademark Law” which has lead to the creation of the country’s “Patent Law,” “Copyright Law,” and “Anti-Unfair Competition Law” thus establishing its own protection system and laws for intellectual property rights. Since joining the World Trade Organization and agreeing to the TRIPS Agreement, China has revised its intellectual property rights laws to reflect its WTO membership. In addition to joining the WTO and agreeing to the TRIPS Agreement, China also signed bilateral intellectual property rights agreements with the United States, the European Union, Switzerland, and Japan to ensure pharmaceutical patent holders in those countries and regions the right to apply for a seven and half year administrative protection in China for their pharmaceuticals.

After seven and half years have passed, Chinese pharmaceutical companies can use the drugs information to form their own generic version that can only be used and sold in China. More than ninety-seven percent of the pharmaceuticals that Chinese pharmaceutical companies produce are generic drugs. As well as mainly producing generic versions of pharmaceuticals, China’s pharmaceutical businesses rarely put their profits into research and development as on average only one to two percent of revenues are going into this sector of the pharmaceutical business. Not only does the research and development sector of the pharmaceutical business in China lack significant resources, but also the technological aspects needed for pharmaceutical patents. Another factor that hinders Chinese pharmaceutical companies from acquiring their own patents on medicines is the fact that, under Chinese law, the ownership of the patent will go to the enterprise owner rather than the inventor which discourages inventors from wanting to create new pharmaceutical drugs. These intellectual property rights laws in China defer developed countries to sell and trade pharmaceuticals as their patents are not protected after a certain number years. Moreover, the unfavorable environment the Chinese government and pharmaceutical business has created for new patents on medicines has made new initiatives in the realm of pharmaceuticals squandering in comparison to the rest of the world (China Chemical Reporter, 2010, pg. 21-25).

Like China, other developing countries have signed bilateral trade agreements called free trade agreements. These bilateral trade agreements are negotiated outside of the WTO and the TRIPS Agreement, and require a higher level of intellectual property protection for pharmaceutical drugs. The higher level of protection of intellectual property has lead to the availability of essential medicines in developing countries to come into question as they delay access to the generic versions. The United States has negotiated eleven bilateral free trade agreements with twenty-three countries since 2001. Other developed countries in the European Union and members of European Free Trade Association have also partaken in bilateral free trade agreements with developing countries. While the agreements initiated by the United States are different from those initiated by the European Union or members of the European Free Trade Association, a “common feature of these agreements is that they include TRIPS-plus standards, i.e. they require the protection of intellectual property rights beyond what was internationally agreed upon in the TRIPS Agreement” (Correa, 2006, pg. 399). These higher standards set by bilateral free trade agreements reduce the availability of vital medicine to developing countries, without hindering the access of medicines in developed countries. The new requirements of the higher standards include an “extension of patent term beyond twenty years; prohibition of use of test date on drug efficacy and safety for certain periods for the approval of generic products; the linkage between drug registration and patent protection; in some cases, limitations to the grounds for granting compulsory licenses” (Correa, 2006, pg. 400). The free trade agreement also violates the DOHA Declaration which was created under the idea to allow better access to vital and essential medicines. Free trade agreements can also lead to compulsory licenses and parallel importation of pharmaceuticals, which is an illegal practice that makes the false promise of providing affordable access to medicines. Many developing countries have signed bilateral free trade agreements under the pretense of gaining commercial advantages. Bilateral free trade agreements restrict access to health care and vital medicines and delay access to generic competition. However, the long term effects of these agreements have not been recorded yet as these agreements are too young to fully analyze their full effects (Correa, 2006, pg399-404).

Intellectual property rights affect access to vital medicines to developing countries in more ways than imposing high prices, as they can also hinder research and development, and the development of health care infrastructure in developing countries. There are about two billion people in the world who do not have access to essential and critical medicines. Life-saving medicines are not being exported to developing countries because of the lack of research of the specific diseases in developing countries, poor health care and infrastructure can make some medical procedures almost impossible, and high tariffs and taxes in developing countries create barriers to providing the proper medicines to those two billion people. The proposed solution to these problems is to create research universities and public sector research institutions in developing countries, so that the research for the much needed medicines can be done, and affordable medicines can be created all within the developing countries. It is impossible to see the magnitude of the effect that pharmaceutical patents have in developing countries as each country requires different essential medicines provided by different pharmaceutical countries that hold different patents. By providing research institutions in developing countries dedicated to the assessment of what medicines are needed in which countries, and thus figuring out which medicines would be the most beneficial can help developing countries decide which pharmaceutical patent to invest in (Sampat, 2009, pg. 9-17).

To better understand the effect of intellectual property rights on both the economy and the development of research and health care infrastructure in developing countries the case study of Nigeria can be looked at to analyze the long term and short term effects. Malaria is the major cause of death among children under the age of five in Nigeria. This particular case study examines the pharmaceutical companies’ selling practices on malaria drugs, and the factors that contribute to those companies’ dispensing practices of anti-malarial drugs. In order to conduct the study thirteen patent medicines sellers were interviewed who disperse their medicines in the rural community of Ugwugo-Nike in Nigeria. The results of these interviews was that the medicine sellers did not gather the proper knowledge on the disease itself, and conducted poor dispensing practices in relation to the number of childhood malaria episodes in the community. At the end of the study it was concluded that more research and care-givers are needed in this particular community to ensure that the proper anti-malaria medicine and the right amount of medicine is dispersed in the area. One recommendation that came out of the study was to property train the medicine sellers in the area and keeps retraining them in order for the sellers to provide proper medicine, and the proper amount of medicine needed to complete a full therapy for malaria. The system also needs to be monitored by private services to ensure the quality of effective malaria treatment (Okeke, et al, 2006, pg. 597-607).

**Counterfeit Pharmaceuticals**

However, counterfeit pharmaceuticals need to be analyzed in the context of providing insufficient health care before the possible solutions for the restrictions placed on accessibility to essential medicines from intellectual property rights to developing countries can be discussed. Currently counterfeit medicines make up more than ten percent of the global market, and of that ten percent of counterfeit medicines that are available, twenty-five percent are consumed in developing countries. To be able to prevent counterfeit medicines from reaching the global market, the World Health Organization proposes that “through effective implementation and enforcement of legislation requiring that medicines be produced and controlled in compliance with manufacturing practices (GMP)” (WHO Drug Information, 2010, pg. 88). One way to ensure prevention of counterfeit medicines is pharmaceutical manufacturing inspections of facilities in which manufacturers are surveyed for their compliance with the World Health Organization’s GMP. In these inspections, the World Health looks for correct manufacturing processes of medicines, what ingredients are being used in the medicines, and whether or not those ingredients are legally obtained. These inspections initiated in June 2001 are mostly focused on pharmaceutical manufacturers producing HIV/AIDS medicines. Since 2001, the inspection program has grown to site inspections as well, which were conducted in China, Egypt, India, Morocco, and South Africa (WHO Drug Information, 2010, pg. 87-90).

Counterfeit pharmaceuticals can encompass a wide spectrum of the pharmaceutical business as counterfeiting can be described as medicines with the correct ingredients though the ingredients have been illegally copied, medicines without the correct ingredients, medicines that do not have active ingredients or insufficient active ingredients, or do not have the correct packaging. It is estimated that by the end of 2010, counterfeit pharmaceuticals will have generated seventy-five billion dollars in the global market. According to the World Health Organization (WHO), developing countries are more susceptible to the threat of counterfeit pharmaceuticals due to “weaker medicines regulatory systems, scarcity and/or erratic supply of basic medicines, unregulated markets and unaffordable prices” (WHO Drug Information, 2008, pg. 277). Out of all of the medicines that have been consumed in developing countries, it is estimated that twenty-five percent have been identified as counterfeited, and in some underdeveloped countries this percentage can be as high as fifty percent. The counterfeit pharmaceutical market can be attributed to the social and political conditions in certain countries. These conditions can be described as “inadequate legislation, trading through several intermediaries/brokers, wholesalers and the distribution chain, no or limited patient access to reliable health care and medicines supply, the high price of legal medicines, and illiteracy and poverty and lack of information or lack of access to information” (WHO Drug Information, 2008, pg. 277-278). To help prevent this problem the WHO/Pan American Health Organization (PAHO) have adopted several activities that can help prevent and fight against counterfeit pharmaceuticals which include: “support[ing] countries with technical advice to establish pharmaceutical policies and regulations and by developing guidelines for quality assurance, good manufacturing practices, purchasing, and distribution of medicines” (WHO Drug Information, 2008, pg. 278). As well as adopting preventative activities, PAHO has also created the Pan American Network for Drug Regulation Harmonization (PANDRH) Anti-Counterfeiting Group which is responsible for strengthening the national regulatory authorities in this region. Through these initiatives, the PAHO and the WHO are trying to eradicate the problem of counterfeit pharmaceuticals; however this problem is a growing global problem.

Counterfeit pharmaceuticals are a global problem and China is becoming the leader among the suppliers of these illegal, unsafe drugs. The counterfeiting of pharmaceutical drugs can be done in many different methods, like the active ingredient can be counterfeited and then sold to manufacturers unbeknownst to them, or the final product can be counterfeited like the expiration date can be forged. Counterfeit pharmaceuticals pose many different health risks for the patients. For example, these patients may get sick instead of getting better, recovery time may take longer or in some cases not at all, and many counterfeit pharmaceuticals contain toxic ingredients which leads to patients’ deaths. Currently, the estimates for deaths around the world attributed to counterfeit drugs are between half a million and one million people per year. Counterfeit drugs not only reach developing countries, but also they reach developed countries like the United States. From 2007 to 2008, over one hundred people died in the United States because of the counterfeit drug heparin, which is used to prevent blood clots in surgery patients. In addition to these direct effects counterfeit drugs have on a population, it also has secondary effects. The secondary effects are issues that concern generational diseases like malaria that will never fully eradicate the problem of the widespread diseases (Kafchinski, 2009, pg. 1-25).

**Developing Countries Struggling with International Trade Agreements**

As counterfeit pharmaceuticals are causing direct and secondary effects on developing countries, the health care systems of countries like Djibouti are suffering because of the TRIPS agreement and pharmaceuticals patents. In 2004 a case study was conducted in Djibouti to research the actor-network theory (ANT) in relation to the “action of social-legal objects understood as objects with a legal origin/dimension studied in their social action, through networks and connections” (Cloatre, 2008, pg.264). ANT is an important theory in understanding the relationship between the patents of pharmaceuticals drugs and social actions. ANT was

created to evaluate how technologies work in society. In relation to this study, ANT was used in the research by conducting twenty-five interviews with scholars from public health, trade, and industry fields in Djibouti. The TRIPS agreement is important in this case study because it helps convey how the developing country of Djibouti took the necessary measures of implementing the pharmaceutical patents system that is outlined by TRIPS, and how this affected the social action in the country. By using the ANT was of examining how a written law can affect the social aspects of a county, a scholar can explain how this relationship works through a social-legal analysis. Through a series of interviews with the major actors of implementing TRIPS in Djibouti, the Ministry of Trade, the Ministry of Health, and the members of the public health filed, the conclusive results stated that “TRIPS in Djibouti as a set of prescriptive rules appeared to be a rather weak social actor” (Cloatre, 2008, pg.272). TRIPS created pharmaceutical patents in Djibouti, however when public health actors were originally interviewed about the impact of pharmaceutical patents on health care these patents were dismissed as having “no relevance to them” (Cloatre, 2008, pg. 273). Though pharmaceutical patents are not written into law in Djibouti, the patents are present in the medicines that are being prescribed, and needed by patients in the prices that the health care system of Djibouti is paying for the pharmaceuticals. As the government of Djibouti pays expensive rates for vital pharmaceuticals, another important factor is that system is predominantly private. By having a private pharmacist system the majority of the medicines that are used in Djibouti are imported, and therefore generics are rarely imported. With a rarity of generics available in the country and patents embedded in almost every medical drug used to treat the population of Djibouti, the developing country has to pay high prices to obtain the much needed healthcare (Cloatre, 2008, pg.263-281).

While the country of Djibouti is dealing with pharmaceutical patents by not writing them into laws, developing countries in the Sub-Saharan Africa, South America, and Southeast Asia have illegally practicing compulsory licensing and importing of HIV/AIDS drug therapies, without paying for the patent of the medicines those pharmaceutical companies hold. In December of 1997, HIV/AIDS stricken country of South Africa passed an amendment that would allow the government to be involved in a parallel importing of pharmaceuticals which allows for the “goods produced genuinely under protection of a trademark, patent or copyright, placed into circulation in one market and then imported into second market without licensing authorization of the owner of the intellectual property right” (Hemphill, 2010, pg. 19). Thus, generic pharmaceutical companies can sell cheaper versions of the needed drugs to South Africa. By allowing this parallel importing of pharmaceuticals, the government of South Africa is violating the World Trade Organization’s TRIPS agreement which the government did in fact sign. As a defense for this illegal importing of pharmaceutical drugs, South Africa is claiming the country needs to do this in order to provide essential HIV/AIDS medicines to its population that the country could not normally afford. After the 2001 DOHA meeting, several other developing countries followed South Africa’s lead and participated in compulsory licensing and parallel importing of pharmaceutical drugs (Hemphill, 2010, pg. 19-41).

**Compromises**

As developing countries will result to illegal measures to obtain vital medicines for their constituents, scholars are trying to find a compromise between pharmaceutical companies and the governments of developing countries. One compromise that has been proposed is that if pharmaceutical companies that hold patents to certain medicines grant out-licenses to generic manufacturers that will create the generic version of the medicine to hand out to developing countries, then developing countries will be able to afford much needed medicines. With these out-licenses, generic pharmaceutical manufacturers will be able to compete with other generic pharmaceutical manufacturers over prices in developing countries, however they will not be able to compete with the company that owns the patent in developed countries. The basis for this proposal is that the regions of Africa, the Indian subcontinent, and the developing countries of Asia only total 1.2%, 1.3%, and 2.6% of the global pharmaceutical market, and thus this small percentage will not harm the pharmaceutical countries financially if they provided out-licenses to generic pharmaceutical manufacturers. Out-licensing has been used by GlaxoSmithKline, Boehringer Ingelheim, and Bristol-Meyers Squibb in South Africa in the past. With the use of out-licensing, long-term medicines that are needed for diseases such as HIV/AIDS can be effectively distributed to a developing country in regular intervals, and thus help create a stable health care system (Friedman et al, 2003, pg. 341-345).

Another proposal to providing affordable medicines to developing countries has come from the pharmaceutical giant, GlaxoSmithKline. In February of 2009, GlaxoSmithKline made the announcement that it would give up the patents to medicines of neglected diseases, and reduce the prices of medicines in the poorest countries in the world. The pharmaceutical company also stated that it would like for other companies to join them in creating affordable health care for everyone around the world. However, pharmaceutical companies will not invest in a patent for a drug that will only be used for a few selected people in a few poor countries as the revenues will not match the costs the companies endure when purchasing the patents. Though, these same companies will invest in patents in drugs that cure “superficial” aliments of the rich that reside in rich countries as they will billions for these drugs. When pharmaceutical companies invest in patents for diseases such as HIV/AIDS the prices for the medicines will be astronomical as the research for curing these diseases is in high demand. While some say the answer to this problem is for the developing countries to buy the generic versions of the medicines, this too can cause a problem as pharmaceutical companies say that if they have to make their prices of medicines compete with the cheaper alternatives they will not have enough money for research. In 2006, UNITAID was formed by an array of different countries that proposed a patent law that would allow the pharmaceutical companies sell the much needed drugs at a lower cost to developing countries, while still selling the drugs at the higher, regular price to developed countries. GlaxoSmithKline’s promised program of offering affordable medicines to all sort of fits in with UNITAID’s goal; however the medicines that would be offered at lowered prices would be experimental medicines, and medicines that are not really in use anymore. Thus, making this offer not as good as it seems (MacKenzie, 2009, pg. 22-23).

Economic reasons have been stated as causing factors on both sides of argument for affordable healthcare; economists have reasoned that access to vital medicine patents in developing countries can be economically achieved. Through the TRIPS agreement it is speculated that compulsory licensing of much needed medicines to developing countries could be an economically sound reasoning for providing patent medicines to developing countries. Open licenses can help provide affordable healthcare to developing countries. Unlike regular patents, open licenses allows pharmaceutical companies to give generic pharmaceutical makers a license to create cheaper drugs with the same patent to sell to developing countries. Open licenses are only allowed in certain countries for a certain amount of time to ensure the patent is still protected in developed countries. This particular solution to the high prices of patent pharmaceuticals is fiscally feasible as the “demand for needed medicines in developing countries has very special properties, contributing to larger deadweight loss relative to extra producer surplus when monopolies restrict output and raise prices” (Flynn et al, 2009, pg. 191). In order to proceed with compulsory licensing, the property rules that are created through patent laws need to be converted to liability rules. This conversion will enable a country to change the resulting deadweight loss into consumer surplus through competitive prices. Thus, the ultimate result will “prov[ide] a measured contribution to research and development expenses through a royalty payment” to the pharmaceutical companies that are granting compulsory licenses to generic manufactures (Flynn et al, 2009, pg. 191).

When compulsory licensing started being practiced it was mainly used for medicines that are used to treat infectious, curable diseases, however in November of 2006 Thailand publicized the country was going to use a compulsory license for the pharmaceutical drug Efavirenz with is used a drug therapy for HIV/AIDS. This was the first country to “break patents on drugs used to treat non-infectious, chronic diseases” (Glaser and Murphy, 2010, pg. 216). Since the 1980s Thailand has reported a pandemic of HIV/AIDS with over half a million citizens living with the disease, and since 2002 only three thousand of those citizens have had access to pharmaceuticals like Efavirenz. After the Doha Declaration was created in 2001, Thailand’s Government Pharmaceutical Organization (GPO) started to create generic versions of drug therapies for HIV/AIDS. As GPO began producing the generic versions of these vital medicines, there was an “eighteen fold drop in price” which allowed for a dramatic increase in the number of patients receiving treatment. With the marginal increase of the number of patients receiving treatment for HIV/AIDS, the mortality rate associated with the chronic disease has “dropped from an average of seven thousand two hundred eighty-two per year between 2001 and 2004 to three thousand eight hundred sixty-two in 2005 and one thousand six hundred thirteen in 2006” (Glaser and Murphy, 2010, pg. 221). In 2006, Thailand created a compulsory license for the pharmaceutical drug Efavirenz, then in 2007 a compulsory license for another antiretroviral drug, Kalentra, was issued, and in the same year a compulsory license was made for a heart related medicine that is patented by Sanofi-Aventis. Thailand’s GPO was going to issue a compulsory license for a cancer drug called Glivec in 2008, when the pharmaceutical manufacturer, Novartis, decided to offer the medicine free of cost to the patients in Thailand (Glaser and Murphy, 2010, pg. 215-234).

While creating compulsory licensing has helped the lives of thousands of Thais, especially with antiretroviral drugs, this decision has created a lot of negative criticism. Thailand’s decision to create compulsory licensing has been denounced by international pharmaceutical companies, the United States Trade Representative and the European Union Trade Commissioner. The pharmaceutical company Abbott, who patented the drug Kaletra, decided to take away six patented pharmaceuticals from Thailand in rejoinder to the compulsory license issued for its pharmaceutical. In response to the heavy criticism of the government’s actions, Thailand has stated the country is within its rights of the Doha Declaration as the country used the compulsory licenses in a “public, non-commercial use” (Glaser and Murphy, 2010, pg. 22). In addition to Thailand’s statement that the country was within the limits of the Doha Declaration, the country’s decision has been backed by a “seven member team from the WHO which included experts from the WTO, United Nations Development Programme and law experts” (Glaser and Murphy, 2010, pg. 223). The team from the WHO has conveyed in their report that the compulsory licensing issued by Thailand was in the country’s right to provide a public health system. While Thailand’s choice to create compulsory licenses for pharmaceuticals used to treat chronic diseases has ultimately caused criticism and strained relationships with pharmaceutical companies and trade commissioners, it has “helped to alter the practice of how developing countries can acquire pharmaceuticals, and helped to expand patient access to lifesaving pharmaceuticals across the global South” (Glaser and Murphy, 2010, pg. 230).

**Human Rights and Pharmaceutical Patents**

The ever present issue of pharmaceutical patents hindering access to vital medicines in developing countries is a part of a decade long wave of human rights activists turning their attention to corporations. The direct focus on pharmaceutical manufacturers and the patents placed on pharmaceuticals is the result of the fourth wave which started in 2001. The evaluation of the ethics of the pharmaceutical industry conveyed the problem of accessibility to vital medicines in developing countries, especially in regards to HIV/AIDS treatments. About ninety percent of the people who are HIV positive live in developing countries where access to antriretroviral drugs for HIV/AIDS is significantly less than the accessibility in developed countries. HIV/AIDS is not only a pandemic in terms of illness, but also in terms of society as “large proportions of a generation are being wiped out, creating a generation of orphans and concomitant social problems” (Joseph, 2003, pg. 427). High mortality rates can result in economic problems, as people of the working age are dying due to HIV/AIDS as they do not have access to antiretroviral drugs. However, the high prices of these drugs make it unaffordable for those living in developing countries. The prices are determined by giant pharmaceutical companies, like GlaxoSmithKline and Merck, which is the basis for the argument made by human activists (Joseph, 2003, pg. 425-452).

Human rights activists are campaigning that giant pharmaceutical companies have the ability to change the high prices of antiretroviral drugs as they own the patents. While advocates of patents state that patents enable a company to receive its rightful monetary gain, it still creates a monopolistic environment. Though, this monopolistic environment has been accredited for stimulating more research and development in the field, as the money generated from pharmaceutical sales helps the companies put more time and effort into this sector of the pharmaceutical industry. However, the underlying problems of pharmaceutical patents are still prevalent in developing countries. Pharmaceutical patents create “inflated prices [which] restrict the ability of poorer people to access drugs that they need, particularly in developing nations” (Joseph, 2003, pg. 432). The reason for the inflated prices, according to pharmaceutical companies, is to put more money into research and development; however the amount invested into this sector is considerable “small[er] compared to certain non-R&D (research and development) outlays” (Joseph, 2003, pg. 433). As well as contributing a small budget to research and development, most of this sector is done at the governmental level or at university laboratories, which is mostly paid through public funds (Joseph, 2003, pg. 425-452).

The next issue in regarding the pharmaceutical industry human rights activists are questioning is innovation. Most pharmaceutical companies invest money into drugs that are labeled as “me-too” or “copycat” drugs that represent a genre of drugs that “add little therapeutic value to existing medical treatments” but these small additions enable pharmaceutical companies to create a new patent (Joseph, 2003, pg.434). With money being invested into “me-too” or “copycat” drugs, innovation is almost non-existent in the pharmaceutical industry. While innovation, research and development, and the profit made off of patents can all be discussed in economic terms, the human rights responsibilities of pharmaceutical companies cannot be justifiable in sense of numbers. Human rights activists are asking pharmaceutical companies to consider the fact that pharmaceuticals are not purchased on a want but rather than a need for the individual. The moral judgment made on corporations is easy to make and figuratively hand out, however a legal judgment is harder to obtain as pharmaceutical companies are not technically doing anything wrong in terms of international trade laws. Currently international human rights law conveys that it is the responsibility of the government and not private companies to ensure human rights are being protected. Though there is a growing trend that wants to place legal liability on private companies that are multinational corporations, like pharmaceutical companies, that can restrict human rights while practicing in a country. However, it is hard to directly associate responsibilities of human rights with pharmaceutical companies, at least in legal terms (Joseph, 2003, pg. 425-452).

**Conclusions**

As human rights activists continue to campaign for corporate responsibility of social action, the general realization that pharmaceutical patents need to be revised in developing countries is continuing to grow. Nevertheless, the bilateral international trade laws that protect patents in international trade have to be changed to reflect the economic capabilities of developing countries in regards to providing essential medicines to their populations. While patents are important in protecting a person’s work and ensuring a person will receive financial compensation for his or her innovation, patents can also create a noncompetitive environment which can inflate prices on a certain innovation or good. The World Trade Organization was created to regulate international trade and to promote fair trade between member countries, however the trade between developed countries and developing countries is unequally balanced from the start as developing countries are dependent on the imports from developed countries. These vital imports help developing countries reach stability, though the high prices imposed by strict intellectual property right laws make development harder to obtain. Reaching development and stability is an all encompassing term that can correspond to government, infrastructure, economy, and the well being of a society. Whereas creating a stable government, infrastructure, and economy can be achieved with outside help, maintaining these stabilities is only achievable with the help of the constituents of the countries. The support of constituents can only come from a population that is stable, and that stability is achievable through a working healthcare system. In order to create a working healthcare system in developing countries vital medicines need to be available to entire societies where chronic diseases like HIV/AIDS and malaria are rampant. Conversely until the high prices on pharmaceuticals that are imposed by patents can be reduced to fit the fiscal needs of developing countries, working healthcare systems are harder to obtain, and thus development is too harder to obtain.

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