The Pharmaceutical Industry and Human Well Being:

Argentina and TRIPS

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Abstract

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This thesis examines the barriers intellectual property law poses for a implementing a just pharmaceutical patent system. Specifically, challenges produced by the WTO's TRIPS agreement for developing countries, with respect to access to patented pharmaceutical products. The case study of Argentina is presented as an exceptionally successful case in comparison to the majority of other developing countries bound by the TRIPS agreement. Argentina has utilized the flexibilities offered by TRIPS and implemented far-reaching social welfare programs to ensure the good health of their citizens. The purpose of this thesis is to critically analyze the agreement and uncover why other developing counties have not observed success as Argentina has in national health. Proposed solutions to the pharmaceutical patent system are analyzed including: the prize system, funding R&D through public means, controlled or tiered pricing, or have developing countries implement IP right exhaustion.

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Introduction

The way health systems and policies interact with individuals directly affects their well being in either a negative or positive way. The evaluation of this interaction is referred to as the 'responsiveness' of a particular health system. If a health system is responsive, interactions with individuals embedded in that system will be possible and effective insofar as improving the well being of those individuals. The purpose of health systems and policies according to the World Health Organization (WHO) is to improve health and ensure unbiased financing of health related structures. The WHO recognizes that incorporating human rights principles into the evaluation process of determining the responsiveness of health systems can help further realize three things: the value of other human rights, authority and accountability, and cohesion. Health systems, when operating suitably, should not only improve health levels but also further the acknowledgement of other human rights that form the foundation of the intrinsic value of health. Human rights are universally validated and, in turn, allow for the demanding of accountability from governments and other actors to fulfill these rights. Additionally, the realization of human rights, particularly the human right to health, can help identify current gaps in a health system where this right is not being met (Gostin et al, 2003, pg. 3). More detail surrounding health and the aspirational right to health will be given later in the thesis.

For the purposes of this thesis I will be assuming that the patent system currently in place will remain a feature of the global health care system. There are powerful vested interests, which make overturning the system unlikely. My task here is to see how it

might be supplemented and improved to better help those who have not benefited the current system.

The pharmaceutical patent system that is typically enforced in developed countries has also been adopted and perpetuated by the World Trade Organization (WTO) in the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. The agreement requires all WTO member countries to meet a minimum standard of intellectual property (IP) rights over pharmaceutical products domestically. The purpose of this enforcement is to increase incentive for innovation and technology transfer between countries. The WTO requires member countries to implement the patent system over pharmaceuticals including developing nations. This system can be considered a health system due to the capability and capacity to provide access to pharmaceutical products globally. This also allows the patent system, if not fulfilling a high rate of responsiveness, to hinder global access to pharmaceutical products, creating a barrier to meeting the aspirational human right to health. This thesis will explain how the pharmaceutical patent system, as a health system, is failing to meet the health needs of populations in developing countries. Finding a potential solution to the shortcomings of the current patent system may be developed after the patent system itself is realized, first and foremost, as a health system instead of primarily a profit making business.

Problem: The pharmaceutical industry and pharmaceutical policies, as they currently operate, do not create an effective system that provides accessible, affordable, and "unbiased" innovation for pharmaceuticals, especially populations in the developing world. The pharmaceutical industry, paired with the current patent system, is

unsuccessful at fulfilling the demand for essential medicines to those living in poverty in the developing world. In short, the pharmaceutical industry is currently not making medicines available to poor populations to the level that is achievable considering the capacity of the pharmaceutical industry. It is often the case in the West that pharmaceutical companies generate great profits. Yet they do not develop drugs that are needed most in the third world due to the lack of potential financial gain. The issue is that the current system is not effective on a global scale as it presently operates. However, there is the attempt to implement the patent system on this global scale through the TRIPS agreement.

Questions: What is causing the current patent system to fail at effectively meeting the demand for essential medicines by the third world's impoverished people? Is it possible to have a pharmaceutical structure under the current patent system that successfully meets the health needs of marginalized third world populations?

Purpose: The purpose of this thesis is to critically examine the patent system as applied to pharmaceutical products. In particular, this thesis will address the potential challenges the TRIPS agreement poses to developing country populations due to the globalization of pharmaceutical patent protection. The case of Argentina will be explored because it has been considered successful at both complying with TRIPS to an acceptable degree and, additionally, providing essential medicines to the local population. An explanation will be sought as to why Argentina, as a developing country, is succeeding at meeting these health needs while operating within the TRIPS agreement and what is preventing the

majority of other developing countries from doing the same. Additionally, there are several proposed solutions to the complications resulting from pharmaceutical patents, which will be considered.

Method or Approach: In order to answer the research questions, this thesis will employ a qualitative research approach and additionally apply a case study. The data collected consists of secondary sources and will be presented in the form of a literature review. The literature review will be followed by a critical analysis of the debate and the resulting evaluation supported by the case study of Argentina.

Thesis Statement: The current critics of the patent system, as applied by the WTO, state that the system successfully accumulates profits for the pharmaceutical companies for the purpose of innovation and financial gain. However, it is insufficient at providing "unbiased" innovation, affordable pharmaceuticals, and accessible drugs to the underdeveloped world. This thesis will explore the possibility of having a pharmaceutical industry governed by the TRIPS patent system that successfully fulfills the health needs of that portion of the global population living in poverty. Argentina is an example of a country with a pharmaceutical patent system that is paired with pharmaceutical and health policies that allow for the industry to provide essential medicines to citizens. I will argue that the Argentinian use of the patent system and TRIPS flexibilities offers a model of a pharmaceutical industry that provides essential medicines to impoverished citizens. However, the international pressure on other developing countries to not implement a

similar pharmaceutical system will require the exploration of potential solutions to the globalization of pharmaceutical patents through the TRIPS agreement.

According to the World Intellectual Property Organization (WIPO), the term intellectual property refers to original intangible creations of the mind such as inventions, literature, symbols, etc. Law, through several different avenues including copyright, trademarks, and patents, protects IP. This protection allows the inventor the right to recognition as the creator, as well as the right to financial gains that may come from selling, using, or making the invention. This thesis will be exploring patents as a form of IP protection. Patents differ from the other forms of IP protection. To obtain a patent, the inventor must disclose to the public the technical information that contributed to the new invention. Once the technical information used is made public, it is believed that there is an increased possibility that the use of this information by others may help contribute to bettering society. In exchange for making this information public, a patent offers the protection that only the inventor is able to use, sell, or make the invention for a period of time. In Canada, patent protection lasts for 20 years, which is also the length requirement under TRIPS (WIPO, Retrieved May 1st, 2015).

Pharmaceutical formulas are one of the most highly contested patentable inventions. This is due to the control a patent owner has over price and distribution of a product, combined with the direct relationship between pharmaceuticals and global health (World Health Organization, 2005). There are two strong opposing sides to the debate. One side hopes to extend the length of patent protection for the purpose of enhancing the incentive to innovate and hereby increasing the amount of pharmaceuticals being invented. The other side wants to exclude or weaken IP protection over pharmaceuticals

for purposes of improving global access to medicines. The concept of incentive to innovate is where the issue gets extremely complex. Patent advocates argue that, without this system of protection, there would be far less incentive for drug companies and scientists to research and develop new drugs. Those who are opposed to patents argue that patents allow for 'biased' innovation where research and development (R&D) funds are spent on drugs for the developed world. People in the developed world can typically afford to pay the high mark ups on pharmaceuticals therefore increasing the profits made by pharmaceutical companies. The case of IP rights over pharmaceutical patents becomes much more complicated when we consider that the pharmaceutical industry is not simply a profit making industry. However, pharmaceutical patents involve an ethic element due to the ability to directly affect human health.

This thesis will fall on the side of the debate against the current patent system as it stands in the TRIPS agreement. However, there is recognition that there must still be an incentive to innovate. I do not claim that the patent system needs to be discarded. However, it is important to realize the shortcomings of the current patent system before deciding what changes should be made. Article 25 of the Universal Declaration of Human Rights appropriately announces the human right to health. This right to health is an aspirational human right, meaning it is a declarative goal. It is also a foundational right leading to the recognition of other human rights. Enforcing this right would mean the world population gaining access to existing pharmaceuticals, even those living in poverty. The right should include having pharmaceutical research focusing on diseases that affect the greatest amount of people. Further, the pharmaceutical industry should be concerned with health advancements before profits (Thomas Pogge, TED Talks).

The human right to health in this thesis will be considered an aspirational right. The human right to health and access to pharmaceuticals will not be considered a positive or negative right. If one has a negative right, they are entitled to non-interference. For example, if the right to health was a negative right, as long as the action of one person was not actively deteriorating someone else's health, the right is not being violated. Negative rights can be respected simply by each individual abstaining from interfering with one another. From a negative rights perspective, the natural health implications that an individual experiences as a result of not having access to pharmaceutical products because of the patent system, is not a violation of the human right to health. It is not a violation because the lack of accessibility experienced is an unintended consequence of the patent system itself (Wiles, pg. 45. 2006). The holder of a positive right is entitled to a particular good or service. However, it can be very difficult to fulfill everyone's positive rights, especially if the sum of people's claims exceeds the resources available. In the case of health as a positive right, the patent system does not develop all of the medicines needed, nor makes them accessible. Therefore, as a positive right, the sum of people's claims in this case does exceed the resources available (Stanford Encyclopedia of Rights, 2011). Considering the right to health an aspirational right transforms the claim into a declarative goal. It is not a guarantee but a commitment made to achieving an increasingly healthier society (Sandhu, pg 1175, 2007).

According to Thomas Pogge, there are three major areas that make patent protection of pharmaceuticals problematic, which will be explained in more detail throughout the thesis. These areas include: sections of the population having a lack of accessibility to pharmaceuticals, drug R&D is biased in favour of the developed world,

and spending inefficiency that can be attributed to the business aspect of the industry (Cernea & Uszkai, 2012) (Pogge, 2011). There have been proposed solutions to replace or work within the existing patent system. The main alternatives include: the prize system, funding R&D through public means, controlled or tiered pricing, or have developing countries implement IP right exhaustion, which places the health of their citizens above IP laws (Barton & Emanuel).

The case study that will be examined is the pharmaceutical industry in Argentina. It is a unique case because Argentina, under the Nestor Kirchner government established in 2003, exhausted international IP rights. This is a decision that has benefits, but also negative consequences. However, this was not the only step the state took to ensure the health needs of its citizens were met. Social welfare programs, such as *Remediar*, provide citizens with essential medicines at no cost as well as professional medical care. By realizing that the required changes needed within the pharmaceutical industry are not going to happen while the current system favors developed country companies and affluent citizens, Argentina has taken action that has greatly benefited their citizens. The exhaustion of IP rights over pharmaceutical products in Argentina has fallen within a grey area of the TRIPS agreement and within the flexibilities they offer to developing countries.

The health, well being, and longevity of those in less developed countries has improved at a faster rate than at any time in recent human history since the institution of the current patent regime. Seeing that the development and use of drugs has contributed to this success, one might wonder why changes are required in a system that has served us so well. The success of the current patent regime can be partly attributed to ongoing

critical analyses and changes being made to improve the system over time. This thesis will be providing further critical review of the current pharmaceutical patent system to acknowledge shortcomings and potentially uncover improvements to the system.

Information About Patents

This chapter will provide an explanation of what patents are as well as the type of IP patents are able to protect. A section exploring why patents over pharmaceutical products can be problematic will follow.

2.1 What is Intellectual Property?

According to the WIPO, the term IP refers to original intangible creations of the mind such as inventions, literature, symbols, etc. (WIPO, Retrieved February 17th, 2015). All recognized IP is placed under one of two categories - industrial property or copyright. This thesis will focus on IP that is categorized under industrial property, which requires a patent (WIPO, Publication 450, Retrieved February 17th, 2015). Ultimately, the term IP and the discourse surrounding IP rights, assumes the consumption of knowledge and ideas by neoliberalism. Neoliberalism is a political theory surfacing in the late 1900s, which holds that the liberty of individuals is fulfilled by limiting government interference

in free markets and, additionally, pushing for economic globalization (WHO, Retrieved May 8th, 2015). IP under neoliberalism can be understood as promoting the privatization of knowledge and ideas for the purpose of financial gain by means of creating a monopoly in the market and incentive for innovation.

IP rights are the protection and benefits granted to the inventor or owner of a registered product. The creator of an invention is, the majority of the time, an organization or company, not just an individual. Typical benefits of IP rights include the right to financial gain that may come from selling, using, or making the invention. The WIPO offers three core reasons for thinking that promoting and protecting IP contributes to human well being. Firstly, progress and human welfare are dependent on society's capacity to invent new mechanisms, especially in the areas of 'technology and culture' (WIPO publication 450, 3). IP rights support the invention of new mechanisms. Secondly, the legal protection of IP inspires the commitment of supplementary resources for further innovation. In short, legal rights provide an incentive to innovation. This incentive is the granted monopoly in the market of the patented invention, creating the potential for great profits. Lastly, the promotion and protection of IP rights stimulates economic growth, generates new jobs and industries, as well as enhances the quality of life (WIPO publication 450, 3). The incentive for innovation provided by patents encourages people and companies to research and develop new inventions. These inventions and knowledge developed may contribute to the progression of society.

2.2 Forms of Protection

Law, through several different avenues including copyright, trademarks, and patents, protects IP. Copyright law is a form of protection that covers creations such as

literary works, musical works, architectural works, graphic works, and sculptural works. In order for an author or creator to secure copyright protection, no registration is required. It is secured automatically when the work is created and presented in a tangible form. Although no registration is required, there is typically a process that is available for creators to register their works. There is a duration placed on copyrighted materials. A work is protected after the date of creation for a minimum of 70 years in the United States. Protection that is provided for copyrighted materials includes signifying that the creation belongs to the inventor or company. After the duration of copyright protection expires, the creation enters what is called the 'public domain'. When materials become part of the public domain, they become publicly available free of charge and for unrestricted use (Copyright Clearance Centre, 2005). After a work becomes part of the public domain, it is still thought to potentially contribute to educating the population or to inspire creativity. (Electronic Frontier Foundation, Retrieved February 17th, 2015).

Trademark protection differs from that of copyright or patented material. A trademark is a "word, name, symbol or device" that is often used in traded goods that signifies the source of the good or material (LawMart Inc., 2015). An inventor or company is required to register their trademark with the patent and trademark office of their country. The protection a registered trademark provides is unlimited, although the creator or company would be required to renew the trademark every 10 years if continued protection is desired. Varying maintenance fees are required to receive and maintain protection in the United States (LegalZoon Inc., Retrieved February 17th, 2015). The protection that is offered by registering a trademark includes the easy distinction by consumers of one company's offerings or services from another company's offerings or

services. The owner of a registered trademark can prevent the importation of foreign goods displaying the same trademark through the possibility of legal action. This would be in the interest of companies selling products of high quality in popular demand to ensure the standards of their products in consumers' eyes are kept in high regard.

2.3 Patents

Patents differ from other forms of protection previously discussed; both in areas of what is granted to a patent holder and what material can be patented. An inventor can obtain a patent on an intangible idea. A patent is a form of IP protection where exclusive rights are granted to an inventor or company by the state for a limited period of time. These exclusive rights include the sole right to make, use, and sell the invention. In return for these rights, the inventor gives the government a complete description of their invention. According to the Canadian Intellectual Property Office (CIPO), this description received from the inventor is made public in Canada so that all Canadians can benefit from the advances in technology the invention provides. In Canada, the protection lasts for twenty years from the date that the patent application is filed (CIPO, 2014). If an inventor receives a patent in Canada, the sole right to use, make, and sell the invention is only guaranteed in Canada. To make these rights valid in another country, the inventor would have to apply for and acquire a patent in that country.

A company or individual would want exclusive rights to be the sole maker, user, and seller of an invention or technology to improve their market position and to recover the costs of creating the item that has been patented. A patent provides the possibility of holding a monopoly in the market until it expires. A patent also grants the inventor the right to be the sole beneficiary of any profits. Patents are enforced by national and

regional patent offices, the WTO, and evaluated by the WIPO. National patent offices are government organizations that take care of all issues surrounding patents from the application process to enforcing restrictions when patents are acquired. The WTO formed the TRIPS agreement, which gives patent protection on a larger scale. It is not a requirement of the patent system to provide international protection, however the TRIPS agreement requires all member countries to provide patent protection to each other. WIPO is a United Nations Agency that administers global IP treaties. These organizations provide patent protection to those seeking it by giving judicial enforcement of IP rights (Thusleem, 2008).

National patent offices exist in many countries enforcing some form of a patent system. This is the office an inventor would seek when attempting to obtain a patent for a new creation. It is also the responsibility of this office to analyze each new creation and determine whether it is worthy of being protected by IP rights. The national patent offices are also responsible for making the information provided by the inventor of a new product available as public record (Lehman, 2003, 5). The national patent offices are government agencies that deal with any domestic issues regarding patents, as well as any global patent matters that involve patent holders of that country.

Although there are bodies that regulate and oversee patent related issues in each country, there are global organizations that provide further assistance with patent agreements and matters between several countries. The WIPO was developed in 1967. It is based in Geneva, Switzerland and is a global forum for IP services, policy, information, and cooperation. The WIPO is a branch of the United Nations and currently has 188 member states (WIPO, Retrieved Feb. 15th, 2015). To member states, the WIPO provides

a policy forum in order to influence international IP protection rights and laws. Further, they offer services that can expand globally to protect patented inventions across borders and resolve international disputes surrounding IP rights. The WIPO is considered a platform where the technical infrastructure is provided to share knowledge involving IP and promotes the implementation of IP rights for the purpose of all countries to benefit in economic, social and cultural areas. The WIPO is currently the most significant resource for developing countries in assisting with IP rights (Lehman, 2003, 6).

The WTO established in 1994, is another global international organization that addresses the rules of trade between nations. The most significant products of the WTO are the agreements that are constructed through negotiation and applied to the member states of the WTO, who are the world's active trading nations (WTO, Retrieved February 15th, 2015). The nations that participate and sign WTO agreements must then ratify the agreement's policies within their governments and apply them domestically. The majority of the policies and agreements implemented by the WTO are a result of the 1986-1994 negotiations referred to as the Uruguay Round. The agreements provide legal ground rules governing business and trade on an international level. The agreements are binding contracts ensuring that governments operate within agreed limits. The purpose of this organization is to provide an international business and trade environment that promotes trade. It also acts as a form of protection for all people affected by the trade process (WTO, Retrieved February 15th, 2015).

A fundamental agreement that will be discussed in this thesis was a product of the WTO's 1994 Uruguay Round, which is the TRIPS agreement. The goal of the TRIPS agreement was to influence the system of international trade to make it more equitable.

The agreement was signed by both developing and developed countries, requiring the developing countries to open their markets to products of the developed countries considered high value added exports. Further, there was the requirement of developed countries to reduce trade barriers to competitive imports (Lehman, 2003, 6). It is argued that pharmaceutical products are one of the most important categories of high technology products that are addressed within the TRIPS agreement. All member countries of the WTO must abide by the TRIPS agreement. Later in the thesis there will be a section that goes into greater detail on the TRIPS agreement, followed by the effects that the enforcement of TRIPS has had on developing countries that are WTO member states.

2.4 Patents and the Pharmaceutical Industry

The application of patents has different implications and outcomes when implemented in different industries. Before new inventions are put on the market, they are usually patented. In every industry is the inventor's goal when applying for a patent is to maximize profits through the use of patent rights. However, the type of technology used to develop the invention will influence how the IP rights are exercised. For example, patents over technology used to develop consumer electronics are usually mutually shared among competitors through the distribution of licenses. Typically, patents over technology used to develop chemical compounds such as pharmaceutical formulas, are not licensed to other competitors and exclusivity is highly valued in the pharmaceutical industry (Lehman, 2003, 4).

Markets are morally neutral, only operating on the principle of scarcity. The principle of scarcity refers to the phenomenon that products on the market that are in demand have a higher cost than those that are easily attainable and available. A higher

price and extensive scarcity of a product in a market is also an indication that the patent on that product is still in effect. When products become widely available for lower cost over time, it is an indication that the patent for that product has expired (Lehman, 2003, 5). While products are under patent protection, it is common in every industry for the high market price to exceed the purchasing power of poor consumers. It is accepted that a significant percentage of the global population is unable to afford many products with patent protection (Lehman, 2003, 5). It is not just a feature of the pharmaceutical market, but also a feature of most markets.

Many of the patented products in the developed world are not necessities. However, not having new technologies and inventions available to the developing world greatly contributes to the economic gap between developed and developing countries. In some circumstances, patented products that are necessities are not made available to the developing world. This often occurs with pharmaceutical products. When individuals of developing countries are unable to afford the new technologies, it is the responsibility of the government to bear the cost of purchasing the products (Lehman, 2003, 5).

The pharmaceutical industry is one of a few industries where the patent equals the product. Capital investment in the pharmaceutical industry is directed more toward R&D and less to the manufacturing of the final product, patent exclusivity is the only effective way to protect and receive significant financial return on a product. This is the case for technology-based industries such as the chemical industry and biotechnology industry. The application of patents in these industries differs from others. It is typical of other industries to use several techniques alongside patents, such as applying trade secrets and pooling patents with competitors (Lehman, 2003, 7). Additionally, it is a characteristic of

the pharmaceutical industry to heavily rely on capital investment to produce a new formula. This capital investment is greatly allocated to laboratory research and clinical trials instead of solely to the manufacturing of the final product. The majority of other industries produce products that demand expensive and complicated manufacturing infrastructure. However, this usually is not the case in the pharmaceutical industry. Although a significant amount of the initial capital goes toward clinical trials and laboratory research, once a formula has been discovered, the manufacture of the final product is usually not costly (Lehman, 2003, 7). Because newly patented pharmaceutical advancements can be easily and cheaply replicated, the application of patents is currently the only way in which an inventor or company can effectively collect a return on new pharmaceutical products.

An aspect that further individualizes the pharmaceutical industry, even from other technology-based industries that also rely on patents, is the lack of formula secrecy. Other technology-based industries are often able to keep their invention undisclosed until they are marketed allowing the length of the IP protection to be fully maximized. In the case of the pharmaceutical industry and medical research, it is required that the formula for new products be disclosed before the time of the official patent enforcement (Lehman, 2003, 7). This is in an attempt to meet a moral obligation, which arises because technology advancements in medical research can have overwhelming effects on human well being. Further, the pharmaceutical industry is one that is profoundly regulated by government agencies to ensure the safety of consumers. This is an aspect that adds to the lengthy process of clinical trials and costly research.

There is a significant amount of time between when a patent is filed and when the pharmaceutical product is made available on the market. The inventor is only able to start making returns and profits once the product is marketed. Therefore, the amount of time a pharmaceutical company is able to hold a monopoly in the market is shorter than the 20-year length of the patent. As mentioned previously, other industries relying on patent protection are able to market products shortly after a patent is attained, allowing the inventors to fully utilize and benefit from the full length of the patent. Since this is not the case in the pharmaceutical industry, the problem has been addressed by some legislation in specific countries by allowing patent holders to apply for an extension on patent protection of their product. Patent extensions have been made available in an attempt to compensate for the lengthy process required within the pharmaceutical industry to meet regulatory demands, preventing maximum utilization of the 20-year protection (Lehman, 2003, 7). This process is in the best interest of the patent holder for the purpose of profit making which adds to the incentive to develop new drugs. However, it extends the amount of time pharmaceutical products will be out of the reach of the global poor. The length of patent extension in the United States is allowed to equal half the amount of time it had taken to meet the regulatory demands of a particular product. Therefore, the amount of potential marketing time lost from regulatory processes is not fully returned through the use of patent extensions (Lehman, 2003, 7). During the time of a patent extension, the patent holders are no longer able to prevent generic companies from developing generic versions of their drugs. Although the generic companies are not able to market or sell the generic versions until the patent extension expires.

It has been estimated that the average cost of bringing a newly developed drug to the market costs pharmaceutical companies US$800 million. Therefore, having an incentive to innovate is thought to play a crucial role in the development of new pharmaceutical products (Boldrin & Levine, 2010, 1). Further, the technology harnessed by the pharmaceutical industry used to produce, package, and ship medicines, fits the constant returns to scale model seamlessly. The cost of shipping the 100 thousandth unit of medicine is equal to the cost of shipping the very first (Boldrin & Levine, 2010, 1). Boldrin and Levine point out that this returns to scale feature of the pharmaceutical industry supports the argument that pharmaceutical companies should be shipping medicines to poor countries. Further, it would likely only cost a few additional cents to produce each unit of medicine to be shipped to the developing world, a cost that has a better chance to be met by the poor consumers themselves and not allowing the pharmaceutical companies to lose any money. However, this argument does not take into consideration the cost required for the R&D of the medicine, which is responsible for the medicine's existence. The argument does not acknowledge the reality that in a globalized world, if the same product is made available at a lower cost in some countries, it will make it's way into places where it is more expensive for the lower cost. This would potentially lead to pharmaceutical companies not receiving enough financial return to cover their initial capital investment.

Due to the strict IP rights surrounding pharmaceuticals, there is no significant competition within the industry because monopolies are granted through patent attainment. Since the 1970s, the pharmaceutical manufacturing and developing industry has become concentrated with only a few major companies holding a dominant position

in the market globally (Bolrin & Levine, 2010, 1). This concentration of a few successful companies is thought to be significantly due to the large cost of R&D of new drugs, allowing only those with the initial capital to develop new products to succeed. Patents have been successful in the case of the pharmaceutical industry in making profits for the monopolists. Patents however, have not been able to benefit the consumers as much as they have the pharmaceutical companies. That is not to say that the pharmaceutical industry under patents has not developed new products. However, the system could be improved in areas of access to pharmaceutical products and unbiased innovation.

It is difficult from a moral standpoint to argue for a system of IP rights protecting pharmaceutical products. Many of the benefits of the system go to the patent holders for purposes of profit making, a worthy goal within other industries. What differentiates the pharmaceutical industry from others is that the availability of the pharmaceutical products developed is responsible for the lives of millions of people. It will be explored that the patent system over pharmaceutical products greatly restricts the widespread access of pharmaceutical products.

2.5 Why Patents are not compatible with Pharmaceuticals

The nature of the market provides a system that is morally neutral. It has been discussed that the implementation of patents is attractive to product developers because, once attained, a patent provides an inventor with a monopoly in the market for up to 20 years. This is a system that works well with fostering good business practices, insofar as it makes significant profits for inventors and companies as well as their shareholders. The system also provides an incentive to innovate certain pharmaceutical products. I will

argue that the current patent system is not appropriate for pharmaceutical products because these products are necessary for quality of human life and societal well being. The solution may not be to discard the patent system but review and increase flexibilities offered to developing countries. The operation of the patent system, in the case of pharmaceuticals, is unable to meet the aspirational right to health. It is also unable to strike a balance between the benefits received by patent holders and providing equal societal benefits.

This thesis explores whether patent protection over pharmaceuticals is compatible with the requirements of justice. It asks what changes to the current system are needed to ensure good health for citizens of developing countries. It is argued by patent advocates that a patent is required to protect the widespread investment in research and clinical testing, which is necessary to get a pharmaceutical product approved and introduced to the market. Once the R&D of a pharmaceutical product is complete and it is approved to be marketed, the manufacturing methods are easily replicated and for a small fraction of the initial development cost (Lehman, 2003, 2). This puts the companies that develop pharmaceuticals at greater risk of losing profits and not being able to cover the initial investment cost. Further, the patent protection of pharmaceuticals is what helps make them available in the countries that provide patent protection, typically developed countries. The extremely high cost of developing a pharmaceutical product currently encourages the private sector to unequally direct R&D funds to products needed in the developed world, where consumers have available funds to purchase them. It is argued that the lack of patent protection in developing countries has caused their own pharmaceutical industries to fall behind those in the developed world.

Developing countries should not be blamed for the lack of essential medicines in the developing world. Rather, the TRIPS patent system plays a major role in this lack of accessibility in the developing world. This is largely due to a lack of regulation over the amount of technology transfer to the developing world and unequal R&D funds from the developed world for developing world diseases. I will review the three predominant factors of the current patent system that negatively affect developing countries and their most vulnerable citizens. This thesis will critically analyze the agreement and seek what areas can be improved to make medicines more accessible to the underdeveloped world.

2.6 Problems With Patents

The current patent system under TRIPS produces complications, which have created a system that is in some ways both inefficient and biased. A system could be developed that could produce better results than the current patent system, or alterations that could be made to the current patent system to eliminate the problems that arise in the current system.

According to philosopher Thomas Pogge, there are three main areas where the current TRIPS pharmaceutical patent system falls short: universal access, biased innovation, and overall spending efficiency (Pogge & Hollis, 2012). The current patent system provides poor universal access to drugs. There is currently little or no incentive for pharmaceutical companies to provide products to poor people in hard to reach areas. People in the developing world are often unable to afford the market price of pharmaceutical products. Pharmaceutical companies do not make the drugs accessible in these developing areas simply because there is no profit to be made by doing this. Generally, drugs are only made available in the developed world due to the amount of

pharmaceutical consumption and ability of people to afford the drugs, even with high mark-ups. Of course, pharmaceutical companies need to generate large incomes in order to fund further R&D and to make money for their shareholders.

Innovation in the pharmaceutical industry is extremely costly. This creates a major bias for pharmaceutical companies when deciding which drugs to devote their limited resources to research and develop next. To increase their chances of generating a greater profit, pharmaceutical companies spend money on researching and developing drugs that are oriented to the developed world. There is no monetary incentive to improve global health when using the current patent system. People living in the developed world are usually in the financial position to pay the market price for pharmaceuticals, where those living in the underdeveloped world are not in the same financial position. The developing world is greatly affected by life-threatening diseases and serious illness. It makes up for 90 percent of the world's global burden of disease where the developed world only accounts for 10 percent of the global burden of disease (Stevens, 2004). This detrimental burden of disease is part of the reason that, on average, people in developing countries are, relative to those in developed countries, unable to generate income to purchase pharmaceutical products. R&D spending that would match the global burden of disease would have 90 percent of pharmaceutical spending go towards the global burden of disease in the developing world. This would benefit those in the worst off position in the global society.

The final major area that can be considered unjust in the current patent system according to Pogge would be the overall spending efficiency. In terms of overall spending efficiency, the current patent system spends a large portion of revenue and funding on

lobbying, patenting, litigation, marketing, and fighting counterfeiting instead of spending it on R&D (York University, 2008). The current patent system is driven by the neoliberal market, which allows for the possible rewarding of this spending which can be considered wasteful. This spending is not contributing to factors relating to health. Instead, it is going toward the marketing of already developed drugs to increase sales, litigation, and lobbying. This type of spending does not necessarily indicate increased innovation or drugs being developed as a result. It has more to do with profit making for the pharmaceutical companies.

2.7 Possible solutions

There have been proposed solutions to replace or work within the existing patent system that will be discussed in the literature review. The main alternatives include the prize system, funding R&D through public means, having controlled or tiered pricing, or having developing countries exhaust IP rights for pharmaceuticals (Barton & Emanuel, 2006).

The prize system, advocated by Joseph Stiglitz, was formulated to solve the problem of lack of incentive for innovation of pharmaceutical products that would be used to meet the needs of those in developing countries. The prize system is typically presented as a government supported fund intended to either replace or operate alongside the current patent system (Stiglitz, 2012). In a prize system, the incentive to innovate a drug is changed from financial gain as in the patent system, to creating a significant impact on health. A medical prize fund would reward the inventors of pharmaceutical products that have produced product with far-reaching health benefits, eliminating the incentive to innovate 'lifestyle' or 'me too' drugs'. The prize system model Stiglitz

proposes would eliminate the possibility of the inventor holding a monopoly in the market and allow competitive markets to lower the prices of the pharmaceutical product. There would still be full public disclosure of the invention. Stiglitz claims that this kind of model is able to redirect scarce R&D funding toward more efficient uses, such as developing drugs for diseases effecting a significant amount of people (Stiglitz, 2012). Thomas Pogge and Aidan Hollis also offer a prize system model, which will be explored more in depth later in the thesis.

Another proposed solution to the current patent system is through public funding. Typically, a public funding system would have R&D of pharmaceuticals financed through a tax or a tax-like instrument to raise a predetermined amount through the government. This could include having R&D funded by a percentage of a country's gross domestic product (GDP). Public funding allows the government to make pharmaceutical products available at generic costs from the moment they are finished manufacturing (DiMasi & Grabowski, 2004, 4). The current patent system funds R&D through consumers paying high prices for pharmaceutical products. However, the patent system does not take into consideration human welfare and does little for the poor who cannot afford the drugs. Public funding as a solution, allows the government to intervene by paying for the R&D of products. In turn, they provide the pharmaceuticals below market value. The government does not require the profits made from high mark-ups on pharmaceutical prices (Hubbard & Love, 2004).

The solution of tiered pricing is a concept that involves selling pharmaceutical products in developing countries at systematically lower prices than the prices they are sold in developed countries. Tiered pricing involves separating the markets of high,

middle, and low-income countries, adjusting the price of the same pharmaceutical product to meet the needs of the consumers in each market. This strategy is not to adjust the directed innovation issues with pharmaceutical R&D in the current patent system, but to simply increase widespread access to consumers. Some consider this a win-win technique for those in need of essential medicines as well as for businesses being able to expand their markets, maximizing overall profits (Moon et al, 2011, 2). However, it has been implemented previously and has not been successful (Moon et al 2011, 9). This is for several reasons including the possibility of other markets retrieving pharmaceuticals from the areas they are offered at the lowest prices.

The final proposed solution to the current patent system is the exhaustion of international IP rights by developing countries. In these cases, when essential medicines are needed in a country but access is limited due to patent protection, generics or 'similar drugs' are manufactured in the country and provided to citizens at low costs. This is a view that is controversial, however, it works in favour of human welfare. This solution is one that will be analyzed in depth in the case of Argentina.

The presented problems that may arise due to patents within the pharmaceutical industry and potential solutions to these issues have been discussed. It has been highlighted that the nature of any market, and the potential benefit that can be received from pharmaceutical products, may be better balanced through a different system. Simply, the current patent system under TRIPS does not effectively maximize the benefits that can be attained from pharmaceutical products. There have been proposed solutions attempting to maximize pharmaceutical benefits while not jeopardizing incentive for innovation.

Literature Review

3.1 The General Debate

There is a persistent controversy concentrated on IP rights. It is a dispute surrounding the infringement on human rights that might be caused by implementing or not implementing international IP rights over pharmaceutical inventions. One side of the debate comes from a capitalist-neoliberal perspective highlighting the grave importance patents have to property rights. This side further advocates for 'private competitive enterprise' as well as the right an individual has to 'the fruits of their labour' (Hettinger, 1989, 31, 37). The opposite side of the debate, a human rights approach to patents, deeply questions the violation of human rights produced by patents, particularly of citizens located in underdeveloped countries (Hestermeyer, 2007, 46). There is the belief that generating great profits is currently being prioritized ahead of positively impacting global health. Additionally, there are scholars who attempt to find a middle ground, endeavoring to design a system to replace patents with the ability to appease both sides of the debate - making drugs more available to the underdeveloped world while at the same time generating the profits necessary for the incentive to innovate. The following literature review will go into further detail of the debate, concluding with an analysis of the contentious implemented solution put forward by the Argentine government.

3.2 Pro-Patent Literature

IP rights have recently become relevant in the global trading arena due to the inclusion of IP rights by the WTO within their TRIPS agreement (Xiong, 2012, xiii). The

objective of the agreement is to enforce the needs of both public interests and private rights. According to Law Professor Ping Xiong, the justification of patents has been driven by several different theoretical approaches including the moral argument, the economic argument, and the incentive argument (Xiong, 2012, 66).

The moral argument dates back to John Locke holding the view that an individual should have a natural property right regarding any product of that individual's labour, if the product is not already appropriated (Xiong, 2012, 66). It is thought that if an individual's invention were useful to society, justice would require that individual to obtain a reward. Hegel and Kant put forward a somewhat similar approach to property rights harnessing the fulfillment of individuals' rights and satisfying social and moral obligations. Under this approach, human fundamental needs require private property rights. An inventor is permitted to private property rights which is enforced by their contribution to human prosperity (Xiong, 2012, 67). Society is morally and socially obligated to grant these rights because it, in turn, is benefitting from new inventions.

There are several avenues used to justify IP rights in the form of patents using an economic based argument. It is believed by most economists that an inventor will not disclose a creation or absorb costs associated with R&D without any IP protection (Xiong, 2012, 68). Seeing that it is required of the inventor to disclose the formula or invention once a patent is granted, the public benefits from the publication of the formula or invention. An invention or formula may contain an advancement in knowledge or technology that could be harnessed to benefit society in other areas. The potential reward that may be acquired by an inventor from IP rights creates an incentive to disclose the technology or information used in the making of their product. This is in the best interest

of the public due to the potential benefit that could be attained through the disclosed information (Xiong, 2012, 68). Additionally, the economic argument justifies patents claiming that the patent system positively contributes to the competitive economic advantage of a country (Xiong, 2012, 68). On a global scale, this would promote technology transfer from developed countries to underdeveloped countries by having a strong IP system encouraging foreign direct investment (FDI) (Xiong, 2012, 68).

Closely related to the economic argument is the incentive argument in favour of patents. The argument states that IP rights, particularly patents, provide incentive for innovation and invention. The incentive, which is the possibility of great reward, drives a willingness of inventors to fund R&D costs supporting the invention (Xiong, 2012, 68). An increase in investment of R&D will increase the amount of inventions created as well as the potential for improved public benefit. The social planning theory and utilitarian approach to IP rights supported by economist William Landes and legal theorist Richard Posner also falls under the incentive argument. The social planning theory calls for a system of IP rights that cultivates a 'just and attractive culture' (Xiong, 2012, 69). Further, the utilitarian approach requires a balance to be achieved between the exclusive patent rights driving the formation of inventions and the extension of public welfare. The enforcement and creation of a system that fulfills these requirements regarding the 'allocation of wealth and resources' is the responsibility of the government and lawmakers (Xiong, 2012, 69).

Xiong, while drawing on many theorists, explains that all three of these arguments justifying patents highlight similar points. Benefits can be gained from a patent system in regards to securing moral rights, increasing access to public goods by means of the

disclosure policy and through promoting FDI with technology diffusion (Xiong, 2012, 69). It is believed that the current patent system has the ability to meet these requirements.

Lawyer Edwin Hettinger does not ignore the complexity of determining ownership rights over nontangible information. However, he emphasizes the increasing significance and importance of IP as a form of ownership (Hettinger, 1989, 31). The emergence of the post-industrial society has led to the increasing importance of secure IP rights. This is due to the critical importance of the production and use of information and technology in the post-industrial era (Hettinger, 1989, 31).

An inventor is faced with a choice once a new product is developed. She is able to keep the formula or invention as a 'trade secret' resulting in no disclosure or public benefit, or she is able to acquire a patent where disclosure is a requirement allowing the public to reap benefits from a possible advancement in technology (Hettinger, 1989, 33). It is in the best interest of the general public to make attractive the option of acquiring a patent for inventors. Advantages that come with obtaining a patent include protection against reverse engineering as well as the exclusive right to make, use, and sell the invention allowing for the maximization of benefits for the inventor. It is noted by Hettinger that the exclusive rights provided to an inventor by obtaining a patent can be hard to comprehend, seeing that several different manufacturers could concurrently possess and use the same IP without impeding on personal use by the inventor. However, the problem is that liberal sharing of IP deprives the inventor of potential profit (Hettinger, 1989, 35).

Patents and other forms of IP rights require full public disclosure of the invention, which guarantees the inventor is not given the exclusive right to utilize the knowledge and information. Hettinger argues that this disclosure is necessary for significant public advantage. Patents increase the likelihood of disclosure of new inventions, enhancing the distribution of information and ideas.

Drawing again from Locke, Hettinger asserts the most powerful justification supporting IP rights that 'people are entitled to the fruits of their labour' (Hettinger, 1989, 36). Inventors create ideas with their personal intelligence and effort. Hettinger argues that a person is inseparable from their labour. Therefore, if individuals have ownership of their bodies and what their bodies produce, they should also be entitled to ownership over the products of their labour. Additionally, private property and property ownership can contribute to sovereignty and individual autonomy, which is valuable in our society according to professor Ronald Dworkin (Hettinger, 1989, 45).

To further emphasize the Utilitarian justification for patents, Hettinger states that if there were no IP rights, then it would be in the best interest of firms and individuals to retrieve the ideas created by others without restriction as opposed to investing the time, energy, and money necessary for R&D (Hettinger, 1989, 48). There would be a lack of incentive to participate in the original development of new technologies or inventions. Public advances and benefits are created through the advancement of technology and new ideas. Creating a system that fosters and encourages original development is in the best interest of human kind and would involve the enforcement of property rights. This utilitarian argument focuses on the public users of IP rather than the developers (Hettinger, 1989, 48).

An article published in the *Journal of International Economic Law* by Henry Grabowski argues that IP rights are significantly more important to the pharmaceutical industry when compared to other technology intensive industries. This is because R&D costs within the pharmaceutical industry are extremely high and generic or imitation is comparatively low, making the industry vulnerable to 'free-rider' issues (Investopedia, 2015). Federal Trade Commission members Roy Levy and Abraham Wickelgren argue that due to the substantial contribution to human welfare that is produced by the pharmaceutical industry, fostering competition within the industry becomes significantly more important (Grabowski, 2002, 849). Further, Grabowski argues that IP rights, specifically patents, have contributed to increased access and development of new pharmaceuticals.

Higher importance is placed on patents in the pharmaceutical industry due to the intensive process required to formulate a new drug, typically costing several hundred million dollars. Providing the developers with a patent better situates them to make back the R&D costs by granting exclusive rights to make and sell the drug. Without patent protection, others would be able to obtain the formula, manufacture and sell the drug without having to pay for the R&D costs. It is also noted that having an 'effective patent life' is important from an economic perspective, since earning a positive return from a new pharmaceutical invention takes many years. The point of time from which a patent term begins is from the time the patent application is filed. After this point, the drug is not on the market immediately and must first go through years of clinical trials (Grabowski, 2002, 852). These necessary procedures prevent a patent holder from receiving financial compensation for the entire length of a patent.

The patent system provides competition within the pharmaceutical industry that cultivates incentive to innovate and produce social returns. The patent system is a public policy instrument used to balance the transactions between the brand name and generic industry competition. Grabowski argues that without a strong patent system in place, the rate at which either the generic or brand name industry would be able to grow would decrease. Further, innovation would decline considerably harming both the developers and the general public (Grabowski, 2002, 853).

The main justifications for IP rights, specifically patents, have been explored. These include employing a strong patent system to respect the moral rights of individuals, increasing access to public goods, and promoting FDI and technology spillover from a moral and human welfare perspective. From an economic perspective, patent enforcement is crucial due to the ability to encourage competition within the pharmaceutical industry allowing for a rapid rate of drug innovation as well as providing the incentive needed to inspire innovation. Finally, Grabowski argues that patents are specifically important for the pharmaceutical industry simply because of its nature. IP rights are an effective way to generate the amount needed to finance drug development and the expiration of these rights promoted further social benefit. These theories claim that the IP rights system, including patents, is an effective avenue used to find the balance between the business and public welfare embedded in the pharmaceutical industry.

3.3 Anti-Patent Literature

The other side of the pharmaceutical patent debate will now be explored. Arguments that contest the current patent system will be examined. They directly oppose

justifications for the current patent system and will be followed by implications faced by developing countries caused by patents.

As mentioned in the previous section, the TRIPS agreement, which is the main model for patent control, aims to strike a balance between the protection of private rights and public welfare. The TRIPS agreement provides a strong monopoly position and control over the price of medicines for patent holders (Xiong, 2012, xiii). Monopolization in the pharmaceutical market directly affects public access to pharmaceutical products if drug prices are inflated. This is an issue with the current TRIPS agreement that puts IP rights, specifically patents, in conflict with the fulfillment of the aspirational right to health. According to Xiong, the right to health as a basic human right would require access to pharmaceuticals as well as a human rights treaty to protect and fulfill that right.

Xiong points out that the patent system is able to foster public access to formulas through the disclosure requirements. However, international trade and investment can potentially obstruct the sharing or transfer of the technology by means of high pricing and 'research blocking' used by the monopolizing companies. Thus far, each side of the IP rights debate has touched upon the same issue: if IP protection is not strong enough, there is a risk that it will not result in more creations and innovation. On the other side of the coin, if protection is too strong, there is a risk that public access will be hindered and corporate profit making will remain the priority (Xiong, 2012, 69).

Is it argued that the current patent system under the TRIPS agreement prioritizes potential profit gain ahead of the global population's well being. Hettinger discusses the nonexclusive nature of intellectual objects such as pharmaceutical formulas. This

nonexclusive quality means that formulas have the ability to be in many places at one time and are not consumed by their use. Further, there is no marginal cost of providing an intellectual object such as a pharmaceutical formula because modern technologies are able to keep communication costs low. It is the patent system that prevents widespread access to IP seeing that use by one individual does not impede others from using the same knowledge (Hettinger, 1989, 35). From this angle, the justification for patent protection is the potential for profit by the patent holder, which is problematic when life-saving medicines are being protected.

Our society places considerable value on freedom of thought and expression. The enforcement of IP rights enriches one individual's freedom, however, it is potentially at the expense of the general public's freedom. Privatizing IP places restrictions on the use and expression of ideas. Hettinger cites John Stuart Mill's argument that individual growth and development are dependent on free thought and speech. Obstructing the free flow of ideas does not only risk repressing individual growth but also the progression of technological innovation and knowledge (Hettinger, 1989, 36). Although full public disclosure is required once a patent is granted, protection lasts 20 years. This restricts the use and implementation of new developments used within the protected information for that amount of time.

Hettinger discusses the Lockean theory perspective of IP rights. This view provides a response to the argument in favour of patents that argues inventors are entitled to the fruits of their labour. According to Nozick, it would be near impossible for an inventor to formulate a creation without utilizing ideas or knowledge previously developed. Nozick questions why inventors receive reward for the existing knowledge

they mix their labour with to develop a new creation. In the current patent system, an inventor that obtains a patent reaps the benefits (Hettinger, 1989, 37). These benefits do not just account for the value added to the existing knowledge, but of the total value of the resulting product (Hettinger, 1989, 37).

This view asserts that the way the patent system is operating, it is granting compensation and reward to inventors that are not deserving of it. Therefore, this is not a system that accurately provides credit and reward where it is due. The Lockean theory of IP rights would argue that an inventor is dependent on the thoughts and knowledge that came before her, making IP a social product. Although the value of intellectual products may be solely the outcome of human labour, the value cannot be credited to one particular labourer. Petitioning the market value of a product of labour will not produce a solution, seeing that markets are only effective after property rights have been established (Hettinger, 1989, 38). A possible solution to this particular problem would result from critically analyzing IP rights granted to inventors.

Even if it were possible to isolate the contribution of an inventor and determine the market value of the contribution opposed to the whole finished product, there is no justification to support the position that an inventor's right to the fruits of her labour naturally entitles her to receive the market value for that labour. As described by Hettinger, "market value is a socially created phenomenon," which depends on the activity of other producers, monetary demand of consumers, as well as the enforced property rights (Hettinger, 1989, 38). Disparities in these social factors will alter the market value of the same fruits of labour. Hettinger provides two objections to the argument that an inventor is naturally entitled to the fruits of her labour in the case of IP

rights. The market value is not something produced by an inventor, and the labour argument entitles inventors solely to the product of their labour. Finally, intellectual products are a result of labour from many individuals, all of whom have claims to the market value the same as the last contributor (Hettinger, 1989, 39).

Hettinger critically analyzes Dworkin's argument supporting private property as a means to sovereignty and important for individual autonomy. Hettinger argues that IP rights, such as patents, are not required to fulfill this kind of sovereignty and autonomy. Obtaining the right to exclude others from using an inventor's creation is not an essential component to one's sovereignty. Only obstructing an inventor's ability to use his or her own creation would violate his or her sovereignty (Hettinger, 1989, 45). Additionally, in the majority of current cases, it is not an individual who obtains a patent but a firm. Therefore, arguing that IP protection supports individual autonomy, is not applicable in most cases.

An argument is made against the utilitarian justification for patents, which states that they provide an incentive to innovate and encourage the progress of science and technology. Hettinger emphasizes that the concern with the utilitarian argument is with the security and survival of pharmaceutical firms and the fulfillment of the aspirational human right to health (Hettinger, 1989, 47). The utilitarian argument holds that the survival of private pharmaceutical companies is one worth promoting because the industry tries to increase the quality of human life. Further, the utilitarian argument asserts that permitting property rights to producers is necessary to guarantee enough intellectual products are available to consumers. However, as Hettinger points out, this approach is contradictory insofar as it establishes a right to restrict current access to

intellectual products to harvest an increase in production and future accessibility of new intellectual products (Hettinger, 1989, 48). What would be important to consider is whether or not patents increase the availability of intellectual products more than they restrict it. IP protection in the form of patents restricts the actual usage of an idea and technology transfer.

Philosopher Thomas Pogge and Professor Ahmad Siddiqi argue against the current patent system imposed by the TRIPS agreement. They claim that the current patent system does not produce widespread access to pharmaceutical products, especially to those living in developing countries. Additionally, the current patent system fosters a pharmaceutical industry that is biased in the allocation of R&D funding. Further, the funds that are received by pharmaceutical companies when they sell their products are spent in ways that are inefficient and wasteful. From the point of view of the world as a whole, these three points suggest that a balance has not been achieved by enforcing patents with regard to incentive to innovate and benefits to the public.

Under the TRIPS agreement, pharmaceutical firms are able to patent a new product, which suppresses generic drug competition. In turn, this makes obtaining pharmaceutical products costly. Global enforcement of the TRIPS agreement forces underdeveloped counties to implement stronger patent protection than otherwise would be rational for them to adopt. This allows developed countries to then profit from the affluent population in underdeveloped countries. The key issue with the global enforcement of strong IP rights is that the poorer populations in underdeveloped as well as developed countries are now unable to afford advanced medicines. Without the TRIPS agreement in place, these advanced pharmaceutical products would have been made

available through the generic drug market significantly cheaper. Therefore, the TRIPS agreement causes critical harms to the portion of the population unable to afford the high mark-ups placed upon patented medicines (Pogge, 2011, 2). The portion of the poor population whom does not have the right to health met are devastatingly poor, and the human right to health is imperative for realizing most other human rights. A lack in realizing the aspirational right to health and supporting it result in avoidable harms - harms which contribute to economic losses that are much more costly than taking preventative measures. The benefits that would be observed from meeting the aspirational human right to health would consist of fulfilling moral responsibility as well as generating a greater level of economic prosperity overall (Pogge, 2011, 2).

Siddiqi continues with the assertion that the market system, which patent protection relies on and supports, can be a source of research bias. Patents fail to provide incentive for firms to spend R&D funding on products to treat diseases without a market. Those living in poverty typically experience diseases that may not affect affluent populations. Because these populations do not have funds to buy necessary pharmaceutical products, firms are not concerned with developing such drugs. The lack of market in this case is caused by people being unable to pay the cost of patented pharmaceuticals instead of a lack of need or demand of a particular product. There is evidence that supports the argument that IP protection only minimally plays a role in promoting the R&D of diseases prevalent in the underdeveloped world, if any role at all (Siddiqi, 2005, 4).

Pogge supports the point that the pharmaceutical industry inspires focused innovation slanted by significant economic inequality and the rewarding of the production

of "me too" drugs. "Me too" drugs are almost exact duplicates of existing drugs (Hollis, 2004, 1). A result of this focused innovation is the so-called "10/90 gap" - 10 percent of R&D funding is allocated to 90 percent of the global burden of disease, and 90 percent of R&D funding is allocated to 10 percent of the global burden of disease (Pogge, 2011, TedTalks). Diseases that are prevalent in the developed world only account for 10 percent of the global burden of disease. However, 90 percent of R&D funding is allocated towards treatments for these diseases. Fostering focused innovation is a hindrance to fulfilling the aspirational human right to health, especially for those living in poverty or in an underdeveloped country.

Lastly, both Pogge and Siddiqi agree that the spending of profits achieved by pharmaceutical firms is in some ways both inefficient and wasteful. Justification for the high mark-ups of pharmaceutical products is that the profits made by pharmaceutical firms will be reinvested in further R&D of other pharmaceutical products. This is thought to increase overall innovation and human well being. However, a significant amount of funds attained from pharmaceutical sales is spent inefficiently and not necessarily reinvested into further pharmaceutical R&D. Pogge argues that overall spending efficiency is diminished by practices such as "lobbying, gaming, patenting and litigation, by deadweight losses, and by incentives for wasteful marketing and counterfeiting" (Pogge, 2011, TedTalks). These are practices on which pharmaceutical innovators have an incentive to spend. For example, high mark-ups on drugs allowed by implementing patents encourage innovators and pharmaceutical firms to exert significant effort and money into marketing and improving sales. Further, money goes into lobbying politicians in order to extend patent periods. The entire pharmaceutical industry under the

TRIPS patent agreement is dependent upon mark-ups of non-generic drugs leaving no room for the consideration of the human right to health globally.

The arguments made by Pogge and Siddiqi against patent enforcement begin to scrape the surface of implications the TRIPS agreement creates for developing counties and those living in poverty. Professor Carlos Correa uses several examples from developing counties to make an argument against IP protection as enforced by the TRIPS agreement from a public health perspective. Complying with the TRIPS agreement in the areas regarding pharmaceutical patents and IP rights has generated challenges for developing countries. An issue that has been mentioned previously is the lack of access to pharmaceuticals when a patent holder excludes direct competition and drives up the price of pharmaceutical products. One of the most well known cases of this is with HIV/AIDS medicines in sub-Saharan Africa where life-saving pharmaceuticals were priced out of reach for those who needed them most (Correa, 2001, 381).

Looking at the structure of the patent system, the majority of developing countries are deprived of the benefits that are provided by IP rights. The lack of benefits obtained by developing countries from the patent system is due to the deficiency of scientific infrastructure and capital in developing countries. This infrastructure and capital would be required to invest in R&D and have a flourishing pharmaceutical industry under the TRIPS agreement. Correa argues that developing patentable pharmaceuticals is beyond the capacity of many developing countries (Correa, 2001, 381). A further disadvantage to citizens of the developing world, as Pogge and Siddiqi argue, is that pharmaceutical companies that have the resources to invest in R&D focus on diseases that are most likely

to produce the highest return for their shareholders. This leads to the neglect of diseases prominent in developing countries.

Correa makes an argument against the idea that enforcement of the TRIPS agreement will lead to an increase in foreign direct investment and technology transfer with regards to pharmaceutical invention. This argument is supported with the example of Latin American counties operating within the TRIPS agreement, many of which have experienced the opposite of the intended result. After the implementation of patents on pharmaceutical products, developing countries are denationalizing domestic pharmaceutical companies or simply closing them down (Correa, 2001, 381). The arguments supported by Correa assert that it is true that patents have the ability to motivate costly R&D. However, the globalization of IP rights raises different challenges and outcomes for developing countries in opposition to developed countries.

The Yale School of Public Health makes a case against the TRIPS agreement from the perspective of recognizing global inequality and unequal distribution of power among countries. Currently, under the TRIPS agreement, flexibilities are offered to developing countries to restructure the system of enforcing IP rights in an attempt to create a balance between incentivizing innovation and meeting public health needs. However, the majority of developing countries that are members of the WTO and required to enforce TRIPS make the choice to not utilize the flexibilities made available (Brennan et al, 2013, 6). Previous authors discussed have shown that the enforcement of IP protection under the TRIPS agreement leads to serious consequences, especially for developing counties. The reason for underutilization of the TRIPS flexibilities is pressure placed on developing countries to comply with the TRIPS agreement from developed

countries. The developed countries have the opportunity for significant gains with stronger IP protection. Therefore, pressure is placed on developing nations to obey patent protection with the use of trade agreements, threats to impose trade sanctions, and obstruction of investment benefits. Developing countries are left with little choice to sacrifice perceived quality of public health for perceived economic benefit (Brennan et al, 2013, 46-47).

Further, developing countries often lack the capacity and resources to gain access to compulsory licensing, one of the flexibilities offered by the TRIPS agreement. Compulsory licensing allows pharmaceutical products to become available at lower prices (Brennan et al, 2013, 6). Compulsory licensing is when a government allows for the production of a patented product without the consent of the patent holder (WTO, 2015). The realm of IP protection on a global scale is a system heavily and unequally influenced by developed countries, which already have the upper hand in the area of technology advancement and the ability to afford R&D leading to patentable drugs. This leverage is used to reinforce the inequality observed by forcing developing countries to enforce strong IP rights, an act that will further benefit the developed countries and contribute to the disadvantage of the developing countries.

This section of the literature review has analyzed the anti-patent literature that questions arguments made by supporters of the patent system. The major points made by several authors on this topic assert that the patent system fails at accomplishing its goal of achieving a balance between creating incentive to innovate pharmaceutical inventions and a concern with public welfare. The system under the TRIPS agreement provides temporary monopoly positions for patent holders within the market leading to high

pharmaceutical product prices and further restricts public access to pharmaceutical products directly. The enforcement of patents restricts the usage of an idea and the transfer of technology. Several authors touched upon the argument that IP rights within the patent system are prioritized well above the aspirational human right to health. Patent rights are also giving patent holders and inventors more than what they deserve, as far as the amount of labour that was contributed toward the invented product.

Some of the issues the patent system poses for developing countries already discussed include the lack of access to pharmaceutical products faced by developing countries, the bias toward innovation of developed world diseases, and wasteful spending. Additionally, the protection provided by the TRIPS agreement for patent holders does not provide any significant benefits for developing counties. In fact, they are losing much more than what is being gained. The patent system reinforces global inequality by providing a more global widespread advantage to the developed countries where most patents are held. Although there are flexibilities provided by the WTO under the TRIPS agreement for developing countries, they are not utilized due to 'bullying' in the form of economic threats against developing countries by developed countries.

3.4 Protection Using a Different System

The exploration of the different arguments surrounding patents on pharmaceuticals is not a simple issue. In this section of the literature review, the implementation of a new system replacing or working alongside the patent system will be explored. Those who support the replacement of the patent system typically acknowledge

the problems with the current system and the need for change. However, what is taken from the advocates of patents is the crucial need for the incentive to innovate. There are several different models that have been proposed and those that will be explored include the prize system, funding R&D through public means, implementation of controlled or tiered pricing of pharmaceutical products, and the option that includes encouraging developing countries to ignore or exhaust IP rights.

The reward or prize system is meant to provide the incentive to innovate in a way that does not rely on the market price of brand name pharmaceuticals, while also creating incentive to develop drugs that are the most beneficial to the global society. Economics Professor Aidan Hollis proposes a reward-based system intended to replace the TRIPS patent system. The system would reward innovators based on the incremental benefits provided to society as a result of their product. The goal of this model is to weld together the inventor's incentive to innovate with social objectives (Hollis, 2005, 1). The reward system has money paid directly to the inventor. This provides incentive to develop a product that has the most significant impact on human wellbeing, seeing that the money paid directly to the inventor will increase based on contribution to human welfare. This system has potential to promote the most efficient R&D allocation. Further, it would create a system where compulsory licensing could be granted without compromising the profits of the inventor or company, making drugs more accessible globally, especially to those living in poverty. The government would provide the funding that would reward the innovators. Hollis argues it would be possible to accomplish this by using the reduced expenditures on patented drugs.

Hollis refers to his proposal as the Pharmaceutical Innovation Fund (PIF) and describes a system to replace the use of patents only in the case of pharmaceutical products. Under Hollis's proposal, once a pharmaceutical product in a country is approved, the inventors or company would register the drug with the PIF and receive payments from the fund based on a formula determining how much benefit the product contributes to human welfare. If a company registers its product with the PIF, they would be required to provide licenses to produce their drug in areas that have a demand for it at zero cost (Hollis, 2005, 11).

Thomas Pogge, using a similar model provided by Hollis, also advocates for the reward system. Pogge named his system the Health Impact Fund (HIF) and asserts that privately funded R&D provides an answer to the issue of biased innovation. Additionally, the impact of new pharmaceutical products will be greater if the prices are lower, increasing accessibility. Under the current patent system, Pogge argues that the most profitable research efforts are the ones that contribute the least to alleviating the global burden of disease. New drugs are also often priced out of reach for those living in poverty (Pogge, 2012, 1). The HIF attempts to succeed in these areas where the monopoly based system for pharmaceuticals fails. A reward is offered for each new medicine produced with the requirement of the drug developer to make available their product at cost wherever it is needed globally. Instead of the HIF replacing the current patent system, Pogge presents the HIF as operating alongside the current patent system giving inventors the choice of which system to register their drug with. Simply put, the HIF is an optional pay-for-performance system for new pharmaceutical products (Pogge, 2012, 1).

The HIF is a system that benefits the producer and the potential consumers. By keeping the patent system an option, the market is still open for brand name drugs. Adding the HIF as an option for inventors adds opportunities where profits can be made by creating a system that incentivizes drugs relative to the underdeveloped world. This system would provide a way in which companies could profit from developing drugs for consumers that cannot pay high prices. This system would provide benefits to the global population by increasing access to new pharmaceutical products at the lowest price possible (Pogge, 2012, 1). On a larger scale, the governments and citizens of countries that implement this system would secure significant cost savings on medicines as well as realize declines in the human and economic burdens of disease.

Both Hollis and Pogge take a similar approach to making pharmaceuticals more accessible using a prize or reward system. In the case of both the PIF and the HIF the focus is to connect the inventor's incentive for developing new pharmaceutical products with new drug development relevant to the developing world. It is a system that would increase human welfare benefits while not compromising the incentive to innovate.

The model involving tiered pricing or a compulsory licensing framework is based on the average income of a country and the burden of disease when determining the price of pharmaceuticals in a given country. There are two possible ways in which the pricing could be determined - by patent-owning pharmaceutical companies setting the prices that would not be binding, or have prices be determined by an international organization such as the WHO. Gorik Ooms *et al* examine a model where tiered pricing would be arranged under WTO governance. If adopted, this would be done through the use of compulsory licenses and would be binding. Compulsory licensing in this case would refer to a legally

sanctioned government action requiring a patent owner to allow other companies to manufacture and distribute a generic version of the patented product (Ooms *et al*, 2014, 5). Additionally, the tiered pricing determined by the WHO in this case would mean the exercise of setting different prices for the same product for different groups of potential consumers.

Ooms *et al* favours a tiered pricing system over compulsory licensing seeing that compulsory licensing does not secure lower prices of pharmaceuticals unless the country receiving the license has domestic manufacturing capacity. When a compulsory license is issued, it is only valid within the territory of the government that obtained the license and can only be used to fulfill domestic demand. Therefore, if there is no domestic manufacturing capacity, it is very difficult to obtain the pharmaceutical products. Based on this issue, the use of compulsory licensing does not fully address the issue of scarce access to pharmaceuticals being experienced by developing countries. Implementing a system of tiered pricing would be intended to fall between the unaffordable prices pharmaceutical products are set at, and the use of compulsory licenses issued by governments disapproved by the patent holder (Ooms *et al*, 2014, 6). Ultimately, what would be required for a tiered pricing framework would be the adoption of the framework by an organization such as the WHO, enforcing tiered pricing on an international level. This would also make the WHO in charge of determining the prices of pharmaceutical products (Ooms *et al*, 2014, 6).

There are different models of tiered pricing, however, the goal of the general framework is to expand access to pharmaceutical products globally by controlling the prices of available pharmaceuticals and lowering them to put them in the reach of citizens

in developing countries. This is a model that addresses the issue of unaffordable medicines in the current patent model. However, it does not address the issue of biased R&D funding allocation. In practice, this model has had major problems. Therefore, it will not be explored further. According to Moon at al, tiered pricing produces economic and political drawbacks. This system does not necessarily result in the lowest sustainable prices and does not guarantee lower prices over time. Under this system, the decisions are left in the hands of private companies and no power is given to government, causing little leverage for citizens to make demands (Moon et al, 2011, pg.9).

Another suggested model to replace the current TRIPS patent system is funding R&D through public means. This framework would plan to finance R&D of pharmaceutical products through a tax or tax-like instrument that is raised at the national level (DiMasi *et al*, 2004, 4). Each country, including developing countries, would be required to raise a predetermined amount that would become the R&D budget. It would be a fixed percentage of a country's Gross Domestic Product (GDP). This system would replace the current patent system and would allow newly developed pharmaceutical products to be made available at generic drug prices immediately (DiMasi *et al*, 2004, 4). This model takes the business and profit chasing aspect out of pharmaceutical innovation and reduces the need for high mark-ups on pharmaceutical products.

The final alternative solution to patents that will be discussed is the exhaustion of international IP rights by developing countries. The WIPO describes the term international exhaustion as the process by which a country does not acknowledge IP rights of a product once it has been initially sold by the patent holder (WIPO, 2015). This is a grey area within the WTO's TRIPS agreement, which states, "Nothing in this

agreement shall be used to address the issue of the exhaustion of intellectual property rights." It offers no promise of punishment for countries that implement such administrations, although such a system is discouraged (Kyle, 2009, 340). Implementing this system makes patent holders vulnerable to actions such as parallel importation as well as reverse engineering. Reverse engineering is a process where, without the release of the pharmaceutical formula or process, a pharmaceutical product can be duplicated or a similar drug can be developed (WHO, 2015). This can break the monopoly that a patent owner holds over a market. Additionally, parallel importation refers to the importation of pharmaceutical products from a source that is not the patent holder and typically costs much less (WHO, 2015).

Countries would implement this kind of system, which is controversial under the TRIPS agreement, in order to provide their citizens with the necessary pharmaceutical products. Developing countries often lack the initial capital required to invest in R&D in order to formulate new patentable drugs leaving them at a disadvantage under the TRIPS agreement, seeing that new pharmaceutical products will not be made available to them at reasonable costs. The system of IP right exhaustion makes it possible to have pharmaceutical products available to poorer people, something that is not possible under the current system.

3.5 Conclusion

The material analyzed in this literature review presents significant arguments related to this thesis and related to the debate surrounding pharmaceutical patents. The review began with discussing literature that supports the current patent system under the TRIPS agreement. What can be taken away from this section is the apparent need for

incentive to innovate. However, the section following pro-patent literature examined arguments that highlight the failures produced by the current patent system. The major assertion that should be taken away from the anti-patent literature is that the patent system fails at providing a balance between profit-making incentive to innovate and the increase in human welfare that can be achieved by pharmaceutical products. Therefore, a system needs to be implemented that produces the incentive for pharmaceutical firms and inventors to want to innovate while maximizing the benefits that can be obtained from pharmaceutical products. Different alternative solutions to the current patent system have been proposed and the major models have been explored in the third section of the literature review. The prize system proposed by Thomas Pogge is seemingly the most promising, seeing that it addresses the major problems with the current system and offers a plausible solution to benefit producers and consumers of pharmaceutical products. However, until such a system is implemented, there is a critical need for widespread access to pharmaceutical products making the exhaustion of IP rights by developing countries an attractive short-term solution.

The following chapters will explore in more depth the TRIPS agreement followed by a case study of Argentina and the results that have been achieved by international IP rights exhaustion as far as public health and economic growth.

The TRIPS Agreement

The patent system was first enforced and adopted within developed countries but, through the application of the WTO's TRIPS agreement, the application of the North American-based patent system has become global. The TRIPS agreement has different effects on developed and developing countries. All countries are subject to the same requirements, putting the developing countries at a disadvantage for several reasons. This chapter will give an overview of the requirements of the TRIPS agreement, the WTO's objective, and the flexibilities offered within the agreement. Further, the effects TRIPS has had on developed versus developing countries will be explored followed by some countries' to the agreement's outcomes.

4.1 Details of the TRIPS Agreement

The TRIPS agreement is considered a controversial contract involving international IP rights. This is because of the combative negotiations that took place to give birth to the agreement. Also, the agreement attempts to bind together the differing perspectives of developed and developing countries when it comes to the role of IP rights (Yu, 2009, 1). Although the agreement was negotiated and came into effect in 1995, developing countries have still, in recent years, expressed discontent with the way the agreement has been understood and executed. Developing countries claim that they have been commanded to do things above and beyond what was negotiated in the TRIPS agreement. Often these excess demands are a segment of newer bilateral and regional

trade agreements. The problem is that the TRIPS agreement and excess demands ignore the local needs of developing countries, national interests, technological and institutional capacities, and the crucial health conditions of developing country populations (Yu, 2009, 1).

The TRIPS agreement is seen by some as a one-size-fits-all solution to implementing international IP rights. This contributes to the agreement not meeting its objectives as well as not increasing availability of pharmaceutical products to the global poor. However, the TRIPS agreement has attempted to counteract any inequalities felt by developing countries by offering flexibilities (Yu, 2009, 1). The purpose of these flexibilities is to further meet public interest and to facilitate development. The flexibilities usually result in pharmaceutical products being made available for a cheaper price in some areas. Further, the flexibilities are meant to strike a balance between the benefits gained by implementing international IP rights as far as creating incentive to innovate and meeting the public need for life-saving medicines.

The objectives of the TRIPS agreement are to be achieved through the implementation and enforcement of international IP rights. The objectives include promoting technological innovation and to further the transfer and dispersion of technology among countries. Additionally, there should be mutual benefit experienced by both the producers of patentable material and the consumers of the technological knowledge and products. This mutual benefit is intended to be instrumental in promoting both economic gain and social welfare. The final written objective of the WTO's TRIPS agreement is for the enforcement of the agreement's requirements to meet and fulfill necessary human rights (UNCTAD, 2004, 118).

Along with providing a written objective, the TRIPS agreement also includes an objective and two principles with the intended goal to acknowledge the responsibility of meeting specific rights and moral obligations. The first principle states that WTO member countries, once implementing and formulating the TRIPS agreement requirements in their own country's laws, are able to embrace the necessary measures to meet public health needs. Further measures can be taken to promote the public interest in sectors that are critical to socio-economic and technological development. However, these necessary measures must be consistent with the provisions of the TRIPS agreement. The second principle states that appropriate measures are encouraged within the boundaries of the TRIPS agreement to prevent any abuse of IP rights by patent holders. Necessary measures can be taken to prevent practices that arbitrarily restrain trade or practices that unfavorably affect the international transfer of technology (UNCTAD, 2004, 118).

The objective and principles of the TRIPS agreement are presented in Articles 7 and 8. They were developed in order to fill the gap that is present in the view of the purpose of the TRIPS agreement found among different countries. It is argued that these articles are a reflection of the tensions felt while the negotiation of the agreement was taking place. One of the concerns of developing countries that has been expressed is that the developed country members are only enforcing one side of the agreement. The side that is being referred to is the protection of technology assets, while the stated principles assert that the protection and enforcement of IP rights is intended to contribute to the transfer of technology. The benefits reaped by a single country is intended within the agreement to be prioritized behind the transfer of technology between countries

(UNCTAD, 2004, 119). When development of a country is placed ahead of technology transfer, the arbitrary use of international IP rights is more likely. This would place the developing countries involved with the agreement at a disadvantage because they do not have the same technological knowledge and advancement as the developed countries. International IP rights that are too strong would prevent developing countries from attaining the critical technological knowledge.

There are three main sections to the TRIPS agreement, which include standards, enforcement, and dispute settlement. The standards section of the agreement refers to the minimum requirements of IP protection that member countries are obligated to enforce. In the standards section, each of the key forms of protection are defined, including what subject matter is eligible for protection, the rights that are to be granted, as well as allowable exceptions to given rights, and the duration of protection established. These standards were formed using the fundamental obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property, and the Berne Convention for the Protection of Literary and Artistic Works. Only with the exception of the moral rights provisions found in the Berne Convention, the main provisions of these conventions have been adopted and become obligatory under the TRIPS agreement (WTO, 2015). Alongside the adopted provisions, during the TRIPS negotiations a significant amount of other obligations were implemented in areas that were seen as inadequate in the WIPO's Paris and Berne conventions.

The second major section of the TRIPS agreement focuses on issues of enforcement. This includes another set of requirements that are concerned with domestic measures and processes implemented for the enforcement of international IP rights. Each

WTO member country is required to pass legislation to administer the minimum requirements of the TRIPS agreement. The purpose of the provisions in this section of the agreement is so that holders of IP rights are able to effectively utilize their rights through the implementation of required laws and infrastructure.

The third major section of the agreement deals with disputes regarding IP rights between WTO members. These disputes are typically regarding compliance of the TRIPS obligations and follow the WTO's dispute settlement procedures (WTO, 2015).

The agreement as a whole outlines the minimum standard of IP rights that must be obeyed by member countries followed by a description of how these rights can be enforced by each individual country. Finally, an outline is given of the possible disputes that may arise between countries regarding international IP rights and how they might be resolved through the WTO. According to the WTO, the agreement also incorporates safeguards against practices such as national and most-favored-nation treatment, as well as some general policies to make sure IP rights do not impede any benefits that should be a result of the agreement. All member countries must abide by the same rules under the agreement. However, developing countries have been given a longer period of time to integrate the TRIPS requirements domestically. It is further noted that, in the special case of pharmaceuticals, there are some transition arrangements that are in operation in cases where a developing country has not applied product patent protection to enhance availability. As mentioned previously, all member states must implement the TRIPS minimum standards regarding IP rights, however, they are permitted to provide more extensive IP rights.

A discussion of specific general provisions required of the member countries will be given followed by patent protection as outlined within the agreement. The main obligation of all member countries is that the application of the minimum standards regarding IP rights must be met domestically. This obligation must be fulfilled internationally in cases of other member countries as outlined in Article 1 of the agreement (WTO, 2015). This obligation extends IP protection beyond having protection applicable only in the country it was originally granted, and extends it throughout all member countries. Articles 3, 4 and 5 include rules regarding national and most-favored-nation treatment of foreign nationals. The national treatment clause within the agreement prohibits discrimination between member country's own nationals and those of another member country's nationals. The most-favored nation clause similarly "forbids discrimination between the nationals of other members" (WTO, 2015). There are some exceptions that apply to these clauses and are also outlined within articles 3, 4 and 5. The objective and principles of the agreement have already been outlined, however, the agreement also puts forward goals. These goals include influencing a reduction in obstructions or barriers to international trade, the promotion of effective implementation of international IP rights, and that the measures taken to promote IP rights do not themselves become obstacles to legitimate trade.

The particular section of the TRIPS agreement that is important to this thesis are the provisions surrounding patents. WTO member countries are required under the TRIPS agreement to make patents available to any inventions including finished products and processes in all technological fields. All new inventions or processes in the technological field must still apply to attain a patent and undergo the same tests before a patent is

granted. Further, it is required that patent attainment be made available and patent rights enforced regardless of the country where the invention was produced and whether a product is imported or domestically produced (WTO, 2015).

There are three exemptions to the rule of patentability outlined in the agreement that can be found in Article 27. One is not able to obtain a patent for an invention or process that is in conflict with morality, including inventions dangerous to humans, animals, vegetation, health, and inventions that are directly detrimental to the environment. This exception to patentability is not just to prevent the marketing of a harmful product but also the manufacturing of a harmful product. It is for the safety of the public. The second exception is available for member countries that wish to exclude diagnostic, therapeutic, and surgical methods from being patented. The third exemption to patentability is the choice of member countries to exclude plants and animals (with the exception of micro-organisms), as well as any biological processes used in the production of plants and animals. However, if a member country decides to exempt product and processes of this nature from patentability, they are required to provide an alternative system of protection other than patents.

Once a patent is offered to an inventor, the rights that are granted must include the rights to manufacturing, using, marketing, the process of selling, and exportation for these purposes. When a patent is granted over a process, protection is required to include rights over use of the process, but also over products obtained and manufactured directly from the patented process. Although all of the rights are granted to the creator or patent holder, the use of licensing through contract is permissible where the patent holder would allow a company to manufacture a patented product through the use of a licensing contract.

Additionally, the agreement states that member countries are authorized to provide, for a limited period of time, exceptions to the exclusive rights awarded through patent attainment. Although, if a member country grants an exception to the rights patents offer over a product, it is required that any exceptions do not irrationally conflict with a normal exploitation of a patent and do not unreasonably discriminate the practical interests of the patent owner. Typically, this would be implemented in cases where legitimate interests of third parties are not being met.

When a patent is granted, it is valid for 20 years from the time the patent was filed, not necessarily from when the product is marketed. All member countries must require the applicant for a patent to disclose the invention or process. When the invention is disclosed it must be done in a manner that is adequately clear and complete so that someone skilled in the field would be able to replicate the product or process. If it is a process instead of a product being patented, it is allowable that the judicial authorities require an inventor to "prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating a likelihood of a protected process was used are met" (WTO, 2015).

The TRIPS agreement offers some flexibility, which includes exceptions to the agreement in some cases to developing countries in order to increase the possibilities of countries being able to fulfill human rights and moral obligations. One form of flexibility offered is the use of compulsory licensing or approval by the government to manufacture a patented product without the authorization of the rights holder. The use of compulsory licenses must be utilized only in the case of certain circumstances and is crucial in the case of pharmaceutical products. The use of a compulsory license is allowable if the

legitimate interests of the public are at risk without access to the patent product. A country is obligated to grant such licenses only if an attempt to acquire a voluntary license with reasonable terms and conditions from the patent holder was unsuccessful. Once a compulsory license is granted, it is only valid for a rational, not unlimited, amount of time. Additionally, there is a requirement on the government to pay sufficient compensation to the patent holder whose product had received a compulsory license for production. Compensation is based on the determination of the economic value of the license and any decisions are susceptible to judicial or independent reviews by a recognized higher authority (WTO, 2015).

Article 40 of the TRIPS agreement provides some recognition that licensing practices and conditions of IP rights have the potential to be harmful by means of restraining competition. Restricting competition through IP rights, in turn, can negatively effect trade and hinder the transfer and diffusion of technology. Because this potential exists, WTO member countries are able to adopt appropriate processes to inhibit or increase control over the licensing of IP rights that may be anti-competitive. Any measures adopted must adhere to the other provisions of the agreement. There is a structural process provided by the agreement where countries that are seeking to take action against anti-competitive practices being implemented in other member countries are able to do so. Member countries are able to enter into consultations with one another, bringing into the conversation information that has been made publically available and is non-confidential that is relevant to the issue at hand. The information will be reviewed and subject to domestic law and also to the conclusion of mutually acceptable agreements. The mechanism provided is a structure that is seemingly safe and regulated.

It can be used as a platform to solve any conflict or disagreement between member countries that might have formed through the globalization of IP rights.

The major requirements of the TRIPS agreement that pertain to the property rights over pharmaceutical products have been briefly outlined including the solutions implemented into the agreement to balance the inequality between developed and developing countries. The next section will include a critical analysis of the TRIPS agreement and potential problems the application of TRIPS can cause for developing countries.

4.2 Complications of the TRIPS Agreement for Developing Countries:

Prior to the implementation of the WTO's TRIPS agreement, the level of IP protection and the enforcement of IP rights varied greatly around the world. These differences, prior to the signing of the TRIPS agreement, became a point of conflict in international economic relations. With an attempt to bring IP rights under common international rule, several WTO member countries were faced with many challenges in formulating their national IP strategy and policies that adhere to the introduced TRIPS requirements (Mathur, 2007, 1). Somesh Mathur argues that there are potential problems embedded within the TRIPS agreement, with heightened concern for developing countries. One predominant concern with the agreement in general is that the outcome will result in efficiency losses. For example, providing pharmaceuticals at a much higher price might counteract any benefits gained from influencing a greater amount of R&D (Mathur, 2007, 21). If pharmaceuticals are priced out of the reach of many people who need them, the benefit thought to be gained through increased R&D and the development of more drugs might be diminished. An additional concern is that if the length of a patent

is excessive, there is potential for more harm to be done than benefits gained by restricting access to pharmaceutical products. It is also a concern for developing countries that the TRIPS agreement does not effectively provide a balance between the rights of those producing the pharmaceutical products and the rights to the consumers or those in need of the products (Mathur, 2007, 21).

To go into more detail, the agreement poses several problems for a significant number of developing countries that have an agricultural based economy. Countries that have an agricultural based economy often suffer the consequences that a strong patent system is unlikely to provide incentive for local innovations and R&D due to the lack of technological infrastructure. The position most developing countries are in does not allow for the implementation of the TRIPS agreement to provide significant benefits. This is mainly due to the lack of domestic patented pharmaceuticals. Instead, a weight is placed on the poorer populations because they have less access to pharmaceutical products. Further, developing countries have faced challenges in implementing the required commitments required by the TRIPS agreement. Mathur notes that making changes to the requirements of the agreement in order to enhance development is unlikely. This is due to unequal power, putting developing countries at a disadvantage and the strength of vested interests developed countries have in implementing international IP rights globally. It is strongly argued by governments and businesses of the developed world that the implementation of strong international IP rights will result in economic growth and a reduction in poverty globally. However, IP rights affect developing countries differently than developed countries. Consequently, it is argued by most developing countries and some NGOs that IP rights provide little benefit to

developing countries, mainly due to a lack of technological capacity being present. Not only are little to no benefits being experienced, developing countries find themselves at a loss because of the cost increase of essential medicines (Mathur. 2007, 22).

Developing countries are noticing a significant pressure to increase the levels of IP protection implemented domestically. This pressure is felt through the demands of the TRIPS agreement, and above and beyond the TRIPS requirements in the form of bilateral or regional trade agreements involving developed countries. The pressure is driven by developed countries receiving significant benefits from increased IP protection, seeing that they are technologically rich. Carlos Correa supports the concerns of developing countries with regards to the TRIPS agreement for several reasons. First, it is not apparent that increased levels of international IP protection do not correspond with significant increases in FDI or technology dissemination to developing countries. It is observable that the benefit of implementing IP rights is the promotion of incentive to innovate due to the granted monopoly to patent holders and the astonishing profits that can be made. However, in order for a country to feel the benefits of IP rights and protection, an effective technological infrastructure must exist at a national level, which is not common in developing countries. Additionally, the evidence supports the view that the majority of benefits of IP rights fall to a small minority of successful large companies. Due to the high cost of litigation, IP protection is biased in favour of large corporations (Correa, 421).

Second, Correa argues that in some industries strict IP rights act as a barrier to technologies instead of promoting their accessibility. This barrier is particularly present for the global poor and notably observable in the case of pharmaceutical products. Patent

protection under TRIPS in the case of pharmaceuticals allows for pharmaceutical manufacturers to demand higher prices than where the price would fall in a competitive market. The prices of pharmaceutical products determine how many people will die from diseases in the years to come.

Third, any issues with compliance of the minimum standards of the TRIPS agreement are to be dealt with under the provisions of the WTO. Further, any adoption of independent trade sanctions by a WTO member country is not permissible by the WTO's rules. However, developing countries are pressured by independent demands of developed countries, mainly the US and the EU, to implement IP rights that go above and beyond the minimum standards of the TRIPS agreement (Correa, 422). There is a lack of enforcement of the use of unilateral pressure by the WTO. It is common for developed countries to threaten to remove trade preferences that go past WTO commitments or threaten to remove development aid to developing countries in order to pressure them in implementing more secure IP rights (Correa, 423).

Fourth, it is outlined in Article 66 of the TRIPS agreement that developed counties have an obligation to provide incentives to companies and institutions to promote the transfer of technology to developing countries. Correa argues that this obligation remains unfulfilled and that developed countries should be obligated to aid developing countries in building an effective and viable technological base.

Developing countries that are WTO members have the general belief that they are not observing significant benefits from the agreement, and concerns that were raised in the Uruguay Round have not been addressed (Correa, 423). The development and access of technologies have remained unequal and the gap is possibly growing between

developed and developing countries. Because of the far-reaching implications of the TRIPS agreement, especially for developing countries, the agreement is one of the most controversial mechanisms of the WTO. After the requirement of developing countries to implement the minimum requirements of the TRIPS agreement, it has been realized that there are not many benefits to be obtained. The global poor are feeling the costs of the TRIPS implementation (Correa, 420). The concerns developing countries have brought to the attention of the WTO have not been adequately addressed during the Uruguay Round and some countries have taken it upon themselves to implement various solutions. In some cases, the solutions are within the provisions of the TRIPS agreement. However, solutions such as compulsory licensing and parallel importation are discouraged by developed countries. In other cases, countries have stepped outside of the provisions of the TRIPS agreement for the purpose of public health and meeting human rights that could not be fulfilled when implementing the TRIPS requirements. The next section will discuss briefly some of the actions taken by developing countries in response to the consequences of the TRIPS agreement.

As mentioned in the literature review, there are several avenues that have been taken by developing countries to make pharmaceutical products more accessible to their citizens. These include taking action that is permitted within the TRIPS agreement after the Doha Round, including the use of compulsory licensing and also parallel importation. These allowances within the WTO laws are somewhat unclear in the agreement. There are no concrete guidelines for when these flexibilities can be implemented and in what ways (Sykes, 2002, 7). These flexibilities have been enforced under different circumstances in several developing countries, and decisions to implement these

flexibilities are frowned upon by most developed countries, due to the fact that practicing the flexibilities may hinder potential profits. There is also action that can be taken by developing countries that is not within the provisions of the TRIPS agreement. However, taking this route has potentially severe legal consequences.

The four main options available to developing countries are: utilizing parallel importation, compulsory licensing, IP right exhaustion, and reverse engineering. Parallel importation refers to the phenomenon where a patent holder initiates tiered pricing - selling a patented product for a lower price in some countries. A country that is being charged the higher price can import the patented product for a lower cost from another country where the original supplier provides it at a lower price. This kind of importation is out of the control of the patent holder. This example also highlights IP right 'exhaustion'. The agreement states that there is nothing that addresses the issue of exhaustion. After the first sale of the patented product, the patent holder may or may not maintain rights over the resale of the product (Sykes, 2002, 7). As discussed earlier, a flexibility offered by the TRIPS agreement is also the use of compulsory licensing, which can be administered with or without the permission of the patent holder in the case of crisis. Because what constitutes crises in the agreement is not concretely defined, some developing countries have fully utilized this flexibility in the case of pharmaceuticals. A good example is India. However, a compulsory license only grants the ability to provide the product domestically and not for the purposes of profit making. These three options mentioned are either permissible by the TRIPS agreement or operate within a grey area of the provisions. However, they are all options frowned upon by developed countries because of the restriction on the amount of profits attainable by the patent holder. The

chapter discussing the case study of Argentina will provide examples of the US filing penalties with the WTO against Argentina for the purpose of scaring them out of utilizing TRIPS flexibilities.

The last solution that will be discussed is the act of reverse engineering performed by developing countries in order to provide patented life-saving medicines to their citizens. This is a solution that is not admissible within the TRIPS agreement provisions. It is in fact something the TRIPS agreement attempts to prevent. The act of reverse engineering involves the unauthorized reproduction of a patented product resulting from the examination and decomposition of the products' construction and composition (Crawford, 2007). The use of reverse engineering requires another company to have the knowledge needed to manufacture a generic formulation of the patented drug and provide it to the people of their country, and possibly internationally for profit. This is not a solution that has been implemented as frequently with the application of the TRIPS agreement now in effect for developing countries. However, this strategy was frequently utilized by India prior to the required implementation of the TRIPS minimum standards applied to developing countries.

The recent required application of TRIPS provisions to developing counties has already brought to light the different consequences that are faced by developed and developing countries because of the TRIPS provisions. It is clear that developing countries do not receive the significant benefits that developed countries receive from the agreement. For the purposes of fulfilling the aspirational human right to health and moral obligation, some developing countries have deviated from the agreement provisions or implemented flexibilities to a level that is discouraged. Argentina is a country that has

implemented some of the discussed solutions to the unequal and disabling TRIPS agreement, mainly that of international IP right exhaustion. The following chapters will analyze the actions Argentina has taken and what kind of effects it has had on the health of their citizens, any economic consequences, and reactions of developed countries.

Case Study: Argentina

5.1 History

Argentina's pharmaceutical industry has a unique history. Some distinctive characteristics that have led to the success of the Argentine pharmaceutical industry include the dominance of 'similar drug' production, domestic company control in the market, and the partnership of the local pharmaceutical companies with the government. Several factors have contributed in the formation of this industry, which will be discussed in this section.

Between 1950 and 1980, an Import Substitution Industrialization (ISI) policy was effective in Argentina. One outcome of this policy was the application of costly tariffs on imported raw materials used in pharmaceutical production, resulting in preference for domestic pharmaceutical products. This led to the expansion of the domestic pharmaceutical industry in Argentina. It was during the ISI period that an environment was created that fostered the growth of an industrial sector composed of local medium-sized companies that achieved significant importance. These three decades of protection allowed the domestic pharmaceutical firms to grow.

Historically multinational companies that have been active in the Argentina pharmaceutical industry have never been stable. The economic crisis that took place in the 1970s resulted in many multinational pharmaceutical companies leaving the country and transferring some of their products to domestic companies. The departure of foreign firms proved to be beneficial to domestic firms with the transfer of technology that took place upon their departure. Domestic firms demonstrated the capacity to fill the gap left by foreign companies. The domestic healthcare system also benefitted from the rising domestic presence in the market because local firms began to cater to domestic health needs. Further, local pharmaceutical companies built strong relationships with the

Argentine government. This contributed to the pharmaceutical companies' political and market capital, making their presence even stronger in the market (Dreyfuss & Rodriguez-Garavito, 2014, 44).

There was little debate over the implementation of pharmaceutical patent protection in Argentina before 1989. Up until this time, the 1864 Patents for Invention Law No. 111 was in effect. This law excluded foreign and domestic pharmaceutical products from being considered patentable material. It stated that the process and composition of pharmaceutical products were considered public goods making them ineligible for patents. Scholars Dreyfuss and Rodriguez-Garavito argue that due to the existing framework in Argentina, including the ineligibility of pharmaceutical products to be granted patents and established industrial policies, a strong and successful pharmaceutical industry was able to emerge (Dreyfuss & Rodriguez-Garavito, 2014, 44). The domestic pharmaceutical manufacturing industry in Argentina at this time was non-research based and thrived on the basis of producing 'similar' versions of foreign-patented drugs. 'Similar drugs' are copies of brand name pharmaceutical products containing the same active ingredient. Argentine firms operating abroad often obtained the active ingredients, otherwise finished drugs were imported and copied (Dreyfuss & Rodriguez-Garavito, 2014, 44). It was much less costly for firms to produce these pharmaceutical products due to the less extensive drug approval process and the initial capital not needed to research and develop the drugs. The 'similar drugs' made available by the Argentine industry were cheaper for the population than the patented brand-name pharmaceutical products. This created competition for pharmaceutical companies in the developed world.

Dreyfuss & Rodriguez-Garavito accentuate that the success of the domestic pharmaceutical firms heavily relied on the production of similar drugs. This type of production excelled due to the lack of IP rights over pharmaceutical products. Domestic pharmaceutical companies were able to market new pharmaceutical products at the same time as the foreign patent holders at much lower prices. This led to high domestic consumption of similar drug variations, and even exportation to some Latin American and Asian markets (Dreyfuss & Rodriguez-Garavito, 2014, 45). For these reasons, foreign drug companies and governments began placing great pressure on Argentina to adopt an IP law for pharmaceutical products to limit 'similar drug' production as well as reduce competition in the market.

The election of Carlos Saul Menem as the President of Argentina in 1989 was accompanied by the debate of implementing patent laws. This was attributed to Menem's strong pursuit of liberalization, privatization, and stabilization, as well as the continued international pressure (Mattson, 2005). The major argument against IP patent implementation was the concern for access to pharmaceutical products for Argentina's poor population. However, the continued success of the Argentine industry and the local population's access to pharmaceutical products was questioned in the 1990s. The General Agreement on Tariffs and Trade (GATT) Uruguay Round resulted in the formation of the WTO and required implementation of liberalized policies and disallowance of industry protection.

In 1995, Argentina became a member of the WTO, requiring the implementation of the minimum requirements of the TRIPS agreement in 1996. For Argentina, this meant creating a domestic patent law that included the protection of pharmaceutical

products. In order to address the concerns of access to pharmaceutical products, Argentina attempted to only provide patents over pharmaceutical processes and did not include protection over finished products. However, in 2000, the National Patent Administration began administering patent protection over pharmaceutical products to appease the TRIPS minimum requirements (Etcheverry, 1996).

The Argentinian domestic pharmaceutical industry started taking a turn for the worse after the economic crisis in 2001. Access to pharmaceuticals became a major problem for the population. The purchasing power of the country decreased disrupting the pharmaceutical expenditure and affecting the drug coverage provided by health institutions (IHS, 2006). In response, the Ministry of Health introduced a new drug policy, which continued to be supported and carried out by the Nestor Kirchner government in 2003 and is still in effect today. The major changes of the drug policy included the exhaustion of IP rights and the promotion of practices such as parallel importation. These policies were implemented for the purpose of increasing access to life-saving medicines for the local population. Promoting social welfare was seen as a priority. In 2002, there was also the establishment of reference pricing for basic medicines, and a law passed requiring all prescriptions to be administered using the generic name of the drug (IHS, 2006). These are policies that are in effect today and will lead into a discussion on the present state and effects of the pharmaceutical industry in Argentina.

5.2 Current State of the Industry

There are several unique characteristics particular to the Argentine pharmaceutical industry that have emerged over the past few decades and contribute to its current

success. These characteristics include the dominant domestic companies, the reliance on similar drug production, and the ability for domestic firms to cater to local health needs.

A small group of both domestic and foreign firms hold the majority of the market share of the industry. There were 15 notable companies operating within Argentina in 2010, nine of those companies being domestic - national companies Bago and Roemmers taking the top two positions (Dreyfuss & Rodriguez-Garavito, 2014, 46). For a larger scope of the market shares, ninety of the one hundred and nine active pharmaceutical companies in Argentina in 2006 were domestic (IHS, 2006). A contributing factor to the success of the domestic firms in Argentina is the support from the government. Domestic pharmaceutical manufacturers in Argentina are provided with benefits from the government, such as favourable tariff protection, giving them an advantage over the multinational firms operating there. An environment has been fostered for domestic firms to flourish, due to the nature of the industry in Argentina. Contributing to this environment is the allowance of the production of similar drugs and other laws and pharmaceutical policies (Taylor, 2013). It is not common for developed countries to export pharmaceuticals to the developing world due to high costs and lack of profit-making potential. Leading to a lack of access to pharmaceutical products in the developing world. Therefore, the exhaustion of international IP rights, parallel importation, and the manufacturing of similar drugs has drastically increased access to pharmaceutical products for citizens in Argentina over the past several decades.

The healthcare system in Argentina is very divided, having national, provincial, and municipal sectors along with public and contributory healthcare options at each level. Household expenses on medicines now account for 30 percent on average. Whereas prior

to 2002, it was much higher accounting for 50 percent of out-of-pocket healthcare expenses (Dreyfuss & Rodriguez-Garavito, 2014, 46). It is proven through health statistics that national pharmaceutical policies implemented in 2002 have significantly contributed to the reduction in health expenses. This is due to various institutions within the healthcare system absorbing most drug expenses. This is largely made possible due to similar drugs being made available at much lower costs than patented brand name drugs. The following sections will discuss what factors contributed to the environment in Argentina that allowed for a successful pharmaceutical industry to develop, as well as economic and health related effects that have resulted.

5.3 The Post Neo-liberal Turn

Latin American countries, including Argentina, have been experiencing a post-neoliberal shift within their governments and policies. This paradigm shift, also referred to as the 'New Left', has led to a change in the role of the state and policies. They are now focused on social inclusion and welfare while also increasing economic growth. Market mechanisms are not forgotten, however, they are not the main focus. The current President of Argentina C. F. Kirchner has explained the post-neoliberal era as a "paradigm shift with society" (Grugel & Riggirozzi, pg.2). Politically, the post-neoliberal shift was a reaction to over-marketization at the end of the 20th century. The most distinguishable feature between neoliberalism and post-neoliberalism in Argentina is the government's attitude to the poor and discourses of citizenship rather than economic management. An area where this shift can be seen is in the pharmaceutical industry. The focus is on providing access to life-saving medicines instead of conforming to the West's

neoliberal model of increased IP rights. The resulting increase in access to medicines has allowed for the implementation of far-reaching health programs in Argentina.

These post-neoliberal policies were implemented after the economic crisis in 2001 and advanced by the Nestor Kirchner government in 2003. Great achievements in areas of economic growth within the pharmaceutical industry and further achievements in health have been observed in Argentina after the implementation of these policies. There are several middle and low-income countries that have attempted to change their national pharmaceutical industries and policies. The most prominent cases are those of Brazil and India. However, these cases differ from Argentina. The contrast between the countries lies in Argentina's focus on social welfare. The relatively new pharmaceutical industries in Brazil and India are not as focused with creating a balance between increasing economic growth and providing citizens with essential medicines. They have taken an approach leaning more toward a neoliberal model and are concerned primarily with economic growth. Their focus is on the global exportation of pharmaceuticals, rather than manufacturing pharmaceutical products catering to the local needs and providing them at affordable costs. These relatively new industries in India and Brazil are not contributing greatly to better health in their own countries because that is not the goal of the industry.

5.4 How the Domestic Pharmaceutical Industry Has Effected Health in Argentina:

The post-neoliberal era has resulted in social welfare policies and programs in Argentina. Health is a major concern when discussing the well being of a population. Several pro-poor health programs and policies have been implemented in Argentina since the 2001 economic crisis. Two major segments of the health care system in Argentina

include the program Remediar and the generic prescription policy. These two implementations will be discussed and the following paragraphs. How the pharmaceutical industry has contributed to the application of the policies and the effects on health that have resulted will be explored.

The shift to post-neoliberalism in Argentina made social welfare programs focusing on health possible due to the change in the pharmaceutical industry. Argentina implemented a far-reaching pharmaceutical intervention through the federal government. The country had gone through a serious economic crisis causing more than 60 percent of people to lose access to health coverage due to the lack of resources and funding for hospitals. During this time, the price of pharmaceutical products rose steeply and many citizens of Argentina were unable to purchase medications. According to the National Institute of Census and Population, in 2002, 60 percent of the population of Argentina could only afford 64 percent of their pharmaceutical needs (Homedes & Ugalde, 2006).

In response to this economic crisis and the issues people faced not being able to purchase life-saving medicines, the Argentine Government launched the pharmaceutical intervention called Remediar. Remediar translates in English as “to cure” or “to medicate”. Remediar was a program that aimed to provide thirty-six essential multi-source medicines at no cost to an estimated 15 million citizens that needed the drugs and were unable to afford them. It was designed as a national vertical program even though Argentina’s health system had been decentralized since the 1970s (Homedes & Ugalde, 2006). A national vertical program specifically focuses on a particular demographic population, disease, or health issue. Remediar was organized as a centralized crisis

program within the highly decentralized health system of Argentina, where each province had its own Ministry of Health.

In order to select which medicines were to be provided through the Remediar program, the most common causes of consultation at the primary health care level were identified. It was estimated through this study that the selective medicines would resolve about 80 percent of the pharmaceutical needs of the citizens that went for consultations at the primary health care centers (Homedes & Ugalde, 2006). Although the federal government implemented the program, it was financed by loans from the IDB (Inter-American Development Bank) along with 40 percent of the money coming from the national government. A total of US$177 million went into the program (Homedes & Ugalde, 2006). Medicines started to be distributed in October of 2002 and planned to end in 2006. At the beginning, twenty-one drugs were administered through 2,200 primary health care centers out of the 5,300 present in the country. The United Nations Development Programme (UNDP) was called on to find international tenders for the procurement of medicines.

There were several purposes of Remediar and it was highly regulated. All of the drugs were identified and prescribed to patients with international non-proprietary names, also known as the generic name (WHO, 2010). All of the medicines were prescribed and dispensed to the patients in unit-doses to minimize waste. To reduce stealing and political interference, Remediar contracted outside organizations with a private distributor just to deliver the pharmaceuticals to the clinics. The private distributor received the medicines from the producers and delivered them directly to each primary health care center. In each health center, a staff member received the medicines and put in an order

for more using the number of prescriptions they received since the last delivery. In order to receive a delivery, the prescriptions and an inventory stock list would have to be provided.

There were regular audits carried out by Remediar. Since the program was implemented in 2002 through to September 2004, 3,253 audits were performed through the program including visits to people's homes to verify that the medicine had been dispensed and in the correct amount. A free phone line was also opened to give information about the program and so that consumers could report any irregularities or complaints. The phone number was made widely available by printing it on all medicine packages along with the message that any users who are asked to pay for medicines should call and report the incident. From 2002 to 2004, the phone line had received 92,000 calls (Homedes & Ugalde, 2006). Remediar was also closely supervised by the IDB. The Caritas and the Red Cross were also asked by Remediar to supervise the program and they did so by sending volunteers to all primary health care centers annually to report the findings of the program and its effectiveness. In order to improve prescription practices, university pharmacologists in different provinces of Argentina provided one-day training seminars. In just one year of the program, over 4,000 professionals were trained in nearly two hundred training seminars. The final feature of Remediar was that along with providing the medicines at cost to the consumers, the primary health care centers were also forbidden to charge a fee for the consultations (Homedes & Ugalde, 2006). The program was intended to follow through until 2007, but continues today with the provision of essential drugs through shipping packages with essential medicines and other supplies, now run by the Health Ministry.

There were both achievements and criticisms of Remediar. However, the achievements outweigh the problems and the program overall has been considered successful in improving access to medications for the poor populations in Argentina. Using the Gini index of distribution, household spending on pharmaceutical products had improved by 60 percent. The number of primary care center consultations for patients since the implementation of the program had increased by 25 percent (Homedes & Ugalde, 2006). The once negative view of primary health care centers by the Argentinians was removed. They proved a continuous availability of medicines improving the state's relationship with citizens. The evaluations carried out by Caritas and Red Cross volunteers demonstrated patients and consumers had a positive view of the program. The program had increased access to essential medicines, improved prescribing practices, and enhanced the health of those living in poverty in Argentina (Homedes & Ugalde, 2006).

The criticisms of the program do not directly speak to what the program was trying to achieve, including the lack of control over rational drug use by those receiving the medicines. The Remediar program was a success for Argentina. It fulfilled the intention of providing essential medicines to those living in poverty and gained the trust of the population, increasing the number of visits to primary health care centers. The program went beyond the intended goal and is continuing in operation through the Ministry of Health. The program addressed all of the issues surrounding lack of access to essential medicines for the poor. The problems with lack of regulation of pharmacies, the dispensing and prescribing practices, and the storage of the drugs were addressed within Remediar. Further improvements included training of the health service personnel,

information being passed from physician to consumer, drugs were made available at no cost to the consumers, and it was made possible to report any issues in the program. Largely, the program was made possible through the domestic manufacturing of generic pharmaceuticals within Argentina, positively impacting access and cost of pharmaceuticals.

In 2002, Argentina took an additional measure to promote affordable pharmaceutical products in the country. A law was passed requiring health professionals to prescribe pharmaceutical products, using their generic name instead of the original name brand. This is a feature of Remediar, however, it is now required for all health professionals operating within and outside of the Remediar program. Further, it is required for doctors to also inform patients of trade names that contain the same active principle in the required medicines, as well as the prices of all possible options (Etcheverry, 1996). This law is intended to benefit the low-income population in Argentina by informing consumers of all options available including those that are more affordable. Most pharmaceuticals available in Argentina are 'similar drugs' instead of 'generic drugs'. Similar drugs contain the same active principle, however, they have not been supported by studies to prove therapeutic equivalence to the brand name drug. Similar drugs are approved in Argentina through The National Medicine and Medical Technology Administration (ANMAT) (Etcheverry, 1996). They are widely available at cheaper costs due to domestic production.

5.5 Effects on Argentina's Economy Resulting from the Pharmaceutical Industry

According to Neil Grubert, Argentina has the fourth largest pharmaceutical market in Latin America and it is one of the fastest growing markets in the world.

Although the growth is a factor that may draw in multinational companies, Grubert states that success for multinational companies is not easy in Argentina. The health care system in Argentina, the limitations of IP right protection, pricing trends, and coverage policies over prescription drugs in the country, all contribute to the unattractive pharmaceutical market for foreign companies (Grubert, 2011). However, these are factors that have led to the success of domestic firms through keeping out highly competitive foreign companies and policies promoting domestic generic drugs.

An article published in Global Data regarding healthcare in Argentina reviews the capabilities of the Argentine pharmaceutical industry with respect to economic factors. It was found that the industry in 2012 was worth US$5.6 billion and is predicted to grow to US$15 billion by 2020. The expansion of the industry is due to several factors. These include the heavy presence of domestically owned pharmaceutical companies and laboratories in Argentina, high quality manufacturing capacities, and reliable regulatory bodies. Domestic pharmaceutical production has been active for decades in Argentina. There are major multinational pharmaceutical companies also present in Argentina, however, the domestic firms have some advantages allowing them to succeed. These advantages consist of domestic firms receiving government benefits including favourable tariff protection. Further, the import costs of raw materials are typically cheaper for domestic firms than transfer pricing would be for the active multinationals. Additionally, the social welfare policies have also helped advance the domestic generic pharmaceutical industry requiring doctors to prescribe pharmaceutical products using the generic name of the drug (GlobalData, 2013).

With the recent implementation of the TRIPS agreement in Argentina, it is likely that the pharmaceutical market might experience an increase of foreign pharmaceutical companies. However, research analyst Fredrico O'Conor asserts that domestic companies will be able to harness the concrete positive reputation that has developed over decades and will be able to maintain competitive leadership within the country (O'Conor, 2006). In 2013, manufacturing was the largest single sector in Argentina's economy, accounting for 19 percent of the country's GDP. A major component of the manufacturing sector in Argentina is chemical and pharmaceutical production. Oddly enough, domestic industries have benefitted in some ways from the unstable economy in Argentina. During recessions, citizens were unable to afford foreign goods leading to an increase in domestically produced goods, including pharmaceutical products (Jaidka, 2013).

Although there are foreseen negative effects of the TRIPS agreement as discussed in previous chapters, the Argentinian economy and access to medicines for the population, has observed the potential for benefit. The Argentine pharmaceutical industry has the potential to further benefit from the compulsory licensing flexibility offered by the agreement. Other developing countries that are unable to manufacture and provide pharmaceutical products domestically in a time of crises have the permission to outsource the necessary pharmaceutical products from countries like Argentina. The pharmaceutical market in Argentina is attractive for these purposes seeing that a reputation has been built for achieving the production of safe and inexpensive products (Dreyfuss & Rodriguez-Garavito, 2014, 43).

5.6 International Consequences Observed by Argentina

Argentina has faced threats of international consequences as a result of their choices regarding IP rights. It was due to much pressure for over a decade from the US government and pharmaceutical industry that Argentina implemented domestic patent law. However, implementation of patent law in 1996 did not end the conflict between the US and Argentina over IP rights. Sanctions against Argentina were enacted by the US in 1997 to display their disapproval of the new patent law. The sanctions involved preventing US$260 million of Argentina's US exports. Scholar Wendy Vicente notes that the US pharmaceutical industry commonly aims international complaints regarding trade at countries with developing industries. This is due to the capability of the growing Argentine pharmaceutical industry to compete against US manufacturers in their domestic markets (Vicente, 1998, 1102). The Argentine market was rapidly growing in the 90s. It would be an attractive market to invest in for foreign companies if there were strict patent laws, creating further motivation for the US to coerce IP rights in Argentina. Once the US placed sanctions on Argentina, they replied with a threat to push back patent protection in the country until 2005, utilizing the TRIPS transition period (Vicente, 1998, 1102). It is important to mention that many international disputes regarding Argentina's pharmaceutical industry and patent law does not stem from non compliance with the TRIPS agreement requirements, but from the Argentine industry not meeting US Trade Representative Demands. Although Argentina is operating within the TRIPS agreement and utilizing the flexibilities offered, sometimes within a grey area, these practices are frowned upon developed countries that are demanding more strict IP protection globally (Vicente, 1998, 1112). Greater IP protection has several financial benefits for large multinational companies and industries. These benefits include improving developed

countries' domestic pharmaceutical interests. Typically, developed countries have the capacity to research and produce new brand name pharmaceuticals by creating less competition in the global market. Global harmonization of IP rights also reduces transaction costs (Vicente, 1998, 1126).

There are two complaints registered through the WTO against Argentina regarding IP rights. Both complaints were put forward by the US, one in 1999 and another in 2000. The compliant in 1999 was regarding the patent protection of pharmaceuticals. The current status of the complaint reads as 'withdrawn' further stating that a mutual agreement had been reached without the WTO having to step in. The complaint alleges absence of adequate patent laws that meet the TRIPS minimum requirements. Just a year later, in 2000, a very similar compliant against Argentina by the US was registered regarding certain measures of protection of patents and pharmaceutical test data. This complaint was significantly more extensive. It attacked from several avenues Argentina's lack of patent protection, including their unjustifiable use of compulsory licensing. However, the status of this complaint was terminated (WTO, 2015). It was not until 2002 that both countries notified the WTO's Dispute Settlement Board that an agreement had been reached appeasing the US on both complaints made. No other countries have made formal complaints against Argentina through the WTO. The complaint in 2000 registered by the US was the last recorded complaint against Argentina.

As discussed within the chapter on the TRIPS agreement, the types of complaints and how they are dealt with internationally through the WTO are limited, seeing that the flexibilities offered by TRIPS are not concretely defined. Additionally, the WTO does

not deal with issues of international IP right exhaustion. Therefore, counties that do not agree with some of Argentina's IP practices have taken it upon themselves to impose other consequences affecting the country to implement strict IP rights. There is a long history of the US threatening and following through with some trade sanctions against Argentina due to disputes regarding IP rights. This began in 1995, attempting to force Argentina into initially implementing the TRIPS requirements, and continued through to 2000 to sway more strict protection (Mattson, 2005).

There have not been drastic consequences faced by Argentina recently, however, this is likely due to compliance with the TRIPS minimum requirements and frequent reviewing and revising of domestic IP laws. The threat of action seems to be more common instead of action itself. These threats cause political fear for most developing countries. It is recorded in the WIPO data that the main IP laws, as well as IP related laws, have been enacted and revised. Changes have been made almost annually from 2003 to 2009. Additionally, Robert Stoll, Administrator of External Affairs for the US Patent and Trademark Office, recognizes that although there are limited minimum requirements of the TRIPS agreement, the provisions are not simple or clear. Therefore, different members of the WTO that are bound by the TRIPS agreement have various interpretations of the agreement, and what needs to be implemented to fulfill the requirements. This has resulted in international arguments over compliance (Stoll, 2000, 234). The result of the open interpretation of the TRIPS agreement has led to the realization that any decisions or questions regarding a country's compliance with the obligations of the agreement needs to be left to the Dispute Settlement Body of the WTO. This has led to developed countries attempting to implement external treaties and

agreements enforcing more strict IP rights, perhaps in replacement of filing formal complaints through the WTO.

5.7 Conclusion

It is not clear how the implementation of the TRIPS agreement will affect the pharmaceutical industry in Argentina in the long term. However, with the agreement requirements being active in the country since 1996, the domestic industry is still thriving. While utilizing the TRIPS flexibilities and potentially operating in some grey areas due to somewhat open interpretation of the agreement, the country has been able to formulate a pharmaceutical and health care system that is effective. Further, to a higher degree, it meets the aspirational human right to health. The industry provides much more widespread access to pharmaceutical products than would be possible with Argentina succumbing to pressure regarding the implementation of TRIPS flexibilities. It is apparent that other developing countries have not benefitted as Argentina has from the TRIPS agreement. This is possibly due to fear of international repercussion from utilizing the TRIPS flexibilities.

The main issue regarding global enforcement of strong international IP rights is the resulting unaffordability of pharmaceutical products for the global populations living in poverty. It is the generic drug market or similar drug production that is happening domestically in Argentina that allows for affordability of pharmaceutical products for local populations. This is also paired with social welfare policies targeting health and the aspirational right to health for poor populations, including Remediar and the generic prescription of drugs. The production of similar drugs was supported by the Argentine government's decision to exhaust international IP rights and to refuse the patentability of

medicines previous to the TRIPS requirement compliance. However, the arguably arbitrary use of the TRIPS flexibilities, including generic and similar drug production, continues domestically.

Argentina has been able to produce a better system regarding biased innovation of pharmaceutical products. The TRIPS agreement provides greater benefits to the patenting of pharmaceutical products that will be more successful in the free market creating incentive to innovate products geared toward wealthy populations. The government of Argentina has domestic pharmaceutical companies produce similar versions of pharmaceutical products that are in demand by the local population. This is a request that helps fulfill the Remediar health care system, where pharmaceutical products are given away to consumers at no cost. If a system is operating where the government is paying for the pharmaceutical products, there is no need for targeting particular segments of the population. It is also a contributing factor that the production of generic or similar drugs requires much less initial capital, therefore, there is not a desperate need to implement extremely high mark ups on pharmaceutical products to make back R&D expenditures.

As discussed in the literature review, it is a concern that the pharmaceutical industry, under TRIPS, allows for inefficient spending of income made by pharmaceutical companies on activities that do not include reinvesting the profits back into further R&D. Spending efficiency is often diminished by practices such as "lobbying, gaming, patenting and litigation, by deadweight losses, and by incentives for wasteful marketing and counterfeiting" (Pogge, 2011, TedTalks). Enforcing strict and extensive patent rights makes a pharmaceutical industry dependent upon high mark ups of pharmaceutical products. With the majority of production in Argentina being of similar and generic

drugs, the industry is not dependent on high mark ups of drugs. The production of generic and similar drugs, as previously mentioned, requires considerably less initial capital and investment for production. High expenditures are not needed for marketing in the Argentine pharmaceutical industry with the market being mostly composed of generic and similar drugs.

The Bulletin of the World Health Organization posted an article in 2004 questioning the health levels attainable by developing countries operating within the TRIPS agreement. The study conducted acknowledges that Argentina had implemented flexibilities incorporated into the TRIPS agreement in order to increase access to pharmaceutical products to the public that would have been otherwise unattainable. Further, it is mentioned that concerns regarding access to medicines may be made worse through the implementation of more extensive IP rights, and if the flexibilities are not fully utilized (Oliveira et al, 2004). It is suggested by the authors of the study that the implementation of several sustainable and equity-based policies are needed. These policies should work in favour of the developing world with regards to the TRIPS agreement and help increase the chances of meeting the aspirational human right to health. These policies include implementing technical support for developing countries and the apparent need of creating a balance between importance of innovation and importance of global health (Oliveira et al, 2004).

Conclusion

Health is an aspirational human right. Access to healthcare, including the availability of essential medicines, is a major part of fulfilling the right to health for humans. If drugs are made accessible, affordable, are of good quality, and if they are used properly, they can provide a solution to many health problems. A large share of the total health budget in many countries is made up of drug costs. However, there are still extensive problems with lack of access, poor quality, irrational use of drugs, and the wasting of drugs despite the importance of essential medicines (WHO, 2001).

The lack of access to pharmaceuticals, due to challenges produced by patents, can prevent medicines reaching the global population. There is an increasing number of pharmaceutical products being made available in the world market. On a global scale, there has been growth in consumption and spending of pharmaceuticals. However, these pharmaceuticals typically do not reach those who need them most desperately, the world's poor. In many underdeveloped countries people are unable to attain the medicines they need due to unavailability, high costs, or a lack of adequate facilities or trained professionals to prescribe them. The WHO has estimated that at least one third of the global population does not have access to essential medicines (WHO, 2001). The number of deaths per annum due to lack of access to essential medicines is already in the millions. These deaths could have been treated by medicines that already exist.

After critical analysis of patent protection over pharmaceuticals, a case has been made that the patent system might be an instrument leading to the infringement of the aspirational human right to health for some segments of the global population. It is argued that patent protection plays a significant role for pharmaceutical products in order to allow the industry to foster further research in development, overall bettering the lives

of all individuals. However, in the current system under the TRIPS agreement, there is a bias present. This bias prioritizes the attainment of great profits for developed country companies over the aspirational right to health for developing country populations. According to Thomas Pogge, the current patent system under TRIPS is problematic in three major areas: the significant profits made are often spent in inefficient and wasteful ways, R&D is biased in favour of the developed world, and pharmaceutical products are widely unavailable for developing country populations.

It has been acknowledged that there is a purpose and need for the current patent system and it is successful in funding expensive R&D. Nevertheless, several different systems have been explored that claim to be able to replace or work alongside the current patent system and fulfill the financial needs of R&D while at the same making pharmaceutical products more accessible globally. The different systems explored include the prize system, funding R&D through public means, implementation of controlled or tiered pricing, and the option of developing countries to ignore or exhaust IP rights. It is not being stated that these have proven to be better than the current patent system, however, providing criticism of the current system is important. The major assertion made in this thesis is that the patent system fails at providing a balance between profit-making incentive to innovate and the increase in human welfare that can be achieved by pharmaceutical products. Therefore, there needs to be a system or policies implemented that produces the incentive for pharmaceutical firms and inventors to want to innovate while maximizing the social benefits that can be obtained from pharmaceutical products.

It has been realized that patents differ from other types of property protection. A patent is able to grant rights over an intangible object or process, where the patent holder is the only person or company allowed to make, use, or sell the invention or process. On the other hand, everyone benefits from the knowledge gained when a patent is issued. In the pharmaceutical industry, it is typically only large companies that are able to fund R&D for the types of products eligible for patents. The majority of the large multinational pharmaceutical companies operate out of developed countries due to the technological capacity of those regions. This leaves underdeveloped countries at a disadvantage in regard to access to newly developed pharmaceutical products when they become patented. There is a reliance on pharmaceutical companies to make drugs accessible through affordable pricing and shipment to developing countries. This need is not met and is justified by multinational companies with the excuse that high mark ups on drugs is necessary for firms to make back the R&D costs of developing the drug. Developing countries should not be blamed for the lack of essential medicines in the developing world. However, the North American based patent system itself plays a major role in the lack of access to pharmaceuticals. This system does not promote technology advancement and spillover to the developing world the way it was intended. Further, equal R&D funds are not put toward researching medicines for diseases relevant in the developing world. The WTO's TRIPS agreement advances this system and makes it a requirement of members to enforce strict IP rights globally, while offering minor exceptions through flexibilities. If policy changes were made to allow developing countries to comfortably implement TRIPS flexibilities, improvement may be observed with access to pharmaceuticals. These policies would include discouragement and

regulation over threats made by developed countries and international consequences resulting from utilizing the flexibilities.

The global enforcement of the patent system through the TRIPS agreement disadvantages the developing countries in the area of access to pharmaceuticals. Developing countries have raised several issues with the TRIPS agreement. These issues include that the TRIPS agreement ignores the local needs of developing countries, national interests, technological and institutional capacities, and crucial health conditions (Yu, 2009, 1). The WTO has recognized some of the inequalities perpetuated by the agreement, which resulted in the availability of the flexibilities offered. These flexibilities include the ability to obtain compulsory licenses. This is a strategy used to bring down the prices of patented pharmaceutical products in developing countries.

The objectives of the TRIPS agreement include the promotion of technological innovation and global transfer of technology to attain a mutual benefit for the consumers and producers, the promotion of both economic and social welfare, and finally, the fulfillment of human rights. The operation and fulfillment of the minimum requirements of the TRIPS agreement in practice has not achieved the objectives outlined. Instead, the developing country populations are further disadvantaged due to patents granting monopolies in the global market on pharmaceutical products, decreasing their availability. The flexibilities offered by the TRIPS agreement are not sufficient in creating a balance between social welfare and financial gain. This is largely due to the political fear developing countries have surrounding the utilization of flexibilities. They are hesitant to use due to international threat. Developed countries discourage these flexibilities and often prevent utilization through the use of threats in the form of trade sanctions or other

consequences against the country. The TRIPS agreement has not taken measures to prevent this from happening.

There are several issues with the TRIPS agreement that negatively affect the developing world. These issues include a potential for overall efficiency loss - providing pharmaceuticals at a much higher price might counteract any benefits gained from influencing a greater amount of R&D (Mathur, 2007, 21). Additionally, it is unlikely that developing countries will reap significant benefits from heightened IP protection due to their lack of technological infrastructure. As far as creating an increase in FDI and technology transfer to developing countries through patent protection, most countries have not seen benefits as Argentina did, so improvement is needed. Patent protection under TRIPS, in the case of pharmaceuticals, allows for pharmaceutical manufacturers to demand higher prices than where the price would fall in a competitive market. This is crucial considering the prices of pharmaceutical products determine how many people will die from diseases in the years to come. These are far-reaching implications of the TRIPS agreement making it very controversial, and it has been realized that there are a lack of benefits for developing countries. As a response to the TRIPS agreement challenges, some countries have implemented various solutions to soften the blow experienced by their populations. Argentina has utilized the TRIPS flexibilities and, in some cases, exhausted international IP rights in order to fulfill moral obligation and the aspirational human right to health in their country.

Argentina's pharmaceutical industry is considered successful in regard to providing essential medicines to the local population. A unique history has contributed to the current pharmaceutical industry in Argentina. This includes the absence of patents to

foster infant industry protection of domestic generic pharmaceutical companies, and far-reaching social welfare policies as a response to economic crises. After succumbing to international pressure, Argentina agreed to implement the TRIPS requirement of IP protection in 1996. However, although they have been discouraged from doing so, the country has utilized the flexibilities offered by TRIPS. They also implemented IP right exhaustion and parallel importation when there is a demand for a pharmaceutical product in the country. Argentina is not appeasing other WTO members with their IP laws. Nevertheless, due to the ability left open to interpret the agreement and develop policies in a country based on that interpretation, the country has met the TRIPS minimum requirements.

It is observable that the success of similar drug production in Argentina, in combination with the health policies implemented in 2002, has positively contributed to increased access to medications for local Argentinians. It has been discussed in the previous chapter that the Argentine pharmaceutical model fulfills the aspirational human right to health more sufficiently than the strict patent enforcement of the TRIPS agreement with no utilization of the flexibilities. This can be seen in areas of access to pharmaceutical products, unbiased allocation of R&D funds, and more efficient spending of profits.

The exhaustion of IP rights is not necessarily the model that all developing countries should take in order to improve access to pharmaceutical products. Going against the dominant system will only be effective for so long and will not foster permanent change. Therefore, changing the dominant system to create a more just global pharmaceutical industry would be a more permanent and far-reaching solution. The

system adopted by Argentina and the apparent problems the TRIPS agreement poses for developing countries does, however, highlight the immediate need for a change. Like many international issues, a significant barrier to change is the unequal power distribution and a biased system that favors those in power.

The realization of the extensive problems with the North American based patent system that the TRIPS agreement is attempting to make a global standard, prompts the realization for the need for change. It has been discussed that the patent system itself is achieving one of its objectives, to create incentive to innovate. The incentive is the potential to earn high profits, which is leading to the biases in R&D funding and lack of access to pharmaceutical products for developing countries. Therefore, implementation of policies within the TRIPS agreement that can prevent international pressure to not utilize the flexibilities will be helpful. The possibility of having a prize system operate alongside the current patent system may also create benefits for developing countries.

As proposed by Thomas Pogge, the HIF would be available for new drug developers to register their pharmaceutical products forgoing obtaining a patent. Once registered, the company or inventor would be required to provide their product at cost wherever it is needed globally. The potential profits would come out of a fund of $6 billion and the inventor or company would be compensated based on how much of an impact their product has made globally in regard to health. This is a system that takes away the bias to fund R&D geared toward the developed world and, instead, provides incentive to develop drugs desperately needed. The issue of inequality is taken out of the equation involving poverty and access to pharmaceuticals. Thomas Pogge intends for this prize system to operate alongside the current patent system.

As it currently operates, the agreement fails to strike a balance between the benefits gained by implementing international IP rights as far as creating incentive to innovate and meeting the public need of poorer populations for life-saving medicines. The most vulnerable populations are feeling the burden of the unequal allocation of benefits. They are not reaping benefits and are being placed in a worse off position because of the agreement.

It should be the responsibility of the WTO to change the requirements and flexibilities within the agreement in order for the results to meet the objectives and goals of the agreement. There are flexibilities offered currently, but developing countries are being discouraged to utilize them by threats from developed countries. The unequal power between members of the WTO and the different effects the agreement has on developed and developing countries should be taken into consideration. Further, the WTO needs to be more involved in enforcing that the developed countries are following the requirements of the agreement, especially in areas that are intended to level the playing field. For example, it is a requirement that developed countries are supposed to actively foster the transfer of technology to developing countries. Additionally, this would also necessitate the requirements of the agreement to be concretely defined. The agreement is a one-size-fits-all solution for many countries with unique situations. A level playing field should be secured before all countries are required to implement the same requirements.

There is also a greater potential for change in the agreement if the developing countries unite and demand change within the agreement. If developing countries come together, they would have more leverage to influence changes than if issues were brought up by individual countries. In order to produce long-term changes with the least amount

of consequences, cooperation would be a better approach than defecting or confrontation. This means that not all developing countries should take the approach Argentina has taken. This approach may bring more international turmoil and consequences. Cooperation and compromise between WTO member countries increases the likelihood of long-term change with benefits for all members.

There are several avenues that can be taken in order to improve the current consequences of the globalization of pharmaceutical patents and the TRIPS agreement. All actors should be involved in potential changes with the priority of global health being at the forefront of all decisions and requirements.

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