

Patent Law and International Justice: Making Pharmaceuticals Accessible to the
Underdeveloped World

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Abstract: An examination of the current system of intellectual property law and the application of the Rawlsian methodology of justice to evaluate the current pharmaceutical patent system. The Thesis then explores the Health Impact Fund's proposed new system to fund pharmaceutical research, which is also applied to the Rawlsian methodology. The merits of the recent proposal are found that alleviate major flaws of the existing patent system.

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Introduction

In this thesis I examine the current system of intellectual property law as it concerns patents for pharmaceuticals. My aim is to show that the present system, while having many virtues, provides incentives which skew the resources used to develop new medications in a way that results in fewer of those resources being devoted to developing medications that would most help those who need them most, the poor people in the world's developing countries. But I am not solely concerned to point out an injustice that results from the present structure of patent law. I also examine the merits of a recent proposal to alleviate some of the existing system's flaws.

I begin by outlining a methodology developed by John Rawls for formulating principles of justice for the basic structure of a developed society. I show that this methodology—which focuses our attention on fairness—is (duly modified) an appropriate methodology for evaluating how just our present patent system is and for helping us modify it in ways that would make it more just, or at least less unjust. I then give a sketch of the current patent system. Following that, I point out the virtues and vices of the existing system and raise the question of how we might retain the former while reducing the latter. Because the development of new pharmaceuticals has in general been a great benefit to mankind, it is something that we ought to devote adequate resources to furthering research in this field. Unfortunately, such research and development is quite expensive. Therefore, I briefly examine the three most obvious ways in which such research might be funded; through charity, government funding and

through patents. Following that, I examine how from a Rawlsian point of view one would examine the current patent system and in what ways it is unjust. I will provide a number of statistics, which are supportive of the Rawlsian conclusion that the current patent system is unjust and pose some possible solutions to these tribulations. I will then briefly describe the Health Impact Fund proposal. I will employ the modified version of the Rawlsian methodology described earlier to evaluate the justice of the Health Impact Fund. I am able to show that, from the Rawlsian perspective, the Health Impact Fund proposal, if adopted would be one of the most just systems to fund pharmaceutical research and development that could improve the health of poor people in developing countries, and on a global scale.

The Rawlsian Methodology

In this thesis the major issue involves justice and international development. In his important works, *A Theory of Justice* and *The Law of Peoples* John Rawls developed a methodology, which I will refer to as the Rawlsian methodology, for developing principles of justice for both individual societies and for relations between societies. I will be using this Rawlsian methodology to determine what justice would require in instances of international relations, and in particular the issues which I am dealing with in this thesis, international patent law as it concerns pharmaceuticals. Rawls illustrates that justice requires fairness or that thinking about fairness helps us when deciding on principles of justice.

The starting point for Rawls's theory of justice is the original position. In this original position people are situated behind what Rawls calls a veil of ignorance. Individuals who are rational and only concerned with their own interests but who are ignorant of their own identity are asked to choose principles of justice to govern all members of their society. Behind the veil of ignorance one would not know if they are male or female, which race they are, if they are educated or not, or which religion they practice, along with many other variables. The individuals behind the veil of ignorance know the general facts about the way the world works, such as the basic needs humans require, and about the society in which they will be living. When a person is rational and self-interested, that is to say they are driven to select in an informed manner, they would choose whatever would seem advantageous to them. However, Rawls argues that people who find themselves in the special circumstances of the original position will be particularly concerned with the situation of those considered worst off in society. Because of this concern with the possibility that one might find, upon lifting the veil of ignorance, that one was among the worst off individuals, Rawls argues that when deciding on principles of justice for society it is rational to employ the maximin decision rule. When using the maximin decision rule one pays particular attention to the worst possible outcomes when making decisions under uncertainty. Indeed, the maximin rule requires one to rank alternatives based on their worst outcomes and choose the alternative that has the best worst outcome. This provides some kind of insurance in case the person behind the veil of ignorance is in fact a member of the worst off in society; they have made

their position the best it could be. Rawls claims that when behind the veil of ignorance individuals will choose his two principles of justice as the basic principles for their society.

Rawls decides on two basic principles of justice, which are the principle of equal liberty and the difference principle. The principle of equal liberty is concerned with the distribution of basic liberties and should be used when designing the political institutions of society and applies to all citizens. Each member of society should have the most extensive set of liberties compatible with the same liberties for all. The difference principle applies primarily to economic institutions and is the principle of distributive justice. According to the difference principle social and economic inequalities should be arranged so that they work to the greatest benefit of the least advantaged in society. This is usually thought to require having goods and services distributed equally unless an unequal distribution would benefit those worst off in society. The difference principle may mean a society will implement projects that require giving some more power, status, and income if in turn it raises the living standards of everyone in the community or in any way make life better off for those in the worst off position in the society. These principles, when chosen behind a veil of ignorance, leave no room—or as little room as possible for humans with limited imaginative capacities—for biases or for unfairness to be present. Both the

individuals and the situation Rawls describes are designed to reflect the fundamental characteristics and principles we think justice should have.¹

Description of the Current Patent System

A patent is a form of intellectual property. 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 advance in technology the invention provides. In Canada, the protection lasts for twenty years from the date that the patent application is filed, as long as the required fees are paid.² If an inventor receives a patent in Canada the sole right to use, make and sell the invention are 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. Patents can only be applied for in the name of the actual inventor. In order to apply for a patent the invention needs to be new, nonobvious or useful. For example, a process, machine, article of manufacture, composition of matter, or an improvement on any of the previously mentioned are all things that can acquire a patent, if applied for by the inventor according to The United States Patent and

¹ For a more detailed account of the matters discussed in this section see <<http://people.wku.edu/jan.garrett/ethics/johnrawl.htm#prin>>

² Canadian Intellectual Property Office, "What is a Patent?" 2011 <<http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01400.html>>

Trademark Office. The types of objects or phenomena that cannot be patented are things such as laws of nature, physical phenomena, abstract ideas, inventions that are not useful or are offensive to public morality. Literary, musical and dramatic works cannot be patented although they can be copyrighted.³

There are several reasons why an inventor may want to obtain a patent. Patents can provide the possibility of protecting and keeping exclusive commercially important technology. 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. It provides the possibility of holding a monopoly in the marketplace until the patent expires. Having a patent on an invention does not guarantee that it will be commercially successful. Holding a patent on something provides the chance of a better market position, it gives inventors the chance to prevent others from benefitting from their ingenuity, and it prevents others from receiving some of the profits from the invention without the patent holders permission. Not only does the patent supply the rights to the inventor as sole maker, user, and seller but also as sole beneficiary as far as profits are concerned.

Patents are enforced by National Patent Offices, the World Trade Organization (WTO), and evaluated by the World Intellectual Property Organization (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 gives patent

³ The United States Patent and Trademark Office, "What Can and Cannot be Patented?" 2013<<http://www.uspto.gov/inventors/patents.jsp>>

protection on a larger global scale and adopted the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). WIPO is a United Nations Agency that administers global intellectual property treaties. These organizations provide patent protection to those seeking it by giving judicial enforcement of the intellectual property rights. If a company thinks that their patent rights have been violated they are able to sue the violator(s) and their National Patent Office would be able to provide official documents to show ownership of the intellectual property.^{4 5}

The current patent system provides certain advantages to the research and development process. It also includes certain complications or features, which have created a system that is in some ways both inefficient and biased. There is the possibility of a system that could produce better results in the pharmaceutical industry over the current patent system. When examining the pros and cons of the existing pharmaceutical patent system we need to consider both how it affects the patent holders and additionally how it affects people who need the drugs that have been patented. We need to consider not just those who now consume patented drugs, but also those who might consume drugs had the system been different and resulted in other drugs being developed. Put another way, we need to look at the issue on a global scale and consider all the

⁴ O.A. Thusleem, "The Global Institutions Responsible for Administering the Patent System," 2008 <<http://www.pharmainfo.net/reviews/patent-system-pharmaceutical-industry>>

⁵ For more information on Intellectual Property Rights see http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf

possibilities that our greatly expanding knowledge of how to use chemical means to enhance human health can best be used to serve all peoples.

For the patent holders there are more positive than negative outcomes when using the current patent system. The current patent system keeps others out of the market, puts restrictions on competitors, generates revenue from licenses and sales, gives the patent holder the right to practice the invention, gives their product credibility, and gives the patent holder the future possibility of marketing themselves to a future employer. When an inventor acquires a patent that gives them the right to exclude others from producing, using, selling, as well as importing and exporting their invention for the length of the patent it keeps others out of the market which can be extremely valuable. This could be considered a government-granted monopoly. The standard justification for the system of patents is that government grants patents for the purpose of bettering society in the long run by creating incentive for innovation. After the patents expire, society will have free access to the new technologies. When it comes to putting restrictions on competitors, an inventor may come up with a new technology for a specific industry and patent that idea however; they might not be able to practice their idea if it infringes on another competitor's patent. It is possible to patent an idea before current restrictions of producing and manufacturing are lifted. This restricts a company's competitors by obtaining the patent for the new technology, regardless of being able to produce the invention. When the competitor's patent expires the inventor will be able to practice the new invention. Patent holders make their profit from selling the patented product but

another profitable practice is to license the technology to others. It is common for a person licensing to pay an initial fee plus royalties. Another possibility is to sell a patent for the remaining time it is in place. A patent is a safe way to prevent another company from producing or selling an invention belonging to the patent holder during the time the patent is in place.

There are few negative components to patenting a product for the patent holder. What might be a problem for the patent holder is the cost and liability. Patents do not only involve the initial application fee but a filing fee, and issue fee, as well as maintenance fees throughout the length of the granted patent. The prices of these fees vary with the size of the business with larger businesses paying more than the smaller businesses. The liabilities associated with patents and the possible lawsuits are other downsides. Competitors may try and overturn a patent if there are great profits in the balance.⁶

The current patent system facilitates positive and negative elements for humans on a global scale just as it does for the patent holders. The pharmaceutical industry's current patent system will have a more pronounced impact for humankind on a global scale rather than on the patent holders. In this case, it is not just profits to consider but better health and quality of life for humans.

⁶ Inventor Basics, "Patent Pros and Cons" 2011
<<http://www.inventorbasics.com/Patent%20Pros%20&%20Cons.htm>>

Josh Bloom⁷, a physician, and Gregory J. Glover⁸, an attorney who specializes in competition in the pharmaceutical industry and intellectual property, argue that a crucial part of the drug development cycle includes the importance of maintaining incentives for pharmaceutical research. They believe intellectual property rights and patents create this incentive. Achieving the promise of pharmaceutical innovation requires the upkeep of strong and foreseeable intellectual property rights. The social value of the pharmaceutical industry is apparent and profound. Not only are patents the source of cost effective treatments that continue to increase life expectancy and improve the quality of life, it is also a significant contributor to the strength of the first world economy. Strong intellectual property protection is essential to a vital innovative pharmaceutical industry. The strength of intellectual property rights protection greatly impacts investment decisions. This investment is essential to enable further pharmaceutical innovation as well as promote competition in the industry. In short, without the current patent system there is little incentive for pharmaceutical industries to develop new drugs, unless they are drugs for people who are willing and able to pay the substantial costs of developing and patenting such drugs. When looking at the patent system strictly as a business, one would be able to conclude that the pharmaceutical industry is a successful industry, however, this is not taking into consideration global health.

⁷ Josh Bloom, "Yes: Innovation Demands it" 2012
<<http://online.wsj.com/article/SB10001424052970204542404577156993191655000.html>>

⁸ Gregory J. Glover, "Competition in the Pharmaceutical Marketplace" 2002
<<http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf>>

Research and Development

Research and development refers to specific practices or certain activities usually performed by a business. Research and development practices and objectives vary from company to company. There are two basic models of research and development. In the first model, the primary purpose of a research and development group is to come up with new products. In the second model, the purpose of research and development groups is to discover and create new knowledge about scientific and technological topics for the purpose of enabling or further advancing the development of valuable new products, processes, and services. Research and development activities are typically carried out by corporate or government entities.⁹

The pharmaceutical industry develops, produces and markets drugs or pharmaceutical products that are licensed for use as medications.¹⁰ This industry is made up of many different companies of all sizes, all of which are subjected to a variety of laws and regulations including patents, testing and safety, and laws regarding the marketing of the drugs. Pharmaceutical companies are similar to other businesses in that they manufacture products that are to be sold for profit in order for that business to survive, grow, and generate profits for their shareholders.

What makes the pharmaceutical industry different than other industries is that the drug business is involved in producing medicines that directly affects the

⁹ Wikipedia, "Research and Development" 2013
<http://en.wikipedia.org/wiki/Research_and_development>

¹⁰ Science Daily, "Pharmaceutical Company" 2012
<http://www.sciencedaily.com/articles/p/pharmaceutical_company.htm>

quality of life for humans and the pharmaceutical industry is very risky. What makes this business risky is that the cost of research, development and innovation is very high. Only one out of every ten thousand discovered compounds actually becomes an approved drug able to be marketed and sold for profit. Each drug that comes to market has to yield sufficient income not just to fund its development but also to fund the development of the thousands of failed compounds, which were looked at on the way to finding the successful drug. On average only 3 out of 20 already approved drugs bring in enough revenue to cover the cost of research and development.¹¹ The early phases of drug development require the majority of investment and funds allocated to pharmaceutical innovation. Unless it is believed that the drug will bring in millions or billions of dollars, it will not be profitable to develop. In order for a drug company to survive it would need to discover a “blockbuster” drug every few years. A “blockbuster” drug is an extremely popular drug that generates annual sales of at least one billion dollars for the company that discovers and creates it.¹² Examples of blockbuster drugs include Lipitor and Zoloft. Blockbuster drugs are typically used to treat more common medical problems found in the developed world such as high cholesterol, diabetes, high blood pressure, anxiety and asthma.

Government appointed medical institutions or boards are responsible for approving drugs developed by pharmaceutical companies. Over the past

¹¹ Ogburu Omudhome, “Why Drugs Cost So Much,” 2002
<<http://www.medicinenet.com/script/main/art.asp?articlekey=18892>>

¹² Investopedia, “Blockbuster Drug,” n.d,
<<http://www.investopedia.com/terms/b/blockbuster-drug.asp>>

decade, the number of drugs approved annually has been within the twenties on average. The approval of a drug only comes after substantial investment in pre-clinical development and several clinical trials with promising results, along with a commitment made by the company for ongoing safety monitoring of the drug.

Pharmaceutical companies in Canada and in other key countries play a big role in the innovative economy. Research and development in this sector is typically focused on developing the next generation of breakthrough therapies and medicines to address unmet medical needs both domestically and globally. The Canadian pharmaceutical sector covers the research of new drugs, the development, as well as the manufacturing of the developed drugs.¹³

Research and development in the pharmaceutical industry can be funded in three different ways; by charities, the government or through patents. The key aim of research charities is to generate knowledge that benefits the public good. Charities provide an important independent flow of research funding that generally compliments the objectives of the research councils and government departments. In the United Kingdom there are hundreds of research funding charities that cover a wide range of objectives. All of these charities are regulated by charity law and are required to follow certain obligations and restrictions on the use of charitable funds for research. For example, there is a prohibition on funding research for the purpose of commercial or private gain. In the UK the Association of Medical Research Charities (AMRC) is the leading member organization that funds medical and health research. The world's

¹³ Industry Canada, "Biopharmaceuticals and Pharmaceuticals," 2012
<http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01702.html>

largest charity, The Wellcome Trust is a member as well as over 100 other charities. The common goal of the members of AMRC is improving human health by funding a large spectrum of research. These charities are able to provide funding for research in various ways. A smaller contribution would be a one-off grant offered in order to kick-start a particular research project or these charities are able to offer substantial funds proposed to fund specific research projects. Medical research charities have some restrictions that only allow them to fund research programs that align with their charitable objectives. This can mean that charities may only be able to fund research projects that focus on a particular disease, a range of diseases, or a broader objective of improving human health through education and research. Research funding charities typically are unable to provide as much funding or money as attaining pharmaceutical patent would bring forward.

Government funding is another way to support research and development of pharmaceuticals. Government funding to businesses for research and development supports innovation. Research and development funding is provided by the provincial and federal governments in Canada and generally takes the form of grants. In Canada, small and medium innovative enterprises are able to apply for or seek government funding and resources if they meet certain criteria requirements. Some of the criteria requires these companies to invest at least twenty percent of their total investment into research and development. This government funding provides some incentive for innovative companies to invest more into research and development over other activities

such as marketing.¹⁴ However, government funding does not provide the pharmaceutical companies with an equivalent amount of money to what a patent on a successful drug would.

Companies that develop drugs typically put their money towards researching and developing drugs that can foreseeably generate significant profits. The drugs that generally bring about the most profit are those, which have a lower impact on global health. These are drugs that are relevant to the developed world where people have money to spend on pharmaceuticals that may not be crucial to their health. People in the developed world have been living in a society that teaches them that every slight abnormality they have can be treated with a drug. They are willing and able to pay money for drugs that treat non-life threatening symptoms or are common medical problems, such as high cholesterol, diabetes, high blood pressure, asthma, and cancer. Because there is such a large market for drugs that treat these common medical problems in the developed world, it is a competitive market. There are generic versions of the brand name drugs made once a patent runs out or slight variations of drugs are manufactured that treat the same symptoms enabling companies are able to enter the market. A lot of money goes into the research and development of “blockbuster drugs” instead of being put towards drugs more relevant to the underdeveloped world. The pharmaceutical industry has a bias towards what types of drugs they develop; this bias falls in favour of those who are living in the

¹⁴ Imperial College London, “Types of Research Funding,” 2013, <<http://www3.imperial.ac.uk/researchsupport/funderinformation/typesofresearchfunding>>

developed world and puts underdeveloped countries at a disadvantage. Even if drugs already exist that treat specific diseases, Big Pharma companies would lose money by making available and affordable these drugs to underdeveloped countries. These can and have led to developing countries creating generic versions of brand name drugs that will not be made available to them by these Big Pharma companies. This can become a major problem if these countries are or eventually become members of the World Trade Organization (WTO).

For example, Brazil began producing generic versions of HIV/AIDS treatments without the permission of the patent holders. Once the developing nations become members of the WTO, they become bound by the organization's intellectual property rights agreements. In 1994, members of the WTO established the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). A result of TRIPS was the establishment of minimum levels of protection for member countries for products including pharmaceuticals. David Fidler, an international law professor at Indiana University, believes "the WTO was a game changer". If a country wanted the benefits of being a member of the WTO they also had to sign TRIPS. All countries that were members of the WTO were granted permission to issue compulsory licenses to produce generic versions of products domestically, including pharmaceuticals without the permission of the patent holder. This was allowed only under circumstances of national emergency. However, the compulsory license establishment has led to controversy and confusion about how and under what circumstances it should be applied. By 2000, there were a number of cases where emerging economies

used the threat to issue compulsory licenses as a tool to influence drug negotiations. This often happened when developing countries were looking for HIV/AIDS meds to be made available. This was somewhat effective because drug companies responded by lowering drug prices, sometimes as much as 40%. However, a 40% price reduction still did not make drugs affordable for those in the developing world. The compulsory license rule was extended by the WTO in 2003 to allow developing countries that do not have the capacity to produce their own generic drugs to import them from other countries that are operating under a compulsory license. This further advanced in 2007 when Canada became the first country to issue a compulsory license to export generic drugs under this rule.

Seeing as this is one of the only ways a developing country is able to provide its citizens with the drugs they require in cases of national emergency to combat epidemics, it illustrates how the patent system with respect to pharmaceuticals is unjust. The compulsory license procedure is frowned upon by the pharmaceutical industry. In the view of the industry, the development of new drugs depends on the defense of patent rights. It is also a common belief within the pharmaceutical industry that developing countries are able to afford these drugs, however, they choose to spend the money elsewhere. They are asserting that drugs are the opportunity cost to spending in other areas. Some pharmaceutical companies use their power to influence developing countries not to attain compulsory licenses. For example, companies will threaten to withhold all new drugs they develop from an underdeveloped country if they attain a

compulsory license. Although these licenses can be the only hope for a developing country to attain required drugs, there can be serious consequences for doing so. This method has been successful in some cases for making drugs available to citizens of underdeveloped countries. It could be anticipated that a system which provides an incentive for pharmaceutical companies to make available drugs and develop drugs relevant to the developing world would be more effective than compulsory licenses.¹⁵

What Makes Pharmaceutical Companies Different Than Other Types of Businesses?

According to *Science Daily* a new study developed by two York University researchers estimates the US pharmaceutical industry spends almost twice as much on promotion and marketing than they spend on research and development.¹⁶ A common claim made by the pharmaceutical industry is that consumers have to pay such high prices for drugs in order to support future research and development of new drugs by the companies. They put forward the message that drugs are expensive but that also shows how valuable they are. Research-based companies claim that they provide a steady stream of innovative drugs that have the potential to lengthen life and enhance its quality; they make the impression that the consumers are the beneficiaries and not the companies themselves. It rarely gets mentioned the amount of money these

¹⁵ Toni Johnson, "The Debate Over Generic-Drug Trade," 2011, <<http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055>>

¹⁶ York University, "Big Pharma Spends More on Advertising Than Research and Development," 2008, <<http://www.sciencedaily.com/releases/2008/01/080105140107.htm>>

companies spend on marketing and promotion, however, what they put forth most is the high price of research and development for new drugs.¹⁷

It would be useful to question the amount of promotion and marketing the pharmaceutical industry actually requires in order to stay profitable and in order to fund research and development. The pharmaceutical industry in the United States spent \$33.5 billion on promotion costs in 2004.¹⁸ Compared to other types of industries and the type of things they produce, there is a noticeable difference in medicines and other consumer products. Medicines and drugs have to do with quality of life and the affordability and availability of these drugs can be matters of life and death. The majority of other consumer product industries spend significant amounts on marketing and promotion in the United States, however, they do not have to do with basic needs, quality of life, or are not matters of life or death. People who have a specific disease will purchase a drug designed to cure a disease if it is affordable and available, not because it is marketed well. It seems as though the only drugs that would be beneficial to market are those that are referred to as first world “luxury” or “blockbuster” drugs that would have a lot of competition. There is a significant amount of competition for these drugs because they are primarily consumed in the first world where people have the money to afford them. Companies will make a very similar drug that treats the same symptoms as an existing drug in order to get into that

¹⁷ Marcia Angell, “The Truth About the Drug Companies,” 2004, <<http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/?pagination=false>>

¹⁸ York University, “Big Pharma Spends More on Advertising Than Research and Development,” 2008, <<http://www.sciencedaily.com/releases/2008/01/080105140107.htm>>

specific market if a profit is to be made. They create slight variations in the existing drug in order to avoid breaking patent laws. The marketing is required to persuade people to buy a certain company's variation of the drug over another. The marketing would not be required in cases for new drug development instead of new drug variation.

Americans spend \$200 billion annually on prescription drugs, however, this number is staggering. This number is growing at a rate of 12% per year, down from a high of 18% in 1999. The increase in drug spending has to do with the increase in the consumption of prescription drugs as well as the increase of the price of the drugs. Marcia Angell, former editor of *The New England Journal of Medicine* and current Harvard Medical lecturer believes our society today is extremely over-prescribed. We hold the belief that if there are slight deviations from the norm than there is something wrong with us that needs to be fixed. The way we think we can fix these problems are with prescribed medications as opposed to changing the behavior and beliefs of society. We allow the costs of these medications to rise because we believe we need them to make a better quality of life and to make ourselves more "normal". Americans spend \$200 billion on prescription drugs but the pharmaceutical industry is worth much more than that. The global pharmaceutical industry is worth an estimated \$400 billion dollars. With this amount of worth comes a great amount of power.¹⁹

¹⁹ Marcia Angell, "The Truth About the Drug Companies," 2004, <<http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/?pagination=false>>

When an industry is worth as much as the pharmaceutical industry is worth, it is a sign of power. The pharmaceutical industry is dealing with life saving drugs, and the lives of many people especially in the developing world that are depending on their innovation and the availability of drugs they produce. This gives the pharmaceutical industry the potential to make a pronounced impact if this power is used in a specific way. If Big Pharma companies took their profits and focused them more towards the research and development of life-threatening diseases and less towards variations of “blockbuster” drugs there would be less of an intention to make great profits and more on curing a broader spectrum of diseases. If this were the main focus then more of an impact would be made. That is not to say that the pharmaceutical industry is not making an impact, however, there is the potential for a greater impact to be made that would affect the quality of life for humanity as a whole.

Pharmaceutical Patents and Rawlsian Justice

If one were placed in the Rawlsian original position in order to choose what justice would require for the pharmaceutical industry, main concerns would lie in accessibility, affordability and improving overall global health. In this position the individual behind the veil of ignorance would be rational and concerned with his or her own self-interest, however, they are unaware of their identity. They would not know if they lived in a developed or underdeveloped society, if they are wealthy or poor, if they have a certain disease, if the current patent system works in their favour and they have drugs available to them at a

price they can afford. If asked to choose principles of justice to govern all members of society regarding pharmaceuticals, an individual behind the veil of ignorance would be particularly interested in the positions of those considered worst off in society. This is due to the ambiguity of their position in society; there is a chance they can find themselves in the worst position in society.

When talking about pharmaceuticals, the worst position in society would be that of an individual with a life-threatening disease, living in an underdeveloped country, having no income to pay for medicines, and not have drugs be made affordable or accessible to them. In this position, because pharmaceutical companies have biases to developing certain drugs due to the current patent system, if the disease this individual has is not relevant to the developed world it is likely pharmaceutical spending will not go into researching and developing a drug pertaining to that disease. This is because the drug will not generate enough profit for drug companies to want to develop this drug; it would not be a good business decision with the current patent system. Even if a drug already exists pertaining to that specific disease, it will not likely be accessible to those in the developing world, even if it were affordable, and chances are this would not be the case due to high mark-ups pharmaceutical companies place on drugs.

Behind the veil of ignorance, an individual who has the chance of being a member of society in the worst position previously described would apply the maximin decision rule. When using the maximin decision rule one would pay particular attention to the worst possible outcomes when making decisions under

uncertainty; they try to better the positions of those in the worst off positions by deciding on principles of justice. This provides some kind of insurance if the person behind the veil of ignorance is in fact a member of the worst off in society; they will try and make this position the best it can be. This means making pharmaceuticals affordable and accessible to those in underdeveloped countries, but with a system that can keep pharmaceutical companies up and running so they are still able to innovate and develop new drugs.

Rawls claims that individuals behind the veil of ignorance will choose his two principles of justice; the principle of equal liberty, and the difference principle. The principle of equal liberty refers to distribution of basic liberties and that all members of society should have the same liberties. When talking about the global pharmaceutical industry, the society one would be deciding principles of justice for would include all humans because it is an issue concerning global health. Principles must be chosen in order to have drugs accessible and affordable to all humans.

According to the difference principle, social and economic inequalities should be arranged so that they work to the greatest benefit of the least advantaged in society. When it comes to justice it is usually thought to have goods and services distributed equally, unless in this case unequal distribution would benefit those worst off in society. In the circumstance of the pharmaceutical industry, it would be more beneficial to have research and development focused on diseases that are life threatening and have a higher potential for harming humans. This would mean reversing the current research

and development biases and having companies develop drugs for those in the underdeveloped world with life-threatening diseases.

These principles when chosen behind a veil of ignorance leave no room for unfairness to be present in the pharmaceutical industry. The fundamental characteristics and principles the pharmaceutical industry should have, in order to be considered just can be determined through Rawlsian justice. Unfortunately, the current patent system is not just, and does not include the principles and characteristics Rawlsian justice would require. However, it is possible to create a system in which these fundamental characteristics and principles are satisfied.

How is the Present System Unjust?

The main areas where the present patent system falls short according to Rawlsian justice and also by Thomas Pogge are in universal access, innovation, and overall spending efficiency. The present 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. Consequently, pharmaceutical companies do not make the drugs accessible in these developing areas 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. Pharmaceutical companies need to generate large profits in order to fund further research and development and to make money for their shareholders. In order to make drugs more

universally accessible, there needs to be an approach that allows pharmaceutical companies to stay in business and to provide drugs for the developing world. One solution would be to create a system other than the current patent system that provides an incentive for companies to innovate and make accessible pharmaceutical products pertaining to developing areas.

Innovation in the pharmaceutical industry is extremely costly, this creates a major bias for pharmaceutical companies when deciding which drugs to research and develop. 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 financial position to pay the market price for pharmaceuticals. The developing world is greatly affected by life-threatening diseases and serious illness; it makes up for 90% of the world's global burden of disease where the developed world only accounts for 10% of the global burden of disease.²⁰ In order for pharmaceutical companies to innovate in a way that would be considered fair and just according to Rawls, it would be required to better the positions of those in the worst off positions. Unequal distribution of research and development spending, in a way that increases the research and development of

²⁰ Philip Stevens, "Diseases of Poverty and the 10/90 Gap," 2004, <<http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf>>

pharmaceutical products oriented towards the developing world is what would be required for justice. Spending that would match the global burden of disease, having 90% of pharmaceutical spending go towards 90% of the global burden of disease in the developing world would benefit those in the worst off position in the global society.

The final major area that would be considered unjust in the current patent system would be the overall spending efficiency. In terms of overall spending efficiency the current patent system spends a large portion of sales revenue and funding on lobbying, gaming, patenting, litigation, marketing, and counterfeiting instead of spending on research and development. The current patent system allows for the possible rewarding of this behavior and spending, which can be considered wasteful. This wasteful spending may lead to more income for pharmaceutical companies in some cases however, this does not guarantee more innovation or drugs being developed as a result. Instead of spending money on wasteful activities, a new system would need to be in place that does not reward this type of spending and that promotes spending more of the sales revenue on research and development of new drugs. Preferably having spending oriented towards developing drugs oriented toward the underdeveloped world where the greater burden of disease is accounted for would make for a more just system.

Overall, the major differences between the current patent system and with a system one might see behind the veil of ignorance is making drugs more universally accessible and affordable, having a system that does not create

biases for innovation unless it benefits those in the worst off positions, and for pharmaceutical companies to spend more efficiently; less on wasteful activities and more on research and development. According to Rawlsian justice, these problems are the main reasons why the current patent system is unjust.

Big Pharma: Studies and Statistics

A study done by York University researchers estimates that the U.S. Pharmaceutical industry spends almost twice as much on promotion, including advertising then it spends on the research and development of new drugs. Marc-Andre Gagnon and Joel Lexchin conducted the study concluding from their findings that there is a need for change in the priorities of the U.S. pharmaceutical industry. The data used was collected directly from the industry and from doctors in 2004. IMS Health and CAM Group reports were examined. These are international market research companies that provide the pharmaceutical industry with sales and marketing data and consulting services. IMS Health interviews pharmaceutical firms where CAM Group surveys doctors. Because the two firms use different methods for gathering data this allowed Gagnon and Lexchin to triangulate their estimations. This data shows the U.S. pharmaceutical industry spent 24.4% of their income from sales on promotion, and only 13.4% of the income from sales on research and development. In 2004 the total domestic sales for pharmaceuticals in the United States was \$235.4 billion. Although this study only included the U.S. pharmaceutical industry, it still shows the depth of the problem. The U.S. has the largest market for pharmaceuticals in the world

representing 43% of global sales and promotion expenditures. The researchers also note that the number of meetings for promotional purposes has dramatically increased in the U.S pharmaceutical industry. In 1998 the number of meetings for promotional purposes was 120,000, and increased to 371,000 in 2004. These statistics and analysis show the pharmaceutical industry is market driven which takes away from the perception of a research drive, life saving, pharmaceutical industry.²¹

Many studies have found that the pharmaceutical industry in North America spends about twice as much on promotion and advertising than on research and development. What is also important to research is what kind of drugs the research and development spending is being used to for and if the data supports a bias in what kind of drugs are being developed. In Canada the average cost to develop a new medicine is \$1.3 billion and \$800 million in the United States. These are statistics often used by pharmaceutical companies in order to justify their need for promotion and advertisement spending, however, the cited sources for this figure is a 2001 report from the Tufts Center for the Study of Drug Development, which happens to receive 65% percent of its funding from drug companies. Most industry analysts, who do not typically receive funding from Big Pharma companies, believe these figures are exaggerated. It is estimated that the \$800 million dollar figure is used to describe only a minority of the most expensive drugs. The Tufts analysis also included the “capital cost”

²¹ York University, “Big Pharma Spends More on Advertising Than Research and Development,” 2008, <<http://www.sciencedaily.com/releases/2008/01/080105140107.htm>>

within the figures, that is, the out of pocket cost plus the estimated revenue that may have been generated if the money spent on research and development had instead been invested in the equity market. Another problem with this estimated cost of developing a new drug is that it is in pre-tax dollars; research and development costs are fully tax deductible.

The 2006 Annual Report of the Patented Medicine Prices Review Board (PMPRD) showed that from 2000 until 2006 the Canadian pharmaceutical industry's research and development-to-sales ratio was below what the industry had promised when the Mulroney government passed Bill C-22. In 1987 the Patent Act was adopted where Canada's Research Based Pharmaceutical Companies made a public commitment that brand name manufacturers would increase their annual research and development expenditure to 10% of sales revenue. In 2006 only 8.1% of pharmaceutical sales revenue was spent on research and development in Canada. This 8.1% also includes research expenditure funded by government grants.

In 2006 there were 99 new-patented medicines. Of the 99 some are new presentations of existing medicines and 24 of the new-patented medicines were new active substances. Of the 24 new active substances only 4 were Category 2, which PMPRD defines as the first drug to treat effectively a particular disease or illness or which provides substantial improvement over existing drugs. One would be able to conclude from this information that the majority of spending on research and development is not put towards generating new medicines but put towards developing a variation of a drug similar to an existing drug already on the

market. Canadians alone spend \$17.8 billion annually on prescription drugs. If more of the sales revenue was put towards research and development it is likely more drugs would be developed and people who need these new drugs would buy them generating more sales revenue.²²

In 1990 the Commission on Health Research and Development (CHRD) estimated that in 1986 out of the US\$30 billion of health research worldwide only US\$1.6 billion was relevant to the needs of developing countries, this is only 5% of all health research. In 1996 the Ad Hoc Committee on Health Research Relating to Future Intervention Options published a study of spending on health research and development in 1992. It was estimated in this report that there was a global investment of US\$55.8 billion for pharmaceutical research and of this the amount devoted to health problems of developing countries was US\$2.4 billion or 4.3% of spending. The CHRD estimated that 93% of the world's burden of preventable mortality occurs in the developing world yet only 5% of research was devoted specifically to health problems of developing countries.²³

Thomas Pogge and the Health Impact Fund

As previously mentioned, the present patent system does a poor job at providing universal access to drugs. Universal access is gravely undermined,

²² Canadian Generic Pharmaceutical Association, "The Real Story Behind Big Pharma's R&D Spending in Canada," 2007, <http://www.canadiangenerics.ca/en/news/docs/The_Real_Story_Behind_Big_Pharma's_R&D_Spending_in_Canada.pdf>

²³ World Health Organization, "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination," 2012, <http://www.who.int/phi/CEWG_Report_5_April_2012.pdf>

even in affluent countries, by extremely high mark-ups and, after the patent period, by inadequate incentives for the competent provision of generics to poor or hard-to-reach patients. The existing patent system has focused innovation which is distorted by huge economic inequalities which allow for the rewards for “blockbuster drugs” and the 10/90 gap, a term coined by the Global Forum for Health Research in 1998. The 10/90 gap refers to the statistic that 10 percent of money spent on all pharmaceutical research is used on diseases that affect 90 percent of the global burden of disease and vice versa, where 90 percent of the money spent on all pharmaceutical research goes towards diseases that affect 10 percent of the global burden of disease.²⁴ Thomas Pogge, a philosopher and Health Impact Fund advocate, claims that the problem of innovation and access can be attributed to the unequal distribution of money in the world. Those working within the pharmaceutical industry will look towards this distribution of money and cater to those who have the most money in order to be more profitable. Within the current patent system companies make their money through patent protected mark-ups. Overall efficiency is greatly diminished by lobbying, gaming, patenting and litigation, by deadweight losses, and by incentives for wasteful marketing and counterfeiting. A lot of money goes to lobbying politicians to extend patent periods and to gaming, which includes name brand companies paying generic companies to delay putting their product on the market as well as litigation. A lot of the profits pharmaceutical companies make

²⁴ Philip Stevens, “Diseases of Poverty and the 10/90 Gap,” 2004, <
[http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.p
df](http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf)>

are going towards these activities, which Pogge considers wasteful. Other wasteful activities performed by these companies include advertising and marketing, what one company spends on getting consumers to switch to their drug another company will spend in order to get those consumers back.

A common solution thought to fix these problems is to have a moral pressure placed on pharmaceutical companies; like individuals, pharmaceutical companies have duties of rescue, this may mean for them providing important drugs at an affordable cost to poor patients and to develop new medicines to help the poor. Pogge does not believe this is the solution to the problems with the existing patent system but that it is in fact unrealistic to expect pharmaceutical companies to act on the same moral scale as individuals. This is because pharmaceutical companies are bound to their shareholders; they are operating in a competitive market and rely on the sustainability of their innovation efforts, which is dependent on mark-ups. The companies would not be successful if they did not make money for their shareholders, if they did not remain competitive in the market and did not place mark-ups on their products.

These problems with the current patent system, believed by many, are the main problems addressed by the Health Impact Fund. What the Health Impact Fund is trying to adjust in the new pharmaceutical patent system is to make drugs more affordable and accessible to those in the underdeveloped world and to also try and eliminate the bias which drives pharmaceutical companies to develop first world drugs over third world drugs. The HIF would incentivize the development and delivery of new medicines by paying for performance.

Performance in this case is referring, to what scale a specific drug effects health. If a drug makes a large impact on peoples lives, in the sense that it gives people with a specific disease a certain amount of added years onto their life or if it successfully treats a severe illness, then the inventor of that drug will receive money from the HIF if the inventor has registered with them. The larger the impact, the larger the sum of money the inventor receives. All pharmaceutical firms worldwide would have the option of registering new medicines with the HIF. By registering, a firm agrees to provide its drug at cost anywhere it is needed, and in exchange for foregoing the normal profits from drug sales. The firm is rewarded based on the HIF's assessment of the actual global health impact of the drug. Governments and other donors would finance the HIF.

What is expected is that governments take money that would have already been allocated to the research and development of pharmaceuticals and put a percentage of this toward the HIF. This system still provides the incentive to innovate and also puts the drive behind this industry back to improving global health rather than financial gain. This system is thought to be more just in terms of Rawlsian justice. Those companies who register through the HIF are paid based on how much of an impact their drug has made. This creates a greater incentive to research and develop a drug that would be oriented towards underdeveloped countries, since they have more life threatening and widespread diseases. It is likely a drug oriented to developing countries would be more profitable for pharmaceutical companies. The system the HIF proposes also provides incentive for innovators to ensure the consumers of their

pharmaceutical products are taking the drugs properly. When the drugs are taken properly they would be more effective, therefore, possibly generating a greater profit for the pharmaceutical company. To guarantee the people are taking the drugs properly, companies may have labels or directions printed in local languages where the drugs are being sent to or other precautions similar to this. This is not only beneficial to the pharmaceutical companies but to the consumers, it is possible that there would be fewer deaths due to taking medicines incorrectly, and the drugs would be more effective when taken properly.²⁵

The Health Impact Fund fulfills all of the areas that the current patent system is lacking. In terms of Rawlsian justice the HIF proposes a system to fund research and development that provides incentive to innovate while providing universal access, promoting innovation that is not biased towards the developed world, and overall spending would be efficient. The Health Impact Fund is not meant to replace the current patent system but to provide an option to pharmaceutical companies to register with the HIF instead of using the current patent system. It would be too difficult to replace the current patent system seeing as it is too embedded in the pharmaceutical industry to be replaced.

Conclusion

Through my thesis I have shown that the current patent system, while having some virtues, providing an incentive for specific innovation and having effected global health, it is unjust according to Rawlsian justice for several reasons. What justice would require according to the Rawlsian methodology for the pharmaceutical industry is that it provides universal access to drugs,

²⁵ The Health Impact Fund, 2013, <<http://healthimpactfund.com/>>

innovation is not biased unless it is in a way that betters the positions of those in the worst off positions in society, and there is overall spending efficiency. Unfortunately, through my research I have found that the current patent system does not hold these characteristics that Rawlsian justice would require for the pharmaceutical industry. The current patent system provides little or no incentive for pharmaceutical companies to provide products to poor people in the hard-to-reach developing world. People in the developing world are often unable to afford the market price of pharmaceutical products; therefore, pharmaceutical companies do not make the drugs accessible in these developing areas because there is no profit to be made by doing this. Innovation as well as research and development is extremely costly in the pharmaceutical industry. In order to fund their research and development pharmaceutical companies generate the largest profits by developing “blockbuster” drugs that are oriented toward the developed world. This creates biased innovation that disfavors those living in the underdeveloped world. Companies will not develop drugs oriented towards the developing world because it is likely through the current patent system that it will not be profitable. Lastly, the current patent system spends the majority of its sales revenue on wasteful activities on marketing and promotion instead of spending more on research and development.

After finding that the current patent system is unjust and in what ways it is unjust, I explored the proposal of the Health Impact Fund. The HIF puts forward a new way to fund research and development for pharmaceutical companies while holding the characteristics for justice the Rawlsian methodology requires. The HIF would incentivize the development and delivery of new medicines by paying for performance; this means a pharmaceutical company would be paid based on a scale of how much their specific drug registered with the HIF makes a positive impact on global health. By registering with the HIF companies would forego the normal profits from the current patent system and

make available their drug anywhere it is needed at cost. This solves the problem the current patent system has with universal access. Innovation would likely be focused on life-threatening diseases and diseases in the developing world because the potential for improving global health is greater if a cure is found for these illnesses, generating a greater profit for pharmaceutical companies. There would be no need for the marketing and promotion of “blockbuster” drugs when the focus is on the improvement of global health. The system the HIF proposes would provide universal access, innovation that is not biased unless it benefits those in the worst off positions in society, and overall spending efficiency.

The HIF is a system that should be adopted because it provides a more just pharmaceutical industry and would improve overall global health. The drive behind the pharmaceutical industry would no longer be marketing and profits from drugs that are only slight variation of already existing drugs, but on the improvement on global health and quality of life.

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