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Patently Underdeveloped: How Misuse of Patent Law by Unethical Business Practices of the
Pharmaceutical Industry Hurts Developing Nations

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Abstract

The present text explores the misuse of patent law in the pharmaceutical industry from its original purpose of the protection of intellectual property rights. Unethical business practices of Big Pharma has stifled innovation and decreased the accessibility of necessary drugs while increasing unethical behaviors. Global cases of malpractice within the industry are examined to determine the necessity for changes in both the pharmaceutical industry and its surrounding environment. The real effects of this issue are experienced in developing nations, in which there is a greater disparity of medication accessibility and affordability as compared to a developed nation. Developed nations have the privilege to value profit margins over individuals' rights to sufficient healthcare because of the structure of multinational corporations and investment in research and development. As a result of profit-motives of the powerful sector of the pharmaceutical industry, "Big Pharma," developing nations are neglected in terms of research and development and distribution of medication due to their lack of profitability. However, due to the wide impact of the actions of pharmaceutical corporations, there must be a perspective of social obligation to society. Additionally, corporate social responsibility, or obligation to act ethically towards society, should be implemented to benefit both an ethical and business angle to alter the negative outlook of Big Pharma upon developing nations. Through an analysis of the HIV/AIDs epidemic as well as other health concerns potentially ailed by patented medication, this paper argues that a mitigation of unethical business practices through corporate social responsibility, change in patent types, and stability of government in combination has the ability to improve medication innovation, access, and affordability while benefiting Big Pharma.

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I. Introduction

Affordable, accessible medication that is vital to the existence of many lives across the globe has become increasingly limited not due to scarcity but rather as a result of artificial inflation of prices. A report by the Secretary-General of the United Nations, published in August of 2008, found that over two billion people do not have access to necessary medication (Ahmadiani and Nikfar 1). Clearly, the message that one-third of the human population have no means of obtaining medication that exists and could potentially prevent life-threatening or serious health issues is alarming. Patent law discourages innovation in the pharmaceutical industry which thereby unethically limits access to lifesaving drugs to people in developing nations. This is because Big Pharma, or large pharmaceutical corporations, utilize patent law in order to boost corporate gain and obtain an impermanent monopoly through unethical business practices. Through these means, patent law is being utilized to stifle innovation, restrict access to medication, and fail to acknowledge life-threatening diseases such as AIDS that only impact a unprofitable demographic of individuals in developing nations.

The primary disciplines through which this argument will be presented are ethics, law, and business. Ethics will be utilized to assign a moral judgment upon the actions of the pharmaceutical industry in order to reason their behavior. Law is the backbone of patent law protections, rights, and obligations. Through this, the negative side effects of predatory practices can be mitigated through court protections of individuals and patients. On the other hand, it can also be used to prop up Big Pharma and enforce their patents in nations wherein the government is too weak to protect its citizens against international policies. Business will show how the unethical practices actually hurt the bottom line. The purpose of using these two disciplines is to highlight the issues within the industry, provide a cause to give attention to, and finally offer

solutions that are capable of fulfilling expectations and obligations to individuals, corporations, and society as a whole.

The following paper will provide an overview of patent laws in their legal origin and backings, and later analyze how the original purpose of these designations have gone awry through intervention of predatory practices of Big Pharma. The primary focus will be on the effects of this intervention on innovation and developing nations, specifically through an examination of the AIDS/HIV epidemic, which is a prime example of patent misuse. An ethical investigation of the actions of the pharmaceutical industry as a whole will be performed. Finally, a demonstration of the ideal conditions under which patent law can and should exist will be described.

II. Why Did Patent Law Appear?

Although patent law has been present for many centuries, its terms solidified after the TRIPS agreement of 1994. Under this agreement, the World Trade Organization had to enforce intellectual property rights of patent holders by controlling inventions that may be “produced, imported, sold or used” without proper permissions of the owner (Ahmadiani and Nikfar 1). This means that there is a legal backing for the implementation and support of patent laws around the world. Although the specific terms of each patent may vary depending on the nation, the TRIPS agreement ensures that patents are legitimate ways to protect ideas. The primary factors of the patent designation to note, however, is that the invention must be in some way novel and provides its respective creator exclusive sole ownership of the idea for up to 20 years.

The purpose of intellectual property laws, during its inception, was to protect the rights of creators. The International Covenant of Economic, Social and Cultural Rights in article 15 found that “the rights to cultural participation, the benefits of scientific progress, and intellectual

property” were all interdependent (Chapman 19). Thus, it was assumed that by protecting intellectual property, the other conditions would be fulfilled. The intention of intellectual property rights in this regard is to benefit the scientific community through protecting ideas of individuals and, by extension, corporations. The Covenant is crucial in shaping the way that pharmaceutical corporations have defended their use of the patent, positing that by protecting their interests, they also improve the scientific community.

Another incentive of patent creation has been the financial aspect of products created through this process. Patent protection was meant to allow creators to receive a return on their research and development (R&D) investment and reinvest their profits into innovative efforts (Qian 436). This notion relates more to the corporate aspect of innovation but is very relevant to the discussion of patent misuse. Corporations use finances to promote innovations in their particular fields through research and development, in which there is a specific focus on creating more patentable product. Under this conception, corporations should reinvest their profits into R&D and therefore patents give them protection from competition so that they can invest more into the products (Yu 1453). Thus, patents should be used to encourage corporations to continue their economic efforts in innovating and creating, for example, new medications that could benefit society. However, large pharmaceutical corporations utilize patent law in a way that contradicts its original intentions, such as through monopolization.

III. When Patent Laws Go Awry In The Pharmaceutical Industry

The issues with patent law can be attributed to the increasing commercialization of pharmaceutical companies, resulting in what modern society calls “Big Pharma.” The creators of patent law assumed that by protecting ideas of inventions, corporations and innovators would be more likely to create more and enhance competition. However, the effects of the TRIPS

agreement meant that patent holders of medicine could monopolize the market at any given price. Haley found that a monopolized drug industry reduces consumer surplus by one-third compared to a normal, competitive market (611). This means that consumers of medication are paying the difference created by government protection of patents. In an industry where insurance of all individuals is not equal nor guaranteed, the effects of consumer prices vary greatly on the finances and health of individuals from different nations. Furthermore, the control of the patents meant that generic versions of medication could not be produced at lower, affordable prices, forcing patients to pay the higher prices of the branded medication. This means that having pharmaceutical corporations in a private market does not necessarily correlate to reasonable prices across the market for all individuals. In fact, through numerous studies and reports, the United Nations found that individuals in developing nations do not have equal access to medications from the private industry (Ahmadiani and Nikfar 1). This demonstrates that the pharmaceutical market, as a result of patent protection, is not free and therefore not fair to consumers who bear the burden of costs. Therefore, the misconception that patent law encourages competition is actually negated by the monopolization of the products.

The current process of commercialization has used patents to protect corporate interests through encouraging investment in the firm rather than protecting individual intellectual property rights. Interestingly, patents may be counterproductive to this strategy of increased profits because it incurs in application costs and financial efforts in lobbying. An unexpected effect of patents is high licensing fees or competition for licensing as a result of sequential innovations (Qian 436). Thus, it is actually detrimental to invest in patents to protect ideas and incur a profit because of the high costs associated with it.

Another purpose of patent law is to protect ideas and encourage innovators to create more unique and novel ideas that can be sheltered by patent laws. However, Mansfield, Shwartz and Wagner found that patents do not necessary lead to protection of ideas, as 60% of patent products were victim to imitation four years after their creation. This issue of imitation is one of the primary reasons why patent protection exists, yet it is not sufficiently addressed by patents in general. Therefore, it is clear that while an objective of the originators of patent law was to protect creators, it has not been fulfilled. This can also be traced to commercialization of pharmaceutical markets. According to Towse, the use of extrinsic motivation through profit negatively influences intrinsic factors of innovation. This is because factors of commercialization such as competition can increase pressure on an innovator or creator and reduce the quality of the product. As this relates to pharmaceutical corporations, the stress upon a patent creator within a corporation will lead to lesser quality or lesser innovative medications. Therefore, it is not beneficial to commercialize pharmaceutical corporations through patent-strengthening as it can negatively affect the business itself.

The root of the aforementioned issues with the application of patent law can be found in an understanding of Research & Development (R&D), which is the sector of a specific corporation that focuses on the creation of new medication. The pharmaceutical industry utilizes upwards of \$1 billion to produce a new drug (Haley 612). This value accounts for marketing, development, production, and distribution. Despite this seemingly large number, the actual amount of profit used in R&D is 1.3%, which is twenty-five times less than the amount of revenue put into marketing (Oppenheim 506). This number emphasizes the value of corporations on selling a product rather than creating one. This is the pinnacle of the issue in that innovation is not occurring as a result of profit-motives of Big Pharma, which thereby goes against the original

principles of patent laws. The higher prices are not associated with more innovation and more effective product for individuals. Rather, corporations are evergreening their products, a process in which an inventor makes a slight adjustment to an existing product in order to hold on to the patent, and monopoly, longer (Qian 2007). Clearly, Big Pharma is not honoring the original purpose of the TRIPS Agreement. This raises questions to its impact on science, if there is one, and how individuals in certain socioeconomic groups are particularly affected.

IV. Why Does This Matter: Chilling Effects on Developing Nations

There are many detrimental effects of corporate unethical interventions in patent law; however, these issues are concentrated into a few groups. It is crucial to analyze its effects to understand why it is an issue at all. Primarily, developing nations reap the negative side effects of patent law misuse through lack of attention and care for medication that is deemed not as profitable as those directed towards developed nations.

Big Pharma corporations are primarily interested in producing drugs that are profitable, which can severely hurt innovation and quality of human life. Evidence shows that pharmaceutical companies focus their R&D in chronic diseases, in which customers are numerous and lifelong. The financial backing of Research & Development efforts are not interested in supporting anti-parasitic or antibiotic medication, despite their prevalence in lower developed nations, but rather anti-hypertensive medicine that relates to wealthier consumers for longer periods of time (Ahmadiani and Nikfar 3). This predatory nature can prevent medications that are beneficial to a majority of humankind as Ahmadiani and Nikfar states, “only 10 % of R&D expenditures is related to problems of 90 % of world population” (3). Evidently, there is a bias against low-income regions because they do not offer the profit incentives despite the large population that remains affected by treatable ailments. The World Health Organization found in

their 2003 world health report that the disparity between developing and developed nations has resulted in lower life expectancies and increased health concerns for developing nations.

Additionally, developing nations often import scientific technology, which can result in issues of information asymmetry between two different states. This is an issue because developing nations do not have the appropriate infrastructure or regulatory system to sift through the information (Chapman 23). This can be particularly dangerous because a lack of scientific literacy and communication channels means that the public is vulnerable to incorrectly used technologies. The World Health Organization found that between 25 and 50 percent of medications in developing countries contained counterfeit ingredients (United Nations). Such ingredients include antifreeze or types of industrial solvent that are found in common medications. As a result, mass poisonings have occurred in numerous developing nations such as Nigeria, India, Panama, and China. Commercializing this industry and supporting that effort through patents inevitably leads to competitive strategies of producing faster or cheaper product at the cost of the consumer. To protect their citizens, governments must focus on filtering medication that may have complications instead of a profit-motive simply for the sake of lives.

Interestingly, developing nations do not place an emphasis on stronger patent laws as compared to developed nations. This is primarily because intellectual property rights award patents that benefit a long-term system because costs are too high in the short-term to be sustained in a developing nation (Chapman 29). Any profits that come from the technological investments return into foreign multinational companies. This illustrates the focus of Big Pharma on developed nations because they can enforce their patents more thoroughly to profit more.

Visibly, developing nations are at the heart of the issue of patent law misuse. Their lack of infrastructure and increasing health concerns combine to deter pharmaceutical corporations from

focusing their attention to them. This is more than a marketing issue because with this neglect, individuals in developing nations have no way of attaining better treatment and health. This bleak situation is most clearly seen through the AIDS/HIV epidemic, in which a combination of all of these aforementioned factors combine to target a specific group of patients who are unable to find affordable treatment.

a. AIDS/HIV Epidemic

The primary purpose of bringing the AIDS/HIV epidemic into this discussion is its density in lower developed nations and reliance on medication to aid patients. According to Byrne et al., there are approximately 36 million individuals infected with HIV across the globe, 95% of whom are located in developing nations (300). This is the same for AIDS patients who require medication, of which two-thirds also reside in developing nations. This is critical information considering the lack of attention towards developing nations in regards to innovative, affordable medication from pharmaceutical companies. The medication that treats these viruses, anti-retroviral (ARV) drugs, is increasingly difficult to obtain in developing nations in large quantities. Studies show that only 7% of those in need of ARV medication can get them (Byrnes et al. 300). This statistic emphasizes the disparity in access to medication and the issues with the monopolistic market. The lack of accessibility of a preexisting drug demonstrates how Big Pharma is not pushing products and investing into marketing of medication that reaches a poorer patient. In fact, the pharmaceutical industry is only interested in selling AIDS/HIV medication in regions wherein the patient can afford a higher cost. According to McNeil, the cost of purchasing fluconazole, a Pfizer Inc. medication at \$18 a pill or \$500 a month, is greater than the per capita income of most citizens of Kenya. This type of issue is only applicable to developing nations where the income is this low.

Another issue within this realm is that pharmaceutical corporations are resistant to investing resources into producing and advancing AIDS/HIV medication. Pharmaceutical companies focused in R&D do not find that diseases occurring in developing countries, such as AIDS, can produce returns on investment (McNeil). This is primarily because patients of AIDS/HIV are concentrated in regions of low income or developing nations. Therefore, there is less incentive to create a product that has a lesser rate of return than a medication that could be sold regularly at inflated prices in a developed nation.

The primary issues within the treatment of AIDS/HIV patients is the lack of accessibility, high costs, and disregard for development of related medication. These are serious problems within the industry because it means that there are no advances being made in a health concern that affects over 30 million individuals around the globe. Individuals are being purposefully neglected and left to deal with a disease that leaves them vulnerable to infections, and ultimately, an early death. Though this is cause for alarm within society, and the clear responsible party is the pharmaceutical corporations, there are questions regarding the need for this particular industry to direct attention towards diseases that do not benefit the bottom-line.

V. Do Pharmaceutical Corporations Have an Obligation to Society?

A primary point of contention when holding pharmaceutical corporations to a higher moral standard is that they are simply another business entity. According to Huebner, the pharmaceutical industry will only have "special duties of beneficence and distributive justice with respect to the impoverished in dire need of their products" if all other industries have the same duties. The mentality that they are obligated to society comes from some universal perception that the trade-off between intellectual property rights and an individual's right to vital medication is taboo. The root of this issue is questioning why a company needs to "assume the

risk, time, and expense necessary to develop a medication for a rare, life-threatening illness affecting predominantly impoverished nations” when it has no profit incentive (Huebner 507). Essentially, Huebner argues that it is not financially reasonable to invest into products that can be available at lower costs to more populations.

Although pharmaceutical corporations are indeed businesses and require money to continue, the issue of human rights remains. The International Covenant of Economic, Social and Cultural Rights declares in article 12 that all humans have the right to the “highest attainable standard of physical and mental health” (Ahmadiani and Nikfar 4). This testament also applies to private enterprises, as well. This means that corporations are liable to allowing individuals access to the highest level of health through medication that is offered at affordable prices. Furthermore, many developing governments do not have the infrastructure to encourage internal R&D and must depend on external parties to produce medication, as seen in the failed generic drugs that resulted in mass poisonings. Pharmaceutical corporations are therefore not just any business entity. They directly affect the lives of individuals through the development, or lack thereof, of medications that can treat or reduce the effects of numerous diseases.

From an ethical perspective, a pharmaceutical corporation’s duty to meeting social responsibility trumps any profit motives. There are no other industries that can provide the same service to individuals because the pharmaceutical industry is expensive and highly focused. The use of patent laws as provided by the WTO has not been used to encourage innovation as Huebner suggests, but rather concentrates innovation in the most profit-inducing sectors of the industry (Ahmadiani and Nikfar). Corporate social responsibility, or CSR, is the business perspective on how to solve the patent law misuse pandemic. CSR should be an expectation of all businesses across all markets because it reduces unethical behavior as a whole and thereby

encourages healthy competition. This will simultaneously increase profits for corporations and allow individuals access to affordable medication.

VI. Corporate Social Responsibility

The purpose of this argument is not to disavow patents permanently but rather find ways to incorporate intellectual property protection in a way that does not harm individuals or society. Therefore, a condition that would benefit patent holders and consumers is the notion of corporate social responsibility (CSR), which can mitigate the negative behaviors of pharmaceutical corporations by encouraging different means of reaching the same profit bottom line. For example, studies have shown that CSR can directly improve innovation through their attractiveness to employees (Bereskin and Hsu 82). This means that employees are likely to feel more comfortable in a workplace without artificial pressure created by corrupt or money-driven superiors. Therefore, they are able to brainstorm more easily to create products that most accurately reflect the needs of the corporation or society.

CSR includes behaviors that improve society, one of which includes philanthropy, which has many benefits. This can affect the profitability of a corporation as philanthropy, which can improve brand imaging, even for higher priced medications, and thereby result in more consumers (Bereskin and Hsu 82). A corporation that is viewed as dependable or trustworthy can increase product revenue because there is a higher volume of product being purchased. Furthermore, one study found that an additional increase in the standard deviation of direct giving through philanthropy results in an increase of patent influence by 18% and patent productivity by 9% (Bereskin and Hsu 85). This allows corporations to involve themselves into needy communities to for more effective R&D development in understanding its core issues.

CSR is the perfect response to unethical business practices because it allows corporations in the pharmaceutical industry to reach the same profits without utilizing patent misuse. It has the ability to generate innovation and higher profits through employee brainstorming and philanthropy, which allows corporations to involve themselves in society and have a better understanding of the needs of communities that require medications. However, other factors such as patent type and government stability are crucial in reducing negative effects of predatory practices on developing nations.

VII. What Model Of Patent Laws Best Promotes Ethical Pharma Practices And Respects Business Concerns?

The implementation of patent law can be improved by altering the primary type of patent law used and giving state governments more control over outside business practices. These in combination can create an environment that discourages unethical actions by corporations in societies where the impact would be the most detrimental. These suggestions should be taken in consideration with the aforementioned CSR and social obligations that encompass both the business and ethical perspective of the patent law issue.

The type of patent law is crucial in reducing mimicry while also promoting innovation. Patent laws can protect individuals from others stealing their work or ideas, but it needs to be restricted in order to prevent price or information monopolies. In India, although the pharmaceutical industry only invests 1.6% of its revenue into R&D as compared to Western nations' 15%, these corporations have increased cost advantages and innovation (Haley 613). These benefits are directly correlated with the use of process-patents as opposed to product-patents, the former of which may actually reduce innovation (Haley 618). In order to equalize the opportunities available to consumers of both developed and developing nations, the number of

drugs developed and sold strengthening patent laws would have to be three times greater than drugs sold without strengthening these laws (Haley 611). Therefore, to reduce monopolization of products, patent laws must be similar across nations.

The position of external forces, such as the government, should not go unnoticed. In a study done by Qian, 26 countries and their respective patent laws were examined for innovation between 1978 and 2002. Qian discovered that the optimal level of patent protection is dependent upon economic development, education, and economic freedom. Therefore, the government plays a crucial role in preventing the overpowering of pharmaceutical corporations in their use of patents. A particular case in 1990s South Africa illustrates the undermining of the TRIPS agreement in favor of protection of citizens as one pharmaceutical company, GlaxoSmithKline, sued the South African government for distribution of generic anti-retroviral medicine (Ahmadiani and Nikfar 8). However, the Pretoria High Court ruled that the basic human right to health overpowered the patent law rights for South African patients and resulted negotiations between the South African government and Big Pharma in aims of reducing the price of branded medication. This is particularly notable in that the law was able to enforce a precedent of importance between human rights and patent rights, which was also seen in the AIDS/HIV epidemic within the same decade.

VIII. How Does This Solution Benefit the AIDS/HIV Epidemic?

All of these said conditions combined create a safer environment for patients with diseases in developing nations. As applied to the AIDS/HIV epidemic, this can greatly improve the accessibility of medication and provide relief to patients of a terminal illness without a cure. In Brazil and India, the government has chosen to ignore product patents in favor of producing generic forms of ARV (Byrne et al. 301). This has made the cost of the medication over 80%

cheaper than the branded versions. This demonstrates a growing protection of consumers by diverting attention from product patents, as Haley noted were negatively correlated with innovation. Therefore, the shift in government action can result in future innovation as well as improved accessibility through cheaper prices. In nations like Tanzania, Ghana, and Nigeria, where the annual health budget is less than \$8 per person, this cost difference can make a substantial difference in distribution of medication by the government (Global Burden of Disease Health Financing Collaborator Network). Additionally, other groups have reacted to the AIDS/HIV epidemic through acting as an intermediary for the pharmaceutical corporations. For example, a non-for-profit manufacturing company in Brazil reduced the amount of deaths attributed to AIDS by 54% between 1995 and 1999 by offering universal access to ARV medication (Byrne et al. 301). This demonstrates the importance of spreading scientific knowledge in order to increase the individual lifespans of those afflicted with AIDS/HIV.

IX. Conclusion

Although patent law was created to protect of innovators through the World Trade Organization, organizations such as the United Nations are alarmed by the human rights violations incurred by pharmaceutical corporations (Ahmadiani and Nikfar 1). It is clearly not beneficial to have corporations have the ability to monopolize a certain market because it leads to inflated prices and inaccessibility to people who require medication to survive. In the name of profit, many Big Pharma corporations are choosing to ignore serious health issues to address in their R&D of products in favor of products that affect a few, wealthier consumers.

Developing nations are the primary casualty of Big Pharma because their citizens, who are already vulnerable to disease, are unable to receive necessary medication. However, this can be resolved through a few different means of change. Primarily, the pharmaceutical industry must

adopt CSR in their behavior and decisions. Additionally, changing the type of patent and supporting government stability can result in an improvement to the breadth and depth of scientific achievements in the pharmaceutical industry. These can improve the quality of life of those afflicted with AIDS/HIV, a disease that is not particularly profitable.

Despite the business structure of pharmaceutical corporations, it is an industry that directly influences the lives of individuals across the globe. Beyond this, it is economically beneficial to invest in medications for ailments, such as AIDS/HIV, that may primarily occur in developing nations. There are many opportunities for returns on investment in these regions if there is a pure competitive market rather than monopolistic entities that are supported by local governments who encourage their existence through the propagation and strengthening of patent law. While it may be appealing to completely end patent law or to create government sanctioned medication, it is crucial to note that innovation that is produced in a regulated, safe environment can actually produce results that are beneficial to every party.

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