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Examining the Ethics of Medical Process and Product Patents

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Intellectual property laws impact all aspects of life by establishing ownership over and regulating almost all commercial goods and processes. These laws are designed to promote creativity and innovation with the hope that new products, technologies, and manufacturing methods will improve society and the lives of those living in it. Intellectual property most directly impacts the healthcare industry by allowing patents on medications, medical processes, and medical technologies. Allowing private ownership over essential goods and services that impact people's well-being raises questions about the ethics of this system and its effects. While the idea of private ownership itself is not unethical, the scenarios that may stem from it can be. I argue that the current intellectual property system allows for unethical scenarios to occur in healthcare worldwide, and that a better balance between private and public interests needs to be implemented on the international stage.

Part I of this paper looks at how the right to health has been established for people internationally. Its goal is to bring to light the responsibilities of countries to ensure that their citizens have access to necessary medications and care. This responsibility should influence a country's intellectual property laws by requiring that these laws do not interfere with this goal. Part II explores international patent laws as they relate to the medical field, and then takes a more in depth look at patent laws in the United States as an example of how countries may choose to go beyond the minimal international guidelines. Part III briefly looks at some of the most important ethical conflicts and considerations with patent laws as they relate to medicine. Finally, part IV discusses how patent laws can lead to problems with access to medications and applies some of the ethical principles discussed in part III.

I. Right to Health

The right that all people have to health has been established worldwide in multiple forums. The Universal Declaration of Human Rights (UDHR), proclaimed by the United Nations General Assembly in 1948, creates a set of standards for people worldwide and declares rights that are expected to be universally protected. Article 25 of the UDHR states that all people have the right to a standard of living that is appropriate for ensuring their health and well-being and specifically asserts that this standard includes medical care (United Nations, 1948). People's right to health was reiterated in 1966 when the United Nations adopted the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The ICESCR is a treaty that outlines the rights of people living in its member countries. Article 12 of this treaty recognizes the right of all people to "the enjoyment of the highest attainable standard of physical and mental health" (UN General Assembly, 1966).

According to World Health Organization (WHO), viewing health as a human right (as done by the UDHR and ICESCR) requires states to certify that people have access to "timely, acceptable, and affordable" health care (World Health Organization, 2017). What qualifies as acceptable healthcare is not clearly defined, but will be understood in this paper to include healthcare that prioritizes the interests of the patient and is conducted ethically. This requirement of countries is further established by article 2(1) of the ICESCR, which requires countries to take steps to ensure that the rights declared in the treaty (including that to medical care) are fully realized (UN General Assembly, 1966). This requirement can be extended to conclude that a country is obligated to make sure that its intellectual property laws do not interfere with its citizens right to health.

II. Patent Law as it Relates to Healthcare

A patent provides exclusive rights over the production, sale, and use of an invention. This invention can be a process, product, machine, or composition of matter. However, in order to receive a patent, an invention must be new, useful, and nonobvious. In the medical field, patents can be used to secure rights over medications, medical processes, and medical technologies. Patents for medical processes can be divided into three categories: 1. Patents over medical procedures; 2. Patents over the use of a drug or medical device; and 3. Patents over techniques for isolating compounds (such as for a medication) or for building medical devices (such as a pacemaker) (Kubick, 2010, 291).

Most international laws on intellectual property are dictated by the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). This agreement was made between all of the member countries of the World Trade Organization and took effect in 1995. TRIPS was designed to establish minimum standards for intellectual property protection in all countries. The agreement provides guidelines that individual countries are expected to follow in their laws and practices. TRIPS requires that countries provide patent protection to inventions in all fields of technology and that these patents last a minimum of twenty years (TRIPS, 1994, Articles 27 and 33). This can be interpreted to mean that TRIPS requires countries to grant pharmaceutical patents (Chorev and Shadlen, 2015). It also allows governments to refuse to grant a patent to diagnostic, therapeutic, and surgical methods for treating humans or animals, plants and animals that are not micro-organisms, or inventions that threaten the *ordre public* (TRIPS, 1994, Article 27). This flexibility allows governments to choose not to grant patents on certain medical procedures, but it is often not utilized.

Further flexibility in relation to medications and other forms of intellectual property related to healthcare were elucidated in the Doha Declaration in 2001. The Doha Declaration was made to clarify concerns about how various aspects of TRIPS related to public health. The declaration reiterates that governments should interpret and enforce the TRIPS agreements in a manner that supports people's right to health (Osewe, Nkrumah, and Sackey, 2008, 10). However, the usefulness of these flexibilities is dependent on a government's ability to take advantage of and implement them.

The ability of countries to choose how they will protect and enforce these internationally held standards is significant because it means that intellectual property protection varies to some extent worldwide. For example, laws regarding intellectual property in the United States go beyond the minimums established by TRIPS. As of 2010, in the US, use of the machine-or-transformation test could be used as a factor when considering the patentability of a product. This was established by the Supreme Court ruling on *Bilski v. Kappos* and can be applied to methods of administering a drug into a person's body (Kubick, 2010). TRIPS does not require these inventions to be covered and other countries have chosen not to grant patents to them. For instance, the European Patent Convention limits the patentability of certain diagnostic methods (European Patent Convention, Article 53).

III. Ethical Principles and Considerations

Medical ethics revolve primarily around four main principles: autonomy, nonmaleficence, beneficence, and justice. However, the principle of nonmaleficence is not impacted by intellectual property laws, and focusing only on these principles would ignore many other considerations that impact ethical decisions in healthcare, such as a patient's right to privacy. Most of these have roots in the Hippocratic Oath, which is a series of ethical promises made by many physicians when they

begin to practice medicine. The statements in the oath are designed to guide physicians as they work with patients. This section explores how patents on medications, medical processes, and medical technologies have the potential to impact each of these principles and considerations. There will be some overlap between subsections because the principles are understood to be prima facie principles and none of these would exist in isolation.

Patient Autonomy.

In medical ethics, autonomy refers to a patient's capacity for self-determination. Self-determination is the ability to make decisions about one's own life (Vaughn, 2010, 9). This means that patients should have a say in their healthcare treatments and any related decisions. For example, conducting a procedure without a patient's permission would be a violation of this principle and would cause obvious ethical concerns.

Patenting medications, medical processes, and medical technologies allows for private owners to have a temporary monopoly over certain inventions. During this monopoly, access to these resources is limited. In order for a patient to fully realize their autonomy, all options should be available to them. By limiting patient options, medical patents prevent patients from fully exercising their right.

Beneficence.

When taking the Hippocratic Oath, physicians promise to take any measures necessary to help those who are sick. This is reflected in the principle of beneficence which requires that medical professionals make an effort to actively advance the well-being of their patients and prevent harm from occurring to them (Vaughn, 2010, 10). Medical patents can limit physicians' ability to promote their patients' health by causing restrictions on what treatments are available to them.

Justice.

Justice is harder to define than autonomy and beneficence as it can be understood on either an individual or societal level, and it can be viewed from multiple philosophical perspectives. On an individual level, justice requires that all patients be treated equally. In situations where access to patented treatment is based on cost, justice is not fulfilled because patients cannot equally receive treatment. However, when viewed on a societal level, determining whether or not justice is accomplished depends on the perspective that it is viewed from.

Distributive justice looks at whether society's advantages and disadvantages are equally distributed among its members (Vaughn, 2010, 12). Under the current patent system, this type of justice is not met for the same reasons justice is not met on an individual level. People in different economic classes have variable access to patented treatments. However, justice is achieved under the current patent system when viewed from a utilitarian perspective. Utilitarianism evaluates the goodness of something based on its overall net benefit (Hooker, 2015). The patent system was designed to encourage innovation to advance society. Advancements in the medical field as a result of offering patents as an incentive justifies the current system because the net benefit for society as a whole is positive over time.

Patient's Right to Privacy.

A patient's right to privacy stems from the requirement that medical professionals respect a patient's autonomy. The Hippocratic Oath requires physicians to respect their patient's privacy. When a patient visits a medical professional, they should feel free to share any problems that they are having with the knowledge that no one other than the professional will be privy to those problems or concerns. Here, the ethical concern arises not from the act of patenting a medication or medical technology, but rather from trying to prove that infringement of a patent occurred.

Proving that infringement occurred, or revealing in any way that a patient has received patented treatment, would violate a patient's right to privacy by revealing the treatment they have received, and thus medical conditions they may have (Sato and Liu, 2007).

Doctor-Patient Relationship.

The World Medical Association's Geneva Oath has medical professionals pledge that the "health and well-being" of their patient will be their highest priority (World Medical Association Declaration of Geneva, 2017.). When visiting a physician, patients expect this to be true. The relationship between physicians and patients is inherently built upon an unequal power dynamic. Typically, a patient has less knowledge about their condition or problem than their doctor, and trusts their doctor to advise and help them. In some situations, patients may be desperate and willing to do anything a doctor suggests.

Introducing the effects of medical patent ownership into this relationship allows for the possibility that the doctor's interests will no longer align with those of the patient. If a physician owns a medical patent, they might be influenced to use their patent. Additionally, if a treatment that a physician would like to use on a patient is patented, the physician might be unable to use that treatment because they would need to get permission to do so. This consideration is especially important in the United States because under section 287 of the Patent Act, health care practitioners can be found liable for infringing upon patents while helping a patient (35 U.S.C § 287). Although this section limits a patent holder's ability to collect damages, physicians may still be found liable for infringement (Kubick, 2010, 285). The influence of patents on a physician's decisions may not be conscious or direct, but it would create a division between the interests of a patient and the interests of the physician. This intrudes upon the relationship between a doctor and their patient which is built upon an understanding of a shared interest in the patient's health.

Rule of Information Sharing.

When they take the Hippocratic Oath, physicians place themselves within a community of medical professionals and make promises to share knowledge as a member of that community. The Oath requires physicians to be willing to share their knowledge with others. In the United States, this obligation is further cemented in the American Medical Association's Principles of Medical Ethics, which requires physicians to "study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public..." (AMA Principles of Medical Ethics § 5). This is known as the rule of information sharing.

The rule of information sharing only becomes relevant to discussions about the ethics of intellectual property laws when a physician is also the person who owns a patent. If a physician owns a patent, they have the opportunity to either prevent others from using their invention or require them to pay for access. If they chose to do either of these, they are failing in their job as a physician to share their knowledge with their colleagues for the purpose of promoting the health of all people, including patients that are not their own. The rule of information sharing stems from the belief that doctors should provide the best possible care to their patients, and patenting certain medical technologies could hinder a physician's ability to do this.

IV. Analysis of The Effects of Patents on Access to Medications

In 2015, a Kaiser Health Tracking poll found that a quarter of Americans say that they have a difficult time paying for their medications. This number rose among those with lower incomes (up to 33%) and those who were considered to be in worse health (up to 43%) (DiJulio, Firth, and Brodie, 2015). People struggling to pay for medications because of their cost is not isolated to the United States, but occurs around the world, especially in many developing countries, where

medications are imported. As discussed in section II, current international intellectual property agreements allow for patents to be granted to inventions related to the healthcare industry. These patents give private owners a monopoly over potentially life-saving medications, medical processes, and medical technologies. A common criticism of this is that allowing private ownership of these necessities limits patients' abilities to access them, primarily because they are priced so expensively.

During the period in which patent holders have a monopoly on a product, the price of a product is typically inflated. For example, individuals are predicted to spend \$45 billion in extra costs for the drug Revlimid (lenalidomide), and \$10 billion dollars in extra costs for Sovaldi (sofosbuvir), before 2028 and 2034 respectively ("America's Overspend n.d.). Patents have been found to increase drug prices in studies on different categories of drugs. Drug prices for both HIV and AIDS drugs and central nervous system drugs were found to increase in the presence of patents (Duggan, 2012; Borrell, 2007). Companies can extend the length of their monopoly using a strategy called evergreening. Evergreening occurs when patent holders add new patents to prolong their exclusivity to a drug, even if the extensions are not necessarily new, non-obvious, or useful. This strategy was used with the previously mentioned drug Revlimid. Celgene, the company that produces Revlimid, applied to get over one hundred patents on the drug. Many of these patents were granted, giving the company a monopoly over the drug until 2036 (Amin, 2018). This strategy is commonly utilized as most of the patents granted to pharmaceutical companies are not for new chemical entities, but for variations to ones that already exist (Wanis, 2010). Monopolies allow companies to create an artificial scarcity of their product and to charge higher prices. When companies choose to do this, the ability of patients to fully exercise their autonomy and the ability of physicians to practice beneficence is hindered because access to treatments is limited. These

problems are further exacerbated by post-TRIPS agreements that put restrictions on parallel imports and data exclusivity, further increasing prices.

Admittedly, there have been efforts to remedy this problem. As mentioned in Part II, the Doha Declaration was designed to shed light on the flexibilities available in TRIPS and the options countries have to protect people's right to health. Countries can use compulsory licenses to gain access to a medication or technology in the event of a public health crisis. This falls under "other use" mentioned in article 31 of TRIPS and is commonly applied with public health problems, such as HIV and AIDS (TRIPS, 1994, Article 31) However, the wording of this in the Doha Declaration does not unambiguously allow for the use of compulsory licenses in situations that are not epidemics. It is not clear whether compulsory licenses can be used to increase access to drugs for diseases such as heart disease (Joseph, 2011, Part 7). Furthermore, the effectiveness of compulsory licensing is dependent upon a country's ability to use it. International pressure applied by developed countries tends to discourage other countries from taking advantage of this flexibility. In 2012, India issued a compulsory license for a cancer drug and was met with an unexpected review from the Office of the United States Trade Representative. Additionally, in 2016, the United States and Switzerland pressured Colombia not to issue a compulsory license for the cancer drug imatinib. This pressure included threats to withdraw financial support from the peace process in Colombia (Hoen et al. 2018). The impact of international politics and power dynamics prevents compulsory licensing from being completely effective as a method to circumvent access problems associated with medical patents. Due to this, options for patients and physicians remain limited.

V. Conclusion

The international intellectual property system was designed to promote innovation and creativity with the idea that doing so would help advance society and improve people's lives by

expanding and improving the products and services available to them. The effects of intellectual property laws permeate every aspect of people's lives, including healthcare. Under the current patent system, patents on medication, medical processes, and medical technologies raise ethical concerns about various aspects of patient care and treatment. It is important to remember that patents themselves are not unethical, but rather the situations that they create may raise some ethical concerns. Furthermore, we should recognize that patents do not exist in isolation but are rather part of a wider system of laws, relationships, and practices. Article 7 of TRIPS requires that the protection of intellectual property promotes innovation and the spread of technology in a way that promotes welfare. It also explicitly states that there should be a balance between these rights and obligations (TRIPS, 1994, Article 7). It is important to find a balance between incentivizing innovation and protecting the right of people worldwide to health. Based on the examples discussed in this paper, this balance is not being achieved by the current system.

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