



The Relationship Between the Patent-holder and Developing Nations: Overcoming the Consequences of Intellectual Property Rights

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Abstract:

Disease is spreading at a faster rate than ever before. Our globalized world is faced with the constant threat of devastating pandemics due to the increase in frequency, intensity and distance with which humans and goods are capable of traveling. Technology, information and resources, which play a crucial role in the prevention, management and eradication of disease, are theoretically more accessible in today's world in terms of their ability to be effectively transported to the most remote regions of our planet. However, the international agreements and policies currently in place create barriers, preventing the achievement of a higher standard of global health. One such obstacle emerges as a result of Intellectual Property Rights (IPRs). On the one hand, these ownership rights acknowledge and compensate scientists for their innovations; this encourages further development of medication. Nevertheless, these rights make drugs unaffordable and inaccessible to citizens of the Global South. IPRs fail to recognize the knowledge of indigenous people, whose ancient herbal medicines often-times inspire the innovations. In doing so, IPRs breed increasing mistrust and tension on the part of those in the Global South towards the Global North. This article provides a case study and possible amendments to Intellectual Property policies with the intension of facilitating trust between communities, establishing a more efficient system of resource distribution, increasing the global standard of living through better healthcare management, and consequently, creating a more stable and safe world.

Résumé :

La maladie se propage à un rythme plus rapide que par le passé. Notre monde globalisé est confronté à la menace constante de pandémies ravageuses en raison de l'augmentation de la fréquence, de l'intensité et de la distance que les êtres humains et les biens sont capables de voyager. La technologie, l'information et les ressources, qui jouent un rôle critique dans la prévention, la gestion et l'éradication de la maladie sont, en théorie, plus accessibles dans le monde d'aujourd'hui quant à leur capacité d'être transporté efficacement aux régions les plus éloignées de la planète. Cependant, les accords internationaux et les politiques en place actuellement créent des barrières qui empêchent la réalisation d'un niveau plus élevé de santé globale. Un tel obstacle émerge du fait de les Droits de Propriétés Intellectuelles (DPI). D'une part, ces droits à la propriété reconnaissent et récompensent les scientifiques pour les innovations ; ceci encourage le développement d'autres médicaments. Néanmoins, ces droits rendent les traitements inabordable et inaccessibles aux citoyens du Sud Global. Les DPS ne reconnaissent pas les savoirs des peuples autochtones, dont les médicaments anciens à bases des plantes sont souvent source d'inspiration pour les innovations. Ce faisant, les DPS alimente une méfiance et tension de part de ceux et celles dans le Sud Global envers le Nord Global. Cet article offre une étude de cas et propose des modifications éventuelles aux politiques de la Propriété Intellectuelle avec l'objectif de faciliter la confiance entre les communautés, d'établir un système de distribution de ressources plus efficaces, d'améliorer le niveau de vie mondial par une meilleure gestion des systèmes de santé et ainsi, de créer un monde plus stable et plus en sécurité.

Introduction

Globalization is defined, for the purpose of this paper, as the increase in sociopolitical and economic interactions between nations. This phenomenon is facilitated by technological advances in communication and driven by international trade and travel. The rapidly evolving multidimensional relationships across political borders create interdependency between societies. There is some debate over the exact origin of globalization; some scholars believe that the process emerged in the 15th century during the period of colonialism. From the beginning of the European expansion, globalization has acted as a facilitator for the spread of disease. Anthony McMichael, an epidemiologist, warns that humanity is entering “the fourth great transition in human disease history;” the first occurred 10 000 years ago with the emergence of agricultural settlements, the second took place 3000 years ago “when the classical civilization of Europe and Asia met” and the third when Europeans came into contact with First Nations Peoples.¹ Nunn & Qian (2010) introduce a concept called the “Columbian Exchange,” in which the Old World gained new crops and innovations, and the New World suffered a drastic reduction in population.² The indigenous peoples of the Americas were vulnerable to the diseases brought to them by explorers. Outbreaks of smallpox and yellow fever during the colonial period wiped out entire tribes. Today, diseases are spreading faster than ever before; mass-migration into mega-cities in which overcrowding and poverty create an ideal environment for bacterial growth is a common occurrence. A recent example is the outbreak of SARS in 2003, which was initiated by a Chinese doctor, infected with the viral respiratory disease, who stayed overnight in a Hong Kong hotel. Despite his limited contact with other individuals during

¹ Yvonne Baskin, “Winners and losers in a changing world,” *BioScience*, no. 48 (1999): 788-792.

² Nathan Nunn and Nancy Qian, “The Columbian Exchange: A History of Disease, Food and Ideas,” *Journal of Economic Perspectives*, no. 2 (2010): 163-188.

his stay, according to Murray (2006), 12 other guests on the same floor were eventually diagnosed with SARS.³

Two monumental actors in global health are the World Bank and the World Trade Organization (WTO). The latter administers the agreement on Trade-Related Aspects of Intellectual Property Rights (IPRs), also known as TRIPs, which provides an international standard for the regulation and protection of intellectual property. IPRs are beneficial in the sense that they provide incentives for the development of new drugs and medicines. IPRs allow for the innovator to experience positive reinforcement; rewarding scientists for their work has the beneficial psychological effect of motivating further research. However, IPRs come at a cost; they breed mistrust on the part of the Global South towards the Global North, creating political and social tension. The world has reached a critical point in terms of healthcare; diseases are spreading faster than ever due to globalization. The need to treat and eradicate diseases implicates many other factors outside the realm of science. This paper outlines the good intentions of Intellectual Property Rights and their grave consequences; a case study of the outbreak of AIDS in Brazil is presented along with possible amendments to IPRs. Economic and political barriers are considered when evaluating IPRs and proposing possible solutions to this global crisis.

Benefits and Consequences of IPRs

IPRs grant the exclusive use of an intellectual creation; these rights are granted by the state. IPRs include patents, copyright and various other examples of academic property related to innovations. Once an idea is established as a property, it cannot be copied or utilized without the authorization of the owner. From a financial aspect, IPRs are beneficial

³ Megan Murray, "The epidemiology of SARS", in *SARS in China: prelude to pandemic?* Stanford: Stanford University Press (2006): 17-30.

to the patent owner. These exclusive exploitation rights of the product enable the possessor of the patent to earn back the monetary funds invested into the research and production of the drug, often times enabling them to make a profit. Without intellectual property, individuals would be reluctant to share their ideas and to pursue them because it would be financially unrewarding and discouraging to not be given ownership and recognition for their innovation. IPRs acknowledges scientists for their innovations, this is a form of positive reinforcement which increases the likelihood of further research. For this reason, it is clear that, from the perspective of the Global North, IPRs are essential for scientific advancement.

However, it is also evident that the existence of such rights makes accessibility and affordability of medical treatment and drugs in developing countries very difficult. There is a discrepancy in the way different groups of people are affected by the same policies. The situation is unsettling; while IPRs regulate the distribution of medication for the purpose of offering the innovator a chance to receive compensation and praise for their significant contribution to the health sector, in many developing countries, the majority do not even have access to the benefits of these innovations, which are quite common in other areas of the world.

There is a strong need to accommodate both the needs of patients and patent-holders, while maintaining the priority of ameliorating access to the bare minimal standard of health care. The process of placing a new product on the market is both financially burdensome and time-consuming. It remains necessary to compensate scientists for their contribution, in the form of countless hours of research and experimentation, to humanity. Without recognition and reward they will be less inclined to pursue a career in research. It is important to note that many nations face catastrophic health problems which must be

addressed sooner rather than later. This life threatening need has caused some countries to reject IPRs and instead grant compulsory licensing. Compulsory licensing is government approval to produce a patented good without the agreement of the patent-holder. There is a great injustice for the millions of people who die from diseases for which treatments exist.⁴

Case Study: Brazil and the HIV Outbreak

Firstly, let's consider a case study of the consequences of IPRs and the controversial decision a nation had to make in order to find an effective solution for their citizens. The interdependence between global health and international organizations is demonstrated in the case of the Human Immunodeficiency Virus (HIV). HIV has a rather lengthy latency period in which the infected individual may not even be aware that they have the disease. This often leads to the unintentional spread of the virus. In Botswana and Swaziland, it is approximated that more than 40% of adults are HIV positive.⁴

In 1996, David Ho was a leading scientist in the creation of a drug that could suppress the level of the virus in the bloodstream. This mixture of antiretroviral medications was not a cure, but rather a treatment that had to be maintained permanently or else the virus would re-emerge. The treatment cost was around \$10 000 to \$15 000 annually, a fee perhaps manageable solely by citizens of the Global North.

Brazil experienced an outbreak of AIDS in the late 1980s, with infection rates increasing drastically in an exponential manner. It was estimated that nations in the Global South would have to pay pharmaceutical companies approximately \$10 000 a year to produce the required medication, while it would cost only \$150 to \$300 a year to produce the same drugs in a laboratory on their own soil.⁵ In an attempt to make antiretroviral drugs universally available, Brazil created an internationally controversial program which would

⁴ Shawn C. Smallman & Kimberley Brown, *Introduction to International & Global Studies*, (Chapel Hill: University of North Carolina Press, 2011), 242

⁵ *Ibid.*, 248

provide medication for free beginning in 1996.⁶ During the course of the next four years, Brazil was able to reduce the cost of AIDS medication by 72.5% through the local manufacturing of two-thirds of the drugs in the treatment.⁷

Brazil's decision to grant compulsory licensing and manufacture generic AIDS drugs created a large dispute. The United States, prompted by the lobbying of pharmaceutical companies, accused the Brazilian government of violating trade law under the system of the TRIPs regime for their disfavor of imported goods.⁸ They threatened the state with the possibility of sanctions and even the closure of numerous pharmaceutical companies since they believed that the policy "would discourage the research needed to produce new HIV/AIDS medication".⁹ The argument for developing countries was supported by many non-profit organizations who emphasized that often-times, medication is developed with the use of public funds and thus the public should have access to it and a say in its global distribution. In response to the accusations, a Brazilian advertisement surfaced claiming that "local manufacturing of many of the drugs used in the anti-AIDS cocktail is not a declaration of war against the drug industry. It is simply a fight for life".¹⁰ Eventually the conflict was abruptly stopped when the United Nations declared access to treatment for AIDS as a human right and the WTO stated at their 2001 conference that TRIPs does not and should not prevent member states from taking drastic measures to protect public health. This resolution prompted many developing countries to seek the expansion of access to medications for their citizens and demonstrated that "global health is not only shaped by

⁶ Smallman and Brown, *Introduction to International & Global Studies*, 248

⁷ Alan Berkman et. al, "A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigating the Epidemic in Developing Countries," *American Journal of Public Health*, no. 7 (2005): 162-172.

⁸ Smallman and Brown, *Introduction to International & Global Studies*, 248

⁹ *Ibid.*, 248

¹⁰ Roy Wadia, "Brazil's AIDS Policy Earns Global Plaudits," *Cable News Network*, August 16, 2001, <http://edition.cnn.com/2001/WORLD/americas/08/14/brazil.AIDS/>.

microbes but also by international organizations”.¹¹ “Globalization is a two-edged sword”¹²; its dual nature cuts both opponents. The spread of disease affects citizens in all areas of the world; viruses which are maintained due to lack of treatment accessibility can be transported to the Global North with ease, through commercial travel and trade. Globalization enables the spread of disease and barriers for health care at the same time as it sets the foundation for international organization and a network of funding for countries facing disasters.

Compensation for Indigenous Knowledge

Another issue with global health that arises in the debate over the existence of IPRs is compensation of knowledge. The majority of medications are derived from plants.¹³ Usually, the discovery of the medicinal functions of plants are rooted in the knowledge of Native Peoples. For example, quinine, used in the treatment of malaria, was invented by Peruvians.¹⁴ It is evident that indigenous peoples had a complex understanding of chemical interactions from their skill in combining various plants to create medications. Thus, the discovery of new drugs is not a one-way exchange of knowledge, technology and resources, trickling from the Global North to the Global South; traditional medicine is finding its way from developing nations to scientists in developed nations.

Unfortunately, indigenous people are not compensated for their knowledge. Rural communities fear that if they share their knowledge, pharmaceutical companies who produce the medication will patent the recipe. Once they lay claim to the idea, IPRs will prevent farmers from continuing local production and sale of the medication. In a sense, even when the idea originates in developing nations, IPRs which are meant to protect the

¹¹ Smallman and Brown, *Introduction to International & Global Studies*, 249

¹² *Ibid.*, 252

¹³ *Ibid.*, 249

¹⁴ Wade Davis, *One River: Explorations and Discoveries in the Amazon Rain Forest*, (New York: Touchstone, 1997), quoted in Smallman and Brown, *Introduction to International & Global Studies*, 249.

ownership of those ideas fail to compensate and acknowledge the citizens of the Global South. In essence, IPRs appear to apply only when it is beneficial for the rich nations.

Some efforts have been made to establish policies to ensure the compensation of indigenous for their knowledge.¹⁵ This topic was discussed, for example, at the 1992 United Nations Conference on the Environment and Development. However, powerful actors such as the USA, objected to the idea thus preventing any agreement or policy from being established. Without copyright laws protecting the ownership of valuable knowledge, pharmaceutical companies are able to produce synthetic versions of drugs. One such case is that of *Artemisia annua*, more commonly known as Sweet Wormwood, which has therapeutic effects against some forms of malaria.¹⁶ The increased need for this Chinese herbal medicine gave rise to the potential for developing an industry since large amounts of the plant were required to create the drug. “The discovery of artemisinin is a triumph that has had both medical and social benefits”.¹⁷ This was an opportunity for farmers to improve their business and for the nation to contribute to the global market. The success of the herb to treat malaria prompted companies to try to create a synthetic version of the plant. If a company were to succeed in creating a synthetic chemical that could mimic the effects of the plant, they would be able to patent the medication and thus farmers would no longer have legal access to sell the herbal remedy. There would also no longer be demand for production of the plant; this would have devastating costs for the farmers and communities which depend on the industry this plant has created. According to an article in the International Weekly Journal of Science by Mark Peplow, Sanofi, a Paris-based pharmaceutical company, succeeded in converting fermenting yeast to produce artemisinin-

¹⁵ Smallman and Brown, *Introduction to International & Global Studies*, 252

¹⁶ R. Thom, “*Artemisia Annua: A Cure for Malaria*”, Unpublished student manuscript (2006), quoted in Smallman and Brown, *Introduction to International & Global Studies*, 251

¹⁷ Smallman and Brown, *Introduction to International & Global Studies*, 251

based combination therapies.¹⁸ The discovery threatened the producers of the natural chemical. However, due to economic barriers, the synthetic substance hasn't achieved the anticipated level of distribution; while sweet wormwood based medicine sells for \$250 per kilogram, the company's no-profit margin is \$350-\$400 per kilogram. As of now, there is no synthetic substance that overtakes the affordability of the natural product. If this were to change in the future, IPRs would be at the center of yet another debate. Once again, it is evident that IPRs fail to protect the rights of those in the Global South.

Decision Making Policy

When looking at decision making policy in the international community, two models provide acceptable frameworks under which to evaluate health issues and identify resolutions. According to Waltner-Toews & Lang (2000), "the role of knowledge and science in both [competing] models is critical" however the two models vary greatly in approach and application.¹⁹ The first is referred to as the Input-Output model and is described as a linear system where science and capital are the two variables inputted and under which increased production with proper distribution results in improved health. In this first model, the main goal of science is to increase production and efficiency.²⁰ This is the dominant model used in international policy evaluation. The second model, currently emerging, is known as the complex model. This model considers health to be a roof held up by pillars such as accessibility, availability and affordability, which shelter factors that range from the economic to ecological state of society and include elements such as culture,

¹⁸ Mark Peplow, "Synthetic biology's first malaria drug meets market resistance" *Nature News* (2016) <http://www.nature.com/news/synthetic-biology-s-first-malaria-drug-meets-market-resistance-1.19426>.

¹⁹ David Waltner-Toews and Tim Lang, "A new conceptual base for food and agricultural policy: the emerging model of links between agriculture, food, health, environment and society," *Global Change & Human Health*, no. 2 (200): 116-128.

²⁰ Ibid.

water and energy. In the complex model “health relies on a diversity of factors”.²¹ There is a growing recognition that the relationships between these factors are more interdependent than previously thought. While consideration of the stability of all these diverse variables is essential in maintaining the sustainability of global health, it is possible that in cases which require immediate solutions, the Input-Output Model is far more suitable. The limitation of the linear system is that it assumes that productivity is the sole goal. Increasing the supply, however, only provides a temporary solution since the issues of diseases implicate a complex system of policies, agreements, cultural and religious controversy and other elements which need to be considered. It appears that while the complex model is an essential tool to understand our interconnected world, without immediate results, our society faces the risk of a rapid reduction in population. When an outbreak occurs, nations seek a quick remedy and in many cases find difficulty with the decreased accessibility and availability of treatment resulting from IPRs. In cases such as the aforementioned Brazilian HIV outbreak, nations chose to, in a sense, violate these laws in order to ensure that public health was prioritized. This is done through the use of compulsory licensing which a nation grants, enabling a laboratory to produce cheaper generic forms. While it is acknowledged that their actions are condemned by some advocates of IPRs and may be seen as discouraging to the scientific community, patents would be useless if there were no patients left to benefit from the medication.

Solutions

Perhaps the most effective model to use in policy making is a combination of the two, where patent-holders are respected so that further innovations are encouraged and their

²¹ David Waltner-Toews and Tim Lang, “A new conceptual base for food and agricultural policy: the emerging model of links between agriculture, food, health, environment and society”

hard work is compensated and, at the same time, the needs of the patients are met with equal attention, placing both production and accessibility at the forefront of the system.

It is evident that IPRs have a large impact on the cost and accessibility of medicines, resulting in a growing focus on methods in which to lower pricing for developing countries, with some nations opting to use compulsory licensing. International organizations, such as the World Health Organization and Centers for Disease Control and Prevention were established to monitor and treat outbreaks. In striving for eradication of diseases and the preservation of life, mechanisms like relaxed patent requirements, voluntary licensing, bulk purchasing and corporate donations have all proven to be effective methods in which to bring about affordability and availability of drugs and treatments without violating TRIPs. It is in the best interest of states in the Global North to provide aid to nations in the Global South in order to maintain world-wide health standards. Developed countries could, in times of crisis, allocate some financial support for developing nations as well as exercise some leniency to infringements of IPRs in certain extenuating circumstances.

It is also the moral duty of the patent-holder to participate in increasing accessibility to drugs and treatments. Their involvement is essential because of the power they possess over their products. Voluntary licensing is an agreement between a state and the patent-holder to reproduce the product at a more affordable price; this compromise ensures that neither side loses. Since negotiations are at the discretion of the patent-holder, the benefits of the agreement largely vary depending on the terms. Providing the owner with control over the distribution and cost of the pharmaceutical product can go both ways. On the one hand, this method ensures that incentives to develop new innovations are still in place since patent-holders still have rights to their properties and in negotiations many nations are able to more easily access new drugs. However, in other instances, agreement terms can provide

minimal aid, leaving nations still unable to treat the disease. This is seen when patent-holders act in self-interest, such as for the sole purpose of placing their product on the market. This usually results in prices which remain affordable only to some, most commonly citizens of the Global North. Nevertheless, this mechanism allows for the potential for some drugs to become accessible in the Global South.

Another possible solution is for an international organization such as the WHO or WTO to monitor the distribution and cost of medicines to ensure accessibility in developing nations. Taxation systems could be established which allocate some of the money paid by developed nations for drugs to be used in the creation of funds which would be used to reduce the price of these same products for developing countries. Bulk purchasing may provide communities with a more affordable cost when they opt for a large amount of drugs. Governments could also provide incentives for private corporations to help fund developing nations' purchase of medication. A good way to do this is by providing tax reductions or reimbursements for donating.

Conclusion

Health is a global issue because of the ability for diseases to cross political and geographical borders; pandemics do not discriminate and, as a result, all global citizens are at risk. The consequences, but nevertheless necessity, of IPRs are evident when it comes to medical treatments and global health. Globalization enables the creation of International Organizations, such as the World Health Organization which fights disease outbreak, and the United Nations which fights for the improvement of health standards.²² It also creates a forum for wealthy nations to provide funds when they are urgently needed by the Global

²² Smallman and Brown, *Introduction to International & Global Studies*, 252

South. Globalization facilitates the exchange of information, technology and resources. At the same time, this phenomenon enables the spread of disease through the increased transportation of people and goods, and occasionally, allows nations and institutes to prevent the production of generic drugs. IPRs create a barrier which prevents the accessibility of medicines in developing countries, at times forcing nations to take drastic measures. The reaction of the Brazilian government to the outbreak of AIDS, although controversial, is admirable due to their intention to save thousands of patients and to sustain the welfare of the state. The decision to grant compulsory licensing was the only solution in their case, but it works solely as a temporary method with consequences of sanctions due to the discrimination of imported goods and the disregard for the rights of the patent-holders. It is essential for the international society to seek a long-term beneficial mechanism to meet the needs of both the patent-holder and the patients.

Two methods which were mentioned in the paper could potentially ameliorate the relationship between the patent-holders and the Global South, as well as solve the problem of accessibility and affordability. One mechanism which should be implemented more and further encouraged is voluntary licensing which enables agreements between the patent-holder and the state at the discretion of the owner. This method has been shown to reduce the cost of drugs and treatments in many cases. A second mechanism suggested was the establishment of a taxation system in which a portion of the cost paid for medicines by the Global North is used to reduce the cost of those same products on the markets of the Global South. Both methods require cooperation and compromise for the well-being of the global public. International organizations and multinational corporations should work with both developed and developing nations to accommodate the needs of all humans. The bare minimum healthcare which allows an individual to survive curable diseases and maintain a

comfortable lifestyle should be recognized by all states and groups as a human right that should be protected. It is only in a system which acknowledges the importance of immediate action and increased productivity, as well as maintains consideration for economic, ecological and cultural factors, that a desired standard of global health can be obtained. This can be done without the abolishment of IPRs which are so essential to the development of new innovations, but rather with mechanisms that cushion the consequences of this system and provide the environment for a sustainable and thriving world.

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