Beyond TRIPS: Questioning the Effectiveness of the Global Intellectual Property Regime

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Access to health in the developing world brings together multiple actors, policies, and strategies in a worldwide effort to provide life saving medicine to those who cannot afford it. With income inequality growing on a global scale, now more than ever, strong leadership and decisive action concerning affordable drug pricing and increased accessibility in developing and least developing countries (LDCs) must occur. A significant barrier to positive global health outcomes originates in patent law — the exclusive ownership of life saving drugs. Since most innovations occur in developed countries, a large transfer of wealth, including rents, occurs from the developing to the developed. While some developing countries, such as Brazil and India, have a pharmaceutical manufacturing infrastructure, the LDCs do not and solely rely upon the capacity of other nations for their pharmaceutical concerns. Therefore, extending patent protections to developing and LDCs is harmful under most circumstance — especially health (Sykes 2002, 14). Yet, patent reform in developing and LCDs will not alter the fact that ”one-third of people in developing countries have no access whatsoever to essential medicines, including the vast majority that are not patented and are manufactured as generics in developing countries" (Attaran 2004, 163). The underlying issue is poverty. However, a patent regime that provides flexibility concerning global health can sustain an open space for economic and individual development.

Pharmaceutical companies and their lawyers argue that patents are necessary to ensure investors and other interested parties that ownership of the underlying drug. In this way, companies are willing to invest capital and time to exploit the drug’s potential. Conversely, some argue patents restrict access to life saving medicines because drug companies charge prices too high for those living in developing countries and LDCs. As you know, producing a drug takes significant investment in capital, expertise, and time. From patent to market takes 10—15 years and costs an average of $1.38 billion to develop a single drug (Associations 2012). The research-based pharmaceutical industry currently spends over $135 billion on R&D per year and the market will reach nearly $1.2 trillion by 2016 (Associations 2012). The drug market constantly expands as innovative drugs treat both new and old ailments while both stockholders and the public gains from these discoveries. Yet, we must not ignore the billions of people lacking access to the life saving medication they may need.

Innovative research and development in malaria and tuberculosis are making strides in health outcomes in the global south, but the terrain of diseases has changed. Due largely to industrialization, urbanization, export-based agriculture, and economic development how and what people eat in developing countries shifted to more processed and cheaper foods (Scott and Harman 2013, 1370). This shift dramatically increased the occurrence of noncommunicable diseases (NCDs). The World Health Organization’s most recent report states that NCDs ”kill more than 36 million people each year. Nearly 80% of NCD deaths — 29 million — occur in low-and middle-income countries" (WHO 2013). Therefore, the blockbuster drugs in developed countries can now save lives in developing countries. The main issue is how to get drugs to those who can’t afford them. A rationale acting company seeking to maximize profits would charge high prices in every market. In this way, the ”highly convex demand curves" of a pricing structure excluding everyone except the affluent results in almost the entire citizenry priced out. Additionally, profit-maximizing companies avoid price discrimination in poor countries because it is more profitable for them to charge monopoly prices. Therefore, ”[t]he government of a poor country that wants lower prices…must accordingly force the company to act against its private self-interest in the larger interests of public health. And the most powerful tool for achieving this end remains that of a threat by the state to impose a compulsory license" (Reichman 2009, 252).

WTO TRIPS Agreement

The WTO IP regime is important to examine since it provides the foundation for the world’s IP regime and enforced framework. All 159 members of the WTO agreed to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). TRIPS was a ”take it or leave it ultimatum" and requirement for further membership in the WTO. While most developing countries suffered because of this agreement, the trade off for these countries was greater access to markets and goods along with a commitment by the developed countries to ”stop imposing unilateral trade sanctions for allegedly inadequate protection of foreign intellectual property rights" (Reichman 2009, 247). Moreover, developing countries expected higher foreign investment and technology transfer as well as opportunities to reap benefits from their own creative industries (Sykes 2002, 15). Prior to the TRIPS agreement, the Paris Convention regulated IP regimes in developing countries, but allowed for ”relatively unrestricted power to regulate public health, with little interference from international intellectual property law" (Abbott and Reichman 2007, 926). Therefore, the TRIPS agreement legally imposed regulations on signatory countries’ sovereign prerogative concerning matters of health effectively stripping the nation-state’s power to ensure their citizen’s right to life — the most fundamental of human rights.

The few of the relevant principles of the TRIPS agreement are as follows. Article 27.1 ensures that ”patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (WTO 1994). While Article 33 provides patent

protection for twenty years from the filing date (WTO 1994). However, governments can refuse to grant patent rights when ”necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment..." (Art. 27.2) or patentable subject matter pertaining to ” diagnostic, therapeutic and surgical methods for the treatment of humans or animals" (Art. 27.3(a)). Additionally, ”some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner’s permission and before the patent protection expires" (WTO 2006) thereby allowing for exploitation immediately following patent expiration.

Striking a balance somewhere between promoting access to drugs along with promoting research and development in new pharmaceuticals, the TRIPS agreement allows for the compulsory license of patents. While there is no explicit mention of compulsory licensing in the TRIPS agreement, Article 31 entitled Other Use Without Authorization of the Right Holder ensures flexibility in the IP regime to allow licensing of patents in certain circumstances. To be sure, the clauses in this article aim to protect the interests of the patent holder, but also provide avenues for developing countries to ensure the health of their citizens if need be. For example, Article 31(b) requires the applicant for a license to have attempted, unsuccessfully within a ”reasonable period," to obtain a voluntary license from the patent holder on ”reasonable commercial terms" (WTO 1994). This requirement may be waived ”in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" (WTO 1994). However, the licensee must pay the patent owner ”adequate remuneration" in any case (Article 31.(h)) (WTO 1994). Other protections to the patent holder ensure that the licensor can continue to produce their patent rights and the compulsory license is ”predominantly for the supply of the domestic market" (Article 31.f) thus creating a non-compete relationship, while ensuring the ”the scope and duration of such use shall be limited to the purpose for which it was authorized" (article 31.(c)) (WTO 1994). The compulsory license process provides an opportunity for developing countries and LDCs facing a public health emergency to gain access to patents. However, significant pushback by developing countries, NGOs, and other vested interests resulted in the Doha Declaration and Amendment that clearly establishes a public health principle in the TRIPS agreement.

The WTO members agreed to the Doha Declaration on TRIPs and public health in 2001 and the Doha amendment followed in 2005 (hereinafter Doha TRIPS Agreement). The Doha TRIPS Agreement prevented ”a further strengthening of the TRIPs agreement at the cost of developing countries' rights and abilities to respond to domestic health challenges (Scott and Harman 2013, 1363-4). The declaration and amendment are not currently permanent because the amendment needs two-thirds of the vote to formally accept the protocol (currently only 45 of the 159 have accepted it with the most recent deadline coming at the end of 2013). Nonetheless, these agreements remain in force. The Doha TRIPS Agreement both allowed developing countries with no pharmaceutical manufacturing capacity to import generic drugs in response to health emergencies (Scott and Harman 2013, 1361) and explicitly highlighted the importance of a nation-state’s public health. Because of this agreement a compulsory license could be given to one country to manufacture and export it to the country facing a health crisis. The Doha Declaration States:

while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: [...]

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The Declaration clarifies ”public health crises" to mean ”a national emergency or other circumstances of extreme urgency" and that an emergency can be either short or long term. Since each member may determine what constitutes a national emergency, the emergence of NCDs in developing countries will clearly fall within the limits imposed by TRIPS — especially given the deaths attributed to NDCs will only increase over the coming years. Since there has been a clearly stated purpose of public health in the TRIPS agreement the interpretive provisions of the Vienna Convention on the Law of the Treaties requires the WTO ”panels and the Appellate Body [to] opt for interpretations that are effectively supportive of WTO Members' right to protect Public Health’" (Correa 2002, vii).

The compulsory license and Doha TRIPS Agreements has not inspired nation states to use them beyond negotiating tools. One scholar notes the process is over burdensome, ”[t]o take advantage of the provisions, a country must notify the TRIPs Council that it wants to be identified as eligible...So far, no countries whatsoever have done so...[and] A further notification must be made each time generics are imported" (Scott and Harman 2013, 1364). Despite all of these powers and flexibilities for countries’ access to medicines, only one country has notified and used the amendment — Rwanda (UNAIDS 2011). In this instance, Canadian drug firm Apotex sent two shipments of AIDS medicines to

Rwanda under Canada's Access to Medicines Regime (CAMR). The Canadian company said the process was long, complicated, and that they would never use that avenue again to procure medicines for developing countries (Mara 2010). For this reason" [m]uch criticism has been levelled at the TRIPs and Public Health Amendment for being too hard for developing countries to make operational, particularly the poorest among them, at which it was aimed" (Scott and Harman 2013, 1364). The use of compulsory license has only been effective when used as threats to lower medicine prices, but overall compulsory licensing or the threat of it to induce lower prices on medicines has seldom had a practicable affect on health outcomes in developing countries and LCDs (Attaran 2004, 161). So, we can conclude that either the patent system is working efficiently or there is a fundamental problem concerning access to health issues in developing countries and LDCs.

Beyond TRIPS, bilateral agreements compounded issues regarding IP and global health. One study found a rapid increase in these agreements since 2010, which require participating countries to incorporate additional IP provisions in exchange for preferential trade terms (Lee 2013, 152). These agreements are commonly referred to as TRIPS-PLUS agreements because they require stronger IP protection than those recommended by TRIPS. These bilateral agreements can undermine the flexibilities provided in TRIPS and the Doha TRIPS Agreements by omitting the space available for developing countries to request a compulsory license in emergency situations (Scott and Harman 2013, 1371-2). The dismal use of compulsory licensing could also be attributed to these agreements' preclusion of use. Therefore, while TRIPS and the Doha TRIPS Agreements provides avenues for access to cheap medicine in developing countries, bilateral agreements significantly degrades the possible use of generics and patents in areas prone to health crisis.

Reforming Academic Licenses and Other Underlying Possibilities

Generally, access to medicines in the global south, for those lacking capital, revolve around weak health service infrastructure, geographic isolation, and the inability of their governments to produce generic drugs. Inherent in patent law is the principle of exclusion. Meaning, if you do not have patent, then you do not have the legal authority to produce the protected drug or diagnostic. Thus, drug companies that patent in developing countries and LDCs can restrict generic drug production and price medicines out of reach of most citizens. One avenue of reform is through activism in academic licensing. The Universities Allied for Essential Medicines (UAEM) argues — Many important medicines and public health technologies are developed in academic laboratories. Their accessibility in poor nations is profoundly affected by the research, patenting and licensing decisions made by universities. We are a group of university students who believe that our universities have an opportunity and a responsibility to improve global access to public health goods" (Medecines 2013).

The UAEM, attempts to influence university licensing to include clauses that limit the ability of licensees to enforce their patents in developing countries LDCs and requires the licensee to grant the university a right to license an "open license" to a country to either supply or advanced "neglected research" (Medecines 2013). This gives the university the capability to innovate and accelerate access to life saving medicines in developing countries. Opponents argue that license provisions like those promoted by the UAEM would hinder incentives to bring academic inventions to the market. However, developing countries and LDCs represent only a trivial proportion of consumption and the big money makers (HIV/AIDS, diabetes, cancer treatments) rely on developed countries' markets for the bulk of their profits (Sampat 2009, 15). Therefore, the equitable or "open license" clauses would not likely deter commercialization. However, negotiating these clauses with firms who have stronger bargaining power, compounded with the few academic inventions that actually get licensed creates many desperate universities and highlights the fundamental tension and limits to reforming access to medicines in the license agreement.

Pharmaceutical companies may not even regulate or patent their medicines in LDCs. One article notes that "the market for patented pharmaceuticals in the LDCs was so limited that companies barely noticed what medicine was available and at what prices" (Haakonsson and Richey 2007, 74). In other words, the market share is so low and the missed opportunity profits are negligible that companies do not even care if their drug is produced. Perhaps the barriers to life saving medicine is not the fault of the corporation or the patent regime. The argument that the IP regime works well is buttressed by the position that some companies just don't care if their products have permeated the market in LDCs without licenses. Moreover, many patent-holding corporations will not file a case against an LDC because this will hurt their image and possibly contradict the corporation's social responsibility commitments. Many pharmaceutical companies donate millions of dollars worth of the medicines to developing countries and LDCs, dramatically decrease prices, or voluntarily license out their patents to manufacturers. While not expanding upon this argument, many scholars and activists argue that corporations understand health disparities and generally provide assistance where possible and when needed.

The underlying issue regarding positive health outcomes is not patents or corporate irresponsibility but poverty. One study found that out of 65 countries in the developing world ”patents and patent applications exist for essential medicines 1.4 percent of the time (300 instances out of 20,735 combinations of essential medicines and countries)… Thus, there are no patent barriers to accessing generic essential medicines in 98.6 percent of the cases we studied" (Attaran 2004, 158). Tackling global health disparities requires going beyond international patent regimes and corporate responsibility. As one scholar notes, ”developing countries cannot rely on an organized response to their problems by the international community. These countries must be prepared to address their public health needs by themselves" (Abbott 2009, 474). Thus, TRIPS or any other bilateral or multi lateral agreement currently enforced will neither alleviate poverty nor provide life saving medicine for the world’s suffering people.

Conclusion

The global disparity in health and access to life saving medication threaten the fundamental right to life. Life saving medications could be subject to compulsory licensing by WTO’s TRIPS agreement. However, not many countries have applied this rule as most countries opt instead to use the compulsory license as a negotiating tool to decrease the price of medications. Neither international patent regimes nor corporate activities cause global health disparities. The issue is poverty.