Compulsory Licensing:
An effective tool to increasing access to essential medicines?

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Realizing that patent protection on pharmaceutical products can restrict access to essential medicines, developing countries in the World Trade Organization (WTO) pushed for the implementation of the Doha Declaration, a declaration which allows countries to override patent laws to protect public health through compulsory licensing. Although the Doha Declaration was implemented and seen as a political win for developing countries, many of those countries were, and still are, hesitant in using the Doha Declaration flexibilities, especially in issuing compulsory licences. In this paper, I will explore the effectiveness of compulsory licensing and look at its challenges, benefits, and setbacks. I will also examine the amendments that have been made to date as well as suggestions to future amendments in improving the feasibility of using compulsory licensing as a tool to increasing access to essential medicines.

Before I jump into discussion on compulsory licensing, I will go over some important and relevant background information. As of July 23rd 2008, 153 countries were members in the World Trade Organization (WTO) [1], an organization which “deals with the rules of trade between nations at a global or near-global level.” [2] Member countries of the WTO must adhere with the agreements set in place by the organization; this includes the General Agreement on Tariffs and Trade (GATT) established in 1948 as well as the more recent Trade Related aspects of Intellectual Property Rights (TRIPs) agreement in 1995 [3]. Of the 18 WTO agreements, the TRIPs agreement was seen to have the greatest impact on pharmaceutical products and access to medicines. The agreement required all WTO members to provide 20 years of patent protection after a patent has first been filed; this includes both process and product patents on pharmaceutical products. [4] Having an invention patented grants the inventor exclusive rights to the invention. Patent holders have the capability to set the price of their patented product to any value they desire because market competition is eliminated. As pharmaceutical products were granted patent protection, drugs became unaffordable to many people in developing countries.
Prior to TRIPs, not only was there a much shorter duration in which a patent is under protection (5-7 years in least developed countries and 15-17 years in developing and developed countries after the patent has been first filed) [4], but there was also no requirement for WTO members to protect patents on pharmaceuticals (though there were other agreements among countries that protected pharmaceutical patents, it was not included in any WTO agreement and 40 WTO member countries did not have patent protection for pharmaceutical products) [5]. Also pre-TRIPs, many countries did not have protection on product patents though they had protection on process patents [6]. This allowed manufacturers to produce a product that was under patent as long as the procedures used in producing the product were different than those used in producing the patented product. Because the implementation of TRIPs required all countries to protect patents on processes and products, countries were no longer able to “reverse engineer” drugs and produce them generically at an affordable price.

In response to concerns of how the TRIPs agreement can restrict access to affordable and essential medicines in developing populations, the WTO issued the Doha Declaration in November 2001. The Declaration affirms that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and TRIPs “should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.” [7] Through the declaration, each member has the right to issue compulsory licences in the events of “national emergencies”, “circumstances of extreme urgency” or for “public non-commercial use. [8]” The member government, under their own discretion, determines what constitutes a public health emergency and what medicines they are entitled to produce. Though compulsory licensing existed before the Doha Declaration [9], the process was cumbersome and required consent from the patent holder.
Compulsory licensing under the Doha Declaration grants governments or government-authorized manufacturers the right to make a patented product without the patent holder’s permission [10]. In life-threatening situations, the issuance of a license allows governments to respond quickly in providing affordable and accessible medication. Compulsory licensing is also used as a negotiating tool to lower prices of drugs. Brazil, a country with an estimated 730,000 people living with HIV/AIDS [11] took advantage of compulsory licensing to make treatment more accessible. Between 2002 and 2003, the Brazilian government, by threatening to issue compulsory licenses during price bargains with pharmaceutical companies, was successful in significantly decreasing the cost of medicines. There was an estimated 73% price drop for the drug Efavirenz, 56% for Lopinavir/Ritonavir, and 74% for Nelfinavir [12]. After the more expensive second line drugs came out, Brazilians were unable to afford treatment as drug prices took a steep increase. In 2007, Brazil issued a compulsory license to produce generic versions of Efavirenz [13], a drug that was costing the Brazilian government US$580 per patient per year. Generic versions of Efavirenz were estimated at less than US$170 per patient per year [14].

Though there are merits to compulsory licensing, the terms relating to compulsory licensing under the Doha Declaration have not met the goal of improving accessibility of medicines in many developing populations. Moreover, compulsory licensing may have even strengthened the barrier to medicines access for those who are most in need. Many underdeveloped countries are hesitant in using the Doha flexibilities due to their lack of manufacturing capacity, political repercussions, and negative economic consequences of compulsory licensing. The following sections of this paper will describe the problems associated with compulsory licensing as well as setbacks relating to its amendments.

When the Doha Declaration was first implemented, article 31, paragraph (f) of TRIPs states that if compulsory licensing is used, “[i]t shall be authorized predominantly for the supply of the domestic
market of the Member authorizing such use.” [15] For many underdeveloped countries, producing drugs domestically is not a viable option as they have little or no pharmaceutical manufacturing capacity. For example, approximately 80% of developing countries lack facilities domestically to produce antiretroviral drugs to combat HIV/AIDS [16]. The WTO’s attempt at a solution to this problem came two years after the Doha Declaration. On August 30th 2003, the WTO revised the provision in article 31 [17] enabling members to issue compulsory licenses to export to countries with limited manufacturing capacity; however, the challenge then shifts to finding willing exporting countries as the August 30th decision poses complex requirements and lacks business incentives. As of September 2008, only seven WTO members have adopted the August 30th decision in their domestic legislations to be eligible exporting countries [18]. To date, there has only been one case where the revision was put into practice.

In 2007, Canada issued a compulsory licence to allow generic manufacturer Apotex to export Apo TriAvir, a combination drug for HIV treatment, to Rwanda [19]. Though Canada was praised for their leadership in being the first to use the exporting flexibility, the case displayed many setbacks which outweighed its positives. The idea of compulsory licensing is to serve populations who are urgently in need of medical aid but Rwanda did not receive the Apo TriAvir shipment until four years after Apotex first started working on the drug. The delay in providing the medicine was caused by the WTO provisions and Canada’s legislation which set out strict outlines relating to eligible drugs that can be exported as well as consent from the patent holder. Because Apo TriAvir is a combination drug and was not on the list of eligible drugs for export, Apotex had to submit further applications to get Apo TriAvir approved. Moreover, the case resulted in huge economic losses for Apotex due to production costs, transaction costs, legislative costs, as well royalties to the patent holder [20].

Another barrier to effective use of compulsory licensing is the TRIPs requirement relating to data exclusivity. The TRIPs Agreement grants the pharmaceutical company who originally produced the
patented drug exclusive rights over the test data of the drug. The test data demonstrates the safety, quality, and efficacy of the product, and is needed as a condition for permitting sale or marketing of a pharmaceutical product. [21] As generic manufacturers do not have rights to access the original test data, they would need to compile new tests on their product even though it is chemically identical to the original product. Again, the WTO’s vision of compulsory licensing as a tool to provide emergency relief to people in need is defeated as generic pharmaceutical products are delayed in entering the market due to new test compilations along with the subsequent approval applications that are required.

Perhaps the biggest concern with compulsory licensing is the ambiguity of its terms introduced in the Doha Declaration. Though the ambiguity is intended to broaden the scope of medical aid that can be provided by not limiting compulsory licenses to specific circumstances, the vague terms in the declaration have led to many questionable actions by WTO members which have hindered the access to medicines for those in need. The TRIPs revisions under the Doha Declaration allow WTO members to override patent laws “in the case of a national emergency or other circumstances of extreme urgency [22].” As “emergencies” and the “adequate remuneration to patent holders” are defined under the discretion of the member governments, there have been cases where members have been abusing the use of compulsory licences. Countries that have been using the compulsory licensing flexibilities have seen a decrease in foreign direct investment as well as trade retaliation from superpowers like the United States. For developing and underdeveloped countries that are trying to stabilize their economies, foreign direct investment is important in helping their nation evolve, and thus, these nations are hesitant to issue compulsory licenses even if their people are facing genuine health emergencies.

Egypt, for example, is a country that heavily supports the use of compulsory licensing. The grounds for issuing compulsory licenses in the Egyptian legislation are vaguely stated and include the right to issue a license if the prices are too high for most consumers or if it is “politically burdensome.”
In 2002, shortly after Pfizer received approval to launch Viagra into the Egyptian market, the Egyptian government, pressured by popular local manufacturers, issued a compulsory license to generically produce Viagra. Viagra, a drug to treat erectile dysfunction, is important but certainly not a drug that is used for “public health emergencies.” From an economic point of view, the positive health effects through compulsory licensing should outweigh the financial losses for pharmaceutical companies. This was not the case for Pfizer and Viagra in Egypt. After being informed of Egypt’s compulsory license for Viagra, Pfizer was angry and halted plans of building a manufacturing facility in Egypt. The Viagra case also discouraged other pharmaceutical companies in investing in Egypt’s market. As a result, Egypt’s foreign direct investment dropped from $1104 million in 1997 to $428 million in 2002.

Thailand is another country that faced a decrease in foreign direct investment due to excessive use of compulsory licences. Between 2006 and 2007, Thailand’s Ministry of Public Health (MOPH) filed three compulsory licenses: two antiretroviral drugs (Efavirenz and Lopinavir/Ritonavir) and a blood thinner for heart disease (Plavix). Though it is arguable whether or not Plavix puts a big enough impact on public health to issue a compulsory license, the broad terms of the Doha Declaration makes this action fully acceptable. Following the licenses, Abbott, the pharmaceutical company holding patents for the drugs, not only announced that they would no longer register new medicines into Thailand’s market, but they also held a campaign to spread false information about Thailand’s licensing process stating that Thailand “has chosen to break patents on numerous medicines, ignoring the patent system.” Between 2005 and 2007, Thailand’s foreign direct investment dropped by $10 billion.

Fearing the same social, economic, and political repercussions, developing and least developed countries, especially with their diverse needs, are not comfortable using compulsory licensing. Both Egypt and Thailand are on the United States’ “Watch List” for having poor intellectual property
protection and are faced with trade sanctions. Furthermore, pharmaceutical companies have lost faith in the compulsory licensing system and do not see the common goal of increasing health access to all as it appears that countries are using the system to their best interests. Even the United States, a country that lobbied heavily against the compulsory licensing flexibilities, issued a license for the drug Cipro fearing the outbreak of Anthrax after the September 11th incident [30]. The rest of the world was in a major uproar for the United States’ double standard.

Despite the negativity surrounding compulsory licenses, the system can be made feasible. The first step is to get all the parties involved on the same page with the common goal of achieving and sustaining a healthy world. Collaboration among governments, WTO delegates, NGOs and industry is important in reaching this goal. Like any significant change, this needs to happen gradually. Nations can start by amending provisions in their legislation which hinder the access to medicines to not just their own people, but to the world as a whole. For example, the August 30th decision can be revisited. Generic manufacturer Apotex stated that they would be happy to continue producing drugs for export given that Canada’s Access to Medicines Regime (CAMR) is amended [31]. Bill 393, a bill proposed to simplify CAMR, has passed two of the three required government readings to date [32]. The bill, if implemented, would provide a convenient one license system to replace the need for individual drug applications, eliminate the list of eligible drugs to export, and discourages unnecessary legal action [33]. The revisions will likely attract more interest from manufacturers and will pave the way for other well developed nations to export medicines under compulsory licensing.

Furthermore, the compulsory licensing terms under the Doha Declaration can be interpreted more consistently if there is a WTO group governing the issuance of compulsory licenses and determining the grounds of a health emergency. With this kind of involvement by the WTO, there is less justification for countries to pose economy-crippling trade sanctions on compulsory licensing users.
Developing and underdeveloped countries can then lift their fears of negative consequences and use compulsory licensing confidently. Consistency in compulsory licensing would also establish faith in the system for pharmaceutical companies.

Ultimately, compulsory licensing has yet to be proved a solution to the TRIPs concerns, however, with groups cooperating to balance private intellectual property interests with public welfare, compulsory licensing can be effective in increasing access to essential medicines. For developing and underdeveloped countries, compulsory licensing may not be the primary tool to accessing health needs, but it will certainly play an important supplementary role to other initiatives such as drug donations and UNITAID’s patent pool [34].
References


[6] Id.


[8] Id.


[10] Id.


[14] Vide supra note 12


[25] Id.


