



WHO

Compulsory Licensing

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WHO—World Health Organization

Introduction

The World Health Organization (WHO), in its *World Medicines Situation* report of 2004, noted that approximately one-third of the world's population lacks access to essential medicines and proper medical treatment. Most patients in developing countries lack access to such medicines due to an inadequacy of physical health infrastructure and expensive drug prices. Although the WHO considers equitable access to safe and affordable treatment vital to the attainment of the highest possible standard of health for all, it is estimated that 10 million people still die each year from lack of access to affordable drugs. Spending on medicines accounts for a major portion of health costs in developing countries. The WHO notes that although trade in medicines is increasing rapidly, most of it takes place between wealthy countries, with developing countries accounting for just 17% of imports and 6% of exports. There are a variety of factors that contribute to lack of access to essential medicines, but there is also a promising solution for alleviating this problem – namely, the advent of the compulsory license.

A **compulsory license** is the granting of a license by a government to use a patent without the patent-holder's permission. This allows governments to “break” a monopoly that a company may have to market and sell a drug in a particular country. By granting a compulsory license, governments essentially allow many companies to produce the same drug. As companies compete with one another to produce the drug at a lower cost, the price of the drug decreases significantly, allowing more people to access the medicine.

This briefing will focus on the major actors involved in influencing compulsory licensing in developing countries, which include pharmaceutical companies, civil society groups, individuals, and governmental actors. First, this briefing will explain the rise of the World Trade Organization (WTO), the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, the Doha Declaration, and the promises that these institutions and agreements hold for compulsory licenses. Next, this briefing will describe a compulsory license issued in Thailand, legislation passed in South Africa, and Brazil's experience with compulsory licensing and the impact that these have had on the populations living in those countries. Finally, this briefing will pose questions probing the members of the World Health Assembly to make recommendations concerning the use of compulsory licenses in developing countries.

History of the Problem

The Rise of the WTO

The **World Trade Organization** was founded in 1995 as an institution to implement a system of trade rules and serves as an avenue through which nations can settle disputes and negotiate agreements to ease trade barriers between each other. Before the WTO came into existence, the **General Agreement on Trade and Tariffs** (GATT), created in 1944, was the primary institution responsible for facilitating the international trade agreements. Because of new policy changes surrounding agricultural subsidies, the evolution of GATT eventually led to the formation of the WTO.



The WTO had a clear and straight-forward mandate: “[to] implement the latest GATT agreement and to act as a forum for negotiation of new trade deals, help settle trade disputes, review national trade policies and assist Less Developed Countries in trade policy issues through technical assistance and training programs” (Manek, 4). The WTO has a much broader scope than GATT: not only does it regulate trade in merchandise goods, it also deals with trade in services, such as telecommunications and banking, and other issues such as intellectual property rights. The WTO has a dispute settlement mechanism in place, which is how it facilitates tangible change in easing tensions between two countries engaged in trade. Membership of the WTO includes 153 countries as of July 2008.

TRIPS—*Trade-Related Aspects of Intellectual Property Rights*

Trade Related Aspects of Intellectual Property

Part of what came out of the formation of the WTO was the agreement on **Trade-Related Aspects of Intellectual Property Rights (TRIPS)** in 1994, which established minimum standards for many forms of **Intellectual Property (IP)** regulation. When an individual or company invents a new product or technology, the company can apply for a patent from governments all around the world. **Patents** are issued by governments and ensure that the inventor of the new product is able to control who can produce and sell the new product. For a pharmaceutical company, receiving a patent on a drug often means that *only* the company can sell the drug for a set period of time, giving them a monopoly. This allows the company to set the price of the drug to maximize profit, which can make drugs very expensive. The TRIPS agreement compelled every nation that was a member of the WTO to create a patent system and enforce those patents. For instance, prior to 1995, India granted very few patents to drug companies who formulated new medicines. This allowed **generic companies** in India to produce the drugs at a fraction at very low prices. However, upon signing TRIPS, India was compelled to issue patents to drug companies that had invented new drugs, preventing generic companies from immediately making those drugs available at a lower price.

One particularly noteworthy feature of TRIPS is that the agreement allows for compulsory licensing. This means that during a public health emergency, governments could ignore patents on medicines and allow generic companies to make the same drug, effectively breaking the patent. Before a country can issue a compulsory license, a country must have attempted to negotiate a voluntary license with the patent holder and must pay adequate remuneration to the patent owner. If a country does not have the capacity to produce generic medicines, it can ask countries like India and China to produce the drug generically and export it to countries that lacked production capacity (World Trade Organization).

Compulsory Licenses and Legislation

Despite the fact that the WTO allows for the use of compulsory licenses, the political complications that arise with them dissuade low and middle-income countries from using them even when the health needs are great. Many rich countries, such as the United States, Britain, and France, are home to pharmaceutical companies that often lose profit when compulsory licenses are granted to generic companies. These pharmaceutical-host countries often pressure developing countries to refrain from issuing a compulsory license. Below are three case studies in which compulsory licenses were granted in three different countries: Thailand, South Africa, and Brazil.

Thailand and the Compulsory Licensing of Efavirenz

Thailand was once a leader in treating HIV/AIDS and conducted several cam-

paigms that helped to reduce the national prevalence of human immunodeficiency virus (HIV) through prevention programs. At the start of the 21st century, however, the level of funding for prevention programs started to decline. In 2000, prevention programs were receiving only 8% of the national HIV/AIDS budget and by 2001 the level of funding for HIV prevention was half of what it had been in 1997 (United Nations Development Program). In 2006, UNAIDS reported that Thailand's government had reduced its HIV prevention budget by two-thirds (United Nations Joint Program on HIV/AIDS). Because of this decrease in funding for HIV prevention, young people, drug users, homosexuals, and sex workers were at a greater risk of getting HIV/AIDS.

Since 2000, the Thai government has provided antiretroviral drugs to people living with HIV through more than 914 public hospitals (Ford et al., 2004). There are many medicines that can be used to treat HIV. Efavirenz is one of the most important ones and has "become a standard-of-care comparator in clinical trials" for initial treatment in adults (Hammer, et al., 2006). Bristol-Myers Squibb and Merck, two giants of the pharmaceutical industry, now market Efavirenz, originally developed by DuPont Pharma. It is expensive compared to other antiretroviral drugs because it is more complicated to make. In 2006, first-line treatment regimens containing 600 mg of efavirenz cost about \$500 per patient per year in **middle-income countries** – which is more than three times the price of some alternatives (Steinbrook). The per capita income of Thailand in was \$4,125 – which means that an average Thai person would have to spend about one-eighth of their yearly income on a single drug, not including the cost of medical services or other drugs that comprise the regimen of therapeutics for HIV. For a country trying very hard to battle the spread of AIDS among its citizens, this amount is quite high. With the decrease in funding for HIV prevention, there were many concerns that the government would not be able to fund its antiretroviral treatment program.

So in November 2006, Thailand's Ministry of Public Health issued a compulsory license for efavirenz, permitting the Thai Government Pharmaceutical Organization to import generic efavirenz from India where the drug is not patented (Steinbrook). Thailand is a WTO member and cited its own laws and the Doha Declaration as the legal basis for the country to issue this compulsory license. According to the Thai Ministry of Public Health, a country has "a right to issue a safeguard measure to protect public health, especially for universal access to essential medications using compulsory licensing on the patent of pharmaceutical products."

With the increased use of generic drugs within Thailand, the government has been able to obtain medicines at a much lower price and thus treat many more people who have HIV/AIDS. By the end of 2006, around 88% of those requiring antiretroviral therapy were receiving it, and by the end of 2007 national HIV prevalence was 1.4%, down from 1.8% in 2003 and over 2% in 1997 (United Nations Joint Program on HIV/AIDS). For a country that has experienced a serious AIDS epidemic, the compulsory licensing of efavirenz has facilitated the rollout of antiretrovirals in Thailand and is improving the health of those infected.

The compulsory license issued in Thailand has received a lot of attention because Thailand has historically been prominent in fighting AIDS, it has a domestic pharmaceutical industry, and efavirenz is a somewhat high-profile medication (Steinbrook). When Thailand issued a compulsory license for efavirenz, Merck objected and wanted the Thai government to consider other options. Before the compulsory license was issued in 2006, Merck was selling this drug at a non-profit price of 1,400 baht per month; generic production would make the drugs half this price (Schuettler). Merck could have provided a voluntary license for this drug but Thailand never discussed the compulsory license with Merck before issuing it. In 2007 when Thailand announced that it would also break the patent on the drug Kaletra, another AIDS medication developed by Abbott, the pharmaceutical industry condemned the decision and Abbott announced that it would cancel applications to sell seven of its

antiretrovirals—*drugs designed to slow the progress of HIV/AIDS*

drugs to Thailand because of the government's actions (Schuettler). In 2007, the U.S Trade Representative's office put Thailand on the "priority watch list" of countries that would be monitored to encourage and maintain effective IP rights protections (The Nation).

South Africa and the Medicines Act of 1997

TAC—Treatment Action Campaign

South Africa has seen major social, economic, and political improvements since it became a new democracy in 1994. There is no doubt that the country has experienced greater political stability, economic growth and degree of freedom. But even though these aspects of society have witnessed improvements, South Africa still experiences obstacles in the areas of economic disparities and health care (Ford). South Africa is a low-income country and has one of the highest HIV infection rates in the world (Marc). Though it has only 0.7% of the world's population, in 2007 it accounted for 17% of the global prevalence of HIV (Karim et al). In 2001, HIV/AIDS affected one-eighth of South African citizens (Ford).

In order to build capacity to respond to the AIDS crisis in 1997, the South African parliament passed the Medicines and Related Substances Control Amendment Act No. 90 – also known as the Medicines Act of 1997. This Act gave the Minister of Health the power to do three things: determine conditions for **parallel importation** of medicines, allow the substitution of patented medicines with generic medicines by pharmacists, and create a "pricing committee" that would act to ensure a transparent drug-pricing mechanism in the country (Muriu). Because this Act would allow for the issuing of compulsory licenses, the Health Minister hoped this would reduce the price of AIDS medication, making it more affordable. In fact, the Act itself states that the purpose of these measures is to "protect the health of the public."

When South Africa passed the Medicines Act in 1997, the US pharmaceutical industry pressured the US government to take immediate action against South Africa. Many alleged that the Act was a breach of TRIPS and that it violated the property rights of pharmaceutical companies in South Africa under the South African Constitution. Immediately, South Africa was placed on the US Trade Representative's watch-list and the country was threatened with trade sanctions by the United States in 1998 (Muriu). Thirty-nine major pharmaceutical companies were involved in the lawsuit against South Africa (Ford). The case was strongly opposed by the Treatment Action Campaign (TAC) – a social movement founded by a group of activists in 1998 that was very concerned with increasing access to HIV/AIDS treatment. In the end, TAC was victorious over Big Pharma partly due to the international outrage at the pharmaceutical industry for their attack on a developing country. African countries usually do not have a very good reputation for upholding human rights laid out in the Universal Declaration of Human Rights (Odinkalu). In this case, where South Africa was able to pass legislation that would ultimately improve the rights of its people, it was faced with hostility. This example shows the length to which the pharmaceutical industry will go to ensure that compulsory licensing is not used, even when there is a dire health need in a developing country.

Antiretroviral Therapy in Brazil

In 1996, Brazilian President Fernando Henrique Cardoso signed a law establishing free and universal access to antiretroviral treatment for those living with HIV/AIDS. This has been one of the strongest parts of the Brazilian AIDS Program. In most countries, antiretroviral treatment is not a viable option because the drugs are too expensive. Of the 6 million people worldwide who needed **antiretroviral** treatment in 2003, fewer than 8% received it (World Health Organization). Under Brazil's policy, however, the number of people receiving treatment has steadily increased from 35,900

in 1997 to 105,000 in 2001 (Galvão). This, of course, has not come at small expense; Brazil's government spent \$232 million on antiretrovirals in 2001 compared to \$34 million in 1997 (Brazil Ministry of Health).

Brazil's government had to make great efforts to provide antiretroviral treatment, and it did so through domestic production and negotiations with international pharmaceutical companies. The high cost of drugs is the largest factor that could contribute to the deterioration of Brazil's program. Interestingly, though Brazil has implemented the TRIPS agreement, it has not utilized the compulsory license or violated any patents. Instead, Brazil has threatened to use the compulsory license, which has proven to be an effective tool for negotiation with pharmaceutical companies to lower the price of medicine. For example, in 2001 Brazil was considering breaking patents for two drugs – nelfinavir manufactured by Roche and efavirenz manufactured by Merck – if the prices of these drugs were not reduced (Galvão). Merck reduced the price of efavirenz by 60% and Roche subsequently agreed to significantly reduce the price of nelfinavir. This strategy has had both positive and negative consequences for Brazil – they have cheaper antiretrovirals, but they will still face a backlash from US-based pharmaceutical companies if they issue compulsory licenses. The epidemic of HIV/AIDS has been spreading very rapidly in Brazil – notably among the poor, women, and those living in urban areas. By December 2003, 310,310 cases had been reported, comprising 220,783 men and 89,527 women; of this number, approximately 48% have died (Galvão). In order for the government to continue to treat and prevent HIV/AIDS effectively, cheaper pharmaceuticals are essential.

Explanation of the Problem

Trade Problems

For the three cases above – where a compulsory license was actually issued in Thailand, where legislation was passed dealing with compulsory licensing in South Africa, and where the threat of issuing a compulsory license was utilized in Brazil – each country experienced significant backlash from the pharmaceutical companies and the United States government. In fact, when the TRIPS agreement was being negotiated, most developed countries pushed for harsher restrictions on compulsory licensing to safeguard their domestic industries (Ford). The United States government actually punishes countries that it believes do not have adequate patent provisions by using the “**301 threat.**” The “301 threat” threatens to impose tariffs or duties on exports coming from a country that issues a compulsory license, making exported products from that country relatively more expensive. This can have the effect of reducing economic growth of developing countries, which helps dissuade them from issuing compulsory licenses. Developing countries, however, feel they should be able to exercise their rights as outlined in TRIPS, which is to utilize compulsory licensing in case of public health emergencies if certain drugs are too expensive for their citizens to purchase. Thus, a certain amount of tension exists between developing and developed countries over the right to use the compulsory license.

Concerns with Innovation

The United States government, through its trade representative, has given multiple reasons why it opposes the issuance of a compulsory license. For example, compulsory licenses potentially jeopardize the research and development of new drugs. One of the main reasons pharmaceutical companies are given patents, or an effective monopoly for a limited time, is so that they can make enough profit to recover the cost it took to make the drug. Some studies estimate that it takes \$1 billion of investment to

bring a new drug to market. When compulsory licenses are issued, pharmaceutical companies lose their monopoly in developing countries and bring in less revenue. Those companies may not recover the cost it took to invent the drug in the first place. This could have the effect of dissuading companies to invest in new drugs in the future, and a cure for HIV or cancer would never be invented because pharmaceutical companies believe they will lose money when compulsory licenses are issued for their products.

Concerns about Importation

Apart from the loss of profits in developing countries, pharmaceutical companies are also concerned about the potential for cheaper generic drugs to be imported to developed countries, cutting into their markets. Indeed, many pharmaceutical companies sell the same drug at higher prices in richer countries because people can afford to pay more. When cheaper generic medicines leak into developed countries, they can significantly reduce the profits of pharmaceutical companies.

Focus of the Debate

With more than one-third of the world without access to lifesaving medicines, the high cost of pharmaceuticals is extremely problematic. The WTO has tried to emphasize and address the importance of allowing access to essential medicines by instituting TRIPS and the Doha Declaration. But the provisions contained in TRIPS and the Doha Declaration have been controversial since the time they were passed. There has always been tension between the United States and developing countries over IP protection. Developing countries “have taken a broader interpretation of the Doha Declaration and believe that the inherent flexibility in these agreements should provide discretion in order to ensure access to medicines when IP regulations do present a real barrier to address health and social welfare issues” (United States Government Accountability Office, 2007). The United States and other Western European countries, on the other hand, believe that the flexibility should be carefully applied and certain conditions should be specified as in TRIPS. This continues to be a fundamental disagreement between the United States and developing countries when dealing with compulsory licenses.

The World Health Organization heavily influences many of the health policies of developing countries. As members of the World Health Assembly and contributors to the WHO’s Essential Medicines List, we are charged with the task of issuing a recommendation on the conditions under which compulsory licenses should be issued. What are the potential consequences of issuing compulsory licenses? How might it affect the economies of developing countries? What will happen if drugs are not made at a low cost? How should we balance maintaining incentives for pharmaceutical companies to innovate with making drugs more accessible at a low price? These are all questions that policymakers must answer to devise a recommendation to countries regarding the use of compulsory licenses.

Recent Developments

On April 22, 2010, Ecuador issued its first compulsory license for an HIV/AIDS drug under newly adopted rules that its legislature passed allowing the country to take advantage of WTO TRIPS flexibilities. According to the Intellectual Property Office of Ecuador, the compulsory license has resulted in significant savings for the Ecuadorian government. The compulsory license was for the drug **ritonavir**, a generic medicine produced by the Indian company Cipla that is used to slow the progression of

HIV/AIDS. Cipla is required to pay royalties to Abbot Laboratories, the United States-based company that developed the drug and holds the patent. South American Ministers expressed support for Ecuador's decision at a joint ministerial meeting in 2009, indicating that compulsory licensing could become more common in South America despite opposition from the United States.

NGO Perspectives

Heritage Foundation

Franklin Cudjoe, a writer for the Wall Street Journal and beneficiary of funding from the Heritage Foundation, found that the main problem associated with delivering services in resource-poor countries is a lack of infrastructure, not high drug prices. He writes, "If the West is any guide, better health systems come with economic development and higher standards of living" and that compulsory licensing will stifle economic development and investment in developing countries without solving health problems. The Heritage Foundation is supportive of a global patent system in which compulsory licenses are used rarely, if at all. According to the Heritage Foundation, a global respect for intellectual property will further foster innovations by guaranteeing a profit margin for pharmaceutical companies to develop new therapeutics. Compulsory licensing is a threat to profits, and thus to innovation of new drugs.

Oxfam International

Oxfam International is generally supportive of governments that take steps to ensure affordability of drugs to treat its population. When a Thai government delegation visited the United States in 2008, Oxfam pleaded for the US to allow the Thai government to take advantage of the flexibilities of the WTO and continue to produce generic medicines for its population. Oxfam stated, "Compulsory licensing is perfectly legal under the World Trade Organizations' rules and national law, and has been carried out in many countries. The WTO's intellectual property agreement provides all countries the right to override patent protection to introduce affordable, generic versions of medicines that help protect public health. Any pledges undermining access to affordable medicines including a decision to stop the compulsory licensing policy will block poor people's access to life-saving medicines that can be made affordable in the future."

Questions for Policy Makers

Policymakers at the international, national, and local levels have a variety of questions to answer. Under what circumstances is it reasonable to issue a compulsory license? What constitutes a public health emergency? How can countries interested in compulsory licensing unite to articulate a shared vision? How might countries against compulsory licenses pressure developing countries to not resort to them? How should the drug development incentive system be changed to ensure innovation and accessibility of medical technologies? These are all questions policymakers around the world must answer in order to advocate for particular policies regarding the licensing of medical technologies and flexibilities in the global order.

Possible Solutions

The World Health Organization is a forum for representatives from different health ministries across the world to find common solutions to transnational problems. Given that the World Health Organization is one of many forums to discuss the impli-

cations of a global system of intellectual property, members of the World Health Assembly may be able to pass a resolution that highlights strategies palatable to both countries in favor of compulsory licensing as well as those opposed.

One compromise might be to create a prize fund that rewards the development of medical innovations for poor countries while still maintaining stringent patents on therapeutics throughout the world. This way, private pharmaceutical companies in the United States can maintain their profit and incentives for innovation while developing countries are able to receive useful, new medical technologies that help address health problems of their people.

Another solution is the **patent pool**, which is a depository of patents that pharmaceutical companies *voluntarily* contribute to. Essentially, all patents in the “pool” can be licensed to generic companies, which pay a royalty for the use of the patent. Individual companies can choose which patents to contribute, allowing companies to contribute patents that are medically useful for poor patients while maintaining control of patents that create profit.

Alternatively, another solution is for poorer countries to band together to more aggressively issue compulsory licenses and take advantage of WTO flexibilities. There may be repercussions from this sort of option, as rich countries could impose trade sanctions on poorer countries that are in favor of compulsory licensing.

Above all, the World Health Assembly should be a forum for countries to discuss these different options and attempt to reach a compromise that can be beneficial to all sides.

Patent pool—*a depository of patents that pharmaceutical companies voluntarily contribute to.*

Guide to Further Research

For further research, there are a variety of organizations with information about the issue of drug licensing. The World Trade Organization has information about its effects on international trade policy on its website at <http://www.wto.org/>. UNITAID has information about the “patent pool” initiative at <http://www.unitaid.eu/en/The-MedicinesPatent-Pool-Initiative.html>. Finally, both Medicines Sans Frontières (known in the United States as Doctors Without Borders) and Universities Allied for Essential Medicines list resources useful to those who would argue for greater access of prescription drugs to developing countries. Look to their websites at <http://essentialmedicine.org/> and <http://www.msfaaccess.org/>.

Conclusion

Not every person in the world has access to essential medicines. Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) says that a state must take the necessary measures for the “creation of conditions that would assure access to all medical service and medical attention in the event of sickness.” The Universal Declaration of Human Rights states that “everyone has the right to a standard of living adequate for the health and well-being of himself and his family.” The WHO believes that “the right to health means that governments must generate conditions in which everyone can be as healthy as possible” (World Health Organization, 2007). These three statements include the provision of equal access to life-saving medications. But these declarations, while valuable in themselves, have been much harder to fulfill – in part because of lack of access to resources needed to achieve health as a human right (Kim, et al). There are many factors that contribute to the lack of access to essential medicines: lack of resources, inadequate investment in research and development for drugs to treat debilitating disease, insufficient production, and inadequate infrastructure for the supply and storage of the drugs. But there is no doubt that the high cost of drugs substantially contributes to the problem (Muriu). Compul-

sory licensing is a potential remedy to prohibitively expensive medicines. However, there are tradeoffs associated with issuing compulsory licenses. Policymakers must carefully consider the costs and benefits of compulsory licensing to ensure the economic and physical welfare of their citizens.

Glossary

World Trade Organization – *An international forum for trade negotiations between countries*

General Agreement on Trade and Tariffs (GATT) – *An international agreement signed in the aftermath of World War II to regulate trade between nations*

Trade-Related Aspects of Intellectual Property Rights (TRIPS) – *A specific portion of the WTO agreements that outlines global regulations for intellectual property*

Patent – *the privilege granted by governments to be the only entity able to use and produce an innovation*

Generic companies – *companies that manufacture and distribute cheaper, generic versions of more expensive, brand name medications*

Middle income countries – *countries that are not yet developed but not in absolute poverty either (e.g., India, Brazil, South Africa, China, Russia)*

Parallel importation – *importing medicines from other countries without the permission of the patent owner*

Antiretrovirals – *medications for the treatment of infection by retroviruses, such as HIV*

301 threat – *a threat to impose economic sanctions on a country engaging in compulsory licensing.*

Patent pool—*a depository of patents which can be licensed at nominal or no fee to developing countries.*

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