

Spring 2010

Intellectual Propriety: Compulsory Licenses Through the TRIPS Agreement and the Doha Declaration on Public Health

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Intellectual Propriety: Compulsory Licenses through the TRIPS Agreement and the
Doha Declaration on Public Health

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April 27, 2010
SIT Geneva Spring 2010

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Preface and Acknowledgements

I wish to acknowledge all those who assisted me in this project both directly and indirectly. I am grateful to the organization officials and experts who took the time to meet with me in Geneva, both on and off the record.

I want to thank Aline Amman, Academic Coordinator Extraordinaire, who kept track of thirty-one undergraduates and two professors throughout Geneva, Bern, Brussels, Paris, and Pula, Croatia via Milan and Trieste (due to volcanic ash cloud that halted flights throughout Europe).

I am grateful to the Huser-Arnal Family of Arzier, Switzerland who welcomed me into their home and provided a wonderful home-stay experience.

I am grateful as well to all of my professors and advisors at Brandeis University (as well as my parents and family) for supporting me in my decision to study abroad in Geneva for the Spring 2010 semester. I am also thankful for my teachers and advisors at Cary Academy (Cary, North Carolina, USA) who first exposed me to the benefits of international study during my junior year of high school.

Finally, I wish to dedicate this work to Martha Peoples. Without her care and support at an early age I would not be the person I am today.

Sam Fuchs

April 27, 2010

Pula, Croatia

Introduction

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS), part of the Uruguay Round of trade negotiations led to the creation of the World Trade Organization (WTO) in 1995, has led to a variety of interpretations and opinions. Though its application goes beyond matters of public health, it is this area that has come under the most scrutiny in the last fifteen years as the gaps between developed and developing countries have widened and exposed the health disparities between the two groups. Tensions over intellectual property and access to newly developed medicines to treat diseases such as HIV and AIDS grew throughout the late 1990s and culminated in the 2001 Doha Declaration on Public Health.¹ While intellectual property would normally be left to the World Intellectual Property Organization (WIPO), developed and developing countries had difficulty agreeing on compulsory licenses during negotiations in the 1980s and early 1990s, and as a result the matter went to the WTO instead.² One of the most controversial aspects of intellectual property has been access to medicines treating HIV and AIDS. The number of those receiving anti-retroviral (ARV) treatment has grown tremendously, which raises the question of the role the TRIPS Agreement and the Doha Declaration on Public Health have played. One cannot attribute success entirely to the TRIPS Agreement but at the same time one cannot deny its impact. This paper will provide an overview of the policies and explain how if nothing else, the power to issue compulsory licenses has aided developing countries in their efforts to provide ARV treatment for HIV/AIDS patients.

¹ Reichman, Jerome H. "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options." *Journal of Law, Medicine & Ethics* 37.2 (2009): 247-263. *Academic Search Premier*. EBSCO. Web. [Accessed 29 Mar. 2010]. 247-8

² Ibid

The Beginning, a Very Good Place to Start: The TRIPS Agreement

As stated in the introduction, TRIPS began as one of the original components of the World Trade Organization (WTO) upon its founding in 1994 following the Uruguay Round of Trade Negotiations. It is little wonder that the Treaty has been the subject of so much discourse and controversy as it placed intellectual property in the realm of commercial trade negotiations. The TRIPS Agreement has never been limited to pharmaceutical products, however it became apparent in the eponymous Doha round of trade negotiations begun in 2001 that pharmaceutical patents were a unique aspect of intellectual property because of the obvious implications on access to medicines.

Reasons for the 2001 Doha Declaration and the 2003 General Statement on Implementation of Paragraph 6

While scholars analyzing access to medicines often cite the TRIPS agreement, they usually mean to refer not to the original treaty but to the Doha Declaration on TRIPS and Public Health, agreed on in 2001 and implemented in 2003. This key item was nothing more than a clarification of the previously agreed upon treaty.³ This measure was necessary, however, because many countries and companies disagreed about the impact of the Treaty's provisions on the trade of pharmaceutical products and public health emergencies. Despite voting on the agreement in 2001, many refused to believe that TRIPS allowed flexibilities.⁴ TRIPS Flexibilities can be understood as the safeguards in place that "limit the rights of patent holders"

³ Sirmalya Nyam. Programme Officer, Innovation and Access to Knowledge at South Centre. Personal interview. 23 March 2010.

⁴ Lecture on TRIPS at Global Health Course at the Graduate Institute in Geneva. 14 April 2010.

so that WTO member countries can provide necessary medications to their people.⁵ The original language implied flexibilities were available, however even those who knew this was true felt that a clarification was necessary and that it needed to be adopted by the entire WTO.⁶

The lack of clarity became apparent in the case of South Africa. South Africa, which has the largest number of people living with HIV/AIDS, purchased patented HIV/AIDS medicines in India because it was less expensive than purchasing them in South Africa, a concept known as parallel imports and a crucial element of the TRIPS Agreement.⁷ In 1998, thirty-nine pharmaceutical companies sued in South African courts saying that the parallel imports were illegal under the TRIPS agreement when in the fact the exact opposite was true.⁸ Undoubtedly influenced by the ever-present AIDS crisis, the African member governments of the WTO, referred to as the African Group, suggested in June 2001 the adoption of a specific text detailing the importance of insuring access to medicines. Additional pressure came from India and Brazil, two of the largest manufacturers of generic medicines.⁹ What began as a small paragraph grew to several pages before its eventual adoption by WTO member governments on November 14, 2001 at the Doha Ministerial Conference.¹⁰

⁵ *International Trade and Health: A Reference Guide*. New Delhi: World Health Organization Regional Office for South-East Asia, 2009. 18

⁶ Lecture on TRIPS at Global Health Course at the Graduate Institute in Geneva. 14 April 2010.

⁷ *International Trade and Health: A Reference Guide* 14

⁸ Barnard, David. "In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries." *Kennedy Institute of Ethics Journal* 12.2 (2002): 159-174. Project MUSE. <<http://muse.jhu.edu/>>. [Accessed 26 Mar. 2010].

Spennemann, Christoph. Legal Expert, Intellectual Property Unit, Division on Investment and Enterprise, UNCTAD. Personal interview. 14 April 2010.

⁹ Love, Roy. "Corporate wealth or public health? WTO/TRIPS flexibilities and access to HIV/AIDS antiretroviral drugs by developing countries." *Development in Practice* 17.2 (2007): 208-219. Academic Search Premier. EBSCO. Web. [Accessed 29 Mar. 2010]. See page 210

¹⁰ Velásquez, Germán. Personal interview. 13 April 2010. Director, WHO Secretariat on Public Health, Innovation and Intellectual Property. World Health Organization. Also see "TRIPS and pharmaceutical patents". *WTO Fact Sheet*. September 2006.

Explanation and Effects of the Doha Declaration on Public Health

At its core, the Doha Declaration and its passage are most significant because it recognized the gravity of public health problems in a trade-related document and forced the WTO to accept that pharmaceutical patents are different than other patents.^{11 12} One does not have to be an intellectual property expert to understanding the impact of the Doha Declaration, and while this paper does not attempt to simply duplicate already published analyses, it is crucial to understand several important terms of the TRIPS agreement and the Doha Declaration to understand how they have impacted the usage of newer medications such as second and third line anti retro viral drugs.

One of the key results of the Doha Declaration was the agreement that countries had the right to issue compulsory licenses. Compulsory licensing occurs when a country ignores the patent protection of a specific product and authorizes another company to produce the patented product. Interestingly, a public health emergency does not have to be present for a compulsory license to be issued, however TRIPS does require a country to make an effort to obtain a voluntary license before issuing a compulsory one. A compulsory license can be granted without first attempting to obtain a voluntary license if there is an urgent need for the product, if it is produced solely for government or non-commercial use, or if it is used to “remedy anti-competitive behaviour”.¹³

The question that remained following the Doha Declaration was how countries that lacked domestic manufacturing capability, often developing or least developed countries (LDCs), could benefit from issuing compulsory licenses if there were no firms to receive them. Article 31(f), of the original TRIPS agreement, a subject discussed in a wealth of academic literature,

¹¹ Lecture on TRIPS at Graduate Institute

¹² Velásquez, Germán

¹³ *International Trade and Health: A Reference Guide* 81 and lecture at Graduate Institute

stated that any production arising out of a compulsory license had to be primarily for the domestic market. Paragraph 6 of the Declaration thus instructed the Council for TRIPS to “find an expeditious solution to this problem...before the end of 2002”.¹⁴ In August 30, 2003, the Decision of the General Council allowed countries unable to manufacture medicines on their own to import from another country as long as both issued compulsory licenses, thus allowing a system of parallel importation.¹⁵ Explained above in the case of South Africa in 1999 and 2000, parallel importation is sometimes referred to as “grey imports” and gives the impression that it is of questionable legality (leaning towards the black market) despite the clarification provided by the Doha Declaration. Because Paragraph 6 is part of the Doha Declaration of 2001 and the General Council Statement on the Implementation of Paragraph 6 (referred to as both the “WTO waiver” and “Paragraph 6 solution”) occurred in 2003, the two are often grouped together in discussion of parallel imports.

Legalizing Arbitrage

The Declaration and Paragraph 6 solution thus legalized a certain degree of arbitrage, the technical term for making a profit by buying a product at a low price in one country and selling it at a higher price in another country. However, regulatory controls established by TRIPS, the Doha Declaration, and the General Council Statement make parallel imports of pharmaceuticals different than the sorts of arbitrage that lead to major trade disputes because it only applies to countries that are unable to produce the medicines for themselves and forbids the sale of the medicines in any market other than the country of need and the country of supply.¹⁶ The

¹⁴ *Declaration on the TRIPS Agreement and Public Health*. Paragraph 6. 14 Nov. 2001. <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>. [Accessed 21 April 2010].

¹⁵ Syam interview

¹⁶ “TRIPS and pharmaceutical patents”. *WTO Fact Sheet*. September 2006. 6

medicines are often marked differently and placed in special packaging to prevent illegal reselling in other countries.¹⁷ While concern for medicines ending up in the wrong hands had been an argument used by pharmaceutical companies against parallel imports, unique product labeling has proven to be simple way to insure that medicines sold at different prices for one country will not affect sales in another country.

Effects of the 2003 General Council Decision on Paragraph 6

The original thinking behind the 2003 General Council Decision was for Paragraph 6 of the Doha Declaration to become an official section of the TRIPS Agreement. While the 2003 Waiver adopted Paragraph 6 as Article 31bis, it remains to be verified by the entire WTO, which has consistently pushed back the deadline for adoption, currently set to take place in 2011. While this is hardly in agreement with the “expeditious solution” prescribed by the TRIPS Agreement, the effect would simply be a formality at this point as the 2003 Waiver gave Paragraph 6, the proposed Article 31bis, its legal authority.¹⁸

Paragraph 6 System and its one-time use – What does it mean and does it indicate success?

Much of the debate over the Paragraph 6 system centers on the fact that it has only been implemented once, in a parallel import agreement between Canada and Rwanda in 2007. Canada announced in September 2003, one month after the WTO waiver, or Paragraph 6 solution, was approved.¹⁹ A Canadian generic pharmaceutical manufacturer, Apotex, agreed to manufacture and export to Rwanda a supply of fixed dose combinations (FDCs) of zidovudine,

¹⁷ WTO spokesperson. Personal interview. 25 March 2010.

¹⁸ WTO spokesperson interview and Nyam interview

¹⁹ “Members ask: Is the ‘Par. 6’ system on intellectual property and health working?” *WTO 2010 News Items*. World Trade Organization, 2 March 2010. <http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm>. [Accessed 25 March 2010].

and nevirapine.²⁰ Interestingly, the exchange was initiated by Canada and *not* by Rwanda, the country in need of the medicine. Apotex asked the Canadian health authorities for approval of their generic drug in December 2005, and did not select Rwanda as its country for export until July 2007.²¹ In a meeting on March 10, 2010, Canadian representatives presented their timeline of the project and pointed out obtaining the actual compulsory license only required two weeks. Responding to claims of an inefficient system, the Canadian delegation explained that it was eight months before Canadian legislation was adjusted to comply with the 2003 Waiver, one year for identifying a country for export, and two months between Apotex's application for a voluntary license from three patent owners and its application for a compulsory license from the Canadian government. Including the Rwandan procurement process, the entire project lasted from September 2003 through September 2009.²²

The Actual Goal of 'Paragraph 6'

As was recently emphasized by WTO Director-General Pascal Lamy, the goal of the Paragraph 6 system was not to issue compulsory licenses, but rather to help increase the availability of medicines at lower prices.²³ In the past ten years the cost of medicines, including antiretroviral drugs that are used to treat HIV and AIDS, have decreased and the numbers of those receiving ARV treatment has skyrocketed. This has occurred for a variety of reasons, including the fact that organizations such as Medecins Sans Frontieres/Doctors Without Borders (MSF) and the Gates Foundation have found ways to purchase drugs at lower costs and because there has been an outpouring of AIDS relief efforts such as UN AIDS, the Global Fund and

²⁰ *International Trade and Health: A Reference Guide* 86

²¹ "Members ask: Is the 'Par. 6' system on intellectual property and health working?" and interview with WTO spokesperson

²² Ibid

²³ WTO interview

others that have been quite effective in increasing the amount of ARV treatment in African countries and throughout the world.

Compulsory Licensing as a Negotiating Tool

Compulsory licenses have served as an important bargaining chip for governments negotiating with pharmaceutical companies.²⁴ While one cannot deny of course that the Paragraph 6 system has only been used once, experts agree that its use is by no means the best measure of whether access to drugs has increased.²⁵ An economic principle known as the specificity rule states that the best way to deal with a policy problem is to correct it at the source. Thus if drug prices are to become lower there must be a carrot or stick for pharmaceutical companies, and the stick can be the possibility of “legal sanctions”.²⁶ Compulsory licenses act as the stick because the threat of one can be enough to convince a company to agree to a voluntary license. Patent owners often prefer issuing a voluntary license than dealing with a compulsory one because they can receive higher revenue from a license they negotiate than one issued by a local government.²⁷ While countries issuing compulsory licenses are still obligated to pay “adequate compensation” to patent owners, the 2003 Waiver stated that payment only needed to be collected once in the exporting country and not in the importing country as well.²⁸ While the more developed exporting country may be able to pay more than the less developed importing country, there is no guarantee that a government and a patent owner will agree on what constitutes adequate compensation.

²⁴ Syam

²⁵ WTO spokesperson interview

²⁶ Reichman 254

²⁷ Syam and WTO spokesperson

²⁸ Reichman 249

History, Theory and Reasoning Behind Pharmaceutical Patents

The parallel import system included in the 2003 decision had obvious benefits for the large generic producing countries such as Brazil, India, and China.²⁹ An additional impact of the 2003 Decision was the extension of deadlines for transitioning to the conditions outlined in the original TRIPS Agreement and the Doha Declaration. The original January 1, 2000 deadlines for developing countries to accept all of the TRIPS provisions, such as instituting both product and process patents, was extended to 2006 and the original 2006 deadline for least developed countries was extended to 2016.³⁰ Included in the texts was the agreement that India would have until 2005 to adjust its patent laws to grant patents on *products* and not just on processes.³¹ India's patent laws historically did not recognize a new combination of chemical compounds as patent-worthy, meaning that if a pharmaceutical company reconfigured an already patented drug to be manufactured differently it would most likely not receive a patent in India.

India has become known as “the pharmacy of the developing world”³² due to its well-established generic drug industry, which can be traced back to the patent system the country inherited from Great Britain after gaining independence in 1947. At the time of the Paris

²⁹ Reichman 249

³⁰ “Transition provisions”. *Pharmaceutical patents and the TRIPS Agreement*. Technical note. WTO. 21 Sept. 2006. <http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm>. [Accessed 21 April 2010]. Also see “TRIPS and pharmaceutical patents”. *WTO Fact Sheet*. September 2006. 5

³¹ Anonymous WTO expert. Phone interview. 22 April 2010.

³² von Schoen-Angerer, Tido. “India: Will Pharma, trade agreements shut down the Pharmacy of the Developing World?”. 19 April 2010. Editorial published on MSF Campaign for Access to Essential Medicines website and in Huffington Post. <<http://www.msfacecess.org/main/access-patents/india-will-pharma-trade-agreements-shut-down-the-pharmacy-of-the-developing-world/>>. [Accessed 26 April 2010].

Convention for the Protection of Intellectual Property in 1883, one of the earliest intellectual property agreements, many countries did not grant patent protection on pharmaceuticals.³³ In India, the Tex Chand committee in 1949 and the Ayyangar committee in 1957 decided to grant process patents on foodstuffs and medicines for only five years. The five year limit meant generic versions of medicines were developed more rapidly than in other countries.³⁴ Today the lowest-priced drugs are found in India, despite adjustments that the country has had to adopt as a result of the TRIPS Agreement. Despite the fact that TRIPS did not define what is considered novel or inventive, it did require countries to grant patents on pharmaceuticals as products *and* ones that would last at least twenty years. India was allowed to have a ‘mailbox system’ for patent applications between 1995 and 2005, which meant countries were able to apply for product patents but the applications would not be examined until 2005. Even today there continue to be disputes in India over product patents.³⁵ In 2007, Novartis brought a lawsuit in India over their leukemia drug Gleevec. Novartis had used a different formula that allowed the medicine to be absorbed in the bloodstream faster and claimed it was a new drug deserving a new patent, however the Indian patent office disagreed.³⁶ While twenty years is a reasonable length of time for a patent, it is important to note that a twenty-year patent on a computer device has dramatically different effects than a twenty-year patent on a medicine.³⁷ There are those who believe that a shorter patent duration could be beneficial in increasing access to medicines, but

³³ Syam

³⁴ Syam and “History of Indian Patent System”. <<http://www.patentoffice.nic.in/ipr/PatentHistory.htm>>. [Accessed 23 April 2010].

³⁵ WTO lecture at Graduate Institute

³⁶ “Novartis concerned Indian court ruling will discourage investments in innovation needed to bring better medicines to patients”. Media Releases – Novartis. 6 Aug. 2007. <http://cws.huginonline.com/N/134323/PR/200708/1144199_5_2.html>. [Accessed 24 April 2010].

³⁷ Dyer, Owen. “BMJ: New 20 year patents threaten to end AIDS drugs for developing countries”. MSF Article. Médecins Sans Frontières. 4 December 2004. <http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=ECEDF48F-9D6F-45DD-AFCD7E55622F351B&method=full_html>. [Accessed 23 March 2010].

the countries in favor of this are in the minority and worry that any advocacy for shorter patent lengths could risk increasing the standard patent durations.³⁸

The Effect of Bilateral Trade Agreements

Many of the flexibilities obtained through the Doha Declaration that are beneficial for developing countries are at risk of becoming diminished by new bilateral trade agreements.³⁹ While the strengthening of intellectual property rights through the TRIPS Agreement was beneficial to pharmaceutical companies, many were not pleased with the results of the Doha Declaration and the 2003 Wavier decision. Companies “persuaded the United States Trade Representative (USTR) to recapture lost ground by means of Bilateral or Regional Free Trade Agreements with developing countries.⁴⁰ Because of WTO principles that forbid giving most favored nation status to any country, any conditions extended to one country by another could theory apply to the former country’s dealings with every WTO member.⁴¹ Scholar Jerome Reichman also claims that the pharmaceutical industry “flooded the world with misleading and self-serving interpretations of relevant legal instruments,” which is definitely not helpful in the realm of intellectual property where is confusing enough without the extra interpretations intended to skew decision making in one direction or another.

There are several views of how pharmaceutical companies have fared under TRIPS and Doha. They gained an increased recognition of intellectual property rights, but would have preferred if the 2003 clarification had not come about as it emphasized how the Doha

³⁸ Syam

³⁹ Ibid

⁴⁰ Reichman 249

⁴¹ Syam

Declaration can be used to the benefit of individual countries.⁴² There is one view that the companies “shot themselves in the foot” after the initial TRIPS Agreement considering cooperation has increased dramatically between the industry and the World Health Organization. Some of their initial complaints had reasonable merit, such as their fear of medicines destined for one country ending up in another country illegally, however this was easily resolved with different colored pills and special packaging.⁴³ All in all, the pharmaceutical industry emerged as the biggest winner from the TRIPS Agreement.⁴⁴ Scholar Frederick M. Abbott concludes the “Patent pendulum is shifting in a major way in favor of Pharma interests”.⁴⁵ Reichman writes that “developing countries lost the war” in losing the ability to easily reverse-engineer medicines to produce generics.⁴⁶ However, many companies are still upset with then-USTR Robert Zoellick for in effect giving away too much because countries have the renewed power to issue compulsory licenses.⁴⁷ It becomes difficult to analyze the effectiveness of this power because countries can succeed in negotiations by *not* issuing compulsory licenses.

Pharmaceutical Industry’s Perspective

From the perspective of the pharmaceutical industry, the TRIPS Agreement and Doha Declaration would not have occurred without the push from the AIDS crisis.⁴⁸ While negotiators from developing countries preceding the Doha Declaration were very clear on not limiting the impact of any new agreement, there were efforts made by the United States to limit the

⁴² Phone interview with an additional WTO expert

⁴³ WTO spokesperson interview

⁴⁴ Reichman 248

⁴⁵ Abbott, Frederick M. “The WTO medicines decision : world pharmaceutical trade and the protection of public health”. *American Journal of International Law*. 99(2) Apr. 2005: p.317-358. LexisNexis Academic. <<http://www.lexisnexis.com>>. [Accessed 23 March 2010].

⁴⁶ Reichman 247-8

⁴⁷ Lecture at Graduate Institute

⁴⁸ Retired Merck executive. Personal interview. 29 March 2010.

applicability either by disease or geographic region. In February 2003, at a Tokyo mini-ministerial meeting, USTR Robert Zoellick proposed limiting any solutions to Africa in exchange for allowing broad language on the “scope of diseases”.⁴⁹ An article published in October 2001 in the *Journal of the American Medical Association (JAMA)* became fairly influential in pharmaceutical circles because it concluded that patents were not the main obstacle to treatment of HIV/AIDS in African countries. At the time of publication, authors Amir Attaran and Lee Gillespie-White found that of the fifteen anti-retroviral drugs (ARVs) in use, only thirteen patents existed in Africa, and eleven were in South Africa alone.⁵⁰ While it is important to note that Attaran received a grant from Merck *after* the publication of his article,⁵¹ his findings are nonetheless still significant. In the 1990s there were few if any patents on ARVs in India, the country of supply, and relatively few in African countries, the countries of use, which begs the question of why everyone looks immediately to the TRIPS Agreement.⁵² Even a current pharmaceutical executive agreed that for the most part the TRIPS Agreement is irrelevant to fighting AIDS in Africa.⁵³ While executives make the important point that a comprehensive public health solution and not simply cheaper drugs is necessary to ameliorate the AIDS crisis, the fact that drugs have become cheaper in the past fifteen to twenty years has undoubtedly removed other barriers to treatment.

⁴⁹ Abbot 8

⁵⁰ Attaran, Amir, and Lee Gillespie-White. "Do Patents for Antiretroviral Drugs Constrain Access to Aids Treatment in Africa?" *JAMA* 286.15 (2001): 1886-92.

⁵¹ Attaran, as well as Velasquez interview

⁵² Interview with retired Merck executive

⁵³ Pharmaceutical official specializing in International Aid. Personal interview. 16 April 2010.

Price Discrimination: Avoiding bad press and fulfilling a moral obligation

While many pharmaceutical companies originally resented⁵⁴ the Doha Declaration placing them in a position similar to that of a public health authority, they eventually realized it was in their interest to sell drugs at lower prices in poorer countries to both preserve their public image and fulfill a moral obligation. Pharmaceutical companies now use a variety of different prices depending on the specific market, however this was not always the case. Price discrimination is a key element of microeconomic theory,⁵⁵ but at the same time there have been some specific cases where monopoly pricing was more beneficial to the companies involved. In addition, for many years pharmaceutical companies were hesitant to charge different prices for the same drugs out of fear that customers in wealthy countries would not tolerate it. Even today companies have to be careful because one cannot automatically “expect the rich to be generous” if they have to pay one thousand dollars for a medicine and others only have to pay one dollar.⁵⁶ Fortunately for AIDS patients in developing countries, however, this line of thinking has not impeded their care because companies have found a common ground between economic incentives and moral obligations.

Economic Arguments for Price-Discrimination:

Jerome Reichman points out, “most economists would agree that in a perfect world” pharmaceutical companies would ‘avoid risk of compulsory licenses by pricing products close to the marginal cost of production so that poor people around the world could afford them’.⁵⁷

Reichman goes on to suggest that pricing based on per-capita gross domestic product (GDP) for

⁵⁴ Retired Merck executive

⁵⁵ Basu, Sudip Ranjan. Economist, International Trade Division, UNCTAD. Personal interview. 14 April 2010.

⁵⁶ Current pharmaceutical executive

⁵⁷ Reichman 251

example, would be an objective way of determining price differences and “reduce the deadweight loss” created when only rich consumers purchase medicines.⁵⁸ The unfortunate truth, however, is that from a purely economic standpoint there are many arguments for non-discriminatory pricing of pharmaceuticals. Reichman analyses the economic analysis of several scholars on the subject, such as Aidan Hollis, Sean Flynn, and Micheal Palmedo, who have written about the “Problem of the Convex Demand Curve” for “essential goods in countries with large income disparities”. In these particular markets firms actually maximize their profits by ‘setting a price unaffordable to at least ninety-percent of the people’.⁵⁹ Hollis’ argument is based on data comparisons between South Africa, a country with a large income disparity, and Norway, a country with a high level of income equality.

While breaking away from this logic can require companies to act against their own self-interest, these same companies are in a unique line of work where their decisions have undeniable implications that can go as far as matters of life and death. Author James Love makes the blunt but accurate claim that even a minimal deadweight loss can lead to dead bodies.⁶⁰

Despite any economic arguments to the contrary, however, “pharmaceutical companies have to have discriminatory pricing” simply because it is the right thing to do. In the 1980s when the AIDS crisis first emerged a diagnosis was almost the same as a death sentence, because no treatments were available until nearly ten years later. AIDS has now become a livable disease, and “No one has ever been criticized for selling a pill at fifty cents a day in poor countries”. While some companies feared that charging lower prices would be a “one-way corridor” to conciliatory pricing, when they finally implemented lower prices the sky did not fall and no one

⁵⁸ Ibid

⁵⁹ Reichman 252, citing endnote #59

⁶⁰ Ibid

asked for compulsory licenses on Viagra (at least not successfully).⁶¹ In the end companies do not suffer tremendous monetary losses and in fact gain good publicity for appearing in touch with the reality of public health crises.

Medical Ethics and Humanitarian Perspective

There are many who continue to see the TRIPS regime as an impediment and not an aid to increasing access to medicines in developing countries. There are criticisms of the Paragraph 6 system as too complex for a developing country without any patent infrastructure.⁶² Professor Robert Bird points out there are 1.7 billion people in world without access to essential medicines and that there are potential “social costs” of compulsory licensing, such as a decrease in foreign direct investment.⁶³ While it is true that a country’s intellectual property (IP) system can influence a company’s investment decisions, a more liberal IP system could actually encourage generic firms to invest even if it deters larger corporations.⁶⁴ In general however, there has been no defined or proven relationship between intellectual property and foreign direct investment.⁶⁵

Many pharmaceutical companies have aid programs where they either donate medicines or sell them at reduced prices to specific populations, and while these can sometimes be more for show than impact,⁶⁶ they nonetheless remain an important way for patients to obtain patented medicines. This can be viewed as an extension or element of Corporate Social Responsibility (CSR), but at the same time it is also fulfilling the United Nations’ Universal Declaration of Human Rights.⁶⁷ Article 25, Section 1 states, “*Everyone has the right to a standard of living*

⁶¹ Retired Merck executive. Egypt actually did attempt to issue a compulsory license for Viagra but the matter was “tainted by appearance of impropriety and self dealing” (See Reichman 254, endnote #109)

⁶² Velasquez interview

⁶³ Reichman 253, endnotes #91 and 92

⁶⁴ Basu interview

⁶⁵ Reichman 256

⁶⁶ Velasquez interview

⁶⁷ Basu interview

adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care...".⁶⁸ The backing of the Universal Declaration of Human Rights has been to the benefit of humanitarian organizations such as Medecins Sans Frontieres/Doctors Without Borders, which played a key role in lobbying for the Doha Declaration in the first place. However some believe that the MSF and others like it have taken matters too far in an effort to maintain the momentum generated by the TRIPS Agreement.⁶⁹ The role of organizations such as MSF in the TRIPS/Doha debate has come into question recently with the March 2010 meeting at the WTO.⁷⁰ While it is hard to argue that MSF's "Campaign for Access to Medicines" is a bad thing, one must ask if developing countries deserve more than free or reduced-priced medicines but full-picture approach as well.⁷¹ Pharmaceutical companies cannot, however, provide a complete public health solution, as that ability rests primarily with local health ministries.

The health needs of developing countries continues to be neglected in general simply because there is not a large market potential involved. Market-driven research and development is often not directed at diseases, such as Tuberculosis, that are generally found in poor populations.⁷² While the small market might make pharmaceutical companies more willing to sell drugs at lower prices, it also makes it difficult for local producers to emerge. Selling antiretroviral drugs is not the most profitable endeavor,⁷³ which brings the matter back to the realm of charity or corporate social responsibility when it really should be in the realm of public

⁶⁸ *The Universal Declaration of Human Rights*. Article 25, Section 1. United Nations. <<http://www.un.org/en/documents/udhr/>>. [Accessed 26 April 2010].

⁶⁹ Retired Merck executive as well as a current pharmaceutical executive who was a former UNICEF official

⁷⁰ "Members ask: Is the 'Par. 6' system on intellectual property and health working?" *WTO 2010 News Items*. World Trade Organization, 2 March 2010. <http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm>. [Accessed 25 March 2010].

⁷¹ Campaign for Access to Essential Medicines. Medecins Sans Frontieres (MSF). <<http://www.msfacecess.org/>>. [Accessed 26 April 2010]. Also based on interview with current pharmaceutical executive

⁷² Syam

⁷³ Motsoeneng, Tiisetso. "Analysis: Drug makers unlikely to reap juicy fruits in ARV contracts". *BusinessReport* (Zambia). Published in The Star, Cape Times, The Mercury and Pretoria News. 25 March 2010. <<http://www.busrep.co.za/index.php?fSectionId=561&fArticleId=5404182>>. [Accessed 16 April 2010].

health. However, local health infrastructure is not always reliable in countries where even doctors and nurses, not to mention multitudes of others, have difficulty feeding their families. If the whole situation sounds more like an exercise in circular logic that is due the fact that in many cases policy proposals on the subject *are* an exercise in circular logic. This pattern only highlights the complexity of the matter and others like it where market forces conflict with ethical desires.

TRIPS in Action: Thailand

Other than the parallel imports between South Africa and Rwanda, the other primary country example is Thailand. In 2006 Thailand issued a government use compulsory license for Effavirenz, an important antiretroviral drug under patent at the time by US pharmaceutical company Merck.⁷⁴ With the exception of “women of childbearing potential”, most adults can take Effavirenz in combination with other HIV/AIDS medicines and experience relatively few side effects that might otherwise impede treatment.⁷⁵ Thailand decided it wanted to import generic versions of Effavirenz from India and eventually manufacture the generic domestically. Merck initially proposed a price that was twice that of the Indian generic, though they later lowered their price to twenty percent above the price in India.⁷⁶ While the actions of Thai Government were completely legitimate under the TRIPS regime,⁷⁷ the United States responded by placing Thailand on its “Special 301” list of countries violating intellectual property rights. The reprisal of the United States was not in concordance with international trade agreements, and

⁷⁴ “Compulsory Licenses – Thailand”. Informational website published by Consumer Project on Technology (now Knowledge Ecology International, or KEI). <<http://www.cptech.org/ip/health/cl/recent-examples.html#BRAC>>. [Accessed 26 April 2010].

⁷⁵ Steinbrook, Robert. “Thailand and the Compulsory Licensing of Efavirenz.” *N Engl J Med* 356.6 (2007): 544-546.

⁷⁶ Reichman, endnote #117

⁷⁷ Reichman 256

the United States even lost a WTO ruling on the matter.⁷⁸ In January 2007 Thailand issued additional compulsory licenses for Kaletra, an important second-line ARV, and Plavix, used to treat heart disease.⁷⁹ In response Abbott Laboratories, a US firm, withdrew registration of Kaletra in Thailand prompting outrage by Médecins Sans Frontières.⁸⁰ There were some accusations against the Thai government for making a profit with in producing the Efavirenz generic, however in reality any profits made were minimal at best and went back to the Thailand public health system, which now accounts for around ten percent of the Thai national budget.⁸¹

Alternatives to Compulsory Licenses

There are a variety of policy proposals aimed at lowering the costs of medicines without using compulsory licenses. One can follow the Belgian model of avoiding Paragraph 6/Article 31bis entirely and using Articles 8 and 30 of the TRIPS Agreement instead.⁸² Professor Kevin Outterson at Boston University School of Law has proposed a “buy out scheme” where medicines would be distributed free of patents in poor countries with monopoly pricing in OECD countries.⁸³ Buying in bulk, or pooled procurement strategies, could be very practical for treating patients in India because of the countries generic manufacturing capabilities.⁸⁴ Price

⁷⁸ Ibid, endnote #136

⁷⁹ “Compulsory Licenses – Thailand”. Consumer Project on Technology

⁸⁰ Lokuge, Buddhima. “Thailand’s compulsory licenses on drugs: Good step for public health or bad precedent for intellectual property?” MSF Article and Statement delivered at US Congressional Briefing. Médecins Sans Frontières. 16 March 2007.

<http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=781C2395-15C5-F00A-25ED08B053B640D2&method=full_html>. [Accessed 26 March 2010].

⁸¹ Reichman 255, endnote #119

⁸² Reichman 253

⁸³ Reichman 257, endnote #151

⁸⁴ Satyanarayana, Kanikaram, and Sadhana Srivastava. “Patent Pooling for Promoting Access to Antiretroviral Drugs (ARVs) – A Strategic Option for India.” *Open AIDS Journal*. 2010;. 4: 41-53.

<<http://www.ncbi.nlm.nih.gov/resources.library.brandeis.edu/pmc/articles/PMC2819698/>>. [Accessed 26 April 2010].

discrimination tools can be included in medicine distribution programs.⁸⁵ A movement that has grown among research universities in the United States in recent years is the group Universities Allied for Essential Medicines (UAEM), where universities conducting pharmaceutical research negotiate with companies to insure the benefits of their work reaches as many people as possible.⁸⁶ Some have even suggested applying the Linux computer operating system open source approach, though the applicability of this to pharmaceutical research is remains to be seen.⁸⁷

Conclusions – How does one evaluate success?

In determining the success of any government or international policy depends largely on the questions used to evaluate it, and the TRIPS Agreement and the Doha Declaration are no exception. Jerome Reichman makes the important observation that there are many risks in comparing Thailand's use of government compulsory licenses and Canada's parallel import system with Rwanda. Since 2003, Cameroon, Ghana, Eritrea, Zambia, and Mozambique have issued compulsory licenses for various HIV/AIDS medicines.⁸⁸ Whether or not this has benefited HIV/AIDS patients in these countries requires further examination of patent and import data that are beyond the scope of this paper. One can safely conclude, however, that at the very least the ability to impose compulsory licenses has allowed these countries to have more leverage in international negotiations.

⁸⁵ Velasquez interview (likely)

⁸⁶ Syam interview and Sampat, Bhaven N. "Academic Patents and Access to Medicines in Developing Countries." *American Journal of Public Health* 99.1 (2009): 9-17.

⁸⁷ Syam

⁸⁸ "Compulsory Licenses – Low Income Countries". Informational website published by Consumer Project on Technology (now Knowledge Ecology International, or KEI). <<http://www.cptech.org/ip/health/cl/recent-examples.html#BRAC>>. [Accessed 26 April 2010].

In reflecting on his work in intellectual property with the World Health Organization, Dr Germán Velásquez admits that the WHO and other organizations were mistaken in emphasizing the powers of compulsory licenses.⁸⁹ Jerome Reichman observes that “minimum standards of patent protection” have increased over time “in keeping with the expressed goals of the Paris Union [of 1883].” However, “every attempt to limit” compulsory licenses from the state has “invariably resulted” in an increase in power of compulsory licenses on the international level.⁹⁰ Thus, recognition of intellectual property rights has increased alongside compulsory licenses. Compulsory licenses have always been part of intellectual property law, but whether or not legal scholars intended them to reach their current level of power in global health is at minimum a debatable matter. There is no question that the situation of those with HIV/AIDS in developing countries has increased dramatically in the last ten years, but whether one can connect this to the Doha Declaration is unclear. If nothing else the subjects raised in the discussion of TRIPS and Doha are important reminders of the powers and responsibilities of both countries and corporations, and that a balanced perspective must continue in future policy negotiations.

⁸⁹ Velasquez interview

⁹⁰ Reichman 247

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