

Cynthia Caramana
6.901 Final Project
Dec 17, 2003

Implications of the World Trade Organization's Intellectual Property Policies on Third-World Countries' Access to Vital Medicines

Over the last few years, international debate has been raging over the impact of international patent law on public health and access to medicines. On the one hand, pharmaceutical investments in drug research and development (R&D) have produced lifesaving drugs that have turned once-fatal illnesses into manageable conditions. On the other, the high cost of the drugs often exceeds a developing country's ability to pay for them. At the heart of the controversy is the World Trade Organization's (WTO) intellectual property policies set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (referred to as TRIPS), adopted in 1994. TRIPS was designed to spur innovation by creating a uniform international framework for protection and enforcement of intellectual property rights. However, many developing countries view the agreement as a barrier to obtaining affordable patented drugs. This report will provide some background on the pharmaceutical industry and examine the development of the TRIPS policy from its advent in 1994 to its current form. Moreover, it will detail and analyze the policy's ramifications for drug accessibility, particularly with respect to third-world countries afflicted with AIDS, and finally propose some new changes and additions to TRIPS that would better facilitate drug distribution to poor countries.

Pharmaceuticals play a significant social role and are crucial for sustaining the fundamental human right to health. For this reason, pharmaceutical products are classified as essential good, with the understanding that they must be accessible to all people. However, this concept of accessibility for all falls short of people living in the world's poorest countries, such as those of sub-Saharan Africa. According to estimates from UNAIDS¹, 34.3 million people in the world have AIDS and 24.5 million of them in sub-Saharan Africa. Nearly 19 million have died from AIDS, 3.8 million of them children under the age of 15. One of the most alarming speculations is that by the year 2010 there will be 40 million AIDS orphans in Africa, most of

¹ An umbrella group for five U.N. agencies, the World Bank and the World Health Organization

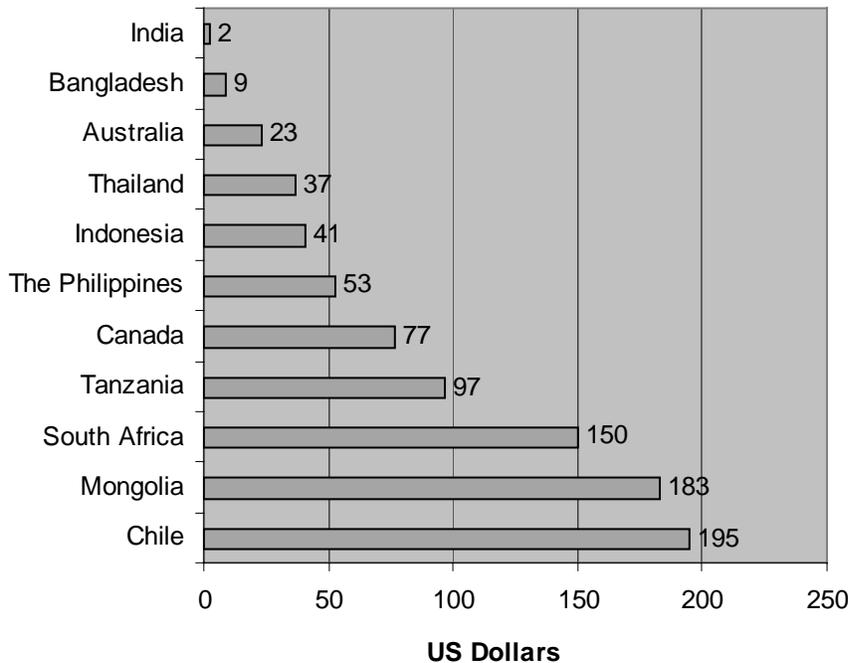
who will have grown up with little or no social structure. The economies of AIDS-inflicted countries have suffered from a lack of labor as working men and women fall sick or leave their jobs to take care of their loved ones who are inflicted with the disease. Less than 7% of people worldwide with HIV and AIDS have access to life prolonging antiretroviral medicine [1]. Although many factors contribute to this lack of access, the prohibitive cost of AIDS drugs remains a major barrier. Pharmaceutical companies maintain that the high prices of drugs reflect the R&D necessary for creating the drug. The financial data in Table 1, however, suggests that R&D expenditures are relatively small compared to marketing expenses [2].

Company	Revenue (Net sales in \$ million)	Percent of Revenue Allocated to		
		Profit	Marketing & Advertising	R&D
Merck	40,563	17%	15%	5%
Pfizer	29,574	13%	39%	15%
Bristol Myers Squibb	18,216	26%	30%	11%
Abbott Laboratories	13,241	20%	21%	10%
Eli Lilly	10,862	26%	30%	19%
Schering-Plough	9,615	25%	36%	14%

Pharmaceutical companies, including Merck and Bristol-Myers Squibb, have recently slashed prices for AIDS drugs in sub-Saharan African countries, selling them below-cost to help stem the tide of the epidemic. Nevertheless, in many developing countries, the cost of treating AIDS patients far surpasses their annual health care budgets, which are commonly much less than \$100 per patient. In the meantime, patent protection for pharmaceuticals is sprinkled here and there throughout the developing world. In the absence of patent protection, developing countries can make and buy generic alternatives at a fraction of the brand-name price. Generic drug companies in India for example can provide a year's worth of triple anti-retroviral therapy at less than 3% of the cost of the same-patented therapy in the United States. Moreover, competition from generic producers has resulted in the lowering of prices by large multinational

pharmaceutical companies. The following table shows that the price of Zantac, an anti-ulcer medication, varies from market to

Table 2. Price of 100 Tablets of Zantac



market, irrespective of per capita income for the designated country [3]. The pricing, however, exhibits a strong correlation with the existence of generic substitutes for each country. The price of patented Zantac is much cheaper in India than in Mongolia, for instance, due to competition from India’s generic substitute for Zantac.

Member of the WTO adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, which introduced intellectual property rules into the multilateral trading system for the first time. Covering not only patents but also trademarks and copyrights, TRIPS lays down minimum standards of IP protection and outlines a set of procedures for enforcement. Under TRIPS, a patent is granted by a specific country or a regional office acting for several countries, to give an inventor exclusive rights over the manufacture and use of his invention for a fixed period of time - a minimum of 20 years for pharmaceutical inventions. Similar to US criterion, patentability under TRIPS requires that an invention be novel, useful, and non-obvious, “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 [4].” Moreover, Article 28 of TRIPS states that the patent holder has the legal right to prevent unauthorized use, making, selling, and importing of his patented product or process. In accordance with TRIPS, WTO members are required to introduce IP standards and develop systems of patent review and enforcement that closely model that of the US and other developed countries. The major shift for countries such as India is that the TRIPS agreement requires a patent regime that recognizes product patents for chemicals and pharmaceuticals. The earlier Indian Patent Act allowed for only process patents in these areas, which created the possibility of reverse engineering drugs.

Shortly after TRIPS was adopted, many developing countries expressed concerns over its adverse implications for accessing essential drugs and addressing public health crises. Namely, increased patent protection leads to higher drug prices making them unaffordable to a vast majority of people who need them. Moreover, developing countries predicted that the access gap between rich and poor, would continue to increase, especially if producers in developing countries have to wait for 20 years before they can have access to innovations. Under pressure from humanitarian groups and strong protests worldwide, WTO members felt the need to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines. They also tried to clarify some of the sticking points of TRIPS, namely the built-in flexibilities to protect public health that the pharmaceutical companies opposed. At the 2001 meeting in Doha, Qatar, WTO members amended TRIPS with a separate declaration referred to as the Doha Declaration. Some of the main points of the Doha Declaration are the following:

- Least developed countries have until 2016 to set up systems for patent review and enforcement. The deadline had been originally set for 2006 [5].
- Members are allowed to license a patented technology without the holder’s consent in the event of an emergency or situation of extreme urgency [6].
- 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 [7].

The Doha Declaration emphasizes that the TRIPS Agreement should not prevent member governments from acting to protect public health. It affirms a government’s right to use the TRIPS flexibilities in order to protect their nation’s public health. However, the Doha

Declaration did not specify conditions for parallel imports (a measure that allows a country to buy the cheapest source, regardless of the stated domestic price), but instead provided the infamous Paragraph 6, which ran as follows: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 [8]."

After much dispute and protest by the US government, the deadlock over intellectual property and public health was finally broken on August 30, 2003. The provision allows poorer countries to import cheaper generics made under compulsory licensing, whereas before, Article 31 of TRIPS restricted compulsory licensed drugs to domestic use only. Although the new provision enables the poorest countries to buy essential drugs at the cheapest prices, it is littered with restrictions. An eligible importing member can only be a "least developed" country or a developing country that does not have adequate facilities to produce the drug in question. The importing country must make a notification to the TRIPS Council that:

- Specifies the names and expected quantities of the products needed.
- Verifies the eligibility of importing member in question (other than a least developed country member) - that it has insufficient manufacturing capacities in the pharmaceutical sector for the products in question.

Importing countries also have to ensure legal administrative means of preventing re-exportation of any such drugs. Similarly, the compulsory license issued by the exporting member has to perform the following:

- Determine the exact amount necessary to meet the needs of the eligible importing member.
- Provide special packaging to distinguish the exported drugs from their domestic counterparts.
- Post on a website the information relating to the quantities being supplied to each destination and the distinguishing features of the products.
- Notify the TRIPS Council of the grant of the license, including the conditions attached to it. The information provided has to include the name and address of the licensee, the products for which the license has been granted, the quantities for which it has been

granted, the countries to which the products are to be supplied, and the duration of the license.

Though the addition of the Doha Declaration and the August 30 provision to TRIPS are progressive steps towards making essential drugs affordable for even the poorest people, the policies have been widely criticized for being too restrictive and laden with time-consuming bureaucracy. Moreover, compulsory licensing is not the final solution to bringing third-world countries affordable access to patented drugs because it relies upon the capability to reverse engineer or import the product without the cooperation of the patent holder. The Aug 30 provision that allows least-developed nations to import from a nation holding a compulsory license relies on the assumption that the disease strains and patterns are similar in the two countries. An antiretroviral medicine that is effective at slowing the progression of HIV strains in Brazil, for example, might not be as effective on the strains in South Africa. Another concern over the policies is that they bog down the process with bureaucracy, preventing a timely delivery of drugs to those in desperate need. For many infected with HIV, having to wait a year, month, or even another day to receive life-prolonging drugs results in their children becoming orphans.

Another obstacle is posed by the pressure that wealthy countries put on developing countries to accept trade negotiation proposals that greatly restrict their rights provided in the Doha Declaration and thus severely limit their ability to safeguard public health. A most notable example is the Free Trade Areas of the Americas (FTAA) trade agreement that imposes extreme IP restrictions on its members. Under the FTAA agreement, Compulsory licenses for pharmaceuticals are restricted to a few diseases (under the Doha Declaration there are no disease restrictions) and prohibited from export, patents are extended beyond 20 years, and impose exclusive rights on pharmaceutical test data that significantly delay the introduction of generic drugs even when no patent barriers exist.

Despite some of their shortcomings, the addition of the Doha Declaration and the August 30 provision have been two major steps in the right direction. I believe that further steps should be taken to reduce some of the bureaucracy required for exporting essential drugs made under compulsory licenses to poor countries that lack the infrastructure to produce them. I also propose that the pricing for essential life-saving drugs be regulated according to a scale based on

per-capita income, so that poorer countries like Tanzania are not required to pay more for a drug than much wealthier countries like Canada (see Table 2). The pricing scale should be set to make the drug affordable to the average citizens of any given country. If the pharmaceutical corporations are unwilling to sell their drugs at greatly reduced prices, then generic companies should be given free reign to sell their versions in those countries. It might not be “fair” to make citizens of wealthier countries pay more for the same drug; however, denying poor people the right to life by withholding life-saving drugs is a far worse injustice. Though it may sound cliché, the message from the Spiderman movie: “with great power comes great responsibility” applies to US and other leading countries of the world. These leaders have a great opportunity to use their power and influence to ease some of the suffering and death that epidemics are inflicting on the rest of the world.

References

1. World Health Organization: www.who.org
2. C.P. Chandrasekhar, J. Ghosh, “WTO Drugs Deal”, *The Hindu Business Line*: www.thehindubusinessline.com.
3. Ibid.
4. World Trade Organization, TRIPS Agreement Article 27.1: www.wto.org.
5. World Trade Organization, Doha Declaration: Paragraph 7: www.wto.org.
6. World Trade Organization, Doha Declaration: Paragraph 5a: www.wto.org.
7. World Trade Organization, Doha Declaration: Paragraph 5b: www.wto.org.
8. World Trade Organization, Doha Declaration: Paragraph 6: www.wto.org.