

FEATURED ARTICLE

PATENTS VERSUS PEOPLE: THE BATTLE OVER  
GENERIC ANTIRETROVIRAL DRUGS IN INDIA

Rachel Rizal\*

*HIV presents one of the greatest global health problems of the late 20th and early 21st centuries. No cure or vaccine for HIV exists, though antiretroviral drugs (ARVs) can be provided for infected individuals. ARVs inhibit the replication of the virus within infected cells, slowing the deterioration of the immune system and the spread of the virus. The development of new ARVs, however, requires years of research and clinical trials by major pharmaceutical corporations. As a result, the drugs are often priced at unaffordable rates for individuals in developing countries. A complex ethical debate exists over the right of developing countries to provide generic ARVs in order to produce low-cost treatments and the rights of pharmaceutical corporations to hold a patent to cover research and development costs. This paper will focus on the debate about generic ARV production by local pharmaceutical industries in India and implications and challenges with regards to other developing countries.*

**Introduction**

Every day, more than 11,000 people become infected with human immunodeficiency virus (HIV) while about 8,000 infected individuals die worldwide.<sup>1</sup> At the end of 2007, there were an estimated 33 million people living with HIV.<sup>1</sup> The developing world, particularly sub-Saharan Africa, suffers the greatest disease burden from HIV. While there is currently no cure or vaccine for HIV, antiretroviral drugs (ARVs) can be given to infected individuals. ARVs inhibit the replication of the virus in their bodies. As a result, an individual's immune system deterioration can be delayed, lengthening his life expectancy. ARVs also reduce the overall rates of HIV transmission.<sup>2</sup>

Through a long process of research and clinical trials, large multinational pharmaceutical companies create new ARVs. Unfortunately, many people in developing countries have limited access to ARVs; they do not have the financial resources to buy costly drugs from multinational pharmaceutical companies. Once a drug is created, other pharmaceutical companies can produce and sell cheaper generic versions of the drug. However, multinational pharmaceutical companies contend that generic drugs steal revenues that cover their research and development costs. Thus, an ethical debate arises about whether pharmaceutical companies in developing countries should be able to provide generic ARVs, despite patent laws, in order to provide low-cost treatments. This paper will specifically focus on the debate about generic ARV production by local pharmaceutical industries in India. The ethical debate has been socially constructed by historical events and reflects that society has drawn attention away from the individuals who benefit from ARVs. The power

of the pharmaceutical industry and its influence over patent agreements have shifted the focus of ARVs, from its life-saving potential to money, power, and discovery.

**Two Sides of the Debate in India**

On one side of the debate are multinational pharmaceutical companies that discover new drugs and express concerns about protecting their business interests. According to the Pharmaceutical Research and Manufacturers of America, estimates show that "it takes approximately 10-15 years and costs roughly \$800 million to introduce a new medicine to the market."<sup>3</sup> One way large pharmaceutical companies protect their huge investments is through patents. When a drug is invented, companies may receive patents from individual countries. Patents are local monopolies for a given period of time that grant the inventor exclusivity in producing or selling the drugs. Although patents allow pharmaceutical companies to charge high prices for ARVs, companies contend that patents are essential to their business model. Multinational pharmaceutical companies do not support the manufacturing of generic ARVs in developing countries. The production of generic drugs will hurt the companies' ability to reclaim both the large expenses incurred during research and development, and their ability to reinvest in other research projects.<sup>3</sup>

The other side of the argument consists of individuals, non-government organizations (NGOs), and certain national governments that support the manufacturing of cheap generic ARVs for India to benefit those suffering from HIV. India is considered the "pharmacy of the developing world," selling essential medicines to developing countries at affordable prices.<sup>4</sup> Generic ARVs from India improve the possibility for people from extremely resource-limited settings to purchase the drugs. For example, Nwagwu from Africa recalled how she had to pay \$500 per month for brand-name ARVs. But, she claims, "the arrival of generic drugs from Indian companies

**\* Author Contact Information:**

Princeton University, Woodrow Wilson School, Class of 2009. Address correspondence to rachel.rizal@gmail.com.

changed all that. I now spend just \$25 on generic drugs.”<sup>5</sup> By purchasing generic ARVs from India, the costs of treating an HIV-infected individual dropped to \$140 from \$12,000 a year.<sup>6</sup>

### **Trade Negotiations**

Multinational pharmaceutical companies, mostly headquartered in developed countries, felt threatened by competitors in developing countries like India and lobbied their governments to negotiate a series of trade agreements to push for stronger intellectual property protections. The pharmaceutical industry, along with other trademark-based industries, felt like victims of piracy and “wanted to gain increased protection for their products.”<sup>7</sup> As a result, the United States and other developed countries spear-headed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In 1995, the developing nations that signed the TRIPS Agreement decided to grant patent protection for pharmaceutical inventions, which prevents competing companies from producing generic drugs for 20 years.<sup>3</sup> India had to change its patent laws by 2005. In return, developed countries increased exports of agricultural and textile products to developing countries.<sup>7</sup>

After the TRIPS Agreement, new ARVs remained expensive because of their patent protections; there was growing concern among developing countries that TRIPS would restrict their access to necessary drugs.<sup>8</sup> In another round of trade negotiations in 2001, the Doha declaration was signed. The declaration clarified that the TRIPS agreement “contains flexibilities that allow countries to enable both the import and production of generic versions of antiretroviral drugs under patent to protect public health.”<sup>9</sup> The declaration stated that countries could grant compulsory licenses to address a national health emergency. Compulsory licenses “enable a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder.”<sup>8</sup> The Doha Declaration theoretically gives countries more freedom to produce generics. However, when Thailand authorized the use of a compulsory license to produce a generic ARV, it faced significant threats of trade sanctions from developed countries. The outcomes of the TRIPS Agreement and Doha declaration reflect that the debate about medicines is embedded in trade negotiations and patent laws, instead of health outcomes.

In 2005, India passed the Patent Amendment Bill to remain in accordance with TRIPS.<sup>10</sup> The new patent law replaced the existing legislation, which had allowed local pharmaceutical companies to produce generic ARVs if they used a different manufacturing process. Local Indian pharmaceutical companies could only produce generic

ARVs if the patent holder granted it a voluntary license to the company. The Patent Amendment Bill severely hurt the drug industry that had thrived in India since 1970 because it limited the manufacturing of generic drugs. After the Patent Amendment Bill, generic supply to developing countries became limited and access to drugs subsequently worsened for individuals in dire need.

### **Social Reflections**

The current patent system rewards innovative scientific discovery, and values the intellectual property issues surrounding it, often more highly than any adverse social implications. The importance of supporting new scientific discoveries is reflected in the 2008 International AIDS Conference. The first sentence in the “About the Conference” section states, “AIDS 2008 will provide many opportunities for the presentation of important new scientific research.”<sup>11</sup> Pharmaceutical companies believe that patents are necessary in order to give them financial security when developing new drugs. They support the idea that “innovation must get its reward.”<sup>15</sup> However, as countries support incentives for new scientific discovery, they establish a trade-off between innovation versus treating infected individuals in the present. The same patents that give pharmaceutical companies incentives to produce new drugs also prevent affordable ARVs from reaching the market. Thus, many HIV-infected individuals do not get access to the latest and most effective ARVs. The patent system creates an environment where access to medicines and innovation are mutually exclusive, rather than complementary. The system allows pharmaceutical companies to make their values of making profit, protecting innovation, and gaining power a priority. As a result, the rest of society is influenced to consider the pharmaceuticals’ values with humanitarian concerns.

Due to the emphasis on innovation, countries that support intellectual property rights and grant pharmaceutical companies patent protection are rewarded with a better reputation. One pharmaceutical executive noted that any country “that aspires to have a genuine global footprint will necessarily have to focus on driving true innovation with greater emphasis on creating intellectual property and a global presence in key markets.”<sup>12</sup> India has been praised for adhering to the TRIPS Agreement. When India passed the Patent Amendment Bill in 2005, newspapers around the world portrayed India as a country poised to be “an economic powerhouse”<sup>13</sup> and “on the road to becoming a world leader in drug research.”<sup>14</sup> India took advantage of the opportunity to bask as a potential leader in the pharmaceutical industry. One Indian pharmaceutical company’s president noted, “We have very good intellectual capacity, good chemistry, and mathematical skills which is the

foundation for the pharmaceutical business.”<sup>13</sup> India’s actions reflect that countries care about power and prestige alongside the protection of the health of HIV-infected individuals around the world.

Multinational pharmaceutical companies are concerned about maintaining control over ARVs. For example, Thailand wanted to use its right to issue a compulsory license for a generic version of the ARV drug, Efavirenz. The Thai Ministry of Public Health stated their interest in producing local generic versions of Efavirenz and wanted to issue a compulsory license “to protect public health, especially for universal access to essential medicines.”<sup>15</sup> Merck, the company that has a patent for Efavirenz, objected to Thailand’s desire to create universal access for ARVs in its country. Instead, Merck offered to sell Efavirenz at a lower price.<sup>19</sup> Thailand listened to the advice of the World Trade Organization and negotiated with Merck for lower Efavirenz prices. The deal reflects that pharmaceutical companies and the World Trade Organization have influence over developing countries’ decisions to grant its compulsory licenses. Furthermore, the patent system and voluntary licenses have created a hierarchy in the pharmaceutical industry. This hierarchy allows large pharmaceutical companies, like Merck, to maintain control of the distribution and sales of ARVs during the patent period.

Indian pharmaceutical companies are aware of the current hierarchy within the pharmaceutical industry and are interested in gaining more power. Scholars have pointed out that after the Patent Amendment Bill, “Indian firms start with a handicap, even before they start the game, in that they do not have the deep pockets necessary to create international blockbuster [drugs].”<sup>16</sup> However, Indian pharmaceutical industry representatives want to attract Indian scientists and researchers back from abroad. Ajit Dang, director-general of the Organization of Pharmaceutical Producers of India, hopes that the Bill will create a “‘reverse brain drain’ from the West back to India.”<sup>14</sup> Again, the concern over power and having the resources to create future drugs draws attention away from providing low-cost ARVs to patients.

Other than power, pharmaceutical companies show that they are most concerned about making profits. For example, Cipla, an Indian-based company and the world’s largest manufacturer of ARVs, has the corporate slogan, “None shall be denied.” However, Cipla charges two-and-a-half times as much for its antiretroviral drugs in India as it does in Africa. Cipla’s reasoning behind this decision is that it has to cover its manufacturing costs. Many people in India cannot afford Cipla’s prices and are thus denied access to lifesaving ARVs.<sup>17</sup> Thus, companies’ economic concerns interfere with their interest of producing ARVs that are

affordable and accessible.

Pharmaceutical companies’ interests in costs and revenues cause concern in the rest of the world with ARV financing rather than the health outcomes of HIV-infected individuals. NGOs’ and governments’ primary concern are the costs and affordability of ARVs before they determine to whom and how to administer treatment. For instance, the international humanitarian NGO Doctors Without Borders has to wait for affordable therapies before it treats people in over 30 countries. Doctors Without Borders claims that the biggest difficulty getting the best available drugs.<sup>18</sup> It negotiates with companies like Cipla to purchase antiretroviral drugs in bulk for the cheapest price possible. Currently, the NGO is faced with the question “do you want to treat more patients on a more affordable combination, or do you want fewer patients on a better combination?”<sup>18</sup> Although Doctors Without Borders is devoted to providing universal access to essential medicines, it has to focus its attention on costs before it can treat patients. The current patent system requires NGOs and governments to compromise its humanitarian desires of helping HIV-infected individuals. At times, they have to persuade and negotiate with pharmaceutical companies in order to treat more people. But, the question remains, should the value of human life be negotiable? And, if so, what is the cost of saving people’s lives?

## Alternative Questions

Currently, the debate about generic ARVs has focused on the manufacturing of the drugs. Pharmaceutical companies have dominated the debate and have successfully pushed for patents that deny low-cost, generic ARVs from being manufactured. However, there are other bioethical questions which can re-center the debate concerning ARVs to focus on individuals. If people shift their questions toward individuals, they can begin to uncover the stakes of centering the current bioethical debate on patent laws and motivate them to make changes.

First, should pharmaceutical companies be given the power to decide prices for patients? Court battles reveal that different pharmaceutical companies fight for the right to sell drugs; therefore, they determine what prices drugs are sold for. In one court battle, California-based Gilead Sciences filed a lawsuit in India regarding its antiretroviral drug, Tenofovir, against the Indian pharmaceutical company, Cipla. Cipla produced the generic version of Tenofovir, Tenvir. Tenofovir costs patients \$5,718 a year while Tenvir costs \$700.<sup>19</sup> Gilead Sciences voiced its concerns about making its ARV drug available to poor people, “We will use this patent responsibly, and will not block access to our medication in India or in other resource-limited countries where the HIV

epidemic has hit the hardest.”<sup>19</sup> However, its actions clearly do not reflect its claim. Tenofovir is too costly for patients in India and other developing countries, denying them access. As the debate over producing cheap ARVs is fought in court between pharmaceutical companies, the people who actually benefit from the treatments are not heard.

Second, is access to life-saving drugs, such as ARVs, a human right? Currently, the high prices of patented ARVs make them appear as a luxury good as opposed to a necessary product. This attitude is reflected by the director of the International Federation of Pharmaceutical Manufacturers, “for people with no income or little income, price is a barrier you know, which might be a Jaguar SJE.”<sup>20</sup> Even in developed countries, ARVs are expensively priced. The ARV Viread costs \$5,718 per patient per year, which makes it difficult for low-income HIV-infected patients to afford the drug.<sup>19</sup> The current patent system does allow for scientific innovation, but at the expense of poor people’s lives.

Third, who should be responsible for distributing ARVs to individuals? Presently there is no international standard to answer this question. The responsibility has fallen in the hands of individuals, governments, and NGOs. Individuals have to pay a monthly or annual expense for ARVs. Some governments provide ARVs to its population. For instance, in Nigeria, the government subsidizes ARVs so that individuals pay \$7 a month.<sup>21</sup> Still other patients receive ARVs from NGOs. Doctors Without Borders provides ARVs to 30,000 people living with HIV / AIDS around the world. By focusing and solving the problem on whom and how ARVs should be delivered, individuals may be more likely to receive ARV.

### Conclusion

The current set of international trade agreements and patent laws does not provide everyone suffering from HIV access to essential ARVs. Instead, the current patent system maintains the dominance of large pharmaceutical companies and gives them the power to decide at what price and to whom they want to sell ARVs. So-called “miracle drugs” that society has encouraged do not reach the hands of everyone who needs them. Developing countries that suffer the greatest disease burden have the least access to expensive drugs. Furthermore, the current patent system allows pharmaceutical companies to decide what type of drugs to produce. Currently, “90% of all medical research involves diseases that cause 10% of the global health burden.”<sup>22</sup> If society agrees that everyone should benefit from medical research, including ARVs, then there has to be a fundamental shift in current laws and attitudes. Individuals have to re-think how they can provide incentives so that researchers and companies will produce

medicines that will have a greater and broader impact on people’s health. Universal access to essential medicines does not necessarily hinder innovation. Rather, future generations of policymakers and leaders face the challenge of creating an environment where both innovation *and* universal access to essential medicines can co-exist.

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