

Western Drug Companies and the AIDS Epidemic in South Africa

In December 1997, the government of South Africa passed a law that authorized two controversial practices. One, called parallel importing, allowed importers in South Africa to purchase drugs from the cheapest source available, regardless of whether the patent holders had given their approval or not. Thus South Africa asserted its right to import "generic versions" of drugs that are still patent protected. The government did this because it claimed to be unable to afford the high cost of medicines that were patent protected. The other practice, called compulsory licensing, permitted the South African government to license local companies to produce cheaper versions of drugs whose patents are held by foreign companies, irrespective of whether the patent holder agreed.

The law seemed to be in violation of international agreements to protect property rights, including a World Trade Organization agreement on patents to which South Africa is a signatory. South Africa, however, insisted that the law was necessary given its own health crisis and the high cost of patented medicines. By 1997, South Africa was wrestling with an AIDS crisis of enormous proportions. It was estimated that over 3 million of the country's 45 million people were infected with the virus at the time, more than in any other country. However, although the AIDS epidemic in South Africa was seen as primary reason for the new law, the law itself was applied to "communicable diseases" (of which AIDS is just one, albeit a devastating one).

Foreign drug manufacturers saw the law as an unbribed attempt to expropriate their intellectual property rights, and 39 foreign companies quickly filed a lawsuit in the country to try to block implementation of the law. Drug manufacturers were particularly concerned about

the applicability of the law to all "communicable diseases." They feared that South Africa was the thin end of the wedge, and if the law were allowed to stand, other countries would follow suit. Many Western companies also feared that if poor countries such as South Africa were allowed to buy low-priced generic versions of patent protected drugs, in violation of intellectual property laws, American and European consumers would soon demand the same.

In defense of their patents, the drug companies argued that because drug development is a very expensive, time-consuming, and risky process, they need the protection of intellectual property laws to maintain the incentive to innovate. It can take \$800 million and 12 years to develop a drug and bring it to market. Less than one in five compounds that enter clinical trials actually become marketed drugs—the rest fail in trials due to poor efficacy or unfavorable side effects—and of those that make it to market, only 3 of 10 earn profits that exceed their costs of capital. If drug companies could not count on high prices for their few successful products, the drug development process would dry up.

The drug companies have long recognized that countries such as South Africa face special health challenges and lack the money to pay developed world prices. Accordingly, the industry has a history of pricing drugs low or giving them away in the developing world. For example, many AIDS drugs were already being sold to developing nations at large discounts to their prices in the United States. The South African government thought this practice was not good enough. The government was quickly supported by various human rights and AIDS organizations, which cast the case as an attempt by the prosperous multinational drug companies of the West to

maintain their intellectual property rights in the face of desperate attempts by an impoverished government to stem a deadly crisis. For their part, the drug companies stated that the case had little to do with AIDS and was really about the right of South Africa to break international law.

While the drug companies may have had international law on their side, the tie-in with the AIDS epidemic clearly put them on the public relations defensive. After a blizzard of negative publicity, and little support from Western governments who were keen not to touch this political "hot potato," several leading manufacturers of AIDS drugs, while still opposing the South African law, started to change their policies. In May 2000, five large manufacturers of AIDS medicines—Merck, Bristol-Myers Squibb, Roche, Glaxo, and Boehringer Ingelheim—announced that they would negotiate lower priced AIDS drugs in developing countries, primarily in sub-Saharan Africa (some 25 million of the 36 million people infected with the HIV virus in 2000 lived in that region). Still the protests continued.

In February 2001, an Indian drug company, Cipla Ltd, offered to sell a cocktail of 3 AIDS drugs to poor African nations for \$600 per patient per year, and for \$350 a year to Doctors without Borders (AIDS is commonly treated with a cocktail that combines up to 10 different antiviral drugs). The patents for these drugs were held by Western companies, but Indian law allowed local companies to produce generic versions of patent protected drugs.

The Cipla announcement seemed to galvanize Western drug companies into further action. In March 2001, Merck announced that it would cut the prices of its two AIDS drugs, Crixivan and Stocrin. Crixivan, which sold for \$6,016 per year in the United States, would be sold in developing countries for \$600 a year. Stocrin, which cost \$4,730 a year in the United States, would be sold for \$500. Both drugs were often used together as part of an AIDS cocktail. Officials at Doctors without Borders, the Nobel Peace Prize-winning relief agency, welcomed the announcement, but pointed out that in a region where many people lived on less than a dollar a day, the price was still out of reach of many AIDS patients.

A few days later, Bristol-Myers Squibb went further, announcing that it would sell its AIDS drug Zerit to poor nations in Africa for just \$0.15 a day, or \$54 a patient per year, which was below Zerit's costs of production. In the United States and Europe, Zerit was selling for \$3,589 per patient per year. This move was followed by an announcement from Abbott Labs that it would sell two of its AIDS drugs at "no profit" in sub-Saharan Africa.

None of these moves, however, were enough to satisfy critics. In April 2001, the drug companies seemed to come to the conclusion that they were losing the public relations war, and they agreed to drop their suit against the

South African government. This opened the way for South Africa to start importing cheap generic versions of patented medicines from producers such as Cipla of India. The decision to drop the suit was widely interpreted in the media as a defeat for the drug companies and a reaffirmation of the ability of the South Africans to enforce compulsory licensing. At the same time, the pharmaceutical companies appear to have gotten assurances from South Africa that locally produced generic versions of patented drugs would only be sold in sub-Saharan Africa and not exported to other regions of the world.

In 2003, Aspen Pharmaceuticals, a South African drug maker, took advantage of the 1997 law to introduce a generic version of Stavudine, and it asked the South African authorities permission to produce up to six more AIDS drugs. Aspen had licensed the rights to produce this drug, and several others, from Bristol-Myers Squibb and Glaxo, the large British company. Bristol and Glaxo had waived their rights to royalties from sales of the drugs in sub-Saharan Africa. At the same time, the companies noted that Aspen was only able to sell the drugs within the sub-Saharan region.

Despite these moves, critics still urged Western drug companies to do more to fight the global AIDS epidemic, which by 2006 was estimated to afflict some 40 million people. For example, in a *New York Times* Op Ed article, noted playwright and AIDS activist Larry Kramer stated that

It is incumbent upon every manufacturer of every HIV drug to contribute its patents or its drugs free for the salvation of these people. . . . I believe it is evil for drug companies to possess a means of saving lives and then not provide it to the desperate people who need it. What kind of hideous people have we become? It is time to throw out the selfish notion that these companies have the right not to share their patents.

Meanwhile in South Africa, the AIDS epidemic continued on its relentless course. By 2006 it was estimated that one in nine people in South Africa, or 5.5 million people, were infected with HIV, and 800 people a day were dying from AIDS-related complications. In 2003, the South African government had committed itself to offering antiviral drugs at low or no cost to everyone with AIDS. By working with pharmaceutical companies such as Aspen and three Indian producers of generic drugs, the government was able to purchase a cocktail of antiviral HIV drugs for \$65 per patient per month. However, by 2006 only 250,000 people were getting antiviral drugs, while at least 700,000 were in urgent need of the drugs. The problem seems to be distribution and particularly a chronic shortage of clinics, doctors, and nurses. Estimates suggested that it may still be years before cheap AIDS drugs are available to all those who need them in South Africa.

Pick ^{Any} 3 questions ✓

Case Discussion Questions

1. Why is it so important for the drug companies to protect their patents?
2. What should the policy of drug companies be toward the pricing of patent-protected drugs for AIDS in poor developing nations such as South Africa?
3. What should the policy be in developed nations? Is it ethical to charge a high price for drugs that treat a life-threatening condition, such as AIDS?
4. In retrospect, could the large Western pharmaceuticals have responded differently to the 1997 South African law? How might they have better taken the initiative?
5. Is AIDS a special case, or should large drug companies make it normal practice to price low or give away patent protected medicines to those who cannot afford them in poor nations?



Sources

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