

Patents and Health in Developing Countries

Background

Every day 30,000 people in the developing world die from curable diseases – diseases for which there are helpful and effective treatments or even cures. One in four South African adults now live with HIV/AIDS. Many who die either cannot afford the medicines or else the medicines are simply not available in their region.

Nearly all medicines produced by drug companies are patented. A patent entitles the inventor of a new product to prevent others from selling, making, marketing, or importing the patented drug, typically for 20 years from the date the patent application is filed. This can provide the patent holder with a monopoly position in the market for that drug, which allows them to charge a higher price and raises their expected profits. Patents are held by many to provide important incentives for drug companies to spend the large amounts of money required to do research and development on drugs. Without the promise of exclusive rights, they say they wouldn't undertake the risky and expensive research and development needed to bring the drug to market. A recent report by Ernst and Young LLP found that for every drug that makes it to the market, pharmaceutical companies must screen 5,000 – 10,000 unsuccessful compounds and 250 compounds undergo preclinical testing which ultimately turns out to be unsuccessful. On average, it costs \$500 million to bring a medicine to market. Moreover, they claim that it is unfair for a pharmaceutical company to incur great financial risk and expense in order to develop a drug, and then allow someone else to “free ride” off of that effort. The benefits should go to the company which put in the effort and resources to invent the drug.

In 1997 President Nelson Mandela introduced the Medicines and Related Substances Control Amendment Act. The Act was intended to help South Africa combat the country's HIV/Aids, tuberculosis, and other infectious diseases, by making vital medicines more affordable, both from manufacturers abroad and from local suppliers. Among other things, it requires pharmacists to prescribe a cheaper, non branded equivalent of brand name (i.e., patented) drugs if it exists.

Pharmaceutical companies took exception to the Act and have now started legal proceedings against the South African government. Until resolved, the Medicines and Related Substances Control Amendment Act cannot be implemented.

Example: Ciprofloxacin

Ciprofloxacin is an important drug in the battle against a wide range of infections including gonorrhoea and tuberculosis. It is patented by the drug manufacturer Bayer in South Africa, where it costs 12 times more than the equivalent product made in India, where the patenting of medicines is still not allowed. Countries where Bayer has been able to patent Ciprofloxacin cannot import or produce the cheap version, so prices are very high. In South Africa, a 500mg tablet of the patented medicine costs Rand 5.59, whereas the low-cost 'generic' equivalent - that the company wants to outlaw - costs just Rand 0.46 - one twelfth of the price. The Medicines and Related Substances Control Amendment Act would enable the South African government to override the patent and import the cheaper version of the drug, but it is being contested by pharmaceutical companies on the grounds that it violates the rules of the World Trade

Organization, to which South Africa belongs and which has rules against setting up certain kinds of trade barriers to imports.

The Court Case

After a three year delay, the court case began on 5th March 2001. During the delay, South Africa is not allowed to import the cheaper, generic versions of drugs - such as Ciprofloxacin - to treat infections related to HIV/Aids. The Southern Africa Treatment Action Campaign - a non government organization which campaigns on health issues - estimates that, in the intervening period, 40,000 people have died from AIDS related illnesses.

Why do drug companies object to the Medicines and Related Substances Control Amendment Act?

The drug companies claim that enactment of the Medicines and Related Substances Control Amendment Act is unconstitutional. In particular, the drug companies argue that it violates their intellectual property rights under the World Trade Organization's Trade Related Aspects of Intellectual Property (TRIPS) agreement signed by numerous governments including South Africa. They argue that this agreement cannot be overridden by South Africa's domestic laws such as the Medicines and Related Substances Control Amendment Act. The drug companies also object to the requirement within the Act that South African pharmacists must dispense cheaper generic medicines rather than patent versions if they can - they say that this unfairly discriminates against their products. And finally, they argue that it isn't in South Africa's best interests to undermine the intellectual property rights of the pharmaceutical companies who are making products which can help South Africans. Tom Bombelles of PhRMA [The Pharmaceutical Research and Manufacturers of America], says that this would create "an active disincentive to research-based pharmaceutical industry involvement in the international effort to improve public health in developing countries, as companies will choose not to develop medicines which will not be patent-protected. Such disincentives are more likely to drive patients and the availability of medicines further apart."

What is said in defense of the Medicines and Related Substances Control Amendment Act?

Defenders of the Act claim that such a law is necessary for meeting the challenge of providing affordable medicines in South Africa. More than one in ten South Africans are HIV positive. In 1998, government figures revealed that only a small percentage of the 165,000 people infected with full blown AIDS were receiving any treatment. A further 1999 survey revealed that 66% of respondents cited cost as the main reason for not seeking health care when they are sick.

In response to the drug companies claims, they point out that the pharmaceutical industry is, by any reasonable measure, the most profitable industry in the United States, almost twice as profitable as the median of all U. S. companies. Moreover, even if the large pharmaceutical companies did lose the South African market because of a lack of patent protection, that market represents only 1.4% of their global market.

Discussion Questions:

1. Do you think that the Act is unfair to large pharmaceutical companies? Explain why or why not.
2. Do you think that patents which delay the availability of cheaper medicines are unfair to those who need the medicines? Explain why or why not.
3. Do you think that South Africans will be better off in the long run with the Act, or without the Act? Justify your answer.
4. Setting aside for the moment the technicalities of whether or not the Act is unconstitutional and just focusing on its own merits, would you argue for the Act or against it? What would your argument be?
5. Suppose that the Act is in conflict with TRIPS. Is your view affected by the fact that South Africa voluntarily agreed to abide by TRIPS, and if so, how?

Case study by Robert Streiffer (University of Wisconsin-Madison). Much of this case was from materials provided by Oxfam's Community Aid Abroad, with additional material drawn from Peter Lurie's Statement before the Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources, House of Representatives on compulsory licensing and parallel imports of HIV/AIDS medicines. (HRG Publication #1490).