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Brazil Breaks Hiv-drug Patent After Failed Negotiations
With Pharmaceutical Giant Merck

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Brazilian President Luiz Inacio Lula da Silva has said his country will import a cheaper generic version of a patented drug to treat AIDS after US pharmaceutical giant Merck refused to give Brazil the price breaks it was calling for. Brazil had previously stated that it would break patents on AIDS drugs if pharmaceutical companies failed to offer adequate price reductions (NotiSur, Sept. 5, 2003). The decision to make a compulsory license for the drug was the first patent bypass Brazil has done, leading US corporate leaders and the government to suggest that they would threaten investment into Brazil and into pharmaceutical research and development, accusations Brazil has faced before (NotiSur, May 25, 2001).

Lula: Merck offer of 30% discount "grotesque"

In early May, Brazil's government announced that it would import a cheaper, generic Indian-made version of the patented Efavirenz drug, making the decision after talks between the Brazil government and Merck broke down.

Merck had offered Brazil a 30% discount on the cost of the drugs, but the country wanted to pay the same price as Thailand, which gets a larger discount. Merck's offer to Brazil priced the pills at US$1.10 instead of US$1.59. But Brazil wanted its discount pegged at US$0.65 per pill, the price Thailand pays. Now, it will source Indian-made versions of Efavirenz for just US$0.45 each. "From an ethical point of view the price difference is grotesque," said Lula.

"And from a political point of view, it represents a lack of respect, as though a sick Brazilian is inferior." Lula said that the compulsory licensing of Efavirenz was a legitimate and necessary measure to guarantee that all patients had access to the drug. Brazil's decision means that Merck, which holds the patent for the drugs, will only get a small royalty for the generic versions of the drugs purchased.

Under Brazilian law and rules established by the World Health Organization (WHO), such a license can be granted in a health emergency or if the pharmaceutical industry abuses its pricing. About 75,000 Brazilians use Efavirenz, out of a total of 180,000 people who receive free antiretroviral drugs from the government.

AIDS activists in Brazil welcomed the decision. "This is certainly an important advance in widening access. We are very happy that Brazil is moving in the right direction," said Michel Lotrowska of nongovernmental organization (NGO) Medecins Sans Frontieres (MSF). Thailand's decision to break Merck's Efavirenz patent, as well as drugs produced by two other firms, led to the country being placed on a US list of copyright violators. It is presently unclear if there will be similar consequences for Brazil.
**Merck, Wall Street say move discourages research**

Merck said that Brazil’s decision could discourage pharmaceutical firms from investing in treatments for illnesses prevalent in the developing world. Brazil’s move, Merck said, sent "a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world."

Developing-world nations have struggled for many years with pharmaceutical corporations on the issue of cheap access to life-saving medicines, with corporations claiming the need for a profit incentive to continue drug development and governments claiming the need to offer treatment to poor populations. Commentators like James Love of the NGO Knowledge Ecology International have argued for decoupling incentives for research and development (R&D) from price by encouraging governments to offer large prizes for researchers who develop drugs.

**NGO proposes prizes, not price, as R&D incentive**

Love and co-presenter Tim Hubbard argued in a Nov. 14, 2006, talk in Australia that the current model of research could be replaced with something better. "The current system of financing research and development for new medicines is deeply flawed by the impact of high prices on access to medicine, the wasteful spending on marketing and R&D for medically unimportant products, and the lack of investment in areas of greatest public interest and need," they said.

"Rather than give drug developers the exclusive rights to sell products, the government would award innovators money: large monetary 'prizes' tied to the actual impact of the invention on improvements in health care outcomes that successful products actually deliver." Industry leaders seem unlikely to agree to such a proposal, given their predilection presenting profit incentives as the best motivators for R&D. The Wall Street Journal called the Lula decision a "dangerous game." "Pharmaceutical companies can't afford to develop new drugs if they can't charge market prices for their existing products," editorialized the Journal. "Drug innovation is a risky business, and companies won't be willing to sink hundreds of millions of dollars into research and development, especially on diseases that affect the poor and sick in developing countries, if they fear their intellectual property will be stolen."

The BBC reports that Thailand has been a leader in the effort to break drug-company monopolies like the ones on Efavirenz, other AIDS drugs, and a heart drug. Its decision has been condemned by the pharmaceutical industry but applauded by NGOs campaigning for wider access to affordable medicines. What Thailand has done is completely legal under international trade regulations. The landmark 1995 World Trade Organization (WTO) agreement on intellectual property, Trade Related Aspects of Intellectual Property Rights (TRIPS), gives governments a large amount of freedom to bypass patents on drugs if they face any kind of health crisis. The language of the agreement is vague. It recommends that governments consult the drug companies first and requires them to pay a small royalty. But crucially, the government can decide what constitutes a health crisis.
Supporters of the compulsory licenses, like Paul Cawthorne from MST, believe steps like Thailand's and Brazil's are correct. He argues that the big pharmaceutical companies make plenty of money from less-essential drugs, like Viagra, and that they spend a lot more on advertising their products than they do on research and development. Much of the research in the US is, in any case, done by government-funded universities, Cawthorne says. He is calling for a radical shake-up in the pricing of a whole range of essential drugs to make them affordable in every country, and he believes Thailand has set an example other governments should follow.

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