

Brazil, Thailand Override Big Pharma Patents

Executing a much-repeated threat, Brazil on 4 May broke sharply with big pharma and for the first time signed a “compulsory license” that allows the country to make or import a generic version of a patented anti-HIV drug. Brazilian President Luiz Inácio Lula da Silva, who signed the decree in a televised ceremony, took this step shortly after Thailand decided on similar action with the same drug—efavirenz—and two others. “Many other countries will likely follow suit,” predicts economist James Love, who runs Knowledge Ecology International, a think tank in Washington, D.C. Love has urged developing countries to issue compulsory licenses, which are permitted by World Trade Organization rules for noncommercial uses of patented drugs,

United Nations Programme on HIV/AIDS, says, “I am really proud of this wonderful political decision.”

Thailand faced similar praise and criticism when it issued compulsory licenses for efavirenz in November and then again in January for the anti-HIV drug lopinavir/ritonavir (made by Abbott Laboratories of Abbott Park, Illinois) and the blood thinner clopidogrel (made by Sanofi-Aventis of Paris, France). “Thailand’s move has stirred up a hornet’s nest,” says Jon Ungphakorn, a former Thai senator who strongly backs his government’s actions.

To the astonishment of Ungphakorn and many others in Thailand, Abbott announced on 14 March that it was pulling applications it had pending to register

latest offers. Merck says it will sell efavirenz to the country for \$237.25 per patient per year—a “no profit” price that Brazil said it would have agreed to—while Abbott reduced the price of lopinavir/ritonavir from \$2200 to \$1000 per patient per year. (Sanofi-Aventis, which sells clopidogrel in Thailand for about \$800 per patient per year, did not reply to an interview request.)

Lawyer Sean Flynn, an intellectual-property expert at American University in Washington, D.C., who supports Thailand’s and Brazil’s actions, says the countries ideally would like to create competition among generic manufacturers to drive prices as low as possible. And Flynn flatly dismisses the “tired” argument that R&D would be harmed by these compulsory licenses, stressing that the drugs were not initially made for developing countries. “They were created for the European and U.S. markets, and that’s where the incentive comes from to invest in developing them,” contends Flynn, adding that patent holders also receive some royalties from drugs sold under compulsory licenses.

Abbott has taken the brunt of the criticism. AIDS advocates in particular have protested its plans to withdraw the registration of its new drugs, including a heat-stable form of lopinavir/ritonavir that’s badly needed in Thailand. “Patients are being penalized,” charges Paul Cawthorne, head of the Thai mission for Médecins Sans Frontières. “It’s disgusting and completely unethical.” Such criticism is misguided, counters Abbott spokesperson Dirk van Eeden: “The Thai government said it will not buy it, so why is there a need for us to register it?” he asks.

Although a handful of countries have issued compulsory licenses for AIDS drugs without kicking up much of a fuss, all involved older, first-generation drugs. Now the second-line treatments are at stake. Economist Love adds that big pharma feels threatened that this movement could go beyond AIDS to heart disease and other ailments. “There’s a big push in Thailand to do it for everything,” says Love.

Merck notes that it “remains flexible and committed to exploring a mutually acceptable agreement” with Brazil, and Thailand on 14 May plans to hold a meeting with Merck, Abbott, and Sanofi-Aventis to attempt again to negotiate lower prices for their products.

—JON COHEN



Lifeline. As more patients fail to respond to front-rank anti-HIV drugs, the demand grows for inexpensive, next-generation therapies.

especially if they involve public health.

Efavirenz is used by nearly 65,000 of the 170,000 people in Brazil now receiving free treatment from the government. Merck offered earlier in the week to cut the price from \$580 per patient per year to \$400, but Brazil noted that a generic version would reduce costs to about \$165—saving the country an estimated \$30 million this year alone. In a statement, Merck said it was “profoundly disappointed” by the decision and warned that the “expropriation of intellectual property sends a chilling signal to research-based companies,” contending that they “cannot sustain a situation in which the developed countries alone are expected to bear the cost for essential drugs.” But Pedro Chequer, the former head of Brazil’s AIDS program who now works for the Joint

seven new medicines for sale in Thailand. Then on 30 April, the Office of the U.S. Trade Representative cited Thailand’s issuing of compulsory licenses as one reason for elevating the country to the dreaded Priority Watch List, a U.S. government warning to countries that it judges do not adequately protect intellectual property, which can drive away foreign investment and impact export tariffs. “It’s surprising that the reactions have been so harsh to a move that is perfectly legal,” says Ungphakorn. “What the United States and Abbott have done to Thailand is to send a message to the whole developing world: ‘Don’t you dare carry out compulsory licenses, or there will be retaliation.’”

Merck and Abbott say they do not understand why Thailand has yet to accept their