Brazil Takes Steps To Import Cheaper AIDS Drug Under Trade Law

By Tove Iren S. Gerhardsen

The government of Brazil has issued a license that will allow the importation of cheaper versions of a patented HIV/AIDS drug after negotiations failed to bring about agreement on price reductions with Merck, the US company holding the patent. Merck said it was “profoundly disappointed,” as Brazil’s action sparked a flurry of positive and negative reactions.

This is the first compulsory license issued in Brazil after several threats to do so since 2001 resulted in lower prices for other drugs, sources said.

In 2001, a World Trade Organization (WTO) ministerial declaration on public health and trade law - called the Doha Declaration on the TRIPS Agreement and Public Health - reinforced countries’ liberties to decide when public health concerns come before intellectual property rights.

A compulsory license is legal under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) if, “prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time,” according to Article 31. But the same article of TRIPS also states that this requirement may be waived in cases of “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”

The Doha Declaration Article 5(b) states that: “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

The product in question is the HIV/AIDS drug, efavirenz (Stocrin), marketed by Merck, and currently used by 38 percent of AIDS patients in Brazil as part of their treatment, the Brazilian Health Ministry said in a statement.

A Brazilian health official told Intellectual Property Watch that Brazil has three steps in its patent law, which incorporates the TRIPS agreement, that have to be adhered to before a compulsory license is issued.
First, it had to declare in a decree that the product in question was of public interest, which the Brazilian government did in Decree No. 886 on 25 April. Secondly, the government was required to start negotiations with the company, in this case Merck, “to push down the price,” he said. And thirdly, the government would have to issue another decree if the price negotiations failed and it wanted to issue a compulsory license.

In this case, after the decree was issued and during the price discussions, “the laboratory offered a discount of 30 percent on the current price of US$1.59 per tablet paid by the federal government,” the health ministry. “This proposal was considered to be unsatisfactory, since Brazil would be able to obtain the product elsewhere for US$0.45.”

Chilling Signal to Researchers or Heroic Action to Save Lives?

There appears to be a general agreement that Brazil is adhering to international trade law in what it has done. Brazil received broad praise among health advocates for its action. But it has not been spared sharp reactions from the research-based pharmaceutical industry, which sees Brazil’s choice to use the trade provisions as a threat to its business model.

“This expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world, potentially hurting patients who may require new and innovative life-saving therapies,” Merck said in a statement. “As the world’s 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease.”

But Peter Drahos, professor at Australian National University, said on the ip-health listserv that, “Brazil’s action will not ‘break’ Merck’s Brazilian patent. The patent has not been revoked by the Brazilian government. The patent continues to operate and Merck remains its owner. Merck will receive royalties based on its use.”

The company said it remains open to negotiation. “Merck has attempted to negotiate in good faith with the government of Brazil, but a fair offer on Stocrin has been rejected,” it said. “While we remain flexible and committed to exploring a mutually acceptable agreement with the Brazilian government to help the country achieve its objective of universal access to treatment, we believe their action is not in the best interests of patients in Brazil and around the world.”

Some sources have suggested that while industry appears to be responding to larger developing country markets such as Brazil or Thailand, the forcefulness of their response may have a discouraging effect on smaller economies considering similar public health actions but lack the legal or political resources to defend themselves on the global stage.

The Geneva-based International Federation of Pharmaceutical Manufacturers and Associations echoed Merck’s view: “Although permitted under specific conditions by the WTO TRIPS agreement,
compulsory licensing is not a solution to improve access to medicines. Improved access can only be assured by adequate financing and collaboration with the innovative companies that develop new therapies,” it said. “Compulsory licensing is a confrontational approach, and may be aimed to benefit local government-owned companies’ commercial interests.”

Daniel Christman, senior vice president for international affairs at the US Chamber of Commerce, warned that the decision could divert investment from Brazil. “Brazil is working to attract investment in innovative industries that rely on IP, and this move will likely cause investments to go elsewhere,” he said. Christman also noted that the action followed just days after the Office of the US Trade Representative upgraded Brazil in USTR’s annual Special 301 report on trading partners protection of US intellectual property rights. The upgrade was related to Brazil’s efforts against piracy and counterfeiting.

Others welcomed Brazil’s decision to go beyond the threats to actually issue a compulsory license. “Brazil achieved lower prices in the past using the threat of CL. However, there has certainly been an erosion of the power of the threats since none of them actually led to a CL. In addition, the prices offered by the companies were clearly not the lowest possible - as the last offer made by Merck in Thailand after the CL was issued has shown,” Gaëlle Krikorian, Researcher at CRESP (Research Center on Health, Social and Political Issues), a research unit in association with the University of Paris, told Intellectual Property Watch.

Thailand offered three compulsory licenses in late 2006 and early 2007 for two HIV/AIDS drugs (including efavirenz) and a heart disease drug (IPW, Public Health, 12 March 2007). Among other countries that have issued CLs for pharmaceuticals are Canada, Indonesia, Italy, Malaysia and Mozambique, the Brazilian Health Ministry said.

On why Brazil has not issued a CL before, Krikorian said, “The most obvious reason is the fear of an open conflict with the United States. The Thai case, and the recent 301 list report (IPW, US Policy, 30 April 2007), indeed shows that despite the Doha Declaration and all the commitments made, the US is ready to be extremely aggressive with countries with producing capacity that use CL for medicines.”

Others highlighted Brazil’s role in bringing down prices of HIV/AIDS drugs over the past years. Thiru Balasubramaniam from Knowledge Ecology International (KEI) said Brazil’s AIDS programme had contributed significantly to the, “remarkable price drop from $10,000 to around $130 for the cost of antiretroviral (HIV/AIDS drugs) combination therapy over the last seven years.”

Ellen t’Hoen of Médecins Sans Frontières told Intellectual Property Watch that this should be a lesson for other developing countries that one actually gets lower prices by issuing a compulsory license instead of only threatening to issue one, and said this was also reflected by the Thailand case.

She said Brazil had achieved a price for efavirenz of $580 per patient per year earlier when it had threatened to use compulsory license. But this was too expensive compared with the price for generics.
(Thailand was offered $244 per patient per year after it issued a CL), and thus Brazil has paid too much for too many years, she said. Both Brazil and Thailand have programmes for universal access to HIV/AIDS drugs.

“With Brazil and Thailand expanding the market for generic versions of efavirenz, greater economies of scale should push prices down further, eventually to less than $.24 per day,” KEI director James Love said.

The Brazilian Health Ministry said the license “enables the ministry of health to import generic versions of efavirenz from laboratories that are pre-qualified by the World Health Organization,” adding that three Indian generic companies meet this requirement at the moment.

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