Brazil issued a compulsory licence for the patented AIDS drug efavirenz, in a move that has drawn reactions among public health and industry representatives. The compulsory licence will allow Brazil to import and eventually manufacture generic versions of the drug more cheaply.

The 4 May move by Brazil follows Thailand’s compulsory licensing of efavirenz and two other medicines in recent months (see BRIDGES Weekly, 13 December 2006). In the aftermath, the patent holder, Merck, reduced the price of its brand-name efavirenz 'Stocrin' in Thailand and least developed countries.

Brazil proceeded with the compulsory licence after failing to reach an agreement with Merck to lower prices. With Brazil seeking a reduction from its middle-income country price of US$1.57 per tablet, Merck's best offer amounted to US$1.10, a 30 percent discount, which it said was "the lowest price of any country with a comparable wealth and disease burden." However, Brazilian Minister of Health José Gomes Temporão said he "told them we needed a 60 percent discount" to come close to the US$0.65 that Thailand now pays. With the compulsory licence, generic imports from India will be available for US$0.45 per tablet.

Efavirenz is currently used by 75,000 of the 180,000 patients that receive free AIDS drugs from the Brazilian government. The health ministry says the compulsory licence will reduce costs by some US$240 million between now and 2012, when Merck's patent expires.

Merck says it is "profoundly disappointed" by the outcome, with the US-Brazil Business Council calling it "a major step backward" that will discourage investment in Brazil.

Meanwhile, public interest and health groups have lauded Brazil's actions. James Love, Director of Knowledge Ecology International noted that "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." On Friday, as he signed the decree granting the compulsory licence, Brazilian President Luiz Inacio Lula da Silva said "between our business and our health, we are going to take care of our health."

TRIPS compliance not questioned

According to the WTO Agreement on Trade-related Intellectual Property Rights (TRIPS), governments do not need to negotiate with patent holders prior to issuing a compulsory licence in cases of national emergency, extreme urgency, government use (though they must provide them
with a royalty fee by way of compensation) or to remedy an anti-competitive practice. Moreover, the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO on 14 November 2001, reaffirmed the right of Members to issue compulsory licenses and the "freedom to determine the grounds upon which such licences are granted."

Despite these measures, Brazil negotiated with the patent holder, Merck, for two years before invoking a three-step domestic legislative process to grant the compulsory licence for efavirenz. Firstly, Minister of Health Temporão issued a decree on 25 April identifying the procedure as a matter of public interest, one of the conditions for compulsory licensing under Brazilian intellectual property law. At the time, he stated that "Brazil is not doing this as a threat, and not even to lower the price of other medicines, but to guarantee its own AIDS programme for patients." Secondly, following the initial decree, a final period of seven days is given to try to arrive at an agreement with the patent holder. According to Temporão, the best offer Merck had tabled in seven meetings over two years prior to this was a two percent price reduction, but once the compulsory licence procedure was initiated they made the offer of a 30 percent reduction. The decree signed by President Lula on 4 May was the culmination of the process, signalling that negotiations had not reached a satisfactory conclusion and that a compulsory licence would be issued.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), whose members include Merck and 25 other international pharmaceutical companies, responded with a statement criticising compulsory licensing as "a confrontational approach."

Contrary to some media reports, Professor Peter Drahos of the Law Programme at Australian National University pointed out that Brazil has not 'broken' the efavirenz patent, since "the patent has not been revoked by the Brazilian government" and "Merck will receive royalties based on its use." While WHO-approved generics will initially be imported from India, the government news agency 'Radiobras' reported that a Brazilian government laboratory would produce efavirenz on a large scale by the end of 2007.

**Thailand, Brazil setting precedent?**

In the past, Brazil has used the threat of compulsory licences to successfully reduce the price of AIDS drugs, most recently striking a deal with Abbott Laboratories in 2005. Indeed, negotiations with Merck in 2001 and 2003 had previously resulted in price drops for efavirenz.

The compulsory licence issued last week was the first Brazil has actually carried through relating to pharmaceutical products. Ironically, it comes just as Brazil was taken off the US Trade Representative's intellectual property priority watch list for its efforts to tackle counterfeiting.

There is some concern among industry groups that, along with the Thai case, a new precedent is being set for the way in which developing countries handle their public health burdens and access to medicines. Notably, significant price reductions were offered by pharmaceutical companies in Brazil and Thailand only with, respectively, the enactment and implementation of compulsory licensing measures (see BRIDGES Weekly, 14 March 2007). Given its leadership role among developing countries, the ramifications of the first Brazilian compulsory licence on pharmaceuticals...
could extend well beyond its domestic AIDS programme.

In a further development, former US President Bill Clinton endorsed the compulsory licences issued by Brazil and Thailand. Standing beside Thai Public Health Minister Mongkol na Songkhla he said "I strongly support the position of the governments of Thailand and Brazil and their decision after futile negotiations." The comments came during an announcement on 8 May that the Clinton Foundation had agreed deals with two Indian generic pharmaceutical companies that would halve the cost of AIDS drugs in middle-income developing countries, and further reduce prices by a quarter in the poorest.

Any ramifications of these developments could be given an early airing at the 60th World Health Assembly of the WHO next week, where Thai Public Health Minister Mongkol na Songkhla has said he will discuss the compulsory licences in Thailand with several "friendly states" from Asia, Latin America and Africa. Meanwhile, it remains to be seen whether Merck will repeat the price drop it offered after the last compulsory licence it faced in Thailand, now that Brazil has followed suit.