

Compromise Averts Compulsory AIDS Drug License in Brazil

After ten days of intense negotiations with Abbott Laboratories, the Brazilian government announced on 8 July that it would not issue a compulsory license for the company's patented AIDS drug Kaletra, as it had threatened to do on the grounds of public interest.

Kaletra, manufactured by Chicago-based Abbott Laboratories, is one of the newer generation antiretrovirals used in AIDS treatment drug cocktails. In March 2005, Brazil's then-Health Minister Humberto Costa warned Abbott, as well as two other pharmaceutical companies, that unless they agreed to drastic price cuts, Brazil would resort to manufacturing their patented AIDS drugs under compulsory license. After Abbott only offered a 26 percent reduction, Brazil's President Luiz Inacio Lula da Silva and Minister Costa on 24 June declared the lopinavir-ritonavir combination that makes up Kaletra a 'public interest medicine', and notified Abbott that a compulsory license would be issued unless the company made an acceptable offer within ten days. The action was motivated by the heavy financial burden that Kaletra imports imposed on Brazil's widely-praised free HIV/AIDS treatment programme.

This was the closest that Brazil had ever come to issuing a compulsory license in its many years of bargaining with brandname pharmaceutical manufacturers anxious to avoid generic production in the country. Had no agreement been found with Abbott, generic lopinavir-ritonavir would have been produced by the state-owned laboratory FarManguinhos, which expected to make it available for US\$0.68 a pill, i.e. 42 percent less than the cost of the brandname product (US\$1.17). The Health Ministry said that FarManguinhos would probably have been able to produce Kaletra within ten months after the issue of the compulsory license. Abbott would have been paid a three percent royalty. The Ministry also specified that the generic version would be produced exclusively for non-commercial public use by domestic consumers.

Some 600,000 Brazilians are estimated to suffer from HIV/AIDS, and about 151,000 of them are currently being treated free of charge. However, the costs of the scheme have skyrocketed in the last few years as more people have taken advantage of the programme. At the same time, the programme's dependence on imported medicines has grown considerably, and now accounts for 80 percent of its budget – for Kaletra alone the government was expected to pay more than US\$90 million this year compared to US\$35 million in 2002.

The Kaletra Deal

The Brazilian Health Ministry said the deal with Abbott ensured a 'significant price reduction' for Kaletra over the next six years, as well as access to a new formulation of the drug to be launched worldwide in two years. It said the agreed price reduction meant US\$18 million less would be spent on the drug next year, while up to US\$259 million would be saved in the next six years. The number of patients treated is projected to grow from 23,400 today to 60,000 over that period. Abbott's own brief statement only noted that the agreement did "not specify a per-capsule price, and [would] not be at the low price quoted for local and generic manufacturers. The price of Kaletra will be dependent on the number of patients treated." The company's spokesperson Melissa Brotz characterised the price cuts as 'volume discounts'.

While the Health Ministry said that Abbott would start, as of 2009, transferring technology that would make it possible for FarManguinhos to manufacture the Kaletra in Brazil, Abbott stressed that the terms of its assistance to enable local manufacture of Kaletra were still under discussion. The company also specified that the production would be for HIV/AIDS patients in Brazil, not for export, and would only start after the patent's expiry in 2015.

Before the deal was struck, Abbott had argued that its price for Kaletra in Brazil was the lowest outside of Africa and least-developed countries, and that as the ninth largest economy in the world Brazil's "demand that it is owed the same relief as developing countries is counter to the spirit of the TRIPS agreement." Brazil's GNP per capita is US\$7,600, but the income of the vast majority of AIDS sufferers is well below the national average. By comparison, the GNP per capita ratio in the United States is US\$37,800.

Health Activists Disappointed

Some health activists regret that the Brazilian government did not go ahead with its plan. Had the license been issued, they argue, it would have fallen within the flexibilities in the TRIPS Agreement confirmed in the Doha Declaration on TRIPS and Public Health. That document states that all WTO members have "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted," as well as the right to determine what constitutes a national emergency or other circumstances of extreme urgency. By setting a precedent, Brazil's success in using these provisions could have encouraged other developing countries to take similar action.

It should be noted that Brazil is not the only country to have used the threat of generic production to obtain price concessions. For instance, during the anthrax scare in 2001, both Canada and the US were poised to issue compulsory licenses for the antibiotic ciproflaxin when the patent owner Bayer accepted to nearly halve the price of its brandname Cipro.

Brazil and Colombia Eye Wider Patent Action

The Justice and Constitution Commission of the lower house of the Brazilian Congress has unanimously voted to exclude product and process patents on AIDS drugs from patentability. The Senate is yet to address the legislation.

In related news, the Colombian Regulatory Authority for Industry and Commerce announced on 8 June the cancellation of 250 patents mostly covering chemical, cosmetic and pharmaceutical products. Originally due to expire in 2014, the patents were held by 13 multinationals, including Pfizer, GlaxoSmithKline, Sandoz, Eli Lilly, Merck and Ciba Geigy. The reasons given for the cancellation were administrative irregularities, including the companies' failure to pay the fees required for continued patent production.