



Abbott Races To Beat Clock In Patent Brawl With Brazil

IP Law Bulletin (Friday, July 08, 2005)--Brazil's government and Abbott Laboratories are in last-minute talks to avoid a compulsory license on the U.S. drug maker's AIDS therapy Kaletra, the company said.

Brazil's ministry of health had given Abbott until midnight on Thursday to reduce its prices, but there was no word Friday morning on whether the two parties had been able to come to an agreement.

Abbott presented a new proposal shortly before the government's midnight deadline for agreement, and health ministry officials were said to be studying the company's final offer. The government's response is expected on Friday.

In the absence of a pricing agreement, the government said it would issue a compulsory license to allow domestic drug makers to produce a generic version of the drug Kaletra.

Kaletra is one of the most widely-used anti-retroviral drugs, which are essential to the treatment of HIV.

Brazil said its decision to break the patent would be based on national and international trade legislation allowing compulsory licenses for drug production as a matter of public interest or during national emergencies.

However, U.S. intellectual property experts said that claim was likely to be contested by drug makers if the company went ahead with the compulsory licensing.

"While AIDS is a serious health problem in Brazil, the magnitude of the epidemic does not compare with rates seen in sub-Saharan Africa," said Ed Remus of McAndrews, Held & Malloy, a legal expert with extensive experience in the pharmaceutical industry.

"Multinational pharmaceutical companies are concerned that, if they give in to Brazil's demands, they will face similar pressures from other countries around the world," Remus said.

George F. Wheeler, also with McAndrews, Held & Malloy, said brand-name drug makers should be alarmed about the prospect of a compulsory license allowing Brazilian drug makers to build the capacity to make generic versions of block-buster AIDS drugs.

"A decision by Brazil to issue a compulsory license would create a slippery slope and could create the foundation for a generic drug industry that could supply other markets as well in the future," Wheeler said.

In a separate development, President Luiz Inacio Lula da Silva on Wednesday named Saraiva Felipe of the allied Brazilian Democratic Movement Party to replace Health Minister Humberto Costa, who belongs to the president's Workers' Party, in an attempt to shore up support for his governing coalition in the face of a corruption scandal.

The press office said that Wednesday's appointment of a new health minister to replace Costa was unlikely to play a part in Brazil's decision whether or not to break the patent.

This isn't the first time Brazil raises the specter of breaking patents on HIV medications. Earlier, Brazil's government health ministry threatened to make generic versions of drugs made by U.S. drug makers Abbot Laboratories, Merck & Co. and Gilead Sciences Inc.

The drugs in question, Abbott's combination pill of the protease inhibitors Lopinavir and Ritonavir, Merck & Co's reverse transcriptase inhibitor Efavirenz, and Gilead Science Inc.'s Tenofovir, account for two thirds of the government's budget for imported AIDS drugs.

In January, Brazilian President Luiz Inácio Lula da Silva was reported to have told executives of Swiss pharmaceutical giant Novartis that his country would continue to challenge patent restrictions on AIDS drugs and other expensive medicines.

Drug makers have responded to Brazil's threat by cutting prices and even donating formulas to state laboratories in Brazil. Roche, Abbott and Gilead Sciences have all agreed to the largest price cuts in five years for antiretroviral drugs.

Last year, U.S. drug maker Merck & Co. announced that it was granting a voluntary licence to the Brazilian government for the production of Stocrin, one of the medicines that make up the anti-AIDS cocktail distributed by the country's Ministry of Health.

Brazil, which has a universal free AIDS program since 1997, has raised the threat several times in an effort to cut the cost of foreign drugs used in its 15-drug anti HIV-AIDS cocktail. Brazil already manufactures eight of the 15 drugs produced under its HIV/AIDS program.

About 150,000 Brazilians currently receive the HIV-AIDS drug cocktail, nearly half the total of 350,000 who receive such treatment throughout the developing world, according to government statistics.

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