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## Brazil Uses Compulsory Licensing Threat in Negotiations

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By: [Natasha T. Metzler](#)

PharmExec Direct



The negotiations between Brazil's Health Ministry and Abbott Laboratories over pricing of protease inhibitor Kaletra (lopinavir/ritonavir) for the South American nation's STD/AIDS program may not be over, as declared July 8.

In an interview with Brazilian newspaper Correio Braziliense on July 14, the nation's new health minister, who took office on the day the deal was announced, said that the agreement is not final. He added that the threat of using a compulsory license to produce a generic version of the drug was still on the table.

Brazil continues to maintain that its right to produce a generic version of Kaletra falls under the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights agreement and the Doha Declaration.

### The Rules: A Work In Progress

Article 30 of TRIPS grants that there exceptions to patent protections and article 31 of the agreement elaborates on these exceptions.

For example, in section (b) it states that the party intending to break the patent must have tried to get authorization from the patent holder on "reasonable commercial terms." But it continues by stating that this is not necessary in the case of national emergencies, extreme urgency or if the product is intended for public, non-commercial use.

In a declaration at the 2001 Fourth Ministerial Conference in Doha, Qatar, the WTO addressed application of TRIPS specifically when it comes to public health issues, including HIV/AIDS, tuberculosis, and malaria. Paragraph 4 of the declaration states:

"[W]hile reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

The declaration continues by saying that members are allowed use their own discretion to determine the standards they use for adopting compulsory licenses.

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An August 2003 decision by the organization's General Council broadened the scope of the Doha agreement by allowing countries without the means to produce their own generic versions of a drug to import drugs from another nation that are made under a compulsory license. This overrode Article 31(f) of the 2001 agreement.

### Was Brazil Out of Line?

Brazil's Health Ministry said that it was necessary for the price of Kaletra to be lowered in order to sustain the nation's STD/AIDS program, which provides free treatments to those infected. The nation's threat of issuing a compulsory license for Kaletra prompted Abbott to announce a deal with the health ministry to reduce the price of the drug in exchange for protecting its patent. Although this deal has not been finalized, because the new health minister is not satisfied, Brazil's pressure appears to have worked successfully.

The affair has drawn the eyes of a variety of interest groups. Some admonish Brazil for its interpretation of the TRIPS agreement. Others salute the nation for its commitment to AIDS treatment.

Nancie Marzulla, president of Defenders of Property Rights, a 501(c)3 organization, said that Brazil should not be able to use the Doha statement on public health as grounds for compulsory licensing. Marzulla stated that Brazil does not a strong enough case for a health emergency.

She pointed out that the incidence of HIV/AIDS is not much higher in Brazil than in the United States. According to the CIA World Factbook, in 2003 0.7 percent of Brazil's population was infected compared to 0.6 percent of the U.S. population.

Brook Baker, law professor at Northeastern University and core member of Health Global Access Project, an 501(c)3 AIDS activism organization, disagreed.

"It is perfectly lawful to issue a compulsory license on public interest grounds," he said.

Baker stated that the standard for using a compulsory license is not an emergency and that any country, not just a poor one, can issue one in the interest of public health.

The Institute of Trade Standards, and Sustainable Development accused Brazil of abusing the public health section of the Doha agreement to build its generic pharmaceutical industry, with hopes of exporting products to developing nations around the world.

"Brazil is basically assuming a role of leadership," said Lawrence Kogan, spokesman and co-author of a paper on Brazil's pharmaceutical patent policy.

Baker asserted that the World Trade Organization created the agreement with the idea of helping developing nations in this area.

"One of the alleged benefits was supposed to be capacity building in developing countries," he said.

### What Will The Future Hold?

Marzulla expressed fear that Brazil's actions would encourage other nations to use the threat of compulsory licensing to reduce the price of imported drugs. But Stephen Bent, partner at Foley and Lardner LLP, said this conflict is part of an "ongoing trend between the developing world an the more-developed world."

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In spite of his belief that the battle will continue, Bent predicted that the WTO would probably not take steps to further clarify the TRIPS agreement unless a nation actually issues a compulsory license. This has not happened, yet.

"It is less painful to negotiate under the gun that it is to try and amend the TRIPS agreement," he said.

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