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**Brazil**
**Brazil Regulator Rejects Gilead Patent Request for Hepatitis C Drug**

*By Ed Taylor*

Efforts by U.S. drugmaker Gilead Sciences to patent its hepatitis C medication sofosbuvir in Brazil have suffered an initial setback at the hands of Brazil's health sector regulator, the National Health Surveillance Agency (Anvisa).

On March 22, Anvisa turned down Gilead's request in what sector analysts saw as a clear attempt to favor the production of a generic equivalent for the breakthrough medication. Anvisa said only that the medication failed to meet the standards demanded by Brazilian legislation for approval of its patent request.

The agency's decision now becomes a recommendation for Brazil's patent office, the National Institute of Industrial Property (INPI), which will have the final word on Gilead's request.

Anvisa has been under extreme pressure from consumer groups to reject the patent and open the door for generics. The battle against a patent for sofosbuvir has been led by Doctors without Borders, whose coordinator for Brazil Felipe de Carvalho said in a press conference on March 27 that the price charged by Gilead "has meant rationing the treatment."

Brazil's public health system in October 2015 began importing sofosbuvir to distribute to Brazilian patients. Gilead set a price of \$4,197 for the 12-week treatment period. By Brazilian standards, the medication is extremely expensive and although 1.6 million Brazilians have hepatitis C, only 30,000 have received the treatment. The health system has limited access to the medication to extreme cases.

***Critics of Gilead Sciences say that without the patent protection, generic versions could be produced at much lower prices.***

Critics of Gilead claim that without the patent, generic versions could be produced at much lower prices. A Brazilian state-owned research laboratory Fiocruz has said it could produce a generic version that would be sold for \$3,000 for the 12-week treatment period. Generic versions in India are

being sold for \$500.

INPI said on March 27 that it has not yet received the documents related to Anvisa's decision and it could not provide an estimate as to when it would issue a ruling on the patent request. Gilead in a statement said it "believes in the technical competence of INPI to evaluate the patentability of our products."

Carvalho of Doctors without Borders told Bloomberg BNA on March 28 that his organization is hoping to use the result in Brazil to strengthen its efforts in other countries.

"What is happening today in Brazil is very important because its decision will influence others," he said.

Sofosbuvir is sold under brand name Sovaldi.

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**Snapshot**

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