

US group seeks to block Gilead drug patent in India

November 24 2013, by Penelope Macrae

A US-based patient rights group said Saturday it has sought to block a bid by California-based Gilead Sciences to obtain an Indian patent for a potentially blockbuster drug to treat hepatitis C.

New York's Initiative for Medicines, Access & Knowledge (I-MAK), which works to ensure affordable access to drugs, said it opposed the [patent](#) for the [drug](#) sofosbuvir to treat the liver-destroying disease on the grounds that it is "old science".

Patent law in India, known as the "pharmacy to the world" for its vast generic drug industry that turns out cheaper copycat versions of life-saving branded medicines, is tougher than in many other countries.

The strict regime has led to a string of expensive intellectual property setbacks for Western drugmakers such as Roche and Pfizer in the quickly growing Indian pharmaceutical market.

"India's [patent law](#) doesn't give monopolies for old science or for compounds already in the public domain," Tahir Amin, director of I-MAK said.

"We believe this patent on sofosbuvir does not deserve to be granted in India and have the legal grounds to prove it," he said in a statement.

I-MAK filed a "patent opposition" suit Thursday at India's Patent Office leaving Gilead, a giant biotechnology company, facing a potentially long

battle to secure the rights to market the drug, said international medical charity Medecins Sans Frontieres (MSF), which is backing I-MAK.

A decision by Indian regulators on whether to grant the patent will hinge on whether they deem Gilead's drug to be a major new scientific development.

The patent opposition move is an attempt to ensure generic versions of the drug can be developed that will be affordable for people in developing countries infected with chronic hepatitis C, which causes deadly diseases such as liver cancer and cirrhosis, Amin said.

Gilead is expected to charge around \$80,000 for a single course of treatment with sofosbuvir when it becomes available in the United States, said MSF.

Even if offered at a fraction of this price in developing countries, "this drug will be way beyond the reach of patients", MSF Access Campaign spokeswoman Shailly Gupta told AFP.

Gilead, one of the world's biggest makers of HIV drugs, did not immediately respond to an emailed AFP request for comment.

Drug analysts see sofosbuvir, which is to be marketed under the trade name Sovaldi, as the prize gain from Gilead's \$11-billion purchase of biotechnology company Pharmasset in late 2011.

The drug is still being reviewed by regulators but could be released in US and European markets next year.

The World Health Organization estimates there are 184 million people infected with hepatitis C worldwide through sources such as transfusions, with the disease causing half a million deaths annually.

Current treatments can take up to a year and only cure about 75 percent of patients.

Gilead's daily pill can cure up to 90 percent of patients infected with the most common form of the virus within three months and eliminates the need for the injectable drug interferon, which can cause unpleasant side-effects.

Sofosbuvir is the first of several oral hepatitis C drugs expected to come to market soon but they are compounds that are "relatively simple and cheap to make", Andrew Hill, a pharmacologist at Britain's Liverpool University, was quoted as saying in the statement.

Hill has published a study suggesting that sofosbuvir could be produced for as little as \$62 to \$134 for a 12-week treatment course.

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