

Treatment Advocates Challenge Patent for New Hepatitis C Drug

Written by Australian Business

Action may speed generic manufacture, helping millions access affordable treatment

NEW YORK, Nov. 25, 2013 /PRNewswire-USNewswire/ -- The Open Society Foundations today welcomed a challenge in India to Gilead Science's patent application for their new medicine, sofosbuvir, by the Initiative for Medicines, Access & Knowledge.

The challenge, filed last week at the Kolkata Patent Office, would prevent Gilead from holding the monopoly on sofosbuvir's production and pricing. This would allow Indian manufacturers to produce a cheaper generic version of the medicine, a first step toward making it available other low-and middle-income countries.

Treatment with sofosbuvir is shorter than current treatments, has higher cure rates, can be taken orally, and is better tolerated. But these benefits are not the basis for a patent. And in India the law states that products that are variants of existing chemical compounds are not patentable.

"Sofosbuvir is not innovative enough at the molecular level to warrant a patent," said Els Torreele, Director of the Open Society Foundations' Access to Essential Medicines Initiative. "This is a battle over whether profits or the lives of patients will drive the hepatitis C response."

Sofosbuvir is expected to be approved in the U.S. and in Europe in the coming weeks and could cost around \$80,000 for a course of treatment. With 90% of hepatitis C patients living in low-and middle-income countries, this price tag will put the treatment out of reach for most.

"Without generic competition from India, patent-holding companies will be too slow bringing down prices," said Tahir Amin, Director of the Initiative

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for Medicines, Access & Knowledge. "This medicine is a variant of known compounds, and Indian law will not allow a company to make billions on it."

Dubbed a "viral time bomb" by the World Health Organization, there are an estimated 170 million people living with chronic hepatitis C globally—12 million of whom live in India. The disease infects nearly 4 million people each year and results in 350,000 deaths annually.

The Open Society Foundations is supporting patient groups and treatment advocates to increase access to hepatitis C treatment in many middle income countries—including Georgia, Ukraine

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Vietnam

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Thailand

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Brazil

, and Russia—where the price of even current Hepatitis treatments place them beyond reach.

The Open Society Foundations work to build vibrant and tolerant democracies whose governments are accountable to their citizens. Working with local communities in more than 100 countries, the Open Society Foundations support justice and human rights, freedom of expression, and access to public health and education.

The Initiative for Medicines, Access, & Knowledge (I-MAK) is a team of lawyers and scientists increasing access to affordable medicines by making sure the patent system works. Armed with the best evidence, I-MAK gives the public a voice in a system that impacts their health and lives. It is a grantee of the Open Society Foundations.

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