

Bayer mulls challenge to India cancer drug ruling

March 13 2012, by Penny MacRae

Bayer AG said Tuesday it was mulling ways to challenge a groundbreaking Indian ruling allowing a local firm to produce a vastly cheaper copy of a cancer drug made by the German pharmaceutical giant.

India's patents chief ruled Monday the price Bayer was charging in the country for the <u>drug</u> was "exorbitant" and ordered the German firm to give a licence to manufacture the medicine to Indian company Natco Pharma.

The ruling marked the first time a so-called "compulsory licence" for production of a patented drug has been granted in the country of 1.2 billion, known as a global generics drug powerhouse.

"We will evaluate our (legal) options to further defend our <u>intellectual</u> <u>property rights</u> in India," Bayer spokesman Aloke Pradhan told AFP.

Natco will pay Bayer a six percent royalty on sales of the drug and sell the medicine for 8,800 rupees (\$175) a month -- compared to the 280,000 rupees the company charges, which is more than 30 times as much.

The drug is used to extend lives of advanced kidney and liver cancer patients.

Patent controller P.H. Kurian granted the right to Natco to produce the drug after concluding Bayer's pricing made it "out of reach" of most



Indian patients.

The decision could pave the way for a rush of other "compulsory licence" applications in India and potentially in other poor nations, allowing access to patented life-saving drugs at a fraction of the cost, patients' groups said.

"This is an event which will cause multinationals to start thinking about differential pricing and how they price products in countries such as India," Rajeshwari Hariharan, lawyer for Natco, told AFP.

Under the World Trade Organization's TRIPS Agreement, which governs trade and intellectual property rules, compulsory licences are a legally recognised means to overcome barriers in accessing affordable medicines.

"(The decision) serves as a warning that when drug companies are price gouging and limiting availability, there is a consequence," said Michelle Childs, a policy director at Medecins Sans Frontieres (Doctors Without Borders).

"The Patent Office can and will end monopoly powers to ensure access to important medicines," she said.

India, known as the "pharmacy to the developing world", has long been a key provider of cheap generic medicines as it did not issue drug patents until 2005, when it was obliged to adhere to WTO <u>intellectual property</u> regulations.

Competition among generic manufacturers in India has reduced HIV drug prices by nearly 99 percent since 2000 -- from \$10,000 per person per year to \$150, Medecins Sans Frontieres said.



But after a new patent law was introduced in 2005, newer medicines are increasingly being patented in India, keeping prices high.

In a separate case also with important ramifications for access to medicines across the developing world, Swiss pharmaceutical group Novartis is challenging India's decision to not grant patents on medicines that according to the patent law are not sufficiently innovative to merit patent protection.

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