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India's Nexavar licensing creates a global debate

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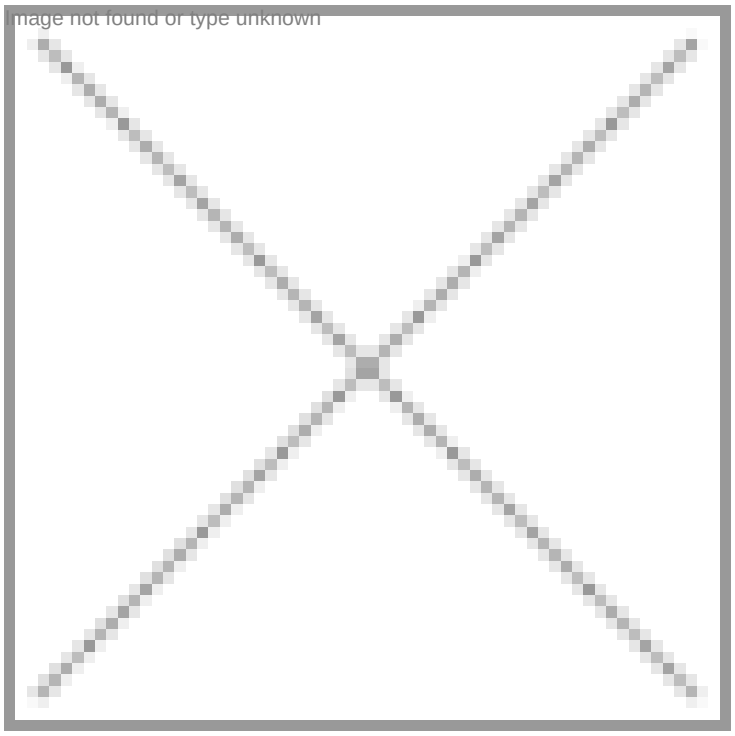

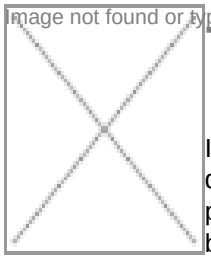

In early March, Nexavar, the brand name of the blockbuster anti-liver cancer drug, sorafenib, sold by Bayer in India in tiny quantities was an unknown commodity. An Indian patient with advanced liver cancer paid 280,000 for a dose of 120 tablets he has to take in a month or spend close to 35 lakh in a year for the drug which could extend life by six-to-10 months. It is not difficult to guess how many of India's estimated 29,000 liver cancer patients could afford to benefit from this biotech wonder drug, developed by a small company, Onyx Pharmaceuticals, in Emeryville, California. Bayer bought the key protein invented by Onyx and developed it into the liver cancer drug. Nexavar became a blockbuster with $1 billion in sales in 2011 for Bayer. The revenue growth was seven percent over the 2010 sales of $934 million.

But all that changed on March 13, 2012, when India's Patent Office granted a request from Hyderabad-based Natco Pharma to compulsorily make Bayer's patented drug and make it available at 97 percent discounted price of 8,800 for a month's dose. Of course, Bayer will get a six percent royalty on Nexavar's sales by Natco.

Predictably, the pharma industry around the world has raised a storm of protest. The US government officially expressed its displeasure at the Indian Patent Office's decision on Nexavar. â€œIs intellectual property safe in India?â€? was the headline in a US pharma magazine. India's biotech industry association, ABLE, too has issued a strong protest against the government's move, saying the compulsory licensing of Nexavar will hit innovation in the country.

There are over 600,000 people with the advanced condition of liver cancer who can benefit from Nexavar treatment. Bayer's sales figures for 2011 indicate that with differentiated lower prices in some patients, just a tenth of the potential beneficiaries actually had access to the drug.

Globally and in India, the biotech industry has been championing the cause of affordable drugs through innovation. And the biotech industry has always projected the image of a patient-friendly sector striving to help patients in need all over the world. And this image has earned the industry a high public profile.

So, is the compulsory licensing of Nexavar a bad idea? After all, the Indian government has only used an option available toit under the global trade provisions. If governments such as India can't use these provisions to increase availability of a key medical product, what is the use of such a facility, ask many health activists.

There is a fear that India may set a trend and the Nexavar decision will be followed by more such compulsory licensing of other drugs patented in the country since 2005. There is no evidence to show that such a trend may be set. After all, this is the first case of compulsory licensing by the country after adopting the new intellectual property regime.

It will certainly help if India's health administrators explain the rationale for the decision on Nexavar and also present the plight of these 29,000 liver cancer patients in the country that convinced the government to take such a decision. Such a step will certainly help calm the industry and also provide some clues to the future decisions on several applications for compulsory licensing pending with Indian Patent office. The biotech industry should demand a position paper on Nexavar and compulsory licensing from the government immediately.

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