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Debate over compulsory licensing of Bayer's Nexavar

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Thecase of Indian pharma company's request for a compulsory license to make a generic version of Bayer's patented drug to treat liver and kidney cancer was settled on March 13, 2012. In a first-of-its-kind ruling, the Indian Patent Office granted permission to NATCO to make anti-cancer drug sorafenib for the India market.

The Indian Patent Office's ruling is subject to certain conditions, such as maintaining account of sales, and payment of royalty at six percent of the net sales on a quarterly basis. The order also makes it obligatory for NATCO to supply the drug free-of-cost to at least 600 needy and deserving patients per year.

Reacting to this, Mr Rahul Dev, managing partner, Tech Corp Legal, India, said, "This has opened up the field for the generic industry to follow suit and could well pave the way for the availability of cheaper drugs for lifestyle diseases. We are likely to see a significant shake out and consolidation in the near future where more generic companies could invoke the compulsory licensing clause of the Indian Patents Act, following the said decision to allow NATCO Pharma to sell a generic version of Bayer's patented anti-cancer drug (Nexavar) at 97 percent reduction. The landmark judgment by the Indian Patent Office is now being seen as a test case and it is almost certain that Bayer will go to court on this issue."

Bayer had contested the Indian company's application for compulsory licensing. NATCO Pharma, based in Hyderabad, insisted that Bayer was not providing the benefits of its patented medicine by making it available to the needy Indian patients at a reasonable cost. India's Patent Office evaluated Bayer's costing mechanism, which was reasoned to be the cause for

prohibitively expensive cost in the Indian market. The drug itself had fast track approval in the US after it was classified as an "orphan drug" required for some diseases, which did not have an attractive market. The Indian Patent Office then invoked the provisions of the Trade Related aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) and granted compulsory licensing as a requirement for public health.

Three years ago, Thailand first tested this TRIPS provision by allowing production of a generic version of an anti-cholesterol drug. The Indian Patent Office's decision on Nexavar has been watched with interest around the world. This decision of Nexavar is going to create heated debate about the requirements of needy patients and the patenting aspects once again globally. The pharma industry, which has invested millions of dollars to produce such innovative drugs, is certainly not happy with India's decision.

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The Association of Biotechnology Led Enterprises (ABLE), a national forum that represents the $4 billion biotechnology industry in India reacted sharply to India's grant of a compulsory license to NATCO Pharma. A statement by ABLE says compulsory licenses should be used only when there is a national health crisis or when life-saving drugs are priced out of the reach of a common man, i.e., under some exceptional circumstances.

The organization further noted that governments are likely to interfere under such circumstances, like when a few countries invoked this provision for making available life-saving HIV drugs to its people. India should always keep in mind that a compulsory license should not be invoked in an arbitrary manner as it will undermine the innovative efforts of this industry and consequently invest in this sector.

Most multinational and Indian Pharma companies spend millions of dollars and many man hours to save patients from life threatening diseases and therefore the intent of all these companies broadly is to alleviate suffering of people. However several times, overseas companies price their drug based on who they think can purchase and do not take into account the millions who could be deprived of a treatment due to affordability.

ABLE pointed out that Nexavar is an orphan drug in the US and not approved by National Institute for Health and Clinical Excellence (NICE) for National Health Service (NHS) use in view of the fact that it increases survival in primary liver cancer by only six months. While on pricing when it is obvious that there is a case on the overall utility of this drug which prolongs life by half-a-year, the question is why should India invoke compulsory licensing in the case of Nexavar?

Raising concerns, the biotech industry forum says, "This is a question that will come up for considerable debate as to whether it is really a true life-saving classification. In future, before such rulings are invoked it might be a good idea to debate on the cost of goods versus the cost of innovation. If we put in mechanisms to compensate the companies which do innovation, then the severity of such rulings will be quite considerably mitigated."

There is going to be demand from health activists and generic pharma makers to seek more such compulsory licenses on essential drugs, which were patented after 1995 under the TRIPS agreement in many developing countries.

The Nexavar test case has indicated that patent holder of vital drugs will be subjected to more scrutiny by major stakeholders of the public health system in the coming months. Patent holder will be forced to act on their patents to benefit people rather than use the rights to price such products out of the reach of the thousands of patients who could potentially benefit from such innovations.

The pharma industry will have to come up with suitable mechanisms to avoid more requests of compulsory licensing and avoid a public relations disaster by seeming to act in a way to reap undue benefits at the cost of needy patients. What use is an innovative drug, if it can't help to cure patients who need it the most, will be the question that will reverberate in communities around the world after this Indian decision on Nexavar.

ABLE expressed its concerns by pointing out that the momentum and global image of India's focus on innovation might be at risk, at a time when the Indian government has declared this as the "Decade of Innovation".