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IPAB upholds Nexavar compulsory license

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In response to Bayer's appeal against the grant of a compulsory licence, The Intellectual Property Appellate Board in Chennai has upheld its earlier verdict. This was the first compulsory license granted to Natco for Bayer's oncology drug Nexavar in March 2012.

The compulsory licence was granted in March 2012 by India's Controller of Patents (the highest authority of the Indian Patent Office) to the generic company Natco for the eight years the cancer drug sorafenib tosylate will remain patented in India (until 2020), and against the payment of a royalty rate now fixed at seven percent, up from the original order of six per cent. Bayer had earlier appealed the decision in September 2012, and hearings were held in front of the IPAB in January this year.

Leena Menghaney, India campaign manager, MÃ©decins Sans FrontiÃ©res Access Campaign has said, "We're relieved with the decision by the IPAB to uphold India's first compulsory licence. The decision confirms that the Indian patent office is able to use all the means legally at its disposal to check the abuse of patents and open up access to affordable versions of patented medicines. Most importantly, the decision means that the way has been paved for compulsory licences to be issued on other drugs, now patented in India and priced out of affordable reach, to be produced by generic companies and sold at a fraction of the price."

According to Pharmed, a leading pharma blog, a Bayer spokesperson has responded to the verdict by saying, "Bayer is committed to protecting its patents for Nexavar and we will rigorously continue to defend our intellectual property rights within the Indian legal system. We will pursue the case in front of High Court in Mumbai with a writ petition. The order of the Intellectual Property Appellate Board weakens the international patent system and endangers pharmaceutical research"

Ms. Menghaney goes on to add, "As with more people living with HIV, tuberculosis or hepatitis need to be switched to more expensive, effective treatments, the need for affordable generic versions of these medicines will be critical to maintain the numbers of people with these diseases staying alive and healthy. We hope that, in the near future, compulsory licences will be issued for the newest drugs to treat HIV and affordable generic versions will be available not only in India, but in the rest of the developing world."

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The price of the Bayer's drug is Rs 2,80,000 per month, while Natco was required to make the drug available within India at a price of not more than Rs 8,800 (approximately US\$175) for one month's treatment.

With this verdict out of the way, now all eyes are on the Glivec case, where pharma giant Novartis is fighting for the grant of a patent on the drug Glivec, on grounds of modifications made in the original drug.

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