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US STAND ON CL UNFAIR

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The grant of compulsory licence by India's Patent Controller in March this year to Natco for the manufacture of generic version of Bayer's cancer drug Nexavar (sorafenib tosylate) has attracted severe criticism from the US Patent and Trademark Office last month. The USPTO deputy director Teresa Stanek Rea termed the grant of compulsory licence as a violation of the agreement on Trade Related Aspects of Intellectual Property Rights administered by the World Trade Organization. The compulsory licence allows Natco to produce the generic version of the drug at a much cheaper price than Bayer's current price in the Indian market. The drug, patented by Bayer in India in 2008, is used for the treatment of liver and kidney cancer, and costs `2.8 lakh for a month's dosage. While granting the Compulsory Licence under Section of 84 of the Patent Act, the office of the Patent Controller directed that Natco to sell the drug at a price of `8,880 for a month's dosage. As per the order, Indian company will also have to pay a six per cent royalty on net sales to Bayer. The issue of compulsory licence for the manufacture of an expensive cancer drug is not only welcomed by the Indian pharmaceutical sector but also thousands of cancer patients in the country. The Patent Controller's order is the first bold step towards using the flexibilities provided under TRIPS against the abuse of patent rights. For Indian generic companies, the order is a major morale booster and can encourage them to fight monopoly pricing policies of the multinationals in India.

The outburst of the US government at India's decision is understandable considering the steadily declining profitability of the pharmaceutical giants in the US and Europe. World's top multinational drug companies are facing a major crisis today with many of their patents getting expired and very few blockbusters are in the pipeline. The US objection to India's decision to grant CL is only a result of the unwarranted pressure put by the desperate MNCs on the US government. The US government is wrong in objecting to the legitimate use of the provisions in the TRIPS agreement. The Indian Patent Act 1970, provides for grant of CL to third party starting from Section 83 to Section 94. Section 83(b) of the Patent Act clearly states that patent are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. The Section 83(g) of the Act says that patents are granted to make benefit of the patented invention available at reasonably and affordable prices to the public. The CL was granted to Natco in consideration of these provisions. Now, the order of the Patent Controller has been already challenged by Bayer and it has to be decided by the Intellectual Property Appellate Board. Be that as it may, the Central government is quite firm that in case of highly expensive patented drugs, the option of CL should be used in future as well in the interest of public health.