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Alerts

Compulsory License Granted to Indian Pharmaceutical Company

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On March 12, 2012, India's Patent Office approved an application by Natco Pharma Limited for a compulsory license to sell a generic version of Bayer AG's kidney and liver cancer drug Nexavar. In 2008, Bayer had filed and was granted a patent on the drug. Also, Bayer had refused to grant a voluntary license to NATCO previously.

This is the first time that an Indian company has been granted a compulsory license under the Indian Patent Act of 2005, which allows the government to require patent holders to grant licenses to third parties. The Patent Act allows any interested person, after three years from the grant of a patent, to make an application for a compulsory license on the grounds that (i) reasonable requirements of the public with respect to the patented invention have not been satisfied; (ii) the patented invention is not available to the public at a reasonable price; or (iii) the invention is not exploited commercially to the fullest extent in India. In its order, the Patent Office reasoned that Bayer had not met the reasonable requirements of the public with respect to Nexavar. It also concluded that Bayer had not exploited the drug commercially to the fullest extent in India or manufactured it to a reasonable extent in India, and that the drug was not available at an affordable price.

NATCO is now legally allowed to make the generic version of the drug, but has to pay a royalty of 6% of net sales of the drug to Bayer every quarter. The compulsory license, which is valid until 2021, allows NATCO to sell its version of the drug, at a price not exceeding 8,880 rupees (approximately $178) as compared to 284,428 rupees (approximately $5,600) that Bayer charges for Nexavar.

Compulsory licenses were provided for under the TRIPS agreement of the WTO and have been used in developing countries like Thailand and Brazil in the pharmaceutical industry. The granting of the compulsory license and a proposed drug-pricing policy by the Indian government has caused concern among multinational pharmaceutical companies that have been trying to strengthen patent protection in India.

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