

ClientAlert

India Practice/Pharmaceutical and Healthcare Practice

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Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies



The Controller General of Patents Designs and Trademarks of India ("Controller") recently granted Natco Pharma Limited ("Natco"), an Indian drug manufacturer, a compulsory license for Bayer AG's ("Bayer") Nexavar (sorafenib), an oncology drug that extends the patient's life but does not cure the underlying condition.

The Controller found Nexavar eligible for compulsory licensing under Section 84 of the Indian Patent Act because (1) the drug was not meeting the reasonable requirements of the public, (2) the drug was not reasonably affordable and (3) the patent was not being sufficiently "worked" in India because it was not locally manufactured.

The Controller's order is subject to appeal. Unless the standards applied by the Controller in the Nexavar case are reversed, there is a significantly increased risk that a number of other patent-protected drug products would be subject to similar compulsory licensing in India.

The Controller held that:

- Bayer had made the drug available to a small percentage of eligible patients (approximately slightly above 2 percent), which did not meet the requirements of the public
- The price of Rs 280,000 per month (approximately US\$5,600) was not "reasonably affordable." The term "reasonably affordable" had to be construed predominantly with reference to the purchasing power of the public
- Natco may sell the drug within India at a price of not more than Rs 8,800 (approximately US\$176) for a pack of 120 tablets required for one month's treatment
- Bayer's patent was not being "worked" in India as Nexavar was not being manufactured in India. Importation from manufacturing facilities outside India did not satisfy the mandatory requirement of working the patent in India
- Natco is required to pay a 6% royalty to Bayer

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Implications of the Controller's Ruling

Compulsory licenses can be granted within a relatively short time-period following application (as little as seven months in the Nexavar case), and applications can be made three years after sealing of the patent in India. Patentees should review their product portfolios to identify vulnerable drug candidates and institute appropriate protective measures to preserve their patent rights against compulsory licensing applications. Such applications could be filed by even current partners of patentees. Patentees concerned about the requirement that the drug be manufactured in India should discuss with their government whether this requirement is consistent with India's obligations under international trade agreements, including the nondiscrimination provisions of the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Affected parties may be able to seek relief under applicable bilateral investment treaties with India depending on the residence of the affected parties and the language of the relevant treaties. Patentees should pay particular attention to structuring their activities in India so as to benefit from the protections afforded by numerous bilateral investment treaties that India has entered into.

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