# India - Natco Pharma seeks compulsory licence under Bayer's 'Nexavar' patent

The pharma war in India recently took a new turn when local generics manufacturer Natco Pharma Ltd (Natco) applied for a compulsory licence under one of Bayer's anticancer drug patents. Natco's application is likely to be followed closely by all patent owners with an interest in the Indian market.

**Background**

Bayer holds an Indian Patent (215758) for the chemotherapy drug sorafenib tosylate, which it manufactures under the trade name Nexavar. The drug is used to treat liver and kidney cancer. Earlier this year, Bayer commenced infringement proceedings against both Natco and another local generics manufacturer, Cipla Ltd, As well as defending the action, Natco applied for a compulsory licence.

Section 84 of the Indian *Patents Act* provides that an interested person may apply for a compulsory licence to work the patented invention on any of following grounds:

1. that the reasonable requirements of the public with respect to the patented invention have not been satisfied;
2. that the patented invention is not available to the public at a reasonably affordable price; or
3. that the patented invention has not been worked in the territory of India.

**Natco's application**

Natco's application is based on an allegation that the patented drug is not available to the public at a reasonably affordable price. It states that three years have elapsed since grant of the patent and that, during that time, Bayer has failed to work the invention in India, with the result that the drug is not available to the public at a reasonable price, and the reasonable requirements of public have not been met. Natco has stated that it intends to exercise the licence only within the territory of India: the generic version will not be exported.

Bayer's Nexavar is priced at Rs. 2.85 lakhs (approx. US$ 5800) for a one month course, whereas Natco plans to sell its generic version, for just Rs. 8,900 (US$181).

The application as filed has been published in the Patent Office Journal dated 12 August 2011. Any interested party may file a notice of opposition within two months of that date. This time period may be extended on request. The notice of opposition must be accompanied by a statement and evidence in support of the opposition and, where it has been filed by the patentee, the terms and conditions, if any, upon which it would be prepared to grant a licence.

The Controller shall decide on the grant of the compulsory licence after giving both parties an opportunity to be heard.

Interestingly, one of the criteria to be taken into account by the Controller (s. 84(6) (IV)) is whether the applicant has made a reasonable effort to obtain a licence from the patentee on reasonable terms and conditions. In this respect, Natco had, in December, sought a voluntary licence for its generic version, and Bayer had refused without any discussion.

**Our Comment**

As this is the first compulsory licensing application of its kind in India, it is difficult to predict how it will be viewed by the Indian Patent Office. More clarity will emerge with time as the application proceeds to the next stages and Bayer's response is revealed. The grant of a compulsory licence to Natco would certainly open the door for other generics manufacturers to apply for compulsory licences, but its likely impact on R&D based pharma majors, and on other patentees, remains to be seen.

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