India – boost to generics industry - IPAB approves compulsory licence under Bayer's 'Nexavar' patent

The Intellectual Property Appellate Board (IPAB) has refused to allow Bayer's appeal against the grant of a compulsory licence under its 'Nexavar' patent. The decision is controversial: while it appears to support the Indian government's aim of making essential drugs available at an affordable price, patent owners believe it undermines their patent rights and discourages investment in research. They also believe it will inhibit the growth of an innovation culture in India.

The matter may not, however, rest there. It is rumoured that Bayer intends to appeal to the Mumbai High Court.

Background

Bayer's 'Nexavar' product is a cancer drug supplied in India at a cost of approximately Rs 2.85 lakhs per month (approx. US$5,500). Natco Pharma Ltd (Natco) obtained a compulsory licence, India's first in the post-TRIPS era, for the manufacture of a generic version of the drug, to be supplied at approximately Rs 8,900 per month (approx US$160). The licence was granted on the basis that Bayer had failed to make the drug available to the public at a reasonably affordable price and that it had not sufficiently 'worked' the patent in India. For further details of the grant see our earlier Alerts 391 and 394.

The IPAB decision

The appeal was heard by a panel of two IPAB members: Justice Prabha Sridevan, Chairman; and DPS Parmar, Technical Member (Patents).

Overall, the Board seems to have upheld the Controller's view that the drug should be made "affordable and available" to the public. While reading the decision in an open court on 4 March 2013, Justice Prabha Sridevan, said, *"[Bayer's]…kidney and liver cancer drug should be available at an affordable price to everybody"* and observed, *"In three years, Bayer has not taken any steps in revising the marketing strategy and cutting the price of the product"*. Regarding the working of patent, however, it seems to have differed slightly from the Controller who held that *'working' under section 84 cannot include mere imports; given that Bayer was merely importing Nexavar capsules into the country, it could not be said to have 'worked the patent'*. The IPAB took the view that 'working' is a flexible term and can also admit of 'imports' in some instances. This would depend on circumstances such as the technology in issue, whether the invention could be feasibly manufactured in India etc. It is not, however, clear whether the 'imports' in the present case would satisfy the 'working' requirement; this should be known once the formal orders are published.

The Board decided, however, to increase the royalty payable by Natco to Bayer from 6% to 7%. Bayer had sought an increase of 15%. The justification for the 1% increase will be known only when details of the order are available, but it seems that the Controller had taken into account a 30% margin being offered by Natco to its retailers. The Board also fined Natco Rs 50,000 (approx. US$900), to be donated to a cancer treatment hospital, for having presented deliberately incorrect evidence during the legal proceedings.

Our comment

While the decision has been hailed as a 'landmark victory' and a further boost for India's already flourishing $25billion generics industry, there are concerns in many quarters that without the incentive provided by exclusive rights, patent owners will not continue to invest in the expensive research and clinical trials necessary for the development of new medicines. The matter is complex and it seems that some middle way will have to be found. In the meantime, pharmaceutical companies should be reviewing this decision carefully and seeking to adapt their marketing strategies and pricing methodologies.

Vatika Towers
10th Floor Block-B
Sector-54
Gurgaon-122002
National Capital Region (Haryana)
India

Tel. +91 124 4655999
Fax. +91 124 4045047
Email info@indiaiprights.com