

Indian Patent Office grants its first Compulsory License

In a landmark judgment, Indian Patent Office has granted the country's first compulsory license to Natco Pharma Limited, a Hyderabad based pharmaceutical company, to manufacture generic versions of Bayer Corporation's patented drug Nexavar that is used in the treatment of Liver and Kidney cancer.

Last year Natco Pharma had filed the application for compulsory license with the Patent Office Nexavar stating that the German company's drug was unaffordable for the average Indian. The drug was reportedly sold by Bayer for roughly USD 5, 500 for a month's course while Natco has promised to sell its generic version for just around USD 175 for the same course.

The application for compulsory requirement was held to meet all the criteria specified in the Indian Patent Act, for the grant of CL i.e. the reasonable requirements of the public with respect to patented invention have not been satisfied; the patented invention is not available to the public at a reasonably affordable price, and the patented invention is not worked in the territory of India.

In view of the aforementioned CL was granted to Natco Pharma and it was settled that 6 percent of the net sales of the drug would be paid to Bayer by Natco.

Additionally following terms and conditions were settled by the Controller:

- The price of the patented, sold by the Natco shall not exceed Rs.8880 for a pack of 120 tablets, required for one month's treatment;
- Natco shall maintain accounts of sale etc. in a proper manner and shall report the details of sales to the Controller as well as to Bayer;
- Natco shall have the right to manufacture the patented drug only at his own manufacturing facility and shall not in any whatsoever outsource the production;
- The CL thus granted is non-exclusive and non-assignable;
- The license is granted solely for the purpose of making, using, offering to sell and selling patented drug for the purpose of treating HCC and RCC in humans within the Territory of India;

- Natco shall supply the patented drug to at least 600 needy and deserving patients per year free of cost;
- Natco shall not have the right to import the drug;
- The CL is for the balance term of the Patent;
- The license does not include any right to represent publicly or privately that Natco's product is the same as that of the Bayer's or that Bayer is in any way associated with the Natco's product.
- Natco's product must be visibly distinct from Bayer's product (e.g. in color and/or shape); the trade name must be distinct, and the packaging must be distinct.
- Bayer will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind to Natco;
- Natco is solely and exclusively responsible for its product and for all associated product liability;
- Bayer, its Directors, Officers, Employees, Agents, and affiliates shall not be held liable in any manner whatsoever for any action of Natco;
- Bayer is free to do whatever it wishes with its residual patent rights subject to the non-exclusive license to Natco; and is free to compete with Natco and to grant licenses to third parties to compete with the Licensee.

Detailed information on the same can be accessed from our website at:

<http://us2.campaign-archive1.com/?u=a0542edcb9b544bfe0160b638&id=b65b42605a&e=>