

CRUNCH TIME: COMPULSORY LICENSING IN INDIA



Pharmaceutical giant Bayer filed an appeal against the granting of a compulsory licence for Nexavar to Indian generic manufacturer Natco, but in March the IPAB dismissed the appeal, as R. Muralidharan and Ashima Katara report.

In a landmark ruling in one of the world's fastest growing pharmaceutical markets, the Intellectual Property Appellate Board (IPAB) of India upheld the compulsory licence granted to Natco Pharma Limited, an Indian drug manufacturer, for Bayer AG's Nexavar (sorafenib tosylate), an oncology palliative drug.

Natco approached Bayer for a voluntary licence which was refused. Natco then went ahead to file a compulsory licence application before the Controller of Patents on the grounds that the patentee had not worked the patent in India and the drug in question was being imported by the patentee even three years after the grant of patent; that the cost of Bayer's patented drug was Rs280,000 (\$5,000) per month and because of the high cost, only about 2 percent of the patients needing the medicines were actually buying it. Natco contended that the requirements of the Indian public were not met in a reasonable way, and that the patented invention was not available to the public at a reasonable cost.

Bayer resisted the grant of the compulsory licence, arguing that an import from other territories is very much 'working of the patent' in India. Bayer argued that it could only sell limited quantities, essentially because the generic competitor had a cheaper substitute which made it difficult for the patentee to get a market for the higher priced product.

Rejecting all Bayer's contentions, the controller granted a compulsory licence to Natco on March 9, 2012. The controller held that Bayer had made the drug available to a small percentage of eligible patients, which did not meet the requirements of the public, that the price of Rs280,000 per month was not "reasonably affordable", and that 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.

The first compulsory licence was granted to Natco on terms that price of the product sold by

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Natco shall not exceed Rs8,880 (\$160) for 120 tablets (one month's requirement). Instead of margin-based royalty as suggested by Natco, the controller fixed a sales-based royalty. Instead of a 2 to 4 percent royalty as provided under the UN procurement norms, the controller ordered 6 percent royalty on net sales, which was based on an ex-factory price minus taxes.

Bayer filed an appeal against the order before the IPAB. On March 4, 2013, the IPAB dismissed the appeal and upheld the compulsory licence granted to Natco.

The IPAB was of the view that the controller was right in holding that the sales of the drug by the appellant at the price of about Rs280,000 was alone relevant for the determination of public requirement and he was also right in considering the purchasing capacity of the public and the evidence available to conclude that the invention was not reasonably affordable to the public.

The IPAB however revised the compulsory licence order to increase the royalty payment to Bayer from 6 percent to 7 percent.

A pertinent aspect in the IPAB decision is the interpretation of the word 'working' under Section 84(1)(c). The controller, while granting the compulsory licence, had



held that importation from manufacturing facilities outside India did not satisfy the mandatory requirement of working the patent in India. The IPAB, on the other hand, held that working should be decided on a case-by-case basis and it may be proved that in a given case, the 'working' may be done by way of 'import', but this cannot apply to all cases. The patentee should show why it could not be locally manufactured. A mere statement to that effect is not sufficient and evidence must be shown.

The IPAB also made it clear that the grant of a compulsory licence is not to favour the licensee, but to make the medicine reasonably affordable and accessible to the public. The IPAB further emphasised that these proceedings are neither against the inventor, nor against the compulsory licence applicant, but purely based on public interest.

Patent-price linkage

It seems that the compulsory licence is based on public interest which is in turn related to the price of the drug. This seems to link patents to price control. A similar attempt at 'patent linkage' was made in 2009 when Bayer attempted to link the Patent Act with the Drugs and Cosmetics Act.

Incidentally, the drug product in both cases was the same (sorafenib tosylate). In the patent linkage matter, it was stated that the nodal ministry for the administration of the Drug and Cosmetics Act is the Ministry of Health and Family Welfare whereas for the Patents Act it is the Ministry of Industry and Commerce. The court held against this attempt at bringing in patent linkage.

On similar lines, the price of a drug in India is decided by the National Pharmaceutical Pricing Authority (NPPA) which is under the Department of Pharmaceuticals in the Ministry of Chemicals and Fertilisers. It is a matter of debate whether this could also be considered as patent-price linkage and on how the courts react to it.

A further development relating to compulsory licences is that a committee set up by the Department of Pharmaceuticals to examine the issues of price negotiations for patented drugs, has recently submitted its report. This report

mentions that once a government-appointed committee fixes a price for medicines which is accepted by the government, this fixed price would be supposed to be reasonable and therefore it won't be possible for the government to use the tool of compulsory licences on grounds related to the price of the patented medicine.

Bayer is said to have disagreed with the conclusions of the IPAB and is likely to approach the court. The case is set to be a crucial milestone in deciding the fate of pharmaceutical business in India in the wake of price control measures by the government. ■

R. Muralidharan is a patent attorney at Krishna & Saurastri Associates. He can be contacted at: murali@krishnaandsaurastri.com

Ashima Katara is an associate, advocate and patent agent in the life sciences department of Krishna & Saurastri Associates. She can be contacted at: ashima@krishnaandsaurastri.com



R. Muralidharan

is an advocate, mediator, law lecturer and a registered patent agent. He has a Bachelor's degree in biology and a Master's degree in

international law and constitutional law. He has participated in some of the leading patent and trademark litigations in India. He also specialises in competition law compliance and acts as a resource person regularly in professional skill improvement programmes.



Ashima Katara

has about eight years of experience in the biotech and pharma IP rights practice. Her key practice areas include patent drafting, search

and analysis opinions, patent prosecution, litigation and patent portfolio management.