



India grants first compulsory licence under Patents Act

Rachna Bakhru, partner with Ranjan Narula Associates, investigates the implications for the pharmaceutical industry in the *Natco v Bayer* case in India

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The pharma battle in India recently took a new turn when generics manufacturer Natco Pharma succeeded in obtaining a compulsory licence to manufacture Bayer's patented anti-cancer drug Nexavar. The decision, which is likely to be appealed by Bayer, raises interesting and difficult issues. While it has been welcomed by India's thriving generics industry and by members of the public who hope to see a reduction in the price of life-saving cancer and HIV drugs, it clearly creates problems for research companies.

Legal background

Since joining the World Trade Organization (WTO), India had been under considerable pressure to make its Patent Law TRIPS compliant. In 2005, it amended the law by introducing product patents, which previously had been expressly prohibited.

These amendments were strongly opposed by both India's domestic pharmaceutical industry and various non governmental organisations. The opposition was primarily driven by fear that the amendments would result in higher drug prices, low access to medicines, and weakening of the local pharmaceutical industry. As a safeguard, and to allay the fears of the local drug industry, provisions for the grant of compulsory licences were included: the government could, in certain circumstances, grant a licence for the manufacture and sale of a patented product, even though the patentee had not given its consent. This was in line with the TRIPS agreement, which allowed countries to

provide for compulsory licensing and to set their own conditions for grant.

The Indian Patent Act of 2005 provided that a compulsory licence could be granted at any time after the expiration of three years from the date of grant of a patent if:

- the reasonable requirements of the public have not been satisfied;
- the patented product is not available at a reasonable price; or
- the patent is not being fully commercially exploited.

The first application for a compulsory licence to manufacture the patented product in India was Natco Pharma's application, filed in July 2011. Prior to this, Natco in 2007 had tried to obtain compulsory licence for two anti-cancer drugs – Suninat and Tarceva – patented in India by Pfizer and Roche, respectively. Natco intended to manufacture and export the said drugs to Nepal. However, the applications did not result in anything as these were withdrawn by Natco.

The application

Natco Pharma filed its application in what was seen as a strategic move to counter an infringement action that had been brought against it by Bayer in relation to the manufacture of a generic version of its patented anti-cancer drug Nexavar. Bayer holds an Indian patent no 215758 on the drug.

Natco claimed that Bayer's patented drug had not been made available to the public at a reasonably affordable price and that the reasonable requirements of the public had not

been met. It further argued that Bayer had failed to work the patent in India within the specified three-year period.

In support of its case, Natco relied upon the fact that Bayer was importing the drug into India and selling it at an exorbitant price. Natco provided various data in support of its argument including data gathered by GLOBOCAN (the UN's cancer project), which estimated the total number of liver cancer patients in India at 20,000, and kidney cancer patients at 8,900. Given these figures, it argued that it was apparent from Bayer's statement of working that the requirements of the public were not being met. Further, given that Bayer already had manufacturing facilities in India, there was no reason for it to be importing the drug.

Bayer argued that a 'reasonably affordable price' should be calculated with reference to the public as well as the patentee: there is a class of people who can afford the drug at its present price, and it cannot be the intention of the legislature to lower the price of the drug for those who are able to afford it. Furthermore, the price of patented drugs of this sort has to be sufficient to support future drug development.

In relation to 'working' the patent in India, Bayer argued that 'worked' means supplying the drug to the Indian market on a commercial scale, not necessarily manufacturing the drug in India. The relatively small demand for Nexavar did not justify manufacture in India. In relation to meeting the requirements of the public, it acknowledged that it had been providing the drug to only 2% of the estimated number of patients in India, but maintained that

this was due to the availability of alternative cheaper drugs manufactured by Cipla and Natco.

In granting the compulsory licence to Natco, the Controller took account of the fact that Bayer had priced Nexavar at Rs. 2.85 lakhs (approx. US\$ 5800) for a one month's course, whereas Natco planned to sell its generic version, for just Rs. 8,900 (US\$181). It also took account of the fact that Natco had undertaken to maintain its price, not to manufacture for export, and to supply the drug free of charge to 600 deserving and needy patients each year. Bayer's admission that only 2% of kidney and liver cancer patients were able to access the drug and that the drug was imported and not being manufactured within India, went against it.

Issues raised by the decision

The Indian pharmaceutical industry has changed remarkably in the last 50 years: while in the fifties it consisted largely of trade in imported drugs, by the eighties it was dominated by major bulk drugs, ie pharmaceutical ingredient producers. During this period, Indian pharmaceutical manufacturers developed their expertise in bulk drug production, relying on both original research and product adaptation. Today, they produce more than 250 bulk drugs focusing, in particular, on the substitution of local for imported products and the use of indigenous raw materials. Currently, India is the world's fourth largest producer of pharmaceuticals by volume, accounting for around 8% of global production. A combination of factors such as low R&D costs and a highly skilled resource pool have contributed to this phenomenal growth. Moreover, the Indian pharmaceutical industry has prospered through the development of reverse engineering skills, which took advantage of the absence of product patents in the country.

The tension between the rights of patent owners and the need for cheaper drugs, particularly in developing countries, is not new. Research companies argue that the development and introduction to market of a new drug requires a huge investment of time, money and effort. If they are unable to enjoy the prospect of a patent monopoly that will hopefully enable them to recoup their costs and make a profit, they will be obliged to reduce the amount of R&D undertaken in future. The data from research companies indicates that the development and introduction to market of a new drug requires the originator to conduct extensive research and testing generally taking from 10-15 years at an average cost of US\$800m. On the other hand,

there is an obvious public interest in members of the public having access to potentially life-saving drugs at a reasonably affordable price.

Given the size and strength of the Indian generics manufacturing industry, it is a force to be reckoned with. Not surprisingly, this case has been keenly followed by the global pharmaceutical industry, as well as IP practitioners both in India and elsewhere. It was widely recognised that the decision would set a precedent both as to what constitutes 'working' a patent in India, and, more generally, what situations would support the grant of a compulsory licence.

The decision overall appears to tilt the scales in favour of the generic manufacturers and is likely to be challenged by Bayer on several grounds including that the Indian Patent Act does not define 'working of the patent in India' to require that the patented product is manufactured in India and importation of

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the product does not suffice. It will further challenge the decision on the grounds that the Controller failed to determine a notional price which was reasonable and affordable. While the Controller accepted Natco's price, the same may not be affordable for some sections of society. As mandated in the Indian Patents Act, the Controller has a duty to find out if the price stated by Natco is a reasonable one. It is arguable whether the demand for the patented invention has to be satisfied by the patentee or its licensee and not by a third party as in the instant case.

Although, consistent with TRIPS, the Patents Act provides that one of the factors to be taken into account in granting a compulsory licence is whether considerable efforts have been made to obtain a voluntary licence. Here a licence was granted after Natco had made only one attempt to obtain a voluntary licence. Again, the Controller appears to have adopted an approach more favourable to the applicant than has been the case in other countries. In Brazil, for example, a compulsory licence for the supply of the anti-retroviral Efavirenz was granted only after the government had had about 16 unsuccessful meetings with

the patentee in an effort to negotiate an appropriate reduction in the price of the drug.

Analysis

Given the likelihood of an appeal, it is not possible to predict the long-term effect that this decision will have on the industry. Certainly, research companies fear a likely surge in the number of compulsory licence applications being filed. Few sections of industry, however, believe that large-scale filing of compulsory licence applications is likely to be sustainable, given the cost of litigation and the lengthy appeal process. Foreign R&D drugs companies have shown their disappointment in the decision and indicated that it could both jeopardise India's position as a potential market for the launch of new drugs and discourage innovation. Some even speculate that invoking such provisions more often would gradually result in a drying-up of investment in the pharma sector in India.

Nevertheless, there are some lessons to be learnt, suggested by the decision itself, which research companies should be considering in the meantime, with a view to pre-empting compulsory licence applications. In some situations, it may be desirable to enter into appropriate licensing arrangements to ensure more effective distribution of the patented product, and in others it may simply help the patentee to keep the potential licensee engaged in negotiations as opposed to outright rejection. By licensing rather than being forced to license, patentees can negotiate the terms of the licence. It may also be possible to introduce differential pricing structures for different sections of the public or working out some mechanism for providing drugs to those who genuinely cannot afford them.

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