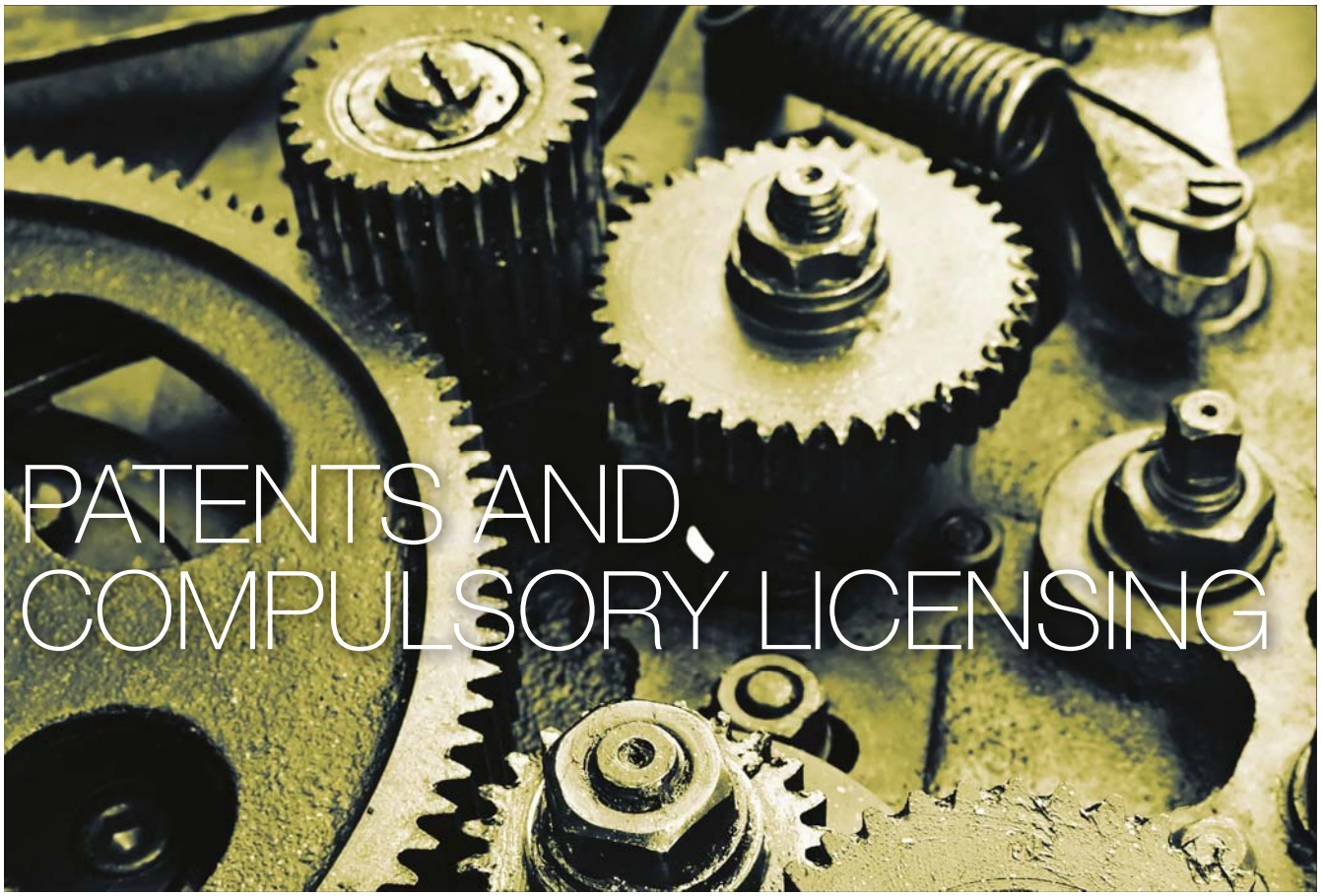

PATENTS AND COMPULSORY LICENSING

Patents in India are granted to encourage inventions and ensure their commercial exploitation. But compulsory licences could threaten the integrity of the system. Vikrant Rana takes a look.

The Patent Act provides compulsory licensing measures to ensure that the patents do not impede the protection of public health and nutrition, and that the patent rights are not abused by the patentee. The compulsory licence therefore serves to strike a balance between two disparate objectives—rewarding patentees for their invention and making patented products, particularly pharmaceutical products, available to large populations in developing and underdeveloped countries at a cheaper and affordable price.

Grant of compulsory licence under Section 84

Any interested person, under Section 84 of the Patent Act, may make an application for the grant of a compulsory licence three years after the date of grant of the patent on the grounds that:

- The reasonable requirements of the public have not been satisfied
- The patented invention is not available to the public at a reasonably affordable price, or
- The patented invention is not worked in the territory of India.

Section 83 of the Patent Act implies that the patent's function cannot include 'imports'. The patentee cannot hold the patent in India and import the product from another country, thereby compelling the Indian consumer to pay an excessive price.

It is interesting to note that, under Section 146, the information that a patentee is required to submit regarding the extent to which the patented invention has been commercially used in India also specifies details regarding importation from other countries.

While Article 27.1 of TRIPS deems importation of goods as equivalent to use of a patent, Article 5B of the Paris Convention allows lack of local use as a ground for issuing compulsory licences.

In India, people are divided on whether or not the ambit of use should include importation. Some believe that use should include importation as well, because it is not possible for every company to establish its manufacturing base in each country where a patent has been granted, as this would result in the end product becoming more expensive. Others believe that the current laws for grant of compulsory licences encourage patent holders to collaborate with local companies to manufacture in India. This brings down manufacturing costs and helps local industry.

Grant of compulsory licence for export

Article 31(f) of the TRIPS agreement undermined the availability of medicines to countries with less or no manufacturing capacity through importation from other countries. WTO adopted a mechanism to resolve this problem by implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on August 30, 2003. The obligation under Article 31(f) of the TRIPS agreement was waived in cases of export of pharmaceutical product to the countries with little or no manufacturing capacity.

The Indian Patent Act was therefore amended on January 1, 2005 and Section 92(a) was incorporated for grant of compulsory licences for exporting pharmaceutical products in certain exceptional circumstances.

The compulsory licence under this section can only be granted if the importing country has also granted one or has, by notification or otherwise, allowed importation of the patented pharmaceutical product from India. However, the developing countries with no patent regime are only required to notify the WTO council of their willingness to import the pharma product subject to paragraph 6 of the Doha Declaration.

It is worth noting that Section 92(a) does not define 'public health problems'. This clearly implies that the exporting country may invoke a compulsory licence under the section even when there is no emergency in the importing country. This can have several implications for the rights of the patentee, and could allow generic companies of the exporting countries to make unethical commercial gains.

Scenario in India

Earlier this year, pharma company Cipla applied for a 'voluntary licence' for Merck's anti-HIV drug Isentress. Natco Pharma had sought a similar voluntary licence from Pfizer to make and sell 'copies' of the US company's HIV medicine in India. Both of the companies cited similar reasons—that the drugs were exorbitantly priced and were inaccessible to Indian patients. If denied voluntary licences, both firms would have the option of applying for a compulsory licence to the Controller General of Patents.

> "COUNTRIES SHOULD BE RESTRICTED FROM MAKING COMPULSORY LICENCES AN INSTRUMENT OF COMMERCIAL POLICY."

Natco Pharma was also the first company in India to file an application for a compulsory licence in 2008 under Section 92(a), to manufacture and export to Nepal, generic versions of two patented drugs: F Hoffman La Roche Ltd's lung cancer drug Tarceva and Pfizer Inc.'s renal cancer drug Sutent. There were several deficiencies in the application, including the import requisition received from the Nepal government being in a language not recognised by Indian patent rules. The application was withdrawn.

Recently, Natco also applied for a compulsory licence, under Section 84, for Bayer's patented drug Nexavar, used for the treatment of liver and kidney cancer. Nexavar is presently available in the market at approximately $6,299 for a month's course. Natco has proposed to sell its generic version, Sorafenib Tosylate, for just about $196. It is alleged that 2.5 million cancer patients in India stand to benefit from this generic drug.

It is interesting to note that so far no compulsory licence has been issued in India. Even when the country was badly affected by Bird Flu in 2006, it refrained and placed an order for Tamiflu with Roche, the original manufacturer of the drug.

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As compulsory licences are picking up at the international level, laws and regulations need to be properly defined to balance the rights of the patentee and requirements of the public.

Arbitrage is one matter of concern. Arbitrage occurs when a patented drug is imported to a market where it is priced low and then re-exported to a market where it is priced higher, without the consent of the patent holder.

Countries should be restricted from making compulsory licences an instrument of commercial policy.

The importing countries also need to ensure that 'reasonable measures' are taken to avoid any counterfeiting of drugs.

Generic companies should be discouraged from exploiting the process and using it to generate revenue.

The issue of adequate remuneration for a patentee needs consideration. The rate of royalty should be determined only after thorough evaluation of R&D cost.

Keeping in view the cost and time spent on the research and development of any new drug, granting of compulsory licences without addressing these key issues would be a major setback for the drug discovery and development programmes in India and abroad. ■

Vikrant Rana is a partner, advocate and patent attorney at SS Rana & Co. He can be contacted at: vikrant@ssrana.com

Vikrant Rana has over 15 years of experience in intellectual property law. He has advised many Fortune 500 companies and some of the world's most esteemed corporations for more than a decade, on a range of contentious and non contentious IP matters. He assists clients in filing applications, in India and abroad for the protection of their intellectual property. He has delivered lectures and presentations at several seminars and conferences on intellectual property and related issues organised at national and international platforms. He is also a member of several national and international IP organisations, including INTA, APAA and AIPPI.