Kluwer Patent Blog

Compulsory License: India

Radhi Shah (USC Gould School of Law) · Monday, August 16th, 2021

Legal basis

The legal basis for compulsory licenses can be found under the Indian Patent Act, 1970 (Indian Patent Act), Chapter XVI, read with Indian Patent Rules, 2003 (Indian Patent Rules).

Requirements for obtaining a compulsory license

Compulsory licensing under the Indian Patent Act is well codified and is in line with international agreements. The purpose behind granting a compulsory license is to maintain the working of patented inventions on a commercial scale in India so that the interest of any person working or developing an invention is not prejudiced.

Section 84 (1) of the Indian Patents Act, 1970, provides the objective behind compulsory licenses and requires that when granting the same, the general considerations enunciated in this section be focused upon. The Indian Patent Act imposes a duty on the patentee to work the patent in India. Under the Indian Patent Act, compulsory license can be granted after the expiration of a period of three years from the date on which the patent has been granted. The grounds include:

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

Under the Indian Patent Act, the reasonable requirements of the public are deemed not to have been satisfied where:

- The patentee refuses to grant a license or licenses on reasonable terms; and
    - a trade or industry is prejudiced; or
    - demand for the patented article has not been met to an adequate extent; or
    - a market for exportation of the patented article manufactured in India is not being supplied or developed; or
    - the establishment or development of commercial activities in India is prejudiced.
- The patentee imposes a condition on the patented invention;
- Non-working of the patent in the territory of India;
- Working of the patented invention in India on a commercial scale is prevented by the importation from abroad.

Section 146 (2) of the Indian Patent Act requires every patentee and licensee to provide information on the extent to which the patented invention has been worked on a commercial scale in India.

Relevant information is submitted by patentees and licensees with Form 27. It is required to be filed every calendar year, within three months of the end of each year.

The information includes the following:

- Whether the invention has been worked;
- If not worked, the reasons for non-working, and steps being taken to work the invention;
- If worked, quantum and value of the patented product;
- If manufactured in India;
- Whether imported from other countries, giving details of the countries concerned;
- Licenses and sub-licenses granted during the year;

Whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

Failure to supply such information creates a presumption of non-working and may contribute in grant of a compulsory license. It is also a punishable offence and invites a fine which may extent up to 10 lakh (13,361.84 USD, at Rs. 74.84 to a USD). Knowingly furnishing false information is an offence punishable with imprisonment up to six months, a fine or both.

Under section 92(1) of Indian Patent Act, a compulsory license can be granted Suo moto by the Central Government in circumstances of:

- National emergency; or
- Extreme urgency; or
- In ease of public non-commercial use.

In order to give effect to the paragraph 6 of Doha Declaration which recognizes WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory license under the TRIPS Agreement, the Indian Patent Act was amended to insert a new provision, section 92-A, on compulsory licensing for manufacturing and exportation of patented pharmaceutical products into any country that does not have sufficient manufacturing capability to address public health problems. Exportation is allowed mainly to those countries where a compulsory license has been granted where such countries have notified or otherwise allowed the importation of patented pharmaceutical products from India.

Under Section 100 of the Indian Patent Act, compulsory license can be issued by the Government on a patented drug for use by the Government. The Bombay High Court in the case of *Garware Wall Ropes Ltd. Vs. A.I. Chopra and Konkan Railway Corp.* allowed third party agencies to use a patented invention on behalf of the Government.

Under section 102 of the Indian Patent Act, Government can obtain a pending or already granted patent for public use. In return the Government must pay the patentee royalties as mutually agreed upon between the parties.

Procedure for granting a compulsory license

Any party interested in obtaining the compulsory license may file a request online or on paper via Form 17, along with fees prescribed with the Indian Patent Office. It is required that the form 17 state nature of the applicant's interest along with facts and particulars on which the application is based.

Under section 87 of the Indian Patent Act, upon filing the application for grant of compulsory license, the Controller at the Indian Patent Office (Controller) shall analyze the prima facie case made by the applicant against the patentee. The Controller takes into consideration:

- The nature of the invention;
- The applicant's ability to work the invention;
- Whether the applicant made any efforts to reasonably obtain a license from the patentee;
- If such efforts have not been successful within a reasonable time period.

A notice will be issued to the applicant if the Controller is unsatisfied with the request and will provide a statement rejecting the compulsory license. The applicant may request a hearing with the Controller, within a month from the date of notice of rejection. At the conclusion of the hearing, the Controller will decide the matter.

If the matter is decided in favor of the applicant, necessary terms and conditions shall be decided for granting of the compulsory license. The royalties to be paid to the patentee will be decided by the Controller. The patentee's investment in the invention, workability of the patentee's invention by the applicant, the selling price of the patented article, and terms of the license will be considered.

However, the procedure mentioned in Section 87 shall not apply after considering the application when the Controller determines that a national emergency or a circumstance of extreme urgency exists.

Opposition to the grant

The patentee or any other person desiring to oppose the application for the grant of a compulsory license may, within the prescribed time (i.e. two months from the date of publishing the application in the Official Journal of the Indian Patent Office), file a notice of opposition via Form 14, along with prescribed fee. Upon notice being served, the Controller will notify the applicant and give both, the applicant and the opponent, an opportunity to be heard before deciding the case.

Termination of compulsory license

A patentee or any other person possessing title or interest in the patent may apply to the Controller using Form 21 together with any evidence requesting to terminate the compulsory license granted under Section 84.

Appeal/Review

An appeal of the Controller's decision to grant or deny a compulsory license can be made to the Appellate Board. The appeal can be held under:

- Sections 84 (1)-(5) Compulsory License;
- Section 85 Revocation for non-working of invention;
- Section 91 Licensing of related patents;
- Section 92 Special provisions for Compulsory License on notifications by Central Government; or
- Section 94 Termination of Compulsory License.

Jurisprudence

BDR Pharmaceuticals v. Bristol-Myers Squibb

The following case illustrates licence sought for Sprycel® which is used in cancer treatment

On March 4, 2013 the Controller rejected BDR Pharmaceuticals' (BDR) application for a compulsory license for the cancer drug Sprycel®. The controller stated that BDR failed to make a prima facie case for the grant of compulsory license. Specifically, the Controller found that BDR had made no credible attempt to procure a license from the patent holder and the applicant had not acquired the ability to work the invention to public advantage. Thus, the compulsory license was denied.

Lee Pharma v. AstraZeneca

The following case illustrates license sought for Saxagliptin® which is used in the treatment of Type-II Diabetes Mellitus

On June 29, 2015, Lee Pharma filed an application for compulsory license for patent covering Astra Zeneca's diabetes management drug Saxagliptin®. The application was rejected stating that no prima facie case had been made out on any of the three grounds under section 84 (1) of the Indian Patent Act.

Reasonable requirements of the public had not been satisfied: Lee Pharma failed to demonstrate reasonable requirements of the public with respect to Saxagliptin® and further failed to demonstrate the comparative requirements of the drug Saxagliptin® vis-à-vis other drugs.

The patented invention was not available to the public at a reasonably affordable price: It was held that all related drugs were in the same price range and that Saxagliptin® being sold at unaffordable price was not justified.

The patented invention had not been worked in the territory of India: Lee Pharma also failed to show the exact quantitative requirements of Saxagliptin® in India. Therefore, it could not be concluded whether manufacturing of the drug in India was necessary or not.

Bayer Corp. v. Natco Pharma

The following case illustrates license sought for Nexaver® used in the treatment of advanced liver and kidney cancer

In 2012, India's first ever compulsory license was granted by the Indian Patent Office to Natco Pharma for generic production of Bayer Corp's Nexaver® (Sorafenib Tosylate), a life-saving medicine used for treating liver and kidney cancer. Bayer sold this drug at a very high rate with one month's worth of treatment costing around Rs. 2.8 Lakh (3,737.89 USD, at Rs. 74.84 to a USD). Natco Pharma offered to sell the drug for Rs. 9000 (120.15 USD, at Rs. 74.84 to a USD) making it affordable for general public. Thus, all the three conditions of Section 84 of the Indian Patent Act were fulfilled.

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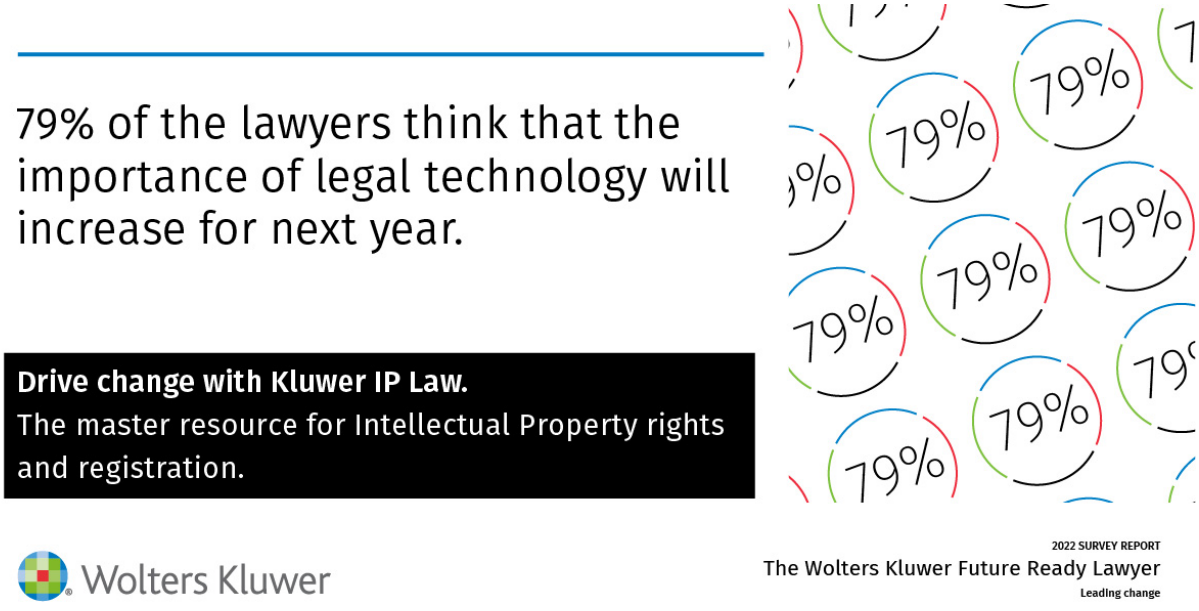

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