

Reading Resource: Patent Law - Assignment, Licenses, and Compulsory License

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1. Introduction

A patent holder may transfer his rights in the patent to any person at any time before the grant of the patent. Such a transfer is achieved either through a license or assignment.

In case of a license, the person granting the license (licensor) generally **retains an interest in the patent**, whereas in case of an assignment, the assignor **transfers his patent rights to another person or entity**.

An **assignment or a license of a patent** or a share in a patent must be in writing, must embody all the terms and conditions governing the rights and obligations between the parties, and must be duly executed. For the assignment to be valid, registration of the document is not mandatory.

2. Working of patents

Grant of patents serve a useful purpose in the encouragement and development of new technology and industry in the State. The temporary monopoly is not considered objectionable, for if it had not been for the inventor who devised and disclosed the invention nobody would have been able to use it.

However, as part of the *quid pro quo*, an inventor must not misuse the patent monopoly and must work the invention to the fullest extent possible on a commercial scale without undue delay to justify a blanket monopoly of 20 years.

Further, the patent system must facilitate transfer and dissemination of technology. Further, patents granted must not impede protection of public health and should act as an instrument to promote public interest. Patent rights must not be abused by the inventor/patentee.

The Government lays a lot of thrust on working of patents and requires every patentee to furnish details of the extent to which the patented invention has been worked in the territory of India. Such details must be furnished in **Form 27**. The Controller may also require a patentee to furnish such information. However, it has been observed that such a requirement is not always complied with by all patentees.

In 2015, a petition¹ was filed in the Delhi High Court seeking directions against the Patent Office and other authorities to compel patentees and licensees to furnish adequate and complete information pertaining to working of patents in India. The Court ordered the Respondent authorities to take necessary steps to ensure compliance of requirements pertaining to working of patents.

To comply with these directions, the Government proposed a few amendments to the filing and submission procedure of Form 27. As per this new procedure, this statement has to be filed every year in compliance with the amended form 27 where the patentee needs to furnish:

- Whether the patented invention has been 'Worked' or 'Not worked'. If not worked, reasons for not working and steps being taken for working of the invention. If worked, quantum and value (in Rupees), of the patented product manufactured in India/ imported from other countries.
- Whether any licenses and sub-licenses are granted during the year;

¹ *Shamnad Basheer v. Union of India* (W.P.(C)5590/2015).

- Whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

3. Compulsory Licenses

A compulsory license is a license granted by the Government to a third party without the authorization of the patentee. Compulsory licenses may be granted on an application made before the Controller any time after the expiry of three years by an interested person under Section 84. Conditions for grant of a compulsory license are described hereinbelow:

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

a. Reasonable requirements of the public

The Patents Act prescribes a list of circumstances in which reasonable requirements of the public will be deemed not to have been satisfied:

- if due to refusal of the patentee to grant a license on reasonable terms:
 - the trade or industry in India or its development or establishment is prejudiced; or
 - demand for the patented article has not been met to an adequate extent or on reasonable terms; or
 - an export market of the patented article manufactured in India is not being supplied/developed; or

- the establishment or development of commercial activities in India is prejudiced; or
- if due to the restrictive conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process:
 - the manufacture, use or sale of non-patented products in India is prejudiced; or
 - the establishment or development of any trade or industry in India, is prejudiced; or
- if the patentee imposes any of the following conditions in the license:
 - exclusive grant back²of rights on improvements in the patented product or process; or
 - prevention to challenge to patent validity; or
 - coercive package licensing³;or
- if the patented invention is not being worked in the territory of India to the fullest possible extent or on a commercial scale to an adequate extent; or
- if the working of the patented invention in India on a commercial scale is being prevented or hindered by the importation from abroad of the patented invention by:
 - the patentee or persons claiming under him; or
 - persons directly or indirectly purchasing from him; or
 - other persons against whom the patentee is not taking or has not taken infringement action.

² An exclusive grant back clause is a clause that requires the licensee to grant back a license with respect to any rights over the improvements to the patent holder.

³ When a patent owner licenses a patent, there may be a requirement of licensing more than one patent in order to commercialize the invention. If the patentee compels the licensee to take license for patents even if it is not required by the licensee, such a license is called a coercive package license. \

b. Reasonably affordable price

The price of the patented invention must be reasonable and must not be beyond the reach of the general public.

c. Working in India

The patented invention must be worked in India on a commercial scale without undue delay and to the fullest extent that is reasonably practicable.

d. Procedure for grant of Compulsory License

- As indicated earlier, any interested person may make an application for grant of compulsory license after the expiry of three years from the date of grant of the patent. The said application can also be filed by a person who already holds a license under the patent.
- The application must state the nature of the interest of the applicant, the facts in support of the case and the conditions which the applicant is willing to accept. The said application should be filed in Form 17.
- After reviewing the application, if the Controller is satisfied that a *prima facie* case has been established by the applicant, he will direct the applicant to serve copies of the application upon the patentee and any other person having interest in the patent.
- Thereafter, the application is published in the official journal.
- The patentee or any other person may oppose the application by filing the notice of opposition within two months from the date of publication. The said notice of opposition shall contain a statement setting out the grounds on which the application is opposed, terms and conditions of the application acceptable by the applicant and necessary evidence in support of the opposition.
- The said notice of opposition is served on the applicant.

- The Controller then fixes a date and makes a decision on grant of compulsory license after giving all parties an opportunity of being heard.
- If the Controller is satisfied that a *prima facie* case has not been established, he will notify the applicant. The applicant can request a hearing at this stage. After hearing the applicant, if the Controller is satisfied that a *prima facie* case has been established, he may publish the application, otherwise the application will be refused.

While deciding the application for grant of compulsory license, the Controller will take into account the following factors:

- the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;
- the ability of the applicant to work the invention to the public advantage;
- the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;
- efforts made by the applicant to obtain a licence from the patentee on reasonable terms and conditions within a reasonable period of six months.

Such factors shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee before the date of application. In such cases, the Controller grants a license in an expedited manner.

On deciding to grant a compulsory license, **the Controller** will determine the terms and conditions of such a license. While granting a compulsory license, the Controller needs to ensure that patented inventions are worked on a commercial scale in India and that the interests of any person working or developing the invention in India is not prejudiced in an unfair manner.

The holder of a compulsory license may make an application for revision of the terms and conditions of the compulsory license after 12 months from the date of grant of the license, if the working of the patented invention, under the existing terms and conditions, gives rise to loss. The Controller may allow or reject such an application after hearing the applicant.

India's first ever compulsory license was granted by the Patent Office in 2012 to Natco Pharma to sell Bayer's patented drug 'Nexavar' for treatment of liver and kidney cancer⁴.

The Controller of Patents was satisfied that all three criteria were satisfied in the said case, namely:

- Based on Bayer's own admission, the Controller found that only 2% of the total number of kidney and liver cancer patients were able to access the drug. Thus, the Controller held that the reasonable requirements of the public with respect to the patented invention have not been satisfied.
- The Controller held that Bayer's pricing of the drug (INR 2.8 lakhs for a therapy of one month) was excessive and did not constitute a reasonably affordable price. He further held that "*reasonably affordable*" price had to be construed predominantly with reference to the public.
- The Controller found that mere importation of Bayer's drug into India did not amount to "working" under the Act.

The said order was confirmed right till the Supreme Court.

In subsequent cases of compulsory licensing in India, the Controller rejected an application for grant of compulsory license made by BDR Pharmaceutical Ltd.(BDR) for BMS' cancer drug 'Sprycel' holding that BDR had failed to establish a *prima facie* case. The Controller held that BDR had not made an attempt to procure a voluntary license from BMS. In another case, the Controller rejected Lee

⁴ Bayer Corporation v. Union Of India, Writ Petition No. 1323 of 2013.

Pharma's application for grant of compulsory license against AstraZeneca's diabetic management drug 'Saxagliptin'. The Controller held that Lee Pharma failed to show what the reasonable requirement of the public was with respect to 'Saxagliptin'. Further, all similar drugs were in the same price bracket as the patented invention.

The Controller also held that Lee Pharma failed to show the exact number of patients being prescribed the patented drug and how many of them were unable to obtain it due to its non-availability and consequently it was difficult to hold whether manufacturing in India was necessary or not. Thus, the application was rejected.

4. Conclusion

The objective of a patent grant is not only to encourage creation and progress of technology but also to promote commercial working of such inventions in India.

India's compulsory licensing regime has often been criticized for being detrimental to the interests of the patentees. It is generally argued that the India government should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patentee on reasonable commercial terms and conditions.

However, the trend, as visible from the above cited case laws, clearly shows that India has sparingly used its compulsory licensing regime. Thus, such criticism is devoid of any merit and is not warranted. Provision pertaining to compulsory license exists in almost all countries as it ensures that monopoly rights conferred under patent law are not abused by the patentee.

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