IP Hotline

July 06, 2011

PUBLIC ACCESS TO THE DATA OF WORKING OF PATENTS IN INDIA...

The Patent Office of India has decided to publish the details of working of the patented drugs on its website[1]. These details will be obtained from Form 27 (under the Second Schedule of the Patent Rules, 2003), a statutory format to be filed by the patentee annually on or before March 31, providing details regarding the working of the granted patents in the preceding calendar year. The information that is required to be submitted includes the quantity and value of the patented product manufactured or imported into India, the licenses and sub-licenses granted. In this form, the patentee is also required to declare whether to the best of its knowledge and information the public's requirement (in relation to the patented product) is met at a reasonable price or not. Failure to submit Form 27 and furnishing inadequate or incorrect information are punishable offences under the Patents Act with a penalty of up to Rs. 10 lakhs per patent. Please refer to our earlier hotline. (https://nishithdesai.com/SectionCategory/33/IP-Hotline/12/66/IPHotline/5807/1.html)

This move by the Patent office will make the data easily available to the general public, which otherwise could have been procured only by way of an application filed under the Right to Information Act.

As a result, domestic companies capable of producing the same products may use this information to evaluate whether they should opt for obtaining a compulsory license to meet the domestic demands if the patentee is not in a position to fulfill the demands.

BACKGROUND OF COMPULSORY LICENSE

The primary purpose of grant of patents is to encourage invention and provide an exclusive incentive to the patentee to commercially exploit the patented invention to the maximum possible. A compulsory license would be granted if the exclusive right is not exploited. The compulsory license provisions are intended to help the government achieve balance between the twin objectives of rewarding innovation and in cases of necessity, to make the product available to the public. The TRIPS also recognizes the need to grant compulsory license in certain circumstances.

Chapter XVI of the Indian Patent Act, 1970 ("**Act**") provides for grant of compulsory license of patents to third parties in certain circumstances. An application can be made only after the expiry of 3 years from the date of grant of the patent and if the voluntary license has been refused to the applicant by the patentee. The grounds under which the compulsory license may be sought and granted, inter alia, include situations where:

- The reasonable requirements of the public with respect to the patented inventions have not been satisfied, or
- The patented invention is not available to the public at reasonably affordable prices, or
- The invention is not exploited commercially to the fullest extent within the territory of India.

Once an application has been made, the Controller of Patents ("**Controller**") needs to take into account the steps already taken by the patentee towards making full use of the patent and importantly, the capacity of the applicant to work the invention to the advantage of the public.

In case of process patents too, the above provisions shall be applicable if the article created by the patented process does not satisfy the abovementioned criteria.

The information that the patentee will provide through Form 27 may be used by the applicant for the compulsory license as an evidence to support its application to prove any of the abovementioned grounds for grant of compulsory license. It would be difficult for the patentee then to refute the claim for compulsory license, if based on the information provided by it in Form 27, the Controller comes to the conclusion that any of the grounds specified above, have been met. Some of the defences that the patentee may have are (i) it has already undertaken steps e.g. by grant of licenses etc. to work the patent in India, (ii) the drug approval process is underway e.g. clinical trials are pending or application with the drug controller is pending.

CONCLUSION:

Though the provisions for compulsory license have been part of the Indian statute for a while, there have not been many cases where the compulsory license has been applied for. Further, the government of India is concerned that due to acquisition of Indian entities by multi-nationals, the Indian entities having foreign investments, would hesitate in applying for compulsory license for patents held by another multi-national. There is no suo moto power with the Controller or the government to grant compulsory licenses, except in situations of national emergency or other circumstances of extreme urgency or in case of public non-commercial use. One will have to wait and watch how the jurisprudence on compulsory license develops in India, and whether publishing the information as regards working of patents really instigates Indian companies to file applications for compulsory licenses.

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*1 www.ip**india**.nic.in*

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