

# EX|P|R|E|S|S Pharma

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## Minimising patent infringement risk before product launch

**Bindu Sharma**, Chief Executive Officer and Founder, Origiin IP Solutions LLP, Bangalore, writes about the risk of patent infringement with regard to the India pharma industry, and how to avoid it

A patent is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention. The grant of patent gives specific right to the patent holder or the patentee by means of which the patentee can prevent third parties from making, using, selling or offering for sale or importing the patented product or the product prepared by using the patented process. Grant of patent gives negative rights to the patentee, ie. the right to prevent third parties from exploiting the patented invention.



### What is patent infringement?

The word infringement has not been defined anywhere in the Patents Act, 1970, but its meaning can be interpreted from the rights of the patentee. That means that violation of any rights of the patentee is deemed to be infringement in Patent Law. Patent filing is increasing globally as well as in India, as indicated by the data provided in annual report of Indian Patent Office, that in the year 2008-2009, 36,812 patent applications were filed in Indian Patent office which is five per cent higher compared to the year 2007-2008. With an increase in the number of filing patent applications, there is obviously a rise in number of patents that are granted and are in force. With increasing number of patents that are in force, there is less freedom for any company to operate within a given jurisdiction and this ultimately leads to a rise in patent infringement risk. In such scenario, if any company

wants to launch a product in a particular market, it is essential to make sure that the launch of such a product is not infringing any third parties' patent rights as there are chances that the product, or the process to make such product or both product and process to be launched, is already claimed in a valid patent of a third party.

### **Freedom to operate search**

Risk analysis in the form of Freedom to Operate (FTO) search or clearance search is a procedure to assess whether or not the product or process is infringing patent rights of any third party. An FTO analysis is performed by meticulously dissecting the product or process into its fundamental components and then scrutinising each component for any attached IP rights.

Though, it is a good idea to get FTO done when technology is in its early stage, it is safe to cross-check the same before a product launch again as the time period between start of research and launch of the product may be large and during that time, there is a possibility of more patents being granted.

Since patent rights are territorial and specific to jurisdiction, the patent granted in one specific country is valid only in that country. A patent granted in US can be used by anyone in India without any risk of patent infringement, provided the product is not exported to US where there is patent protection for the product. A patent has a limited life of 20 years from date of filing or priority, whichever is earlier, and thereafter, a patent is in public domain and can be used by anyone without risk of patent infringement. This means that if the product has to be launched in India, one has to focus on the patents which are in force in India and are likely to be infringed upon product launch.

### **How is an FTO search done?**

FTO can be performed by a patent searcher who has deep understanding of the subject as well as patent law of the territory where FTO needs to be performed. However, legal opinion on infringement can only be given by an advocate or patent attorney. A person, who is not an advocate, can perform the search, present the results in a desirable format but shall preferably not give a written opinion on legal issues related to infringement,.

FTO search involves thorough patent search in a given jurisdiction and identification of relevant patents. The patent claims, which are likely to be infringed, are mapped on the product or process to be launched. This study gives clear idea on chances of infringing third party's patent rights. FTO is therefore an informed, reasoned, and calculated best estimate of infringement liability in a given jurisdiction at a given period of time.

### **Identification of relevant patents**

Identification of relevant patents for FTO shall be done very carefully as the final opinion or search report depends solely on it. A patent may lapse and cease to be in force if the applicant does not pay the renewal fee in time. Even though the patent has expired due to non payment of renewal fee, the applicant has one chance to restore it by paying renewal fee within 18 months from the date the patent ceases to have effect. Therefore, this period has to be considered while checking enforceability and validity of patents.

In European Union member countries, a Supplementary Protection Certificate (SPC) is a sui generis, extension of a patent under a specific, different set of rights. This type of right is available for medicinal products, such as drugs and plant protection products, such as insecticides and herbicides. Thereby, while performing FTO, SPC status shall be taken into account.

Calculating term of patent is vital part of an FTO search. The term of patent in case of international applications filed under the Patent Cooperation Treaty designating India, shall be 20 years from the international filing date accorded under the treaty, and shall be considered while checking validity of patent.

### **Consequences: Cases-in-point**

Patent litigations have also cost millions of dollars to companies in legal expenses and awarded damages due. On October 12, 1990, Eastman Kodak had to pay \$909,457,567 to Polaroid in a patent infringement case and almost went bankrupt. Kodak was also forced to shut down its \$1.5 billion manufacturing plant, lay off 700 workers and spend nearly \$500 million buying back the 16 million cameras it had sold between 1976 and 1985. Damages of \$873 million were paid to Polaroid at the end of a prolonged 14-year litigation process which finally ended in 1990. Kodak was out of the instant picture business for 15 years. By way of

another example, on April 22, 2005 Medtronic, the world's largest medical technology company, paid \$1.35 billion to settle a patent lawsuit.

As evident from the Bajaj/TVS litigation, the losses related to patent infringement do not necessarily result only from damages granted by courts. TVS was put under great loss due to a temporary injunction issued against the sale of its bike called 'Flame', after pumping large sums of money into product development and launch. The case reiterates the fact that patent infringement assessment must be done at a very preliminary stage such as making plans for product development, devising research programs, product launch plan formulation and so on.

### **Relevance to Indian pharma industry**

Generic pharma companies are trying to match every brand name drug with a copycat version without bothering much about the valid patent rights of third parties. There is a high possibility that patent infringements and incorporation of any patented technology without risk assessment may have fatal consequences. Hence, it is essential for generics drug manufacturers to be aware of the risks, patent liabilities and respective consequences before entering any regulated market. A miscalculation in patent expiry dates of brand name drugs leading to the launch of a generic product would result in a patent infringement suit, thereby costing billions in settlement. The FTO search enables pharma companies to identify the areas of research open to them.

### **Possible way out**

The best way to prevent the risk of infringement is to have a license from the patentee. In September 2003, three pharma companies, Cambridge Antibody Technology, Micromet AG, and Enzon Pharmaceuticals, announced that they had signed a non-exclusive cross-license agreement. In the agreement, all three parties obtained substantial "freedom to operate" under some of each other's intellectual property, to conduct research and develop a defined number of therapeutic and diagnostic antibody-based products. Agreements of this kind have become common practice in certain sectors, as companies seek to ensure that their products, processes and services do not infringe on the patent rights of others.

If you are planning a new product launch, there may be risk of infringing patents rights of third party/ies. It is good business practice to obtain an opinion of counsel and get thorough

FTO search done. This opinion should be obtained before undertaking or continuing any activity that might be considered an infringement. Good FTO analysis and opinion can prevent patent litigation that can be an expensive, uncertain and risky affair, and, as the saying goes, prevention is always better than cure.

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