The annual R&D budget of the research based corporations in pharmaceutical sector runs into hundreds of millions or even billions of dollars. The complete development of a new drug molecule costs nearly $1 billion.¹ This is certainly a big investment for most of the innovators and therefore needs protection. On the other hand, in a non-pharmaceutical sector R&D expenses are generally not as huge as in the pharmaceutical sector, yet there is a fashion of extensive patenting. Such an approach can cause a major risk for a company commercializing a new process or product without proper pre-emptive steps. The company might later find out that the competitor(s) already holds the patent over same technology, which the company intended to use in a new process or product.

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*The views expressed in this article are solely of the author and do not necessarily reflect views of the employer.

A patent infringement case in US costs about 1-3 million dollars in legal fees for each party.² In some pharmaceutical cases, legal fees can however, run upto 30 million dollars or more.² For example, in India, MATRIX Laboratories Ltd (MLL), Hyderabad-based pharmaceutical major, received lump sum of Rs 95 crore towards settlement of a potential patent infringement suit with a multinational.³ With further strengthening of intellectual property regime in India, more and more cases are likely to be heard of.

Patent Infringement Insurance

One of the tools that may act as a safeguard to financial risk, is patent infringement insurance. It is generally provided in the form of an insurance policy by insurance companies to protect either an inventor or a third party from the risks of unintentional infringement of a patent. For inventors, patent infringement insurance covers their legal costs if they have to sue an infringer to enforce their patent and for third parties, it covers their legal costs if they are sued for patent infringement by an inventor. The patent infringement insurance is popular in other countries and it is now gradually increasing in India also. A few years ago, New India Assurance issued a patent infringement insurance policy to an IT company.⁴

The flip side of such patent infringement insurance is that, it is generally considered too expensive because of high rates of premium and also it covers only financial risk, not the reputation risk.

Freedom to Operate Search

Another very effective and less expensive tool is freedom to operate (FTO) search, which enables one to make an informed business decision and also warns when you are unintentionally invading boundaries of other patents, so one is less likely to end up with legal disputes. In fact, many companies already practice FTO search before starting new research work for development of new processes or products to save themselves from subsequent financial and reputation losses.

A good FTO search can minimize the risk and can give an indication that a new product or process is
techno-legally safe but it is difficult to say that the invention for which search has been conducted is absolutely safe for commercialization because FTO search can not be organized beyond practical limitations such as time, money and technical resources. For example, if a company ‘A’ has developed an improved false ceiling but to take full advantage of this technical advancement it should be attached with real ceiling using a fixation technology. However, another company ‘B’ holds the key patent on fixation technology. In this case, company ‘A’ does not have ‘freedom to operate’ in this field. One potential resolution would be to look for license to use fixation technology patent from company ‘B’.

FTO analysis basically starts with search of patent literature for granted and pending patents. On the basis of this analysis, a techno-legal opinion is formed, whether a product, process or service infringes intellectual property owned by others. The FTO search can be carried out using the databases available on the websites of various intellectual property right offices. The addresses of these offices can be found at the WIPO website i.e. www.wipo.int. Interestingly, the databases of such intellectual property offices are available free of cost. On the other hand, paid databases are also available online for FTO search. But before making final opinion, it is important to consider limitations associated with patents. The company willing to commercialize a product, process or service can use these limitations as an opportunity.

**Limitations of Patents**

**Territorial Rights**

Patents are territorial rights. If a company has been granted a patent in ten countries and has not sought protection in other countries considering them less commercially important, then in the left countries where no protection was sought, the knowledge enters in public domain. In these countries, there will not be any need of permission or licensing.

**Term of Patent**

Patent protection is granted for a maximum of 20 years, provided renewal fees has been paid timely to the concerned patent office. Once this term expires, the patent comes into public domain and any individual or company can use it without any permission or licensing. On the other hand, because of non-maintenance, many patents lapse and come in public domain even without completing their term of 20 years.

**Claims**

Claims are considered the most important part of patent document as claims define the scope of invention for which protection is claimed. If a technical advancement is mentioned in description but not claimed, it is not considered to be patented and subsequently comes in public domain.

**Strategies to Avoid Legal Disputes**

Nevertheless, after a FTO search, if it is found that one or more patents are blocking freedom to operate; the following strategies may be opted to sort out the matter without any legal dispute.

- In-licensing
- Cross licensing
- Inventing around
- Patent pool

**In-licensing**

Purchasing the patent or in-licensing can be a way to get freedom to operate. Here, terms and conditions such as, specific period of time or specific market can create a bottleneck, and the patent holder can ask for big amount of money or yearly royalty, etc.

**Cross Licensing**

Cross licensing is the act in which two companies exchange licenses in order to be able to use certain patents owned by the other party. For example, if two companies A and B possess their own patent rights for embodying technologies applicable to invention of new processes and products. And, both parties are desirous of acquiring certain rights under the other party's patent rights to use other party's technology for new developments. In this situation, each party can grant such rights, in accordance with the terms and conditions, to the other party.

**Inventing Around**

Inventing around is a mechanism in which substantial changes are made in existing process or product to avoid infringement of patent holders rights. By this way, licensing fees can be saved, but before starting inventing around, a genuine consideration to expected cost should be given.

**Patent Pool**

Patent pool is a patent consortium of at least two companies working in almost same technological field. Companies put their patents in a pool for the collective benefit. Grover, Baker, Singer, Wheeler,
and Wilson formed one of the first patent pools in the year 1856 to sort out their legal disputes.

**Conclusion**

Irrespective of means chosen to curb the odds of encountering expensive patent litigation and reputation losses, it is worthwhile for companies, in any field of technology, to look into the matter of patent infringement risks in the early stages of research and commercialization process of a technology or a product. In-licensing, cross licensing, inventing around and patent pooling may be used to avoid future disputes. Before launching a new product, a systematic FTO search should be carried out to decrease the possibility of infringing patents of others; also it should be kept in consideration that FTO search minimizes the risk but does not eliminate any minimum possibility. However, on the basis of FTO search, it is always advisable to consider inherent limitations of patents before venturing.

**References**