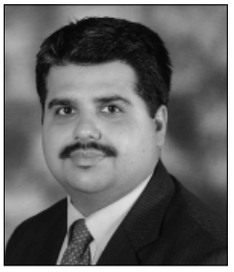
Role of IPR in Forming Legal Strategies for Pharma Industry

Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era. This article chalks out the evolving role of IPR in framing legal strategies for pharmaceutical industry.



Ravi Bhola
Partner
K&S Partners, Bengaluru

Shivakumar
Sr Associate
K&S Partners, Bengaluru

Pranav Mysore
Sr Associate
K&S Partners, Bengaluru

In the era of globalisation, there is a constant technological race especially in the field of pharmaceuticals to develop new/improvised drugs. Due to this, pharmaceutical companies are making huge investments on R&D and hence, it is imperative to protect the Intellectual Property (IP) associated therein and obtain returns by its commercialisation. Accordingly, it is no surprise that IP, particularly patents have become important in framing legal strategies for pharmaceutical companies, right from the commencement of research till the expiry of patents. Frequently, pharmaceutical companies strategise on procuring and enforcing their patents, however, such strategies are not focused on how to maintain their patents when challenged for validity. On the other hand, economic liberalisation has seeded a competitive market pressurising the competitors to come out with generic or biosimilar versions for which suitable strategies have to be formulated[1].

The exclusive monopolistic rights over an invention granted to pharmaceutical companies under the existing Indian Patent Regime are affected by issues such as restrictions during procurement of patents, lack of presumption of validity, use of patents under "Bolar Provision" and so on.

Restrictions for procurement of patents come by way of issues relating to patentable inventions, lack of enablement and pre-grant opposition by third parties. It is pertinent to mention here that the recently proposed guidelines by Indian Patent Office for examining pharmaceutical applications recommend enablement for all the groups claimed under "Markush Structure". The guideline with respect to enablement for all the groups under "Markush Structure" is unique in the sense that other jurisdictions accept enablement for some of the groups while Indian Patent Office suggests enablement for all the groups. Though these guidelines have not come into force and there may be a debate on this aspect, it is still better to consider these guidelines while drafting the application.

In addition to lack of enablement, it is seen that presently most patent applications in the field of pharmaceuticals do not comply with requirements of "enhanced therapeutic efficacy" under section 3(d) of Indian Patents Act, 1970. Often, while filing application for patent on an invention, enhanced efficacy data is misconstrued as the activity data of the compound so claimed. Per contra, enhanced efficacy data would mean a comparative data demonstrating enhanced efficacy of the compound so claimed over closest known compounds. Such misinterpretation has resulted in rejection of several patent applications in India. Although other countries do not have such an express provision, they do conduct examination and raise objections under inventiveness as it is sometimes raised under section 3(d). Lack of enhanced efficacy data not only affects the patents from being granted by the patent offices, but also allows third party to file pre-grant opposition. Such rigorous process during prosecution and a right given to third party to oppose grant puts evergreening of patents under scrutiny.

Even if a third party loses out on filing a pre-grant opposition, options to invalidate a granted patent are available by way of post-grant opposition or revocation of patent. Yet again, these provisions act as a check on evergreening of patents amongst other legislative framework. On the other hand, patentee can institute infringement action against the infringer to protect and safeguard the interest in the patent, thus preventing anyone from practicing patentee's invention for commercial gains.

During proceedings such as opposition, revocation or infringement, the strategy lies in providing appropriate information that would support and strengthen the stand taken by concerned parties. For example: A patent is said to be infringed on the grounds that the patentee has monopoly over a particular compound A. The patentee identified that a third party is infringing the patent by selling salt Y of the compound A. It was found during proceedings that the patentee had filed another application for salt Y of the compound A which was abandoned later. The defendant argued that it is imperative from these facts that the plaintiff (patentee) themselves considered compound A and salt Y of compound A to be different from one another. Such being the case, the patent covering compound A cannot be said to be infringed by the defendants product - salt Y of compound A, even though the patent claims relate to pharmaceutically acceptable salts of compound A. The Hon'ble Delhi High Court held that the plaintiff ought to have shown the defendant's product remained equivalent to compound A to establish prima facie case of infringement[2]. The decision was appealed and the order is yet to be passed in this case. It appears that the case would have been in favour of the patentee if the activity of the compound A and its salt form Y was shown as equivalent. Even though such proof could be furnished at the appeal stage, the issue could have been resolved in the preliminary stage itself if it was proved. Another important factor to be considered based on this case is to decide on the need for filing independent patent applications for related subject-matter as such filings have a bearing on the parent application at a later date. One probable option that pharmaceutical companies can consider in such situation is to file a divisional application/patent of addition depending on case to case basis rather than filing an independent application for related subject-matter.

Having said the above, there are certain provisions in the law which allow third party to use patent granted to the patentee. One such provision relates to compulsory licensing, wherein any person interested may request for issuance of an involuntary licence to practice a granted patent, subject to certain conditions - meeting reasonable requirement of public such as accessibility and affordability, in addition to working of the patented invention in India. IPAB has held that the term "Worked" has a flexible meaning based on the specific facts[3] . If the working of the invention is not feasible, the onus lies with the patentee to prove as to how the working was not feasible without merely making a statement to this extent.

Another provision under which a patent can be used by third party is "Bolar Provision" which is present in legislative framework of many countries. Bolar Provision is a specific enablement towards using the patent without authorisation of the patentee for the purpose of research, development and to obtain approval from regulatory authority. India has added one extra element to this Bolar Provision which enables a person to even sell the patented product. The legislative intent incorporating this element to the existing known Bolar Provision should not be misinterpreted to state that any person can sell/manufacture the drug on a commercial scale. It has to be interpreted in a manner which is necessary for procuring approvals from various quarters of the Government.

Hence, Indian Bolar Provision has to be interpreted to state that any person can use/manufacture/sell /import the patented drug solely for the purpose of research and development and for the purpose of procuring regulatory approvals. Any misuse of this provision would be construed as infringement and necessary action can be instituted by the patentee.

Generally, the regulations in obtaining approval under Bolar Provision or after the expiry of the patent is simpler for generic drugs compared to biosimilars owing to the differences in the process by which the patented drug and biosimilars are produced. Thus, it is necessary to furnish clinical trial data for biosimilar versions while seeking approval from a regulatory authority. Though the regulatory aspect is not binding on Indian Patent Provisions for approving a patented drug, pharmaceutical companies are bound by such provisions for not selling the approved drug for commercial purposes until the expiry of the patent owing to the issues of infringement. In conclusion, framing right legal strategies based on the provisions available within the Indian legal framework would help pharmaceutical companies in addressing issues relating to procurement, enforcement and commercialisation of patents. Such strategies would lessen the challenges even if one cannot avoid the issues completely. ■

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References:

1) www.ircc.iitv.ac.in/ipcourse/patent.html
2) Merck v/s Glenmark – CS (OS) 586/2013 –Delhi High Court – order dated 05-04-2013.
3) Bayer vs. NATCO – OA/35/2012/PT/MUM – IPAB – order dated 04/03/20138)

Contact: avishek@knspartners.com