Recent surge in pharma patent litigation

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The next decade or so in the pharmaceutical patent space in India will be interesting to watch out for. As more product patents get granted there will be an increase in the pharma patent litigation space, predicts ***Gowree Gokhale****, Partner, Intellectual Property and Pharma regulatory practice and* ***Ajay Chandru****, Senior Member, Intellectual Property practice, Nishith Desai Associates, Legal & Tax Counseling Worldwide*


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The recent surge in India in pharma patent litigation is mainly attributable to the amendment made to the Patents Act, to bring it in line with Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS is administered by the World Trade Organisation (WTO). The importance of the TRIPS stems from the fact that it lays down minimum standards that the member countries need to provide to protect intellectual property (IP). TRIPS was a result of intense lobbying by developed countries like US and Japan, who wanted to have uniform standards for the protection of IP, throughout the world, primarily to protect the interests of innovator drug companies. Under TRIPS, if a member country does not adhere to its obligations then another member country can lodge a complaint with the Dispute Settlement Body (DSB) of the WTO.

IP laws of several developed countries like India and least developing countries did not meet the minimum standards laid down under TRIPS. The developing countries were given a period of ten years from the ratification of TRIPS to amend their domestic laws to bring them in line with TRIPS. The most important amendment that India was required to make in its patent law by 2005 was the introduction of product patent for pharma substances in India.


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Under the first codified Indian patent law viz. the Patent and Designs Act, 1911, product patents were allowed for pharma substances in India. During this period the pharma industry in India was dominated by foreign companies with over 80 per cent market share. Most of the drugs in India were not locally manufactured but were imported. This resulted in the cost of drugs being significantly high. In 1970, the Indian Government, with an objective to bring down cost of drugs and to develop a robust domestic pharma industry, amended the Indian patent law that allowed only grant of process patents and not product patents. As a result, domestic

pharma companies could reverse engineer patented drugs to make generic copies of the patented drugs. Thus, the prices of the drugs significantly decreased which fostered the growth of the domestic pharma industry.

In 2005, due to its commitment under TRIPS, India introduced product patents for pharmaceutical patents. It was feared that this would result in drug prices becoming significantly higher and would affect the domestic pharma industry and would also affect access to essential medicines. In order to allay such fears the Indian government introduced certain safeguards in the amendment to the Patents Act, such as Section 3 (d) that prevents ever- greening of patents and also revised compulsory licensing chapter.

The introduction of products patent resulted in innovator foreign drug companies launching their patented products in India. During the interim period from 1995 to 2005 the Indian Patent Office (IPO) under TRIPS was required to accept product patent applications, also known as mail box application. However, this application would be examined only after 2005, i.e. once product patents were allowed in India. So, essentially any launch of patented drugs would have to happen only after 2005. During this period around 9000 mail box applications were filed.

A majority of the product patents started getting granted only in 2009. As a result, the innovator foreign drug companies started filing infringement suits against domestic pharma manufacturers, which led to a sudden increase in patent litigation in the pharma space. These litigations over the past few years have resulted in a number of decisions being rendered by patent office, Intellectual Property Appellate Board (IPAB) and Indian courts who have established jurisprudence on the substantive provisions of the Indian Patent law, which were introduced in 2005. A well-developed jurisprudence provides certainty based on which key decisions in patent strategy, patent prosecution and patent infringement analysis can be taken.

However, some recent decisions of the Indian courts have raised concerns among foreign innovator drug companies, on whether Indian patent law is TRIPS compliant. The recent decision of the Indian Supreme Court in Novartis vs. Union of India, where the Court upheld the decision on the rejection of a patent application by Novartis for its beta-crystalline form of Imatinib Mesylate (Gilvec), and the decision of the IPAB and the

Bombay High Court upholding the decision of the Controller of the Patents for grant of Compulsory License to an Indian pharma company NATCO Pharma Limited for Bayer's Indian patent on Sorafenib Tosyalte (Nexavar) have raised concerns.

Such decisions have brought the attention of the US pharma lobbies claiming that Section 3 (d) and compulsory licenses provisions are not TRIPS compliant. The Indian government has stated that the current Indian patent law is TRIPS compliant. Whether, provisions such as Section 3 (d) and compulsory licenses are TRIPS compliant or not is a question for the WTO DSB to decide. There have been talks in past from the Health Ministry to issue the second compulsory license for Dastanib after Nexavar. However, Department of Industrial Policy and Promotion (DIPP) rejected this proposal.

Another major cause of concern for the foreign innovator drug companies has been the delay in the grant of patent and the lack of transparency at the Indian Patent Office. Currently, on an average it takes around four to five years from the date of filing of the patent, for a patent application to be granted or rejected. A patent is valid for a period of 20 years from the date of filing the application irrespective of when it is granted. Such a long delay affects the foreign innovator drug company's ability to recover their investment, as the life of the patent gets significantly reduced from twenty years. Further, unlike the US and Europe, there is no provision under Indian law to extend the validity of the patent in view of the time taken to obtain regulatory approval.

Recently, there has been some initiatives by the Indian government to increase the numbers of examiners at the IPO and also to improve the infrastructure including digitising the records to reduce pendency rates. The IPO has recently issued guidelines to examiners for examining pharmaceutical patent applications after consultation with stakeholders. These guidelines are likely to bring in uniformity to examinations of the patent applications and as a result may reduce the pendency of patent applications. On the transparency front, the IPO has in the past few years made all the patent prosecution history data files available online on their website. This has proven to be a boon, especially for patentees as it increases the accountability of the IPO.

It has been almost 10 years since the product patent regime was introduced. It was initially believed that it would let multi–national companies take over the major market share from Indian domestic pharmaceutical companies and it would disrupt their business model of selling generic reverse engineered drugs, but this has proven to be far from the truth. The pharma market in India is dominated by branded generics, making up for 80 per cent of the retail market. It is estimated that only one to two per cent of the pharma market in India is made up of patented drugs, which are being sold by multinational innovator drug companies.

One of the main reasons for such a low market share for patented drugs in India is that most of the patented drugs have been in the life saving diseases segment. Accordingly most of the patent litigation in India has been concentrated in the life saving diseases

segment.

However, recently there has been a change in this trend, as patent litigation has started in non-life saving diseases segment such as diabetes. India has the largest pool of diabetic patients in the world and the number of diabetic patients in India is expected to double in the next 10 years.

The next decade or so in the pharma patent space in India will be interesting to watch out for as more and more product patents get granted there will be an increase in the pharma patent litigation space. There will also be a shift to patent litigation in the non-life saving drug space, which is mainly attributable to increase in affluence, rise in life expectancy and the onset of lifestyle related conditions among Indians.

As Indian companies mature from generics to innovator drug companies they will also desire that Indian patent law becomes more patentee friendly. There is definitely a need to relook at some of the provisions of the Indian patent law and ascertain whether they are really achieving the intended objective, or merely creating a hurdle for growth of the pharma industry. Availability of affordable drugs can be achieved through other mechanisms such as price control and government procurement.