

Ready for round 2?

*When we think of pharmaceutical and biotechnology industry one issue that comes to our mind is patent protection. How are companies coping with evolving patent laws? **Suja Nair** reports*

Legally speaking a patent is an exclusionary right given by the government or the authorised authority to its inventor for a particular duration, in respect of his invention. The procedure of granting patents and the rules binding the patentee are different in every country as per their national laws and international treaties.



The most important fundamental of progress is innovation and it can be achieved with proper patent laws that can ensure innovation friendly environment across the world. "An innovator friendly environment opens the door for various types of economic opportunities, including attracting foreign direct investments in the country," avers Tapan Ray, Director General, Organisation Of Pharmaceutical Producers Of India (OPPI).

The first patent law to be introduced in India was by the British government in 1911 but at that time they were priced in such a way that it was affordable to only few people. But all this changed in 1970 when a new patent law was enacted under which only processes could be patented and not the products. This enactment saw the birth of a whole new industry called generics. With more generics in the market there was a steep decrease in the price of the drugs leading to accessibility and affordability of many life-saving drugs.

But in May 1994 India signed the WTO agreement that included Trade Related-aspects of Intellectual Property Rights (TRIPS). The World Trade Organisation (WTO) agreement that became effective for India from 1st January 1995 had a clause requiring the country to change from process to product patents. Moving in that direction, the Patents Act of 1970 and the Patent Rules of 1972 were amended and the new Patents Act was finally passed by the Indian Parliament in March 2005. India's shift from a process patenting system to the product patent regime as part of its commitments to the WTO made the Indian pharma market more attractive for global pharma giants.

Battle it out

"I strongly recommend introduction of Pharma Master Files (DMF) concepts and focus on therapeutic quality. Whether there is a single authority or not for pharma licensing, there shall be a policy for considering pharma products and combination of pharma products single standard operating procedure for granting marketing authorisation"



- Dr M Venkateswarlu

Patents fights are not un-common in India. There has been spate of patent fights that have spurred up the issue of patents and its acceptability in India. Dr Gopakumar G Nair, Patent Attorney and CEO, Gopakumar Nair Associates, feels, "Protection for inventions must be available through patents, but licensing and co-marketing should be encouraged in sensitive areas such as medicines. Patent management strategy in sensitive areas of healthcare must incorporate public health management strategy also."

Former Drug Controller (India)
Dr V's Pharma Consultancy

"The judgments emanating from the Indian judiciary are as good as any in US or Europe. The courts are interpreting and enforcing the law as it is, same applies to patent law. While there is no 'protectionism' as such in drafting of the Patents Act, 1970, Indian law makers have taken care to make use of the flexibility available in 'TRIPs', to draft and enact a patent law, which takes care of the interests of the Indian public and public interests, especially in the field of healthcare and pharma to ensure continued availability of affordable medicines"



- Dr Gopakumar G Nair
Patent Attorney and CEO Gopakumar
Nair Associates

There are many prominent patent cases like Bayer vs Cipla and BMS vs Hetero etc. One of the high profile patent fights in the pharma sector had been Novartis' fight for patent protection for Glivec. The patent rejection for Glivec was one of the first instances of India using the special clause (3-d) in its patent law to prevent patenting of inventions that were known earlier. The ruling of the patent office was based on the pre-grant oppositions filed by Indian pharma firms Sun Pharma, Okasa and Time Cap Pharma Labs against the five-year-old application of Novartis.

In a recent case the Delhi High Court dismissed Swiss pharma firm Hoffman La Roche's petition and allowed Indian pharma company Cipla to manufacture and sell the generic version of Roche's patented lung cancer medication, Tarceva (erlotinib). The court dismissed Roche's plea that the Indian company should be restrained from manufacturing and selling the generic version till the issue of patent rights was decided through litigation.

Is protectionism a matter?

In both cases, the ruling was against the MNC's and in favour of generic companies. Both cases have been high-profile cases where landmark decision was given. Is this a show or protectionism on the part of Indian judicial system towards generics?

Expressing his views Ray opines, "In its current form the patent laws appear to be somewhat protective in nature towards the domestic generic companies. Absence of data protection and less than adequate patent enforcement mechanism within the country will bear testimony to this fact. Probably because of all such reasons, in the pharma space, India is attracting much lesser foreign direct investments than China, in the post IPR regime."

It seems that at present India needs a robust enough patent management systems and procedures within the country, for the countries own interest. Such world class patent management systems will be able to protect the long term interest of the innovators of India and not just for the acceptability by the West. Ray point outs, "Like the China of yesteryears, Indian patent offices currently receive good number of patent applicants from the West because they have been operating within the IPR regime since long. Tomorrow in India this situation is bound to get reversed, as the country gets used to the new paradigm, just as what is happening in China today."

However refuting the same Nair retorts that the current spate of patent litigations in Indian courts are primarily due to the haste and impatience on the part of a few MNC pharma companies to aggressively and prematurely enforce patents and to "tame the Indian (IP) shrew". "The judgments emanating from the Indian judiciary are as good as any in US or Europe. The courts are interpreting and enforcing the law as it is, same applies to patent law. While there is no 'protectionism' as such in drafting of the Patents Act, 1970, Indian law makers have taken care to make use

of the flexibility available in 'TRIPs', to draft and enact a patent law, which takes care of the interests of the Indian public and public interests, especially in the field of healthcare and pharma to ensure continued availability of affordable medicines," avers Nair.

Take on patent law in India

Ray informs, "The patent management strategies in our country are evolving and may be for that reason, are not robust enough, as yet. When we compare India with China it can be noticed that there is still some work needed to be done. For instance there is a big gap within the patent management system which undoubtedly shows the absence of regulatory data protection. Even China provides data protection for six years; along with this they also have effective 'patent linkage' system in place, but all this has not been institutionalised in India, as yet."

Ranga Iyer, Managing Director, Wyeth believes that India is proceeding in the right direction and that we should learn from the shortcomings and strengthen our patent regime by improving clarity, removing ambiguities and enhancing transparency. "Patents are meant to encourage innovation—this object should guide the patent office. Patents are not something against national interest to be given grudgingly. Patents are required to encourage innovation and meet unmet medical needs of the patients," Iyer ascertains.

The importance of patents can never be sidelined since it encourages investment and R&D. Ideally a good patent regime aims at promoting innovation that will bring relief to patients, recognition to scientists and revenue to companies which they can plough back into R&D to produce newer, better medicines.

A S Krishna, Director-External Affairs, MSD affirms, "India has clearly recognised the importance of innovation and R&D for a knowledge economy like ours. The adoption of product patent regime is clearly a right move in that direction." However, he points out that in order to make the law more innovator friendly, there is need to address some critical issues in the interpretation and implementation of the law.

Elaborating on the same, Iyer feels that patents are rewards for innovation that help mankind. He states, "Under the current law, incremental innovation is patentable only if you can establish significantly better efficacy. Innovations that contribute to better compliance and reduced side effects also need to be encouraged through patent protection. Any innovation that fulfills a medical need should be patentable. Similarly, data protection for a fixed period of time during which period others wanting to market the drug should generate their own data—it is in the doctors' and patients' interest."

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- Tapan Ray
Director General
Organisation Of Pharmaceutical
Producers Of India (OPPI)

"Robust IP law is key to R&D in a country. Amendments to the law should be made with a view to make it more robust leading to spur in R&D investments and making India a hub for pharma research thereby enhancing economic opportunities. These moves would go a long way in giving comfort to research oriented companies irrespective of the fact whether they are Indian or a MNC"



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Change needed?

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In order to bridge this gap and to safeguard the interest of the investors it is essential to fill the gaps that threaten to shift their focus from India to other countries like China. Dr M Venkateswarlu, Former Drug Controller (India), Dr V's Pharma Consultancy, feels that regulatory changes will give confidence to countries trying to procure medicines from India. Easiest way to achieve these changes is to harmonise with the global regulatory guidance from organisations like ICH, ASEAN, WHO etc. Harmonisation will provide an opportunity to improve India's share in the global generic market. "I strongly recommend introduction of Drug Master Files (DMF) concepts and focus on therapeutic quality. Whether there is a single authority or not for drug licensing, there shall be a policy for considering drug products and combination of drug products single standard operating procedure for granting marketing authorisation (which is not operating today)."

Ray informs, "The amended Indian Patents Act 2005 although is a commendable step towards attracting foreign direct investments in the country, it falls short of international expectations. Dr Mashekar Committee's revised report also points towards this direction while deliberating on patentability of 'incremental innovations'."

There are areas of concern which could ultimately prove to be an impediment not only in the R&D environment in the country but also to attract its fair share of FDIs, especially compared to China like patentability [section 3(d)], regulatory data protection, pre-grant opposition, patent enforcement, and patent infrastructure. Ray observes, "There is a general misconception within our country that effective redressal of the above areas of concern by the Government of India will only help the multinational companies and go against the interest and progress of the domestic Indian companies. Such a view, in my opinion is myopic. As the domestic Indian pharma companies will keep taking significant strides in the R&D space of the country, the above areas of concern will keep bothering them, as much. Tightening of these loose knots at this stage will help all innovators and above all the country as a whole, in the long run."

However Nair clarifies, "The 'patent practice journey' from 2005 to 2009, clearly indicates and strongly gives out the message that the Patents Act, 1970 does not need amendments in the near future. The smooth sailing from 2005 to 2009, without any challenge in the DSB of WTO, the largely confirming recommendation from the Mashelkar Committee to Indian Patentability criteria, the trend of patent prosecution in Europe and USA, indirectly enforcing the Section 3(d) criteria are all confirming this view." He feels that there is no need for any amendments except that the rules for smooth operation of Section 92-A (Doha Declaration-based exports against overseas compulsory licences) should be incorporated.

Evolving in its own way

Indian patent law is for the good of Indian inventors and Indian public. It is a wrong perception that our domestic laws should impress others or other countries however there are certain issues that affect the industry as a whole. Though we have a fairly good patent regulation there is still a lacuna in the system. Elaborating about the problems Gowree Gokhale, Partner(IP), Nishith Desai Associates, averred that the product patent regimen that is followed in India is good and is evolving steadily. However she adds, "Today we need to develop a strong jurisprudence in order to evolve in a better way as there are certain procedural issues that are faced by the applicants like the issue of granting pre-grant opposition anytime before the patent is granted. This is because there is a delay in issuing certificate. Another issue is that there is multiplicity of proceeding due to which patents constantly remain under threat of invalidity."

A strong product patent law shows how strong the countries law is in protecting innovation, which also increases foreign ventures and investments. According to Krishna, "Robust IP law is key to R&D in a country. Amendments to the law should be made with a view to make it more robust leading to spur in R&D investments and making India a hub for pharma research thereby enhancing economic opportunities. These moves would go a long way in giving comfort to research oriented companies irrespective of the fact whether they are Indian or a MNC."

Future deadlock?

Situation in India with regard to product patents is quite different from that of west since in the developed countries product patents have been in existence for many years. With time gradually India will also reach that stage. Right now we need better clarity in some of the regulations and time-bound implementation. For example, there should be a timeframe for submission and disposal of oppositions to patent applications etc.

India has being accepted as a patent and regulatory country but the West is expecting more control over violators. At present, patent and regulatory controllers operate independently. Venkateshvaralu opines, "There is a need for patent controllers to educate the drug regulatory authorities on patent related issues. They should come out with consolidated information like in the US (Orange book) containing various information, for example patent status updates etc. They should also have a communication channel between the patent office and the drug controller's office where the patent office can have all information lying with the drug regulator and vice-versa. This will enable both the authorities to take decisions."

Expressing his concerns Nair concludes, "There is a worry due to the increasing non-uniform and arbitrary approach in patent examination and prosecution which varies non-confirmingly between examiners, controllers and the four patent offices in India. Even though, there are some efforts, of late, to improve this lacuna, only time will tell if India can 'bell the cat'."