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Moving in the right path, but still a long way to go

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PATENT REGIME

Moving in the right path, but still a long way to go

On January 1, 2005 India brought in an amendment to the Patent Act to comply with the World Trade Organization rules. But nothing much seems to have changed since then. However, this has brought some level of confidence among the multinationals looking at India for partnerships/ tie-ups. But still a lot needs to done and it will take time for things to move in the right direction.

On April 28, 2005 the Thomson Scientific unit of the Thomson Corporation announced that Derwent World Patents Index (DWPI) will now include Indian patents, both pre-grant applications and granted patents. The inclusion of Indian patents in DWPI, the world's most comprehensive database of value-added patent documents which currently contains details of over 28 million patent documents in 13.5 million unique invention records, follows the culmination of the government's long process of amending India's national patent laws to ensure they conform to Trade Related Intellectual Property Rights (TRIPS) norms.

"Following the recent legislative changes, the number of patent filings is forecast to jump from current annual levels of about 10,000 per year to over 25,000 annually, with a corresponding increase in patent litigation. Since India has now become a major player in the IP arena, we recognized the importance of giving our users comprehensive and quick access to Indian patents," said Brian Tyler, executive vice president of corporate markets, Thomson Scientific.

The inclusion of patents granted in India is also significant for DWPI because it is expected that Indian patent activity will increase dramatically, particularly in the fields of pharmaceuticals, biotechnology and information technology. In the past, India only permitted patents for processes and not products. With new amendments to the Patent Act, it is now possible to obtain product patents in pharmaceuticals and agrochemicals, telecom and software industries. The total R&D expenditure in India has also considerably increased, leading to new drug development projects and the creation of facilities essential for the development of new drugs.

In addition to this, the Swiss pharmaceutical company Roche has finally ended the high drama on December 21, 2005 by granting Hetero Drugs, a Hyderabad-based pharmaceutical company, a sub-license for the production and marketing of Oseltamivir (generic "Tamiflu"). This is the first instance in which a sublicense has been granted since the introduction of India's new patent legislation in 2005. This legislation complies with international patent laws. Roche and Gilead Sciences filed patents for Oseltamivir in India of which some have been granted and the remaining process and product patents are currently under evaluation by the patent office in India.

These two instances will give an idea about having the Product Patent Act. India recognized product patents for food products, pharmaceuticals and agro-chemicals starting calendar year 2005 and is applicable to all these products patented after 1995.

Sharing his experience, Mohanbir Sawhney, the well-known technology and e- commerce guru, said, "the Indian software and business process outsourcing companies need to change course. From merely offering software and IT â€“enabled services, it is time to think KEPS â€“ knowledge enabled products and services."

This is true not only for the Indian software industry - a leading export earner for the country - but also for the Indian life sciences, pharmaceutical and biotechnology industries which are growing rapidly and attracting the attention of the world's leading pharma and biotechnology companies. This is just because of the India's entry into the product patent regime in January 2005. At present these companies are actually into the contract research and manufacturing or in licensing agreement with the multinationals for marketing their products in India, offering services in the form of clinical research and clinical data management. Yes this will help earn profits but in the long run, they will lose their margins to others by paying royalty (take the case of Monsanto's Bollgard technology where it is receiving a good amount of royalty from companies like Mahyco, Nuziveed, Rasi and Ankur Seeds). So to keep pace with the changing global scenario, Indian companies may have to look at innovation. Otherwise they will end up making marginal profits.

Now that it is a little over a year since India entered the IPR regime, it is time to look back and review how the pharma scenario has changed. "Many pharma multinationals have now started looking at the Indian market with a renewed interest, albeit with a cautious approach watching the progress of IPR implementation in letter and spirit. There is a spurt in capitalizing on outsourcing opportunities as the global pharma companies are under pressure to contain the costs," observed Dr Ajit Dangi, director general, Organization of Pharmaceutical Producers of India, Mumbai.

Sharing similar views, Nitin Deshmukh, head â€“ private equity, Kotak Mahindra Bank Ltd and director, Association of Biotechnology Led Enterprises, said, "The Patent Amendment Act 2005 has changed the perception about India. The multinational companies are now looking at India and pretty much open for discussing with the local companies. This has given a boost to many local companies who have been certainly going up the value chain."

Rajesh Jain, joint managing director, Panacea Biotec, New Delhi, echoed similar views. He said, "Although one year is too short to make an assessment of the impact of product-patent regime, the failure to obtain "new use patent" on pre-existing drugs as per approved product-patent regime of the country, has changed the mindset in Indian industries to develop new drugs, vaccines and diagnostics. Thus, a few major biotech/pharma companies have geared up to develop novel therapeutic requiring R&D, along with producing generic and biogeneric drugs that could be marketed internationally. In fact, companies that thrived on alternate production-methods by taking advantage of erstwhile process patent regime have been forced to reconsider their long-term strategies."

He continued, "The product-patent regime is gradually changing the mindset of the Indian biotech industry for "discovering new drugs" by exploiting its vast biodiversity and largely unexplored biological resources. The investments in R&D are certainly going to be the 'key factor' in the coming year to help Indian pharma/biotech industry become globally competitive. Although producing generics and biogenerics or bio-similars of patented expired drugs make a good business sense, this will be a short-term business module.

Better and efficacious drugs that have been developed as result of the intensive science based discovery would in long run be a keystone for the biotech and pharma industry. However, fears exist in the biotech industries in their ability to protect Indian product-patent in other countries. To fight a legal battle against industry giants in rich nations would be an uphill task for an Indian pharmaceutical firm. Although Indian industries has not faced this situation as yet, much thought needs to given in this area, specifically role of the government of India in protecting the Indian product patent rights."

"This has not affected Panacea Biotec as we did not adopt alternate production method route in our strategy. We add 'unique values' to the existing drugs. We have several international patents on our novel drug delivery systems. In fact, we are using the opportunities provided by new product-patent regime by investing considerably in R&D in identified strategic biotech areas. We hope to get leads for new drugs, therapeutic and vaccines in years to come. This would also add in to generating our own IPR," Rajesh Jain added.

Issues of concern

Before the Act came into force, the general public and the NGOs had a perception that the prices of medicines will go through the roof top. But the post-IPR regime has turned out to be a myth as expected. In fact, Dr Ajit Dangi said that the 2005 November MAT ORG/IMS numbers show that overall there is only one percentage point growth due to price increase over 2004.

Dr Swati Piramal, director, strategic alliance and communications, Nicholas Piramal India Ltd, Mumbai, also shared similar opinion. She said, "There is competition in the market and prices have fallen in reality. As against the general notion of price hike after India entering the patent regime, the prices in reality have fallen. Still 98 percent of the drugs are off patent and are already available in India. So there is not much difference."

However, Dr Ajit Dangi observed that the much awaited National Pharmaceutical Policy Part A (Draft) has been announced and it is hoped that government will move from micro managing price control to price monitoring. Compulsory negotiation of price before introducing a patented product as suggested in this Policy could, however, be a dampener and will erode India's credibility in implementing IPR regime in a fair and transparent way and might seriously affect the introduction of newer patented drugs in the country resulting in non-availability of many modern therapies to Indian patients. Overall the situation still remains as "work in progress".

On the pricing front nothing much has happened at present by the switch over, yet the awaited National Pharmaceutical Policy will have to be looked at seriously. "This seeks to ensure that existing products in the market are not immediately and significantly impacted by the switch over to the product patent regime. But in the long term, the product patent regime will have a far-reaching impact on the domestic pharmaceutical industry as the new product introduction will become increasingly difficult for Indian companies. This will significantly alter the structure of the Indian pharmaceutical industry and the pattern of new product introductions in the country. In future, introduction of patented drugs by Indian companies would be possible largely through in-licensing arrangements with patent holders. Two to three years from now, this would start having significant implications in terms of ageing of product basket for most pharmaceutical companies in India. Domestic companies would need to re-align their geographical coverage, research and manufacturing strategies to meet the imperatives of the product patent regime," said Kirit Javali, partner, Law Offices of Jafa & Javali Advocates, New Delhi.

In addition to pricing, issues such as narrowing the definition of Patentability, broadening the scope of Compulsory Licensing and lack of Data Protection continue to be areas of concern from the perspective of international research based companies, appointment of several committees to look into these areas gives some comfort. "It is understood that the report of these committees will be out very shortly," said Dr Ajit Dangi.

Things are moving at the government level but in reality much needs to be seen. The government has to expedite the process. Only then can the Indian companies look at competing in the era of globalization and competition.

"In the US it takes just two years to get the approval for product patent. But in our country it will be definitely more than that. Things are improving. The government has to appoint more examiners. There should be more patent attorneys. As far as I know, no patents were granted in product section so far from
the Indian patent office," adds Dr Swati Piramal.

On the other hand, Kirit Javali said, "Intellectual Property is a specialized subject needing specialized expertise and knowledge to deal efficiently and expeditiously. The establishment of an Intellectual Property Appellate Board is a recognized system, which already exists in many countries, including in India under the Trade Marks Act, 1999. We do require specialized fast track courts for exclusively deciding IPR matters. For this it would be prudent to set up an IPR Tribunal on the lines of the MRPT Commissions and other such tribunals. All this would be in the interests of the industry as companies have invested heavily in technology, time and resources."

"The power of mass intellect is the power of India today. The brain product is the future of Indian economy. The Intellectual Property or the brain products are to be protected properly by IPRs to strengthen economy. Indians can do that, they have the capability no less than others. The only thing to do is 'To enhance awareness of IPRs' and 'To reduce fearness of the same' amongst the common people.Rather it is the time to accelerate a mass program like 'Patent For Public (PFP)' and only then India will be able to compete with the whole world. I believe India is already moving on the right path, " says S Chandrasekaran, Controller General of Patents, Designs and Trade Marks.

A long way to go

India kept its promise with the WTO and brought in the Patents (Amendment) Act 2005. The Act attempts to combine the inventive spirit of scientists with the innovative spirit of private sector enterprises. India has an advantage in terms of large manpower, educational institutions, public funded research institutions, which places the country to take up the challenges and take on multinationals.

As noted earlier, the big pharmaceutical companies are considering bio/generics and contract research/manufacturing as a growth model. It may not be possible for them to grow beyond a certain point through this route. These models could be applied to supplement the strategy of expanding the domestic market. But to mainly depend on these for the further growth would take the Indian companies away from innovation. They just can't afford to take a risk on investing huge sum on innovation. Varaprasad Reddy, managing director, Shantha Biotechnics said, "One can't take up research activities/ innovation without resources - both capital and human resources. The life sciences and biotechnology companies are losing the best talents to the IT industry because of the high returns there. Here the gestation period is also long and returns are low."

The government has to bring both public and private sectors together on research and development in number of areas. It has to pump in more investments into R&D activities. Offering incentives to private sector will support them to concentrate efforts on need-based innovations and those strategies that would largely free
Indian firms from getting into dependent relationships with multinationals.

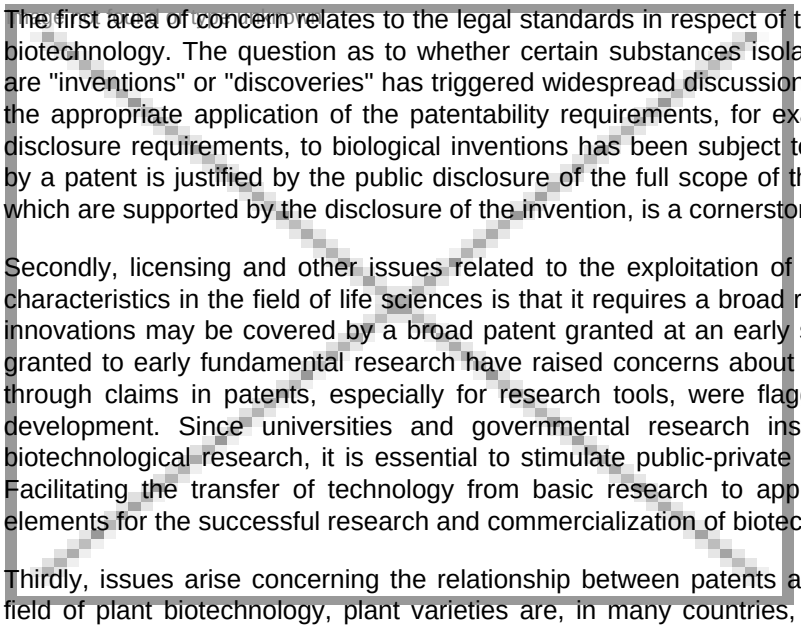
The companies should also look at adopting the model of IPR compliance which involves training of existing personnel as technology mangers or appointment of new personnel with pharma/biotech background as persons dedicated to acquisition of R&D benefits from academic and research institutes. It will support the firms to acquire global competitiveness, protecting business and enhancing profits. In this regard firms have taken steps and have separate IPR cells.

"India is at a crucial juncture where it is emerging out of its protective oyster onto the open arena. Like a new born wilder beast it will have to sense the world and get on its feet with speed to strategically escape global predators and chart its course for survival and growth and service the needs of a growing society with accessible and affordable products and services with accountability and responsibility," said Prabuddha Ganguli, CEO, VISION â€“IPR, New Delhi.

In spite of all these issues, Nitin Deshmukh is optimistic about the future of patent regime in India. He says, "Considering the present scenario we can hope that Indian biotech companies can apply for product patent in next 5-6 years."

Biotechnology and patents

There are other issues as far as patents and biotechnological inventions are concerned. According to World Intellectual Property Organization (WIPO), the issues surrounding patents and biotechnological inventions can be grouped into a number of categories, which are partly inter-related. These following issues could be resolved through discussion and continuous debate.



The first area of concern relates to the legal standards in respect of the scope of patent protection for inventions in the field of biotechnology. The question as to whether certain substances isolated or derived from naturally occurring living organisms are "inventions" or "discoveries" has triggered widespread discussion. In addition to the question of patentable subject matter, the appropriate application of the patentability requirements, for example, inventive-step, industrial applicability (utility) and disclosure requirements, to biological inventions has been subject to an intense debate. Since the exclusive right conferred by a patent is justified by the public disclosure of the full scope of the patented invention, defining the breadth of the claims which are supported by the disclosure of the invention, is a cornerstone of the patent system.

Secondly, licensing and other issues related to the exploitation of patents are also areas of discussion. Since one of the characteristics in the field of life sciences is that it requires a broad range of comprehensive research activities, down-stream innovations may be covered by a broad patent granted at an early stage of innovation. The number and breadth of patents granted to early fundamental research have raised concerns about patent thickets and royalty stacking. In particular, reach-through claims in patents, especially for research tools, were flagged as a potential impediment to further research and development. Since universities and governmental research institutions also play an important role in the area of biotechnological research, it is essential to stimulate public-private partnership, generate revenue and protect investments. Facilitating the transfer of technology from basic research to applied research and commercialization is one of the key elements for the successful research and commercialization of biotechnological inventions.

Thirdly, issues arise concerning the relationship between patents and other forms of intellectual property protection. In the field of plant biotechnology, plant varieties are, in many countries, protected by a sui generis system, such as the UPOV system. In the era of post-genome research, innovation in the area of, for example, bioinformatics, is characterized by biological information and its processing methods. Copyright protection and protection of databases, if available, are other forms of intellectual property protection, which may be of relevance in this area.

Finally, the relationship with other relevant issues, such as the conservation and preservation of the environment (including the protection of biodiversity), and moral and ethical dimensions of the protection and commercialization of biotechnological inventions has been discussed in many fora.

Narayan Kulkarni with inputs from Rolly Dureha