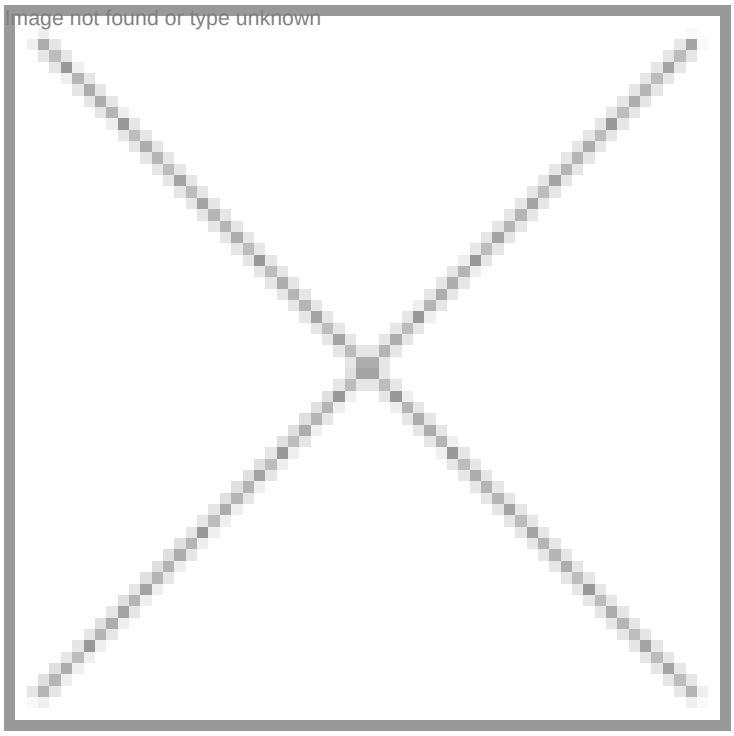
BioSpectrum the business of Bio & Health Sciences

Bio Pharma

11 February 2005 | News

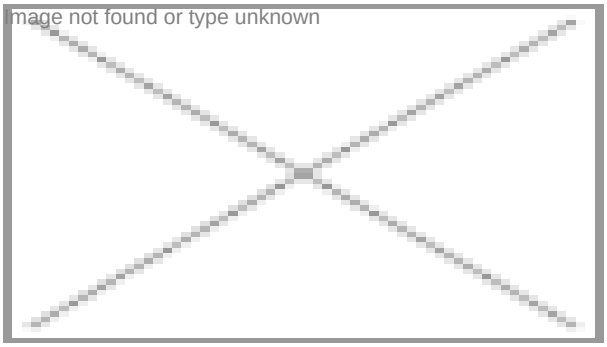
Image not found or type unknown



Innovation Dawns

With the advent of the product patents regime, Indian companies have to enter the era of innovation, which is going to separate leaders from mere generics drug players

On December 26, 2004, the Indian government promulgated the Patents (Amendment) Ordinance 2004 as also the Patents (Amendment) Rules, 2005 to comply with the TRIPS obligations. Though the Ordinance was promulgated only recently, Indian pharmaceutical companies have been gearing up to the WTO regime and are adopting a strategy of R&D-based innovative growth. Indian pharmaceutical companies, which did not spend even a fraction of a percent on R&D 10 years ago, are now spending 6-8 percent of their annual turnovers on R&D against the international norm of 12 percent. The transformed Indian pharma industry is itself looking for patent protection, particularly the biotech sector, in which India has bright prospects.



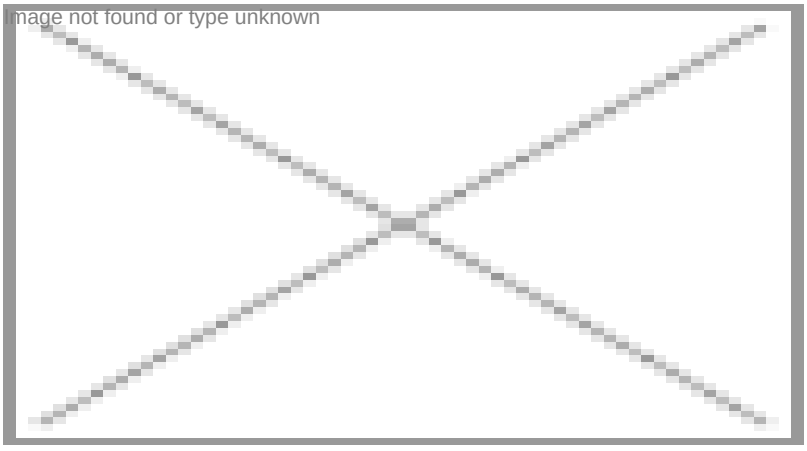
Reacting to the ordinance, R Rajagopalan, president, Discovery Research, Dr Reddy's Labs said, " Personally I feel, this ordinance would boost R&D activities and accelerate growth of the Indian pharmaceutical companies. India has a strong intellectual capital and whatever potential India has shown in IT business, the same sort of impact will also be seen in the pharmaceuticals industry."

Considering the importance of patents, Dr SN Maity, former controller general of patents, designs and trade marks, observed, "The brain product is the future of Indian economy. The brain products are to be protected properly by Intellectual Property Rights to strengthen the economy. Indian companies can do that as they have capability no less than others."

India's approach

With the product patents regime, Indian biopharmaceutical companies will not be able to make or sell products patented by MNCs unless they have been licensed to Indian biopharma-ceuticals companies. The biopharmaceutical companies including biotechnology companies who have not invested in R&D may find themselves pushed out of the market as they have to compete with multinationals, which have new products generated through extensive R&D.

But the Indian biotechnology stands second to none in terms of innovative capability. It has skilled and intellectual scientific pool that can do wonders in R&D. Chandrajit Banerjee, senior director, Confederation of Indian Industry noted, "Indian companies have seen this coming and have accordingly realigned their strategies to gear up for the change. The underlying fact is that they should focus on innovation in their R&D and also utilize the benefits of the new product regime."



Research based companies will however be able to successfully compete with MNCs at global level, leave aside at the domestic marketing level reverberate industry majors. It will take number of years before new-patented products generated by the R&D efforts of Indian companies would be marketed, said Rajesh Jain, joint managing director, Panacea Biotec Ltd.

Leading companies are investing on R&D to generate their own IPR and come up with new products. Companies realize that it will take a number of years to develop their own pharmaceutical products. They are eager to join hands with MNCs for co-developing and or co-marketing of patented products of MNCs. Developing their own IPR is today a very important component of their long-term strategy.

The new law has the provision allowing the government to force the patent holder to grant licenses to the local company in the case of emergencies or for exporting medicine to countries facing public emergencies. This will also pave way for inlicensing agreement between Indian companies and multinationals. In this regard, many Indian companies have already started discussing with the multinationals to launch their patent products in India.

Besides Indian companies would gain from manufacturing of biogeneric, bio-comparative and bio-improvic products that are either off patent or likely to be off-patent soon. Indian companies have also found a new route of growth namely "contract manufacturing". The global companies have realized that it is advisable to outsource manufacturing and focus more on research and marketing. Indian companies will find contract manufacturing as a means for high growth returns. "The real impact for outsource is expected in the next few years from the generic drugs market. The market for generic is growing annually by 14 percent. Indian companies are likely to concentrate on generic molecules, bulk drugs and intermediates," noted Rajesh Jain of Panacea Biotec Ltd.

Rajiv Gulati, chairman and managing director, Eli Lilly and Company (India) Ltd, a leading provider of biotech drugs, observed, "It is not only the biopharmaceutical sector, but also the overall pharmaceutical sector that has been bracing up by putting more resources on R&D efforts. The day is not far when a drug developed, commercialized and marketed in India by an Indian firm sees the light of the day."

Government Initiatives

The government has taken steps after signing TRIPS agreement on IPR related issues in general and product patent in particular.

Infrastructure modernization: According to reports, the Rs 120-crore modernization plan of the patent offices across the country is nearing completion. The offices in Delhi and Kolkata will be ready by March, Chennai office by April and the Mumbai office by June. The Patent Information Service, Nagpur has been developed as an Intellectual Property Training Institute (IPTI). Besides launching a website of IP offices, a distinctive logo for IP administration has also been designed.

The government is also working on to set up Integrated IP offices in each of the four metro cities so as to house all activities in one building. C-DAC has undertaken comprehensive computerization of operations of these IP offices and the initial level of computerization has been completed.

Front office software has been installed to generate computerized information about status of patent applications, receipt for filing of patent applications, etc. Online search facilities have also been established and the patent offices have been provided with ISDN facility to ensure uninterrupted connectivity. Improved novelty search in patents is being ensured through connectivity to international databases. Further, CD-ROMs were also acquired for this purpose and library facilities strengthened. Over 70,000 patent records were digitized and a searchable database would also be put on the website.

According patent office website www.patentoffice.nic.in, the output of patent offices vis-Ã -vis the year 1999-2000 has nearly trebled. This has gone up from 2,800 cases in 1999-2000 to over 10,000 cases in the year 2002-03. Out of a cumulative backlog of around 45,000 patent applications, preliminary scrutiny reports have been issued in respect of over 42,000 applications.

The problem of backlog of pending patent applications is being addressed both through legislative and administrative measures. Administrative measures have already started showing results in terms of improved output. These will be further complemented by the legislative measures contained in the Patents (Amendment) Act, 2002 and the Patents Rules, 2003, expected to be brought into force shortly.

Human resources: Of the total sanctioned staff of 271 (technical), there were 155 people working day and night to complete the process within the given time of 52 months. In all there are 600 people (including technical and support staff) working in different places across the country. The Patent office has been recruiting people for technical posts (examiners) since 2001. But with no lucrative future prospects they were not sticking to their jobs.

However 62 new examiners (for patents) were recruited recently and trained by IPTI, Nagpur. IPTI offers unique opportunity to gain first-hand knowledge and training in patents and other IPRs. It is the only institute of its kind in the country set up by Ministry of Commerce and Industry, Government of India. In addition to this, about 181 examiners will also be recruited shortly.

The patent office has also been making efforts to update the skills of the registered agents, as there has been lot of changes that have taken place in the last few years. There were 617 registered patent agents across the country. The advocates, who had the registered way back in 1945 as agents are still holding the registration numbers. These agents claim to be experts but most of them are not up to the mark, say industry people. The patent office is taking steps to update their skills on the latest developments in the field of IPR.

Status of applications

The applications by both the Indian as well as the MNC companies at the patent offices have been swelling since January 1, 1995. The patent offices in the four metros as on December 31, 2004 received a total of 8,926 applications for the grant of product patent. Of which the patent office has received 2,488 requests for examinations. According to reports, majority of the applications were from US companies.

For the multinational companies, which have branches in India to market their products in the country, the filings are done under the PCT (Patent cooperation Treaty) from the US by the parent company. Rajiv Gulati of Eli Lilly and Company (India) Ltd said, "Sitting here, we are not aware of the exact numbers. It is difficult for us to make a guess as ours is basically a marketing company that has a bunch of biotech drugs discovered by the parent corporation."

Although the industry people and the officials find it difficult to make a guess on the breakup of applications between different

industries, it was noted that around 7,000 applications could be from the pharmaceutical sector and the rest in the areas of agro-chemicals. Take for example USV. It has about 21 applications filed which includes three for biotechnology, 10 for chemical process research and eight for drug delivery systems research. Biocon has filed over 200 patent applications, both national and international. It ranks No.4 among all companies in India in this area. Panacea has filed 93 patent applications, of which 48 applications are available in black box.

It is difficult to assess the total numbers of biopharmaceuticals/biotechnology companies who might have dropped applications in the mailbox. Nitin Deshmukh, director, Association of Biotechnology Led Enterprises (ABLE), observed, "There are applications filed from biotech companies. I am not very sure on the number of applications filed from biotechnology industry. Considering the total number of applications, less than one percent of this number might be from the nascent biotechnology industry. About 20 companies from biopharmaceuticals and about 10 bioagriculture companies could have filed the applications for product patent."

The government has initiated steps to modernize the IP offices so as to speed up the process. Progress has been made in areas such as modernized infrastructure, extensive computerization, human resource development, digitization of records, efficiency, transparency and operational environment of global standards (see the box on Government's initiatives). Yet, there are issues that need to be addressed immediately.

"To speed up the process, the patent office has to hire more examiners and strengthen the existing infrastructure. It has already issued an advertisement for recruiting as many as 200 examiners. And we have also suggested the government to link all the offices of IPR based at the four metros and requested the government to set up dedicated IPR court. Countries like Indonesia already have such courts, " commented Dr Ajit Dangi, director general, Organization of Pharmaceutical Producers of India (OPPI), the premier association of pharmaceutical manufacturers.

Rajesh Jain pointed out certain that changes like electronic filing of patent application, information on status of the filed application, discussion on objections by the patent officer and applicant via telephone or videoconference would help in speedy filing and examination of the applications. "It is going to be tough for the patent office as the people working there are obstinate to any kind of changes," said Nitin Deshmukh of ABLE.

According to Rajiv Gulati, "Resource is the biggest challenge although government has already done a fair bit in augmenting the resources at these offices. Continued focus on upgrading the manpower with ongoing training would definitely help in tiding over the current situation." Chandrajit Banerjee of CII too felt the same. He said, "The ability to examine cutting edge, innovative technologies for patentability lies primarily with the capability of the examiners. First of all there is a dearth of number of examiners in the Indian Patent Office. Second, there is an urgent need for upgradation of their qualitative skills through training to meet International Standards. Lastly, there is a need to establish specialised IP Courts for litigations arising out of opposition to patents."

Process deadline

Though over 200 examiners are working day and night to complete the process, the industry believes it would take at least two-three years before all the applications are disposed. Rajiv Gulati felt, "It might take two-three years for the companies to be able to offer their patented products in India." Rajesh Jain observed, "Patent office used to take five-seven years to process the applications, but with the modernization of the patent offices, the time to process the application has been drastically reduced. The Section 11(b)(3) provides that the request has to be made to process application of black box so that process is completed within 12 months of December 31, 2004 or 48 months from the date whichever is later. In view of a large numbers of applications, it is likely that it will take years before any of the applicants is granted patent. Once the patent product is granted, it usually takes five-eight years to complete the clinical trials and regulatory approval and introduce the product in the market."

However, the government maintained that it would complete the whole process before 52 months. Ashok Jha, secretary, Department of Industrial Policy & Promotion said, "The specific timelines have been put in place for granting patents. It has been reduced from a maximum period of 104 months to 52 months and the minimum period from 27 months to five months."

What's in for innovators?

Product patent will help big Indian pharmaceutical companies as well as the multinationals. The industry hopes that the patent ordinance will be converted into a full-fledged law by Parliament, when it comes for discussion during the Budget session. However, most of them believe that there will not be too many changes in the Indian pharmaceutical industry as the government has just promulgated the ordinance and has to remove many ambiguities in the ordinance. At least for the next two years, things will continue without much change they opined.

Decisions on fresh investment with focus on R&D, clinical trials and productive collaboration between Indian and international

companies will take place only if there is an assured climate of world-class patent protection. When India is on threshold of growth on all fronts, the government should help to open up the healthcare sector as well. The government has agreed to revisit the ambiguous provisions of the patents ordinance and rules to make the product patent regime credible and protect the interests of consumers and producers.

Panacea Biotec feels that MNCs do have some amount of diminishing edge over the Indian companies since they have been investing on R&D at a desired level leading to new IPR and new products. "The initial edge of MNC over the Indian biopharmaceutical companies will vanish in a couple of years since it is expected that many products based on Indian biopharmaceuticals IPR will be launched in the market very soon globally," said Rajesh Jain.

Rajiv Gulati noted that a patent is a patent, whether it is granted to an MNC or an Indian biotech company. "The overarching philosophy is whoever chooses to invest in research, will reap the consequent benefits as the days of reverse engineering are certainly going to end," he said. Echoing similar views Chandrajit Banerjee said, " Irrespective of MNCs or Indian companies, the edge is for all companies which are innovative in their product profiles and who are continuously innovating and introducing new products."

Patent has assumed great importance in recent times since its basic function-to promote innovation-is an essential component of economic growth and social evolution. Patent is not just an incentive to invest in the innovation process per se, but is also increasingly important for trade and industry worldwide. For developing countries like India, patent is an essential component of the framework to attract foreign investment and faster technology transfer. So the coming days are for innovator companies and the era is for innovation.

Narayan Kulkarni with inputs from Rolly Dureha in New Delhi and Srinivas Rao in Bangalore