

The New Patent Regime: Implications for Pharma & Agrochemical Sectors

Komal Shah

The introduction of the new patent regime in India will impact the Indian economy and industry in several ways. The Patent Act 1970 (the "Act") now complies with the requirements of the TRIPS Agreement, which includes patenting of chemical, agrochemical and pharmaceutical products.

It is important to understand the impact of the new patent regime: the challenges to be faced by the Indian industry and governing bodies and the fresh opportunities that are being created. This article discusses the challenges such as the lack of IP-awareness, lack of training, the legal infrastructural and resource requirements. Restrictions on the sale of patented products, as well as the opportunities such as unleashing the true value of developed intellectual property and capital, and exploiting patent laws to obtain competitive positions in the markets are also highlighted.

The Recent Patent Ordinance (2004)

As India became a signatory to the TRIPS agreement, the Patents Act 1970 (the Act) was modified to provide an interim period of transition, from 1995 to January 1, 2005, by providing the facility of mail-box applications and the grant of Exclusive Marketing Rights ("EMRs"). The recent Patents (Amendment) Ordinance, 2004 (the "Ordinance") officially allows the patenting of chemical, pharmaceutical and agrochemical products, and the provisions of the EMRs have been removed. The mail-box applications filed in the interim period from 1995 until now will be examined from January 1, 2005. The ordinance also brings about changes in the manner in which the grant, publication and opposition of patent applications will be handled. The new provisions allow both pre-grant and post-grant opposition. All patent applications will be published after the expiry of a period to be specified by the Rules of the Act, except in the cases of secrecy or when the patent application has been withdrawn or abandoned. The applicant prior to the grant of the patent shall have the rights and privileges as if the patent were granted on the date of publication, but may not engage in an infringement proceeding until the patent has actually been granted. The ordinance also prevents any resident of India from filing a patent application abroad, before obtaining permission from the Controller of Patents. The application for an invention must first be filed in India, not less than six weeks before being filed abroad. A new provision with respect to compulsory licensing will allow the grant of license to manufacture and

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export patented products to any country where there is insufficient or no manufacturing capacity in the pharmaceutical sector to address health related problems, provided such a country has allowed the grant of the compulsory license as well.

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Impact on Pharma Industry

Of all the chemical industries, the pharmaceutical industry faces the largest challenges and opportunities as well. While the new patent regime will not allow manufacture of

Implications

The allowance for patenting chemical pharmaceutical and agrochemical products will have far-reaching effects. While it was easy for generic companies in the previous years to 'reverse-engineer' a process to make a drug, it will not be possible for these companies to manufacture and sell a drug for which a patent has been granted in India, any more. In order to sell a drug, which has been patented, the generic player will have to obtain a license from the patent holder to sell the drug. This would mean narrower profit margins for the generic companies and also lead to a less competitive Indian market.

The long-term result could mean increased prices for medicines and health care. While the local companies have not been very aggressive in developing and screening new drug candidates, due to financial risks involved with drug discovery, product patents will simply add to the existing financial risks. Besides having funds for research and drug discovery, companies will also have to set aside funds for patents and intellectual property rights. Even if generic companies may not be innovative and file patents, they will still have to seek non-infringement opinions to ensure that they are not violating other patents.

While patenting of agrochemical and pharmaceutical products is now possible, there are many things, which cannot be patented under the Act. Methods of agriculture, methods of treatment, surgical procedures and methods of using a known drug for a new therapeutic use, which are patentable in the United States, are not patentable. While actual drugs can now be patented, the Indian consumer is protected in some ways, as methods of surgical procedures and treatment, which can often be life-saving, will still be free from patent protection.

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generics as was done until today, it will allow the pharmaceutical industry to become more research-oriented and innovative. Indian scientists and engineers, who actually possess great research skills, will now have the incentive to develop innovative products and also receive recognition. Since basic drug discovery is extremely expensive, a lot of activity in improving formulations and drug delivery systems is expected. Besides protecting intellectual property, the Indian companies who are already IP-savvy, will take benefit of the provisions of patent laws in other parts of the world such as the United States. Ranbaxy has recently filed an Abbreviated New Drug Application, challenging Pfizer's top selling drug, Lipitor, in the United States according to the provisions of the Hatch Waxman Act of 1984, which facilitates a faster launch of a generic drug. Pfizer has filed a suit against Ranbaxy, but if Ranbaxy wins, not only will it have access to the world's largest selling drug, but it will also have a six-month exclusivity period, until which no other company will be able to launch a similar product. Though such strategies involve high costs and risks of patent infringement suits, it is extremely important for generic companies to develop and explore patent strategies to exploit the pharmaceutical laws and regulations and receive sizeable benefits. While such provisions are not available in India and not even Europe, the Drug Controller of India must consider the value and impact of such provisions in the near future to provide generic drug products for new molecules, which have been patented, and to provide the Indian consumer with equivalent yet novel generic drugs, which have been priced competitively.

The agrochemical industry on the other hand, has not made much progress in the area of intellectual property. Pharmaceutical companies have filed majority of the mailbox applications. New molecule discovery also has been limited in the

Intellectual Property

agrochemical industry and local competition and markets are not conducive to growth and new development. Several opportunities lie in the area of new formulations and even new molecules, which can by-pass patents held by the large multinational companies. However, the agrochemical industry suffers from lack of IP-awareness, low profit margins and basic innovation.

Promote Innovation

Besides offering challenges, the new patent regime will foster and promote innovation and growth in various ways. Industries will be able to unleash and benefit from the intellectual property they have developed. Scientists should unleash the true value of reverse engineering, by actively filing patents for new processes and products. The failure to patent the results of innovative research can lead to huge financial and strategic losses, as illustrated by Xerox's decision

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in 1979 not to patent its invention of the graphical user interface that later formed the basis of Apple's Macintosh and Microsoft's Windows personal computer operating systems. As a result, Xerox lost its first-mover advantage to other players in the market. As is seen with the case of Xerox, companies must use IP audits and screens for new technologies and hidden IP assets to identify patentable technologies and actively file patents. This will also lead to the creation of new jobs. Indian scientists have always succeeded in various ways to by-pass patented processes through reverse engineering and as a result created novel processes of creating the same product. Scientists must learn to circumvent existing patents to create 'disruptive' technologies and build a patent wall around their product's key differentiating features. Gillette has patented the methods involved in manufacturing the floated angle geometry design of the

Sensor shaver, for example, which were most critical to the product's success.

Simply filing patents and obtaining patents is not the end to obtaining value out of innovative research and intellectual property. Companies must develop an overall patent strategy and continuously work at exploiting and leveraging their patents. Dow is a case in point. In the early 1990s, the dormant

29,000 patents were each identified, valued, and assigned to one of 15 major business units, which thereafter assumed financial responsibility for its use. An intellectual asset management team was set up, which after conducting an IP audit, saved 50 million dollars in taxes and maintenance fees on unneeded patents. Furthermore, since the audit was completed in 1994, patent licensing revenues rose from 25 million dollars to more than 125 million dollars.

Awareness of Intellectual Property

One of the larger challenges that need to be addressed is the understanding and awareness of patents and intellectual property. Though the government is actively promoting the awareness of IP, through institutions, such as patent facilitating centers, workshops, seminars, and as the industry itself prepares employees through internal training and conferences, a lot of work still remains pending. First of all, there is a serious burden of patent applications to be handled by the Indian patent office, and this number will only continue to rise. As patent officers get trained actively, the patent office must also set guidelines for the industry to understand patents. Succinct guidelines in drafting patents, particularly claims, principles of claim drafting, and guidelines in interpreting claims must be provided to industries and patent officers. Claims form the most important part of a patent application, and provide the necessary protection from infringement. The United States Patent and Trademark Office provides guidelines in terms of drafting claims, explaining what is acceptable by the patent office and what is rendered unacceptable.

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Controller of Patents, there are still ways to by-pass this requirement. This provision has been made for secrecy of certain inventions, such as those affecting the defense operations in a country. However, if a foreign company collaborated with an Indian company through contract research, wherein all the intellectual property was at first assigned to the foreign company, there would be no requirement for

the foreign company to file the patent in India. This is still a precarious provision and requires further scrutiny and improvisation.

The new patent regime will now force Indian scientists to document in significant ways. Though traditional medicine has been used for years to treat mankind, today we do not have any accessible literature to cite the use of traditional medicine. Patenting forces the inventor to make available to the public, the details of the invention, including a 'best-mode', which enables another person 'skilled in the art' to implement the invention without much trial and error. It is also important for the gurus of traditional knowledge and medicine to understand the impact of not having accessible published information related to already known traditional knowledge. It would be important for a country like India to be able to protect its traditional knowledge and wealth without allowing the patenting of already known traditional therapeutics.

Conclusion

In the end, even though the patent regime will be closing doors for several businesses, it will be opening doors for new opportunities including strategic research. Indian companies will actually learn to protect intellectual property and derive benefit from it. Several jobs for scientists and lawyers with relevant backgrounds will be created and research in companies will be given a more strategic route. However, it will be very important for the Indian patent office and the policy makers to be able to enforce these laws in an efficient manner. Our legal system has not yet set a good precedent for this new patent regime, and in the interest of innovation, research and new developments, it is extremely important to have an independent system for enforcing patents. □