

## Patents and the Indian Pharmaceutical Industry

a report by

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### Introduction

The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favourable government policies and limited competition from overseas.<sup>1</sup> However, the liberalisation of the Indian economy is revolutionising Indian industries as they begin to emerge from domestic markets and gear up for international competition.

The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Factors such as protection of intellectual property are increasing in significance due to the growing recognition of the need to ensure protection of valuable investments in research and development (R&D). Efforts are being made in India to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive to technological advances and is in keeping with its global commitments.

### Patent Law in India

Patent rights were introduced in India for the first time in 1856 and, in 1970, the Patent Act 1970 ("the Patents Act") was passed, repealing all previous legislations. India is also a signatory to the Paris Convention for the protection of industrial property, 1883, and the Patent Cooperation Treaty, 1970. The Patents Act provides that any invention that satisfies the criteria of newness, non-obviousness and usefulness can be the subject matter of a patent. Some of the non-patentable inventions under the Patents Act include methods of

agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals or plants or substances obtained by a mere admixture, resulting only in the aggregation of the properties of the components, etc.

With regard to pharmaceuticals, in the case of substances intended for use or capable of being used as food, drugs or medicines or substances produced by chemical processes, patents are granted only for the processes of manufacture of such substances and not for the substances themselves. Hence, pharmaceutical products are currently not granted patent protection under Indian law.

India had a product patent regime for all inventions under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.

*"Thus, under our existing patent laws, molecules, which are products of chemical reactions, are as such non-patentable in India. This restriction, coupled with the restriction on mere admixtures resulting in aggregation of properties in which the components do not exhibit any synergistic behavior, severely limit the items, which can be patented in India. "Actives" prepared by chemical synthesis are as such non-patentable in India even if they exhibit functional properties. Likewise, standard drug formulations in which the ingredients behave as mere admixtures also do not qualify for patents in India. In such cases only the process, i.e. the method of making the product is patentable."*<sup>2</sup>

The lack of protection for product patents in pharmaceuticals and agrochemicals had a significant

1. Over 20,000 registered pharmaceutical manufacturers exist in the country. The market share of multinational companies has fallen from 75% in 1971 to around 35% in the Indian pharmaceuticals market, while the share of Indian companies has increased from 20% in 1971 to nearly 65%. <http://www.indiapharmachem.com>
2. Pradubuddha Ganguli, Gearing up for patents: The Indian scenario, p. 47.

impact on the Indian pharmaceutical industry and resulted in the development of considerable expertise in reverse engineering of drugs that are patentable as products throughout the industrialised world but unprotectable in India.<sup>3</sup>

As a result of this, the Indian pharmaceutical industry grew rapidly by developing cheaper versions of a number of drugs patented for the domestic market and eventually moved aggressively into the international market with generic drugs once the international patents expired. In addition, the Patents Act provides a number of safeguards to prevent abuse of patent rights and provide better access to drugs.

reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price.

Patents for certain substances that are not food items or drugs as such but that are capable of being used as food items or drugs are deemed to be endorsed with the words “licence of right” immediately on completion of three years from the date of the sealing of the patent. The effect of endorsing a patent with the words “licences of right” is that any person who is interested in working the patented invention in India may request the patentee to grant a licence. The granting of a licence would be on

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The term of patents in the case of processes or methods of manufacture of a substance intended to be used or capable of being used as food or as a medicine or drug is for a period of seven years from the date of filing or five years from the date of sealing the patent, whichever is less. Patents relating to all other inventions are granted for a period of 14 years from the date of filing the patent, unless shown to be invalid.

The Patents Act also has provisions relating to compulsory licensing. On the completion of three years from the date of sealing the patent, any person interested in working the patented invention may apply for a compulsory licence with respect to the invention. The controller of patents may direct the patent holder to grant such a licence upon the terms as may be deemed fit, only if he or she is satisfied that the reasonable requirements of the public with respect to the patented invention have not been met or that the patented invention is not available to the public at a reasonable price.

In addition to compulsory licensing, the Patents Act includes a provision for “licences of right” where, in certain cases, the central government can, after the expiration of three years from the date of the sealing of the patent, apply for an order that the patent may be endorsed with the words “licences of right”, on the grounds that the

terms that have been mutually agreed upon, even if he/she is already the holder of a licence under the patent. In case the parties are unable to agree on the terms of the licence, they can apply to the controller of patents to arrive at a settlement of terms.

#### **The Impact of the World Trade Organization on Pharmaceutical Patents**

The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and “one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry”.<sup>4</sup> India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS.

India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India’s patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be

3. “TRIPs and Pharmaceuticals: Implications for India”, <http://www.cuts-india.org/1997-8.htm#Pharmaceutical%20Industry%20in>

4. Zafar Mirza, WTO/TRIPs, Pharmaceuticals and Health: Impacts and strategies, The Society for International Development, SAGE Publications.

granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria.

Compulsory licence provisions under Indian law will be required to be limited and conditional to comply with the TRIPS Agreement, and the government will grant such licences only on the merit of each case after giving the patent holder an opportunity to be heard. In addition, there will be no discrimination between imported and domestic products in the case of process patents, and the burden of proof will rest with the party that infringes.

India has decided to avail itself of the full transition period for developing countries and has until 1 January 2005 to extend patent protection to pharmaceutical products. In keeping with the TRIPS commitments<sup>5</sup>, India has started on a process of amending the Patents Act by providing exclusive marketing rights (EMRs) and creating a mailbox system for patent applications for a period of five years or until the patent is granted or rejected, whichever is earlier.

from applying for patents outside India without approval of the Indian government.

The new legislative measures to meet India's TRIPS obligations are currently in the process of being finalised. The Patents (Second Amendment) Bill 1999, which introduces product patents for pharmaceuticals and agrochemicals in India's patent law, is yet to be enacted, and recent press reports have indicated that the Bill is soon to be tabled before the Indian parliament.

### Patents and the Future of the Indian Pharmaceutical Industry

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent-expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced the most advanced medicines through reverse engineering.<sup>6</sup> Foreign firms were required to pay royalties for international drugs, while Indian companies could

*Indian companies need product patent protection to encourage research in developing inexpensive drugs that suit the Indian disease profile.*

This provision was introduced in the Patents (Amendment) Act 1999, which grants the inventors what is known as "pipeline protection". If the applicant has already filed an application for his or her invention in any convention country and a patent or EMR has been granted in that country on or after 1 January 1995, the applicant would be eligible to file for patent to pharmaceutical and agrochemical products in India. These patent applications will be kept pending.

When India changes its patent law as per WTO recommendations, the pending patent application will be eligible for product patent. Until such patent is granted or rejected or for a period of five years (whichever is less), the applicant will be granted EMRs in India if the application is found eligible. The amended Patents Act also provides for compulsory licence for the EMR on the same lines as patents and also omits a provision that prohibited Indian inventors

access the newest molecules from all over the world and reformulate them for sale in the domestic market.<sup>7</sup> Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms.

The obligations imposed on India under the TRIPS Agreement are going to have a significant impact on India's successful bulk and formulation-oriented pharmaceutical industry. Indian companies will have to compete with the multinationals by focusing on drug development and thereby producing their own patented products. Alternatively, Indian companies could focus on producing patented drugs under license from foreign companies or concentrate on generating revenues from producing generic drugs.

Currently, conflicting views exist within the Indian drug companies with regard to India's transition into

5. Article 70 (8), read with Article 65 (2) and (4) of TRIPS, obligates developing countries to provide for a mailbox mechanism for depositing applications and an exclusive marketing rights regime.

6. "Four Opportunities in India's pharmaceutical market", The McKinsey Quarterly, Number 4, 1996.

7. Trade & Development Case Studies, <http://www.itd.org/issues/india5.htm>

8. *Id.*

the product patent regime.<sup>8</sup> Some of the existing pharmaceutical companies believe that product patents will pave the way for innovation in India, while others hold the view that the high cost of R&D will stifle the growth of the Indian pharmaceutical industry.

The key to survival for Indian pharmaceutical companies would be the exponential growth of R&D expenditure. Indian companies need product patent protection to encourage research in developing inexpensive drugs that suit the Indian disease profile.

*“Already the larger firms are increasing their total R&D expenditure as a percentage of sales and they are beginning to move in the direction of new molecule discovery rather than concentrating solely on development research. While some firms may not make the transition, signs thus far suggest that a number of Indian firms will successfully weather the transition and come out as more innovative companies.”*<sup>9</sup>

In addition, the advent of product patents is bound to be a boost for multinational companies that have previously been reluctant to invest in India in the

absence of product patent protection, and it will increase competition in the domestic market.

### Conclusion

The process of liberalisation initiated in 1991 has helped develop policies that are focused on attracting capital from overseas and making India a global industrial base. The resultant inflows of foreign direct investment and technology transfers have created an environment for dynamic growth and increased competitiveness of Indian industry.

*“The current revenues of the Indian pharmaceutical industry are estimated at US\$5.5 billion and it is expected to grow at a compounded annual growth rate of 19% and touch US\$25 billion in revenue by 2010.”*<sup>10</sup>

India is slowly moving into global markets and competing with international quality standards and prices. Although R&D is an important factor to ensure a competitive edge in the international arena, the future of the Indian pharmaceutical industry hinges on patent protection. ■

9. Jean O Lanjouw, “The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?”, Center Discussion Paper No. 775.

10. “Indian Pharma Revenues to touch US\$25 billion by 2010”, The Economic Times, 1 May 2001.

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