

# Patent Protection and the Pharmaceutical Industry in the Indian Union

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India has had success in the pharmaceutical sector with its expertise in reverse technology and is presently focusing on setting policies to promote domestic and foreign investment. Under the TRIPS agreement, developing countries, like the Indian Union (India), were given a 10-year transition period to integrate their patent laws with those of developed countries.<sup>1</sup> With the deadline of January 1, 2005 for product patent protection fast approaching, India is set to emerge as one of the top R&D powerhouses for pharmaceutical and biotech development in the world.

The cost of developing pharmaceutical products is growing dramatically in the international market and India has increasingly been seen as a destination to reduce the cost of development by about 30-40 percent.<sup>2</sup> Moreover, with one of the largest pools of human resources available, India, the largest democracy in the world, is poised to become one of the largest pharmaceutical producers and one of the largest consumers in the world and a world leader in the pharmaceutical industry.

## HISTORICAL BACKGROUND

Indian patent law has had its historical roots in the English patent system. The first patent system appeared in Calcutta (now Kolkata) and granted exclusive privileges to inventors for a period of 14 years.<sup>3</sup> In 1872, the Patent and Designs Protection Act was passed, followed by the Protection of Inventions Act of 1883, and the Indian Patents and Designs Act of 1911.<sup>4</sup> The Indian parliament passed Patent Act of

1970 to promote and develop the domestic pharmaceutical industry to produce pharmaceuticals for the Indian people to alleviate the country's health problem.<sup>5</sup> This was accomplished *inter alia* by removing patent protection for pharmaceutical products.

Under the Patent Act of 1970, the term of a process or method patent was limited to five years from the date of sealing or seven years after the filing date, whichever is shorter.<sup>6</sup> The Indian Patent Act of 1970 effectively offers no protection for pharmaceutical products. The Act gave the Indian pharmaceutical industry decisive competitive advantages by allowing companies to copy the patented products by changing the method by which the patented drug was produced and to market them in India. In effect, the 1970 Act made it possible for many new Indian companies to enter the market for patented pharmaceuticals, without having to cover large R&D expenses. Additionally, the Act placed the burden of proof on the patentee to prove infringement. For process patents, for example, the patentee must ascertain that a particular product could only have been made through a patented process.<sup>7</sup>

In addition to the Patent Act, the Drug Price Control Order of 1970 introduced strong pharmaceutical price controls in India. These price controls were coupled with a compulsory licensing system, which allowed the government to require all private-manufacturing enterprises to be licensed thereby allowing India to select a firm in the country to make a particular drug and sell it at a prescribed price with a small royalty to the patentee.<sup>8</sup> In addition, "parallel importing" or importing of competing generic drugs from other countries, to provide cheaper access to necessary drugs (e.g., AIDS drugs) is also permitted. Parallel importing involves purchase of proprietary drugs from a third party in another country rather than from the patent holder, and allows countries to take advantage of the fact that the prices of drugs vary considerably from one country to another.

Compulsory licensing combined with parallel importing and a protectionist patent system produced remarkable results by spurring the development of a powerful independent pharmaceutical industry,

although one based on generic copies, and obliterated Indian dependence on multinational pharmaceutical corporations. Unfortunately, concurrently, lack of Indian patent protection for products shifted focus away from new product development and product innovation. Scientific research was mainly limited to government institutes and agencies. The so-called "free-riding" allowed the industry to devote very little investment in developing new drugs. Foreign investment in India was restricted by the limitations imposed by socialist centralized economy, unnecessary controls and concern with the lack of product patent regime. Liberalization of the Indian economy in early 90s has helped the generic pharmaceutical industry and as a result India became dominant in bulk and generic drugs. However, currently, the Indian Pharmaceutical industry's R&D spending is a pathetic 1.8 % of the total turnover.<sup>9</sup> Thus, India paid a stiff price in terms of new product innovation due to the absence of a product patent regime.<sup>10</sup>

## AMENDMENTS TO THE 1970 ACT

Transitional patent protection in the form of Exclusive Marketing Rights (hereinafter "EMRs") was brought into force by the Patent (Amendment) Act of 1999.<sup>11</sup> To fulfill commitments to WTO and the TRIPS, India was obliged to provide a means (Mailbox) for accepting applications for pharmaceutical or chemical products, apply applicable priority rights and provide exclusive marketing rights (EMRs) for such products. It is almost as if these applications go into a black box; said box to be opened and all applications therein to be examined when the legislation is changed in 2005. In the transitional period until 2005, EMRs are to be granted for a period of five years, provided the case qualifies for the prescribed EMR eligibility criteria.<sup>12</sup>

At the Fourth Ministerial Conference in Doha, Qatar, in November 2001, WTO members agreed to work on the implementation of the present agreements, as well as to launch new negotiations. The Doha Declaration emphasizes that the TRIPS Agreement does not prevent member countries from acting to protect public health, clarifying the flexibility available, particularly with regard to compulsory licensing and parallel importing.<sup>13</sup>

Recognizing the above facts, recent patent law amendments in India are intended to bring Indian patent law closer to the TRIPS Agreement. The latest in the series of these amendments are contained in the Patents Amendment Act of 2002 and the Patent Rules of 2003.<sup>14</sup>

The Patents (Amendment) Act 2002 brings the following significant changes into force:<sup>15</sup>

- The definition of "invention" is broadened to more closely conform to Article 27 of TRIPS Agreement. "Invention" is defined to mean a **new product** or process involving an "inventive step" and "capable of industrial application." "Inventive step" is defined to mean features to make the invention non-obvious to persons skilled in the art.
- Under Section 3 of the Patent Act 2002, new categories of inventions are excluded such as, plants and animals in whole or any part thereof other than microorganisms; and an invention which in effect is traditional knowledge. This covers anything that has its origins in history including all Ayurvedic drugs.
- "Single Inventive Concept" has been incorporated in Section 10(5) of the Patents Act.
- The term of patent is extended to 20 years from the date of filing for all patents granted after commencement of the Act.
- Patent applications will be published after 18 months from the priority date or the date of filing, whichever is earlier. Once the patent publishes in the Official Gazette, the patent term begins. Publication in the Official Gazette also marks the beginning of the opposition period, during which the public has four months to oppose a patent on statutory grounds.
- A patent application will be examined only on the filing of a formal request by the Applicant or any interested person within 48 months of the filing date.
- The time period to file the reply to the First Examination Report (FER) and put the application in order for acceptance is reduced to 12 months from the date of forwarding of the FER by the Indian Patent Office. The same is non-extendible.
- In a suit for infringement of a process patent, the court may direct the defendant to prove that the process employed by him or her is different from the patented process, provided the subject matter of the patent is a process for obtaining a new product, there is substantial likelihood that the identical product is made by the process and the patentee is unable through reasonable efforts to determine the process actually employed. However, the patentee must first prove that the product is identical

to the product directly obtained by the patented process.

- With respect to biological material patents, a deposit of the biological material with a depository designated by the government of India is required.
- Non-disclosure or wrong disclosure of source or geographical origin of a biological material used in the invention and anticipation of the invention through prior knowledge, oral or otherwise, within any local or indigenous community are additional grounds for opposition/revocation.
- Section 107A brings the "Bolar Exception" provisions to Indian patent law where an act of making, constructing, using or selling a patented invention solely for obtaining regulatory approval under the laws of India or another country do not constitute an act of infringement.

At this juncture, it should be noted that a majority of the drugs sold in India are outside the purview of the new product patent regime, since product patents will be granted only to those drugs that are patented after 1995. The impact of product patents will be felt once new products patented after 1995 enter the domestic market, as the Indian companies will not be able to manufacture generic versions of the same. Indian manufacturers will continue to sell those grandfathered pharmaceuticals. There are legal tools under Indian patent law to overcome patent monopolies if necessary to ensure availability for certain drugs to the Indian population. Further, under Article 27 of the TRIPS Agreement, a country may exclude an invention from patentability if exclusion is necessary to prevent commercial exploitation of that invention "to protect public order or morality, including to protect human, animal, or plant life or health."<sup>16</sup>

The first and second amendments in 1999 and 2002 did not make the Indian patent regime fully TRIPS compliant. In addition, there have been demands from domestic lobbies for a review of the grounds for compulsory licensing to broaden the grounds for invoking compulsory license and under easier practical terms than declaring a national emergency, a process that requires legislative and presidential assents. There is also a demand for an administrative committee to arbitrate disputes of economic significance. Some of these demands have neither been incorporated nor adequately provided for in the provisions of the Patent (Second Amendment) Act 2002. India has yet to

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implement so-called "pipeline" protection, which would extend patent status to products already under patent elsewhere when their subject matter first becomes available in India. Further, if India grants a patent for a "mailbox" application for which generic versions are marketed via a new process, the question also exists as to whether or not existing generic versions of such products will be allowed to remain on the Indian market. Moreover, on May 4, 2004, the U.S. placed India on the Priority Watch List for lax IP laws along with 14 other countries.<sup>17</sup> Hence, a third amendment is necessary before January 2005.

Last year, the government initiated the process for the third amendment to the Patents Act of 1970 introducing the Patent Amendments Bill of 2003.<sup>18</sup> The proposed third amendment would finalize and introduce a TRIPS-compliant product patents regime in the country for foods, pharmaceuticals and chemicals. The "mailbox" applications, which number around 5000, will also be taken up for examination from January 1, 2005.<sup>19</sup> The amendment would also introduce provisions that address domestic concerns and balance the concerns of national and public interest, especially those relating to Indian public health.

## **INDIA'S ROLE IN THE GLOBAL PHARMACEUTICAL MARKETPLACE POST 2005**


Post 2005, as India embraces stronger intellectual property rights, India stands to gain from greater direct investment by multinational pharmaceutical companies, new focuses for Indian pharmaceutical companies in brand development and an expansion of India's role in the global marketplace, especially in research trials, and production.

In addition, the Indian companies will also have opportunities in contract manufacturing and contract research and co-marketing. The FDA regularly inspects and approves Indian pharmaceutical manufacturing facilities. Patent law changes could



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consign smaller, weaker Indian pharmaceutical manufacturers to bankruptcy but for successful firms, the U.S. healthcare system's need for less expensive generic drugs presents a great opportunity. Unlike the past, when American consumers would not accept a product made in India, consumers are willing to obtain medication cross-border and via mail to avoid higher prices. Moreover, the potential of the global generics market, given the fact that majority of the blockbuster drugs are expected to go off patent soon, is also a good opportunity for Indian pharmaceutical companies. Several pharmaceutical companies such as Dr. Reddy's, Ranbaxy, and Biocon have already made their global presence felt and have entered the U.S. generic market. Several Indian pharmaceutical companies including Cipla, Lupin, Wockhardt, Nicholas Piramal and Torrent are engaged in R&D activities. Further R&D initiatives undertaken by Indian pharmaceutical companies could see the launch of innovative drugs by these companies.

On the other hand, strict patent protection will significantly increase the price of new patented drugs such as AIDS drugs for the Indian people. Indian manufacturers will not be able to copy new drugs patented on or after January 2, 2005.<sup>20</sup> Fortunately, less than 10% of India's list of essential drugs are covered by patents worldwide.

Accompanying stronger patent protection there will also be greater incentives for collaborative research and global alliances. India is currently focusing on attracting multinational pharmaceutical companies to choose India as the preferred hub for their global R&D and manufacturing operations. After 2005, when patent protection is provided, jobs will be displaced from the developed countries like the U.S. to India, due to the very competitive scientific talent that is available in India. Outsourcing of pharmaceutical production is growing in America, to lower-cost countries like

India.<sup>21</sup> The need to reduce the total cost of drug development has resulted in the increasing trend toward outsourcing research to specialized Contract Research Organizations as well as conducting clinical trials in countries like India, where costs are one seventh that of America or Europe. These opportunities will not occur unless India becomes TRIPS compliant.

## CHALLENGES TO NEW IP LAWS IN THE INDIAN UNION

India faces several challenges in implementing stronger IP laws. The first challenge is to pass new pieces of legislation through the Parliament. As a thriving democracy with a multiparty system, where political coalitions are the order of the day, it is a daunting task to legislate any laws that are perceived as anti-people or anti-poor.

Secondly, even if the laws are promulgated through the parliamentary process, they could be challenged on various Constitutional or other grounds in the Supreme Court. The first and recent grant of an EMR to Novartis for its anti-cancer drug 'Glivec' has reinstated faith in government's commitment towards the patent regime. However, the opposition that the EMR approval has received from the domestic pharmaceutical industry indicates that bringing a third amendment to The Patent Act, 1970 and its implementation will be easier said than done. Also, Constitutional validity of the Patents (Amendment) Act, 1999 was challenged in the Supreme Court by a public interest litigation (PIL) petition alleging it was against the public interest, public health and national interest.<sup>22</sup> Such litigations have substantially delayed realization of a TRIPS compliant patent regime in India.

A third challenge to implementation of new IP laws is the inadequate patent office capacity level in India to ensure the application of patent criteria and examination of patent applications. With implementation of new IP laws will come an increase in the number of patent applications submitted to the Indian Patent Office. India has the unique distinction of having four independent examination centers located at Kolkata, the head office, with branches at New Delhi, Mumbai, and Chennai. Although there has been a major overhaul of the Indian administrative framework covering modernization of the Patent Office, including computerization, a backlog of patent applications still exists.

## CONCLUSION

India has come a long way in the past 35 years under the protectionist patent regime,

having developed a strong presence in the bulk drug and generic industry. India is making forays into indigenous new drugs as well as branded drugs for multinationals. Today, India stands poised to capitalize on the global and domestic opportunities the new patent regime can provide. **IPT**

## ENDNOTES

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