Product Patent Protection – India’s Interest

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TRIPS, the intellectual property component of the Uruguay round of the GATT Treaty, developed a strong debate among developed and less developed countries. Developed countries welcomed the TRIPS agreement on the ground that their business interests incurred large losses due to imitation and use of their innovations by the less developed countries and, the introduction of IPRs would encourage the flow of foreign investments, transfer of technology and for greater research and development in the less developed countries. But the less developed countries negatived such introduction on the ground that the stronger IPRs result into drastic rise of product prices and also may cause harm to infant high tech industries. India was a strong opponent of TRIPS Agreement particularly the proposal for product patents on pharmaceutical innovations on the belief that “the better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.” However, India unwillingly signed this international treaty on TRIPS and committed to introduce pharmaceutical product patents in the country.

Intellectual Property (IP) is the product of the mind or the intellect and Intellectual Property Right (IPR) is a legal right which authorizes it’s holder to have an exclusive right of use of intellectual capital. IP is protected at law in the same way as any other form of property. Initially these intellectual property laws are territorial as such their applicability is restricted to their territorial jurisdiction. But now due to developments in international trade and cultural exchange these laws are made flexible for adoption by different states. This harmonization became possible due to adoption of various international treaties by different countries such as adoption of World Trade organization (WTO) Agreement on ‘Trade Related Aspects of Intellectual Property Rights (TRIPS)’.

TRIPS is an international agreement came into force on January 1st, 1995 lays down certain minimum standards for protection and enforcement of IPRs in WTO member countries. It provides different norms for different areas of intellectual property i.e., copyrights and related rights, trade marks, geographical indications, industrial designs, lay out designs of integrated circuits, protection of trade secrets, patents and plant varieties. It’s main objective is to remove all impediments to international trade through promoting an effective and adequate protection of IPRs. To implement TRIPS agreement

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different transition periods are provided for different countries. Generally five-year transition period was granted for most of the developing countries, i.e., these countries are required to fully comply with the TRIPS Agreement by January 1st, 2000. For other developing countries transition period is upto January 1st 2006, which is further extended to January 1st 2016.

However, certain developing countries whose transition period expired on January 1st 2000 and did not provide product patent protection for all areas of technology as on that date an additional five-year transition period (January 1st 2005) was granted to implement product patents protection in all such areas of technology not previously protected. Being India is one of such countries which did not provide product patent protection for pharmaceutical products at the end of their transition period, i.e., January 1st 2005, is now under obligation under TRIPS Agreement to extend product patent protection to its pharmaceutical products.

The introduction of pharmaceutical product patents in India was highly criticized by many critics. According to them this patent protection restricts the scope of developing countries easy accessibility to essential medicines. On the other hand some critics welcomed the patent protection on the ground that it encourages for more pharmaceutical products research and innovation within India thereby more innovative and quality pharmaceutical products be introduced into Indian National Markets. Thus, there exists a strong belief that the revised Indian patent law provides better and improved pharmaceutical products in India.

Patent Protection under Patent Law means an exclusive right for an invention of a new and useful device, design or process. This right can be assigned to others through a license agreement with the patent holder. The license agreement discusses what the licensee can do with the invention of the patent holder in exchange of royalty payable to him. In India Patent Protection can be availed by filing a patent application with the Controller of Patents under the Patent Act, 1970.

The Indian Patents Act, 1970 is the parent legislation implemented in 1972. It made pharmaceutical product innovations unpatentable in India thus greatly weakening IPR protection. It permitted the innovations to be freely copied and marketed in India though it is patented in other countries. Further this Act laid certain restrictions on import of finished formulations, imposed high tariff rates and introduced regulations for strict price control in par with the 1970 Drugs Price Control Order. All these gave a strong background for the development of Pharmaceutical Industry in India. However, this development made use by the domestic and international pharmaceutical companies free of cost. Many of the developing and under developing nations relied on the Indian Pharmaceutical industry for inexpensive copies of these pharmaceutical products.

To restrict this free supply and to give full compliance to the TRIPS Agreement the Indian Government amended the patent law as ‘The Patents (Amendment) Act, 2005 in the midst of strong opposition by both domestic and foreign pharmaceutical companies. This Act was the replica of the Patent (Amendment) Ordinance, 2004. It was published in
the Official Gazette on April 4th 2005 and deemed to come into force from January 1st, 2005. Some of the salient features of this Act are

- Extension of product patent protection to all areas of technology, i.e., drugs, foods and chemicals;
- Deletion of the provisions on exclusive marketing rights;
- Introduction of transitional provisions for safeguarding exclusive marketing rights already granted;
- Granting compulsory license for exporting medicines to countries having insufficient or no manufacturing capacity and to meet emergent public health situations in par with the Doha Declaration on TRIPS and Public Health;

This Patent (Amendment) Act, 2005 replaced process patents with the product patents. Process Patent gave the monopoly on the process as such but not on the product produced out of such process whereas Product Patent gives the monopoly on the product itself. This Act allows the payment of royalty for all those process patent holders from such enterprises which made significant investment and were producing and marketing the concerned product prior to January 1st 2005 and continue the same as on the date of grant of product patent. On payment of royalty no infringement proceedings shall be instituted against such enterprises. (Section 11A)

The process patent differs with the product patent. It is more consumer-benefit oriented rather than commercial in its approach. Under the Process Patent, more than one manufacturer using the patented process with a slight modification of its version can produce the same drug. This led to competition in the market between different producers producing the same drug thereby accelerating the growth of pharmaceutical industry in India and easy accessibility of drugs at low prices. On the other hand the product patent on drugs permits the patent holder either to produce the patented drug on his own or allow others to produce with his permission. As a result of this limited scope for production the patented drug prices tend to increase greatly and shall be out of reach for majority people of India.

With the Patent Reform 2005, two kinds of generic drugs are legally allowed to produce and market in India. They are the generic drugs already off patent in regulated markets prior to 1995 and the generic drugs patented prior to 1995. Nearly 80-90% of the generic drugs fall into one of these two categories. These reforms are expected to cause serious price concerns for the domestic market and for the poor countries to which Indian Companies export their pharmaceutical products. However, there exists a strong belief that these post patent reforms serves as a base for fixing the pharmaceutical product prices competitively.

In granting product patents there exists a trade-off between the costs incurred by the country granting the patent due to monopoly pricing and the gains accruing to it due to encouragement to innovative efforts.

The introduction of pharmaceutical product patent protection maximizes the inventor’s profits and drug prices. This results into low consumption of drugs thereby indirect
welfare loss to the Indian Drug Consumers. Many a times the product price includes the
direct costs of administering the patent system and enforcing patentee rights through the
courts in case there exists any patent infringement disputes.

This privilege of getting maximum profits enables the investor to invest more of his
profits in Research and Development and, discovery and testing of pharmaceutical
products. This leads to an increase of consumer welfare. Further, the new patent law
requires the disclosure of specifications of all new technologies in order to make them
easily available for others to apply in their own research and development. Also the
innovating firm can reveal it’s invention without losing it’s control and hence can render
parts of its innovation at lower costs to countries like India.

Thus, the Patent Reform 2005 is a turning point for the Indian Pharmaceutical Industry.
It raised the expectations from the industry both in terms of product and service quality.
Foreign Companies too are showing their pharmaceutical business interests in India
because India with regulated markets are increasingly complying with Good
Manufacturing Practice, Good Laboratory Practice and Good Clinical Practice guidelines.
Undoubtedly such Patent Reform is bound to influence the overall competitive structure
and business models for domestic pharmaceutical companies. It is likely to bring certain
underpin changes in the quality, prices and availability of products. Hope the government
takes all the possible steps to control the pharmaceutical product prices for easy
accessibility to a common man.