PRODUCT PATENTS AND ITS EFFECT ON INDIAN PHARMA INDUSTRY

Introduction

Patents are international issues; hence its laws are equally complicated. There are many issues involved like product & process patents, license of rights, compulsory license which may snag even a common man. One of the major implications of TRIPS in Indian patent law – Product patent can be studied by the comparative analysis of the Patent Amendment Act 2005 with TRIPS.

Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement obliges the WTO member nations to make laws to include Art. 27.1 So that patents shall be available and enjoyable without discrimination as to the place of invention, field of technology band whether products are imported or locally produced. It also provided a transition period of 5 years for developing countries[1]. This provision of TRIPS gave birth to new amendment to the existing patent laws of both developed and developing nations. In US Patent Law 35, US sec. 104 dealing with inventive activity was modified in accordance with TRIPS requirement as to non discrimination, as to place of invention[2]. The Indian Patent Act 1970 also extended product patent protection to agro chemicals, food and pharmaceuticals, which were kept outside the purview of product patents. Sec.5 that excluded all the above fields from product patents was omitted by Patent Amendment Act (PAA) 2005[3].

It was a known fact that India needed to reintroduce product patents. Some opined that this was the sole requirement for the Indian Patent Law to become TRIPS compliant. It is often assumed that India changed its Patent Law only because of international pressure on TRIPS compliance issue. But it is always left out that local industries were also demanding higher level of patent protection. The sea change brought by India's participation in international trade also demanded a strict Patent law.

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1 Article 65.4 of TRIPS Agreement

2 Prabuddha Ganguli IPR unleashing the knowledge economy;1st Edition, TATA Mc Graw hill pub; 2001; p.80

3 Section 4 of PAA 2005

Debates on omission of section 5:

The omission of sec 5 from the parent Patent Act 1970 kindled lot of debates and provoked opposition to the Patent Amendment Bill. The reason is that the Indian Patent Act 1970 helped the pharmaceutical industry to achieve rapid growth rates as only process patents were granted for medicine and drugs. This helped Indian pharma industry to reverse engineer patented drug molecules. This mechanism was followed in India to produce medicines at low cost for poor people. As a result of omission of sec 5 the generics of drugs which have been granted process patents since 1995 will not be available in Indian markets leading to increase in drug prices.

The period of patent is also extended to 20 years unlike the one which was for 5 or 7 years in process patents. Moreover India has agreed to award product patents on New Chemical Entities that had been patented in any of the Patent Co-operation treaty member Countries on or before January 1st, 2005. As a result the generics of drugs which had process patents since 1995 will not be available in Indian market without the prior permission of the company that has the patent.

On analyzing the provision it was conceived by many commentors that Section 4 of PAA 2005 is a serious set back for India's economy, pharma industry's growth and to public health. Nevertheless it seems TRIPS compliant.

Conclusion

On one hand the process of amending Indian Patent Act 1970 has opened new vistas for Indian pharma industries while on the other it has become a threat for right to health and life of common people. The amendment has enabled global firms to take up renewed interest in Indian pharma industry. In spite of the evolution of pharma industry, in the light of new amendment to Patent law, many global players are still skeptical due to uncertainties in the law. Some of the areas of concern include narrowing the definition of patentability to New Chemical Entities broadening the scope of compulsory licensing to include affordability and lack of data protection. Another concern with respective MNCs is that the new patent law extends to products that are in R&D pipeline and doesn't cover most products already in the market leaving many products exposed.

Access to medicine is the primary concern of the public in a country like India which has introduced product patenting. The generic drug industry is very well affected by the PAA 2005. The Act has failed to protect their interest, as the generics which were producing and marketing drugs for which patent applications made in “mailbox” would be compelled to pay “reasonable royalty”. The term reasonable royalty in sec 11-A (7) of PAA 2005 is not properly defined leaving the choice to the patentee to decide the same without any standards. Canada has fixed the reasonable royalty at 2% leaving no scope for any ambiguity. This might either generate a lot much litigation for demand of unreasonable royalty or infringement suits. The following can be introduced to make easy access to medicines

- ✓ Using TRIPS flexibilities including compulsory licensing, without surrendering to MNCs’ pressures and to guarantee drug production by generics at low cost.
- ✓ Develop India’s rich traditional knowledge on ayurvedic and other alternatives to encourage collection of ancient literary works to protect the same from being patented by other countries.
- ✓ Introduce drug price control mechanism
- ✓ Encouraging new invention by proper R&D activities.

The new law should not come in way to stop the economic progress of the country and to vitiate the constitutional right to health and life. Henceforth proper measures should be taken to protect the interest of the public which is the eventual objective of the Patent Legislation.

Article by
C.BamaPriyaDarshini M.L.,
Advocate
JURY BRAIN LAW OFFICES