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Review Article

Implications of patents on cost of medicines in pharmaceutical industries

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ABSTRACT

The Indian pharmaceutical industry with a market capital of 7.5 billion in 2011-2012 offers more than 27000 brands of medicines including average new launches of about 2000 products in year. Surprisingly, for the common ailment of pain alone over 3325 brands are available and choosing the most safe and effective drug amongst them is practically not possible by the poor patient. After Supreme Court's decision in the V.P. Shanta Case[1], medical profession has been brought u/s 2(1) (o) of the CPA 1986. With implementation of the Patent (Amendment) Act 2005, the cost of medicine would be dearer to patients. In 2007, Madras High Court rejected the writ by Novartis which had challenged the validity of the Indian Patent Law. This lead cost benefits through cheaper medicines by Indian Companies like Cipla & Bayer, Delhi HC 2010 paved the way for cost relief to patients after litigating patent issues.

1. INTRODUCTION

A patent is intellectual property right that grants an inventor the right to exclude others from making, using, selling, offering to sell and importing an invention for limited period of time in exchange for public disclosure of the invention [2]. The first Indian Pharmaceutical Company, Bengal Chemical and Pharmaceutical Works, which still exists as government owned drugs manufacturer, appeared in Calcutta in 1930. For the next 60 years, most of the drugs in India were imported. The government encouraged the growth of drug manufacturers in Indian companies in 1960 and with the Patent Act 1970, enabled the present status. This Patent Act removed composition patent from food and drugs, while it kept the process patents, these were shortened to a period of 7 years. The lack of patent protection in Indian market undesirable to MNC's. Indian Companies carves a niche in both the Indian and the world market including USA, UK etc because of their expertise in reverse-engineering new process of mfg. Drugs at low costs. Ranbaxy, Cipla, Biocon, etc. have so far taken a baby step towards drug innovation and patent application. In 2011-2012 the sales of Indian Pharmacy is due to touch US $7.5 billion [3]. The top rank in last 5 years has been shared by Ranbaxy, Glaxo, Cipla, Dr. Reddy, Nicholas, Mankind, Lupin, Cadila etc.

2. TRADEMARK IMPORTANCE IN PHARMA

A trademark is usually applied to the name of the product and may go on forever, that is Kleenex, Tylenol etc. Companies may lose their trademarks if the company does not protect its mark and it falls into the public domain. Aspirin is not a trademark for US as it has become a common name for ASA and therefore Aspirin can be used by any company. Brand name, trade name and trademark are all used interchangeably. A trademark for the same drug may differ from country to country. A patent is good for 20 years from the time of registration and only applies to a new discovery or invention. Anyone can make a product once his patent is expired, which is called as generic drug. Only the original company can use trademark, for eg. Aspirin is the trademark for ASA or their own trademark.

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3. IMPACT OF POST PATENT LEADING CASES

The patents are not given for new forms, uses or minor modification of existing drugs unless they differ significantly with regard to efficacy. This is ever-greening which is disallowed under patent law.

A. Gilead Patent Case

The United States patent and trademark office (USPTO) rejection of four patents held by Gilead Sciences on a key HIV drug Tenofovir, paved the way for affordable treatment of millions of patients. For the domestic generic industry, the development encourages production of the drug in the country, and gives them opportunities to export to developing countries. Its lowest price in Brazil is $ 2766 per patient per year, which was halved at $1400 after threat of compulsory licence and one seventh of the price by Indian generics such as Hetero Drugs, Cipla and Matrix offered drug at as low as $195 per patient per year [4].

B. Novartis Case

Novartis had challenged the validity of Section 3(d) of The Patent Act,1970 in the Chennai patent office, its patent application for a new use for its cancer drug, Gleeve was rejected by the patent office in January 2006 [5].

C. Ranbaxy Vs. Pfizer Case For Lipitor Battle

Ranbaxy Laboratories in its patent litigation with Pfizer [6] over cholesterol lowering drug Lipitor (Atrovastatin), for reissue of patent, USPTO allowed Ranbaxy to launch its generic Atorvastatin in the US market by March 2010.

D. Pfizer Case

Court invalidates Pfizer's reissue patent for Celebrex (painkiller). The companies exclusivity will expire on May 30, 2014. Tevan, Mylan and Activis have already received U.S. food and drug administration approval to being producing the drug generically once Pfizer's patent expire [7].

4. CONTROVERSIAL ARGUMENTS REGARDING COST OF PATENT DRUG *VS*. GENERIC DRUG

Patent provide incentive to innovate. The cost of developing a new drug has greatly increased [8]. Patented drugs are more expensive than their generic counterpart. Patent protection for pharmaceutical products in the developing countries can help to encourage the development of new medicines for disease that affect these countries by providing protection for the investments that need to be made by pharmaceutical companies. However, patents on drugs can also make it more difficult for developing countries to afford the medicines they need. To overcome this problem the world trade organization (WTO) has create regulations regarding export of such drug to developing countries before patent expiration [9]. Many experts agree that the drug price competition and patent term restoration act has a significant effect on the availability of generic substitute for brand name drugs [10].

5. SUGGESTIONS AND CONCLUSION

Impact of The Patent (Amendment) Act 2005 includes:

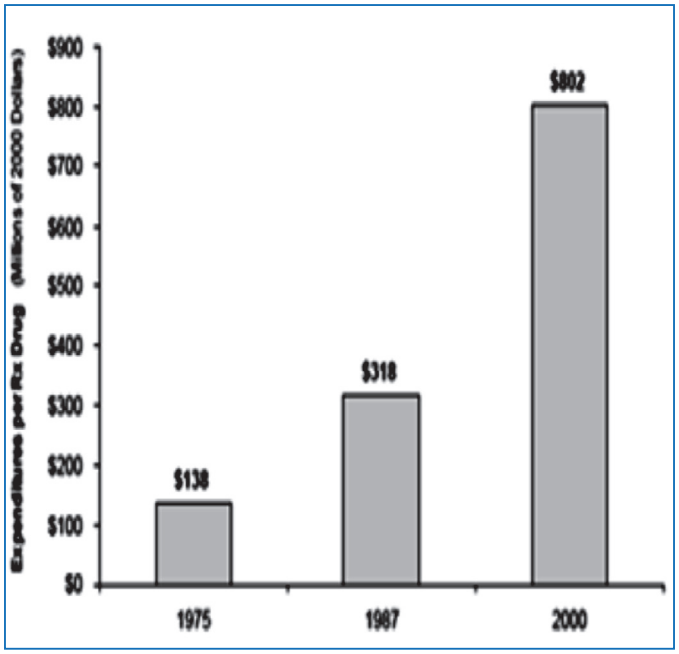

Fig. 1. Bar graph showing increase in cost for developing new drug

1. Deletion of the provisions of Exclusive Marketing Rights.
2. Revocation of Patent in Public Interest (Sec, 66) empowering the Govt. to revoke a patent when found mischievous to the State.
3. Conditional Grant of Patent (Sec. 47).
4. Acquisition of invention and patent for public purpose (Sec. 102).
5. Bolar provision (Sec 107(A)): Facilitate production and marketing of patented products after expiry of patent. Pharmaceuticals should take this opportunity for promoting generic drugs.
6. Grant of Compulsory Licence (Sec. 82 to 94). This relates to compulsory licenses in order to protect public interest. These provisions check the abuse of patent rights. Sec. 92 of this law provides for action in case of national emergency, extreme urgency and public non-commercial use, and can be invoked without the grace period of 3 years from grant of patent [11].

It is concluded that the importance of patients and the imposition of patents is of utmost significance for costs of drugs. In Indian prospective, compulsory licensing in Swine Flu, Dengue etc. must be resorted and government must invoke such provisions.

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