PROVIDING HEALTHCARE THROUGH APPROPRIATE PATENT SYSTEM IN INDIA

ABSTRACT:
India recognized the product patent for pharmaceutical products from 2005, which created a lot of controversies surrounding accessibility and affordability of medicines. Indian government accepted Product patents from prospective effect rather than retrospective effect. In addition, a number of safeguards were also mentioned that restrict frivolous patents. Inclusion of section 3(d) in the amended Patent Act assures that the provisions of Patent system are not misused by pharmaceutical companies. In India around 80 % of population incurs Out-of-pocket expenditure on healthcare, which is very high compared to certain developed countries. In addition less than 5% of population is covered by health insurance. Even health insurance premium has to be paid by individuals. Public health expenditure on healthcare is very low. The cost of medicine occupies a major share in overall healthcare cost borne by patients. A few measures are proposed in this article to balance incentives for innovation and access to affordable medicines.

Key Words: Patent system, India, Healthcare

INTRODUCTION:

The Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement has created a lot of debate at international level. The debate revolves around the impact of TRIPS agreement on availability and accessibility of low cost affordable medicines. Indian pharmaceutical industry is regarded as supplier of low cost quality medicines to developing and developed world. Indian pharmaceutical industry took advantage of liberal patent regime, which was framed with the objective of making India self reliant in the field of pharmaceuticals. Indian Patents Act 1970 provided for only process patent in the field of agrochemicals, food and pharmaceuticals. In addition, the duration of patent was restricted to only 7 years from date of filing or 5 years from date of grant, whichever was earlier. For next 25 years Indian pharma industry grew by leaps and bounds manufacturing and marketing generic version of patented medicines without fear of infringement. Access to affordable medicine by large mass of people helped improve the health status and growth of indigenous pharmaceutical companies. Indian government signed TRIPS agreement that was a part of General Agreement on Tariffs and Trade (GATT) abiding to provide Product patents in India from 1995 for all fields of technology, including pharmaceuticals. India being a developing country was given 10 years transition period to fully comply with the requirements of TRIPS. Indian pharmaceutical industry faced a serious problem as they could no longer manufacture and market generic version of patented molecules. The Patents Act 1970 was amended thrice- in 1999, 2002 and 2005 to make it fully compliant with requirements of TRIPS. The Indian government viewing access to affordable medicine as prime concern, provided for product patents from prospective effect rather than retrospective effect. This proved to be a big relief to pharmaceutical companies as the products manufactured and marketed by them till 2005 would not infringe on the existing patents. The Indian government included safeguards in the final text of amended Patent Act 2005 to restrict grant of patent for trivial improvements. The Indian government also provided safeguards with respect to drugs that are manufactured and marketed by Indian pharma companies after TRIPS implementation.

PHARMACEUTICAL INDUSTRY, RESEARCH AND PATENTS:

It is widely acknowledged that patents and IPR play an important role in research and development (R&D) in health and pharmaceutical sector. Patents are considered important considering high cost of R&D (Correa, 2000). A study conducted by Tufts University Centre for Study of Drug Discovery and Development (CSDD) it takes nearly USD 800 bn to develop and market a new drug. Pharmaceutical industry tries to recover the cost on research and development by patenting their invention. This would prohibit competitors from entering the market. According to reports by Pharmaceutical Research and Manufacturers of America (PhRMA), 5 of every 10,000 compounds investigated enter clinical trials and of these 5 only 1 is subsequently approved for marketing. Thus the industry argues that whatever amount is spent on Research and Development needs to be covered as most of the money that is used for R&D does not yield any new medicine (PhRMA, 2006). Opponents often argue that pharmaceutical industry spends more on marketing than on R&D. According to Schweitzer (1997) the marketing expenses for three of the largest US pharmaceutical

companies — Merck, Pfizer, and Eli Lilly — ranged from 21 to 40% of annual sales revenues, while the R&D expenses varied between 11 and 15% (Brekke and Straume, 2005). Gagnon and Lexchin (2008) have also identified that the amount spent by US pharma industry on promotion is twice as much as it spends on R&D. The industry's claim that the patents are required for protection of R&D work carried out does not seem convincing. Only 1% of the medicines developed over the past 25 years were for tropical diseases and TB, which together account for over 11% of global disease burden (WHO 2004a). According to WHO report on The World Medicines Situation (WHO, 2004b), only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden — the so-called 10/90 Gap. The role of medicine patents in an era of increasingly global trade rules is a key issue in arguments over access to essential medicines, as demonstrated by the conflict over access to antiretroviral medicines for people with HIV/AIDS in low-income countries. According to Commission on Intellectual Property Rights (CIPR) a commonly used indicator of technological capability is the extent of patenting activity in the US and through international applications through the Patent Cooperation Treaty (PCT). In 2001, less than 1% of US patents were granted to applicants from developing countries, nearly 60% of which were from seven of the more technologically advanced developing countries (CIPR, 2002). However, today's developed countries had excluded pharmaceutical product patents according to their developmental requirements. The examples include Germany until 1968; France, 1960; Japan, 1976; Switzerland until 1977; Italy until 1978; Spain until 1992; Portugal until 1992; Norway until 1992; Finland until 1995, and Iceland until 1997. (Scherer and Watal, 2001; Nogues, 1990). This clearly shows that countries need to adopt a flexible system with regard to patent that would help advancement of country technologically, socially and economically.

BACKGROUND OF TRIPS AGREEMENT:

The TRIPS agreement covers a range of Intellectual Property issues. The Uruguay round of GATT negotiations was used by developed countries to introduce a number of issues that were not considered part of trade negotiations and one of these issues included introduction of patent system and other forms of Intellectual Property Rights (Sengupta, 2005). Before the Uruguay round of GATT negotiations many countries had not granted patent protection for pharmaceutical products. These countries include developed countries such as Spain and Portugal and many developing countries such as India, Brazil, Mexico, Egypt were reluctant to extend patent protection to pharmaceutical products. The controversy over the agreement on TRIPS heightened when, in December 1991, Arthur Dunkel, the then Director-General of the GATT, submitted a complete draft accord to help negotiators concentrate on final text of the draft. During the Uruguay round of negotiations between 1986 and 1993, the strategy of some of the developing countries was concentrated on limiting the expansion of the TRIPS agenda. Before the TRIPS agreement, countries had more flexibility in excluding certain sectors of the economy from patent protection in their national laws (Alikhan and Mashelkar 2004). It appears that the inclusion of TRIPS on the agenda of Uruguay round was a last minute political compromise and TRIPS featured as a footnote on a crowded agenda of the Uruguay round of negotiations

(Adede, 2001). It has been said that the text of TRIPS agreement was originally formulated by the pharmaceutical multinational companies of major developed countries and was presented and pushed by the governments of the respective countries (Chaudhary and Gurbani, 2004). Ultimately, after several round of negotiations, countries agreed to adopt standards set out in TRIPS agreement, which culminated in 1994 and set the way for establishment of World Trade Organization (WTO). India, along with other developing and underdeveloped countries, became a member of WTO. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS (Zacharias and Farias, 2002).

PROCESS PATENT TO PRODUCT PATENT: TRANSITION FOR INDIAN PHARMACEUTICAL INDUSTRY:

The Patents Act 1970 was framed after years of deliberations and was based on the recommendations of two expert committees including Justice Rajagopal Ayyangar Committee. The Ayyangar committee (1957-1959) noted that foreign patentees were acquiring patents not "in the interest of the economy of the country granting the patent or with a view to manufacture there but with the object of protecting an export market from competition from rival manufacturers, particularly those in other parts of the world" (Ramanna A, 2003; Narain S., 2005). Indian Patents Act 1970 specifically excluded patent coverage for pharmaceutical products and only allowed process patent (Fink, 2000). The Indian Patent Act of 1970 thus constituted a 'narrowing' of the IPR regime (in opposition to TRIPS), increasing the incentives for Indian firms as second innovators (Ramani and Maria, 2005). Prior to Patents Act 1970, medicines were largely imported from developed countries. MNCs operating in India were largely importing medicines from their country of origin. The Patents Act 1970 provided impetus to indigenous companies to make generic medicines that could be available at a fraction of the cost compared to patented medicines. The Patents Act 1970 legalized "reverse engineering" in India which resulted in a robust domestic pharmaceutical industry (Chaudhuri, Chatterjee and Mehta, 1997). India signed GATT agreement and thus was bound to honor obligations under TRIPS agreement providing a uniform patent term of 20 years from the date of filing. This meant that Indian companies could no longer "reverse engineer" patented molecules and sell in Indian market. The forte of Indian companies, so far, was the liberal patent law that allowed them to market generic version of patented medicines. The signing of GATT agreement was considered to be detrimental for Indian pharma industry. Many groups opposed the idea of signing GATT agreement and adhering to TRIPS requirements, as it was felt that the cheap generic medicines from India would dry up and may render medicines unaffordable to a large section of the society. The Indian Patents Act 1970 has been amended thrice since India became a member of WTO. Indian pharmaceutical companies are considered to be the supplier of quality medicines at affordable prices. The thriving pharma industry that took advantage of process patent was no longer allowed to do so and thus, Indian companies cannot market molecules patented by other companies. This means that Indian pharmaceutical companies need to develop their own molecules by investing in basic R&D.

Indian government has tried to curb the practice of "evergreening". The amended Patents Act 2005 includes Section 3(d) which prohibits a company from patenting new form of existing substance unless enhanced efficacy is demonstrated over a previously known substance. This is particularly important as MNCs tried to extend patent life beyond normal 20 years by filing for additional patents on salts, esters, polymorphs etc. once the patent on any blockbuster molecule was set to expire. Some of the MNCs were denied patents for new form of existing substance. Glivec case was a landmark case where the new form on existing compound Imatinib was denied patent protection in India. In another case, the Delhi Patent Office rejected the German pharmaceutical company Boehringer Ingelheim's product patent application for its paediatric form of anti-AIDS drug nevirapine. These cases show that the government of India is interested in supporting domestic pharmaceutical companies by providing essential safeguards in the Patent Act.

HEALTHCARE IN INDIA:

In India, only around 15 percent of the population has any type of health insurance, primarily through employers. In 1999 the Indian government opened the insurance market up to private insurers; however, their market share is still quite small, barely covering 1 percent of the population. In India, the share is even higher, increasing from about 70 percent in 1987–88 to more than 80 percent in 2002–03 (Yip and Mahal, 2008). At about $20 (in purchasing power parity, or PPP), India's per capita public spending on health—currently about 1.1 percent of GDP—is much lower than that of most other countries with comparable per capita GDP. Private health spending far exceeds the public spending. At about 80 percent of total health spending, India has among the highest shares of private (household) spending in the world (Deolalikar et al., 2008). These figures show that out-of- pocket spending on health is high in India including the cost of medicines.

AMENDED PATENT ACT AND ITS IMPLICATIONS:

Indian made final amendments to its Patent Act in 2005 and made it fully TRIPS compliant. This Act received assent of the President of India in April 2005 and was effective from January 1, 2005. The amendments in Patent Act tried to ensure a balance between incentives for investment in R&D and access to affordable medicines. The amended Act tried to restrict the practice of "evergreening" that was followed by several multinational pharmaceutical companies. "Evergreening" means extending the life of patent by patenting trivial innovations in form of its use, shape, dosage form, strength etc. The practice of "evergreening" prohibited the competition among manufacturers that would drive the prices of medicines down. Amended Patent Act 2005 introduced a Section 3(d), which states that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes,

combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;". This section created a lot of controversy as multinational companies opposed the move by saying that it does not comply with the requirements of TRIPS, whereas several sections of Indian society regarded it as a deterrent to "evergreening". The implications of this section were seen when the Patent on anticancer drug Glivec (Imatinib Mesylate) was rejected as company filed a separate patent application for different salt form of the same molecule. In another case, Delhi Patent office rejected the the German pharmaceutical company Boehringer Ingelheim's product patent application for its paediatric form of anti-AIDS drug nevirapine (Singh, 2008). More such cases may be seen in future. While amending the Patent Act, Indian government ensured that frivolous patents are not granted that would prohibit the access of affordable medicine. Further, the Act was implemented with prospective effect rather than retrospective effect. This means that molecules that were patented by research based companies after 1995 in India, can be manufactured and marketed by Indian companies by paying reasonable royalty to patent holder. Had this not been the case, many Indian pharma companies would have to withdraw several medicines from the market, which were quite economical compared to patented medicines.

SUGGESTIONS FOR MAKING MEDICINES ACCESSIBLE AND AFFORDABLE IN INDIA:

Following measures are proposed in order to make medicines accessible and affordable to a large section of Indian population.

a. Prices of new patented medicines may be negotiated by the government through National Pharmaceutical Pricing Authority (NPPA).

When a pharmaceutical company intends to market a new medicine, the government taking into account the cost of manufacturing and reasonable profit, should negotiate the price of medicine with the manufacturer. The government can take appropriate measures it deems fit, if price charged for a medicine is high. NPPA should be entrusted with the task of negotiating the prices with the manufacturer.

b. List of life threatening diseases should be prepared for which, if a drug is granted patent, should be brought under price control.

A list of life threatening disease would help government to decide the grant of patent for medicine used to treat a particular illness. If a company files a patent application for medicines used to treat a life threatening disease, appropriate measures to avoid abuse of patent rights may be enacted.

c. For incremental innovations of existing molecules, grant of "Petty patents", which is of much shorter duration than the regular patent term, should be granted.

For incremental innovations such as modification of salt, ester, a dosage form or strength of medicine, a mechanism for grant of "petty patents" or "utility model patents" should be provided. The "petty patents" or "utility model patents" are granted for a shorter duration, usually of three years than usual term of twenty years. A shorter protection of incremental innovation would prevent companies from filing a totally new patent even for an incremental innovation.

d. Use provisions of "Compulsory License" proactively.

Indian government has not used the provision of “compulsory license” and should be proactive in issuing “compulsory license” to protect public health, if situation demands

e. A review and monitoring board that keeps a check on price of patented medicines. Company(ies) need to justify high cost of medicine.

To set up a review board to monitor prices of patented medicines that are marketed by pharmaceutical companies. If the board feels that the price charged by a pharmaceutical company for marketed medicines are high, it should submit its review and recommendation to government for corrective actions.

f. Government of India can encourage people to opt for medical insurance so as to cover the expenditure on healthcare including medicines.

Encouraging people to opt for medical insurance would reduce the burden on healthcare. Out-of-pocket expenditure on healthcare and medicines would come down.

CONCLUSION:

Indian government should ensure that implementation of product patent does not affect accessibility and affordability of medicines to people. In order to ensure availability of quality medicine at affordable price, patent system should be used judiciously. Indian Patent Act 1970 that was amended in 2005 has ensured that pharmaceutical companies do not misuse the patent system. Provision of effective safeguards and its appropriate implementation would ensure balance between incentive for innovation and access to affordable medicines.

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