PATENTING OR MONOPOLY OF PHARMACEUTICALS IN INDIAN SCINERIO

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Summary

Patent is a legal protective incentive to the innovator which offers both recognition and monterey benefit to the inventor. Patenting of pharmaceuticals has been one of the important factors in the tremendous growth of pharmaceutical industry world-wide. The growth of the pharmaceutical industry is dependent on the research and development process which is only feasible in strong patent system in the country. Patent provides an opportunity to recoup the cost of invention, which is quit substantial in many cases and to make profit out of the invention. In lieu of above in India the patent may be granted as per Indian patent act, 1970 and patenting of pharmaceuticals was only effective from 01.01.2005 onwards to protects the rights of inventors engaged in the research and development of pharmaceuticals. This article may improve and update the knowledge of readers regarding the patenting or monopoly of pharmaceuticals.

Keywords: GATT, TRIPS, IPR, WTO, Secretes, Pharmaceuticals

Introduction

Research and development is a vital instrument for growth and expansion of pharmaceutical Industry, because it leads to invention of new drug, new therapy and new dosage form. This process involves a huge amount of resources in terms of manpower, money and time which cost to company. The only way to realise this investment and earn the profit on the same is through commercial exploration of the new invention by the proper marketing strategies, protection of new creation for the benefit of the inventor so that competitors cannot offer the similar product in the market[1]. A patent may be viewed as a contract between a nation and the inventor giving him the exclusive rights to make use or license his invention for a specified period of time and in exchange, the inventor describes his invention in sufficient detail to permit those skilled in the art to employ it. Patenting of pharmaceuticals has been one of the important factors in the tremendous growth of pharmaceutical industry world-wide. Patents have given the inventors the necessary incentive to develop new processes and molecules which are widely used in therapy. All over the world the system of granting Patents of new invention has been accepted to protect and encourage intellectual faculty of man and also to improve the living standards. The progress and prosperity of the nation depend on the level of scientific, industrial and technological development. The people behind that are inventor and research workers and they have to be encouraged and inspire to accelerate their research and

development activities by providing them proper incentives, assistance and rewards for their valuable work. A strong patent system helps in fast and better industrial, technological and economical development of the country and a motivation to the innovator and industry. In the area of the pharmaceuticals patent become the pivotal element for the growth and development of the industry along with the improvement in the health status of the country by providing the newer and better molecules to the society. The word wide growth of the pharmaceutical industry is dependent on the research and development process which is only feasible in strong patent system in the country. The principle objective of pharmaceutical industry is to produce commercial products for economic gain. However, any industry will not initiate high-risk, long term projects without knowing that the results of its research effects can be legally protected from competitors. Collectively these sanctioned privileges are called intellectual property right and include trade patents, trade secrete comprise private information about special technical procedures and formations that a company wishes to protect from others[2].

A patent is a legal document that gives the patent holder exclusive rights to implement the described invention commercially. On the other hand a patent is a public document that must contain detailed description of invention, so it informs other about the nature and limits of inventions, allowing them to decide whether they should continue working in a particular direction or try to use the patented invention as a springboard to other possible inventions.

Patent

A patent is a government granted and secured legal right to prevent others from practicing i.e. making, using or selling the inventions covered by the patent[3]. A patent is a monopoly right, grant by the law, to commercial use of an invention that is new useful and adequately disclosed[4]. A patent is a document which describes an invention and creates a legal situation in which the invention can normally only be exploited with the authorization of the owner of the patent. In other words, a patent protects an invention and grants to the owner, exclusive rights to use his invention for a limited period of time. Patent is one of the oldest form of intellectual property protection, the aim of a patent system is to encourage economic and technological development by rewarding intellectual creativity. Patent protection will provide a reward not only for creation of an invention, but also for the development of an environment to the point at which it is technologically feasible, marketable and useful to the public and desirable for the public good. It provides an award for disclosures of the creation of something new as well as for the further development, or refinement, of existing technologies. Patents are available for any inventions, whether processes or products in all areas of technology. A chemical compound, a machine, a product and a process for developing or making things can be patented. On the basis of above it is can be assumed that a patent cover every area of technology as pencil to helicopter[5].

Objectives of patents

Most countries have regulations to protect intellectual property right like patents, copyrights and other protective forms governing industrial and artistic creations. The main objective of patents protection is to-(i) encourage research and invention. (ii) induce an inventor to disclose his discoveries. (iii) offer a reward for the expenses of developing inventions to the state at which they are commercially

practicable. (iv) providing an inducement to invest capital in new lines of production which might not appear profitable if many compete simultaneously.

Criteria for granting a patent

The agreement on trade related aspects of intellectual property rights provide three criteria and conditions for an invention to be patentable-(i) Novelty-the first of those criteria is that it has to be new meaning that the invention must never have been made before, carried before or used before. (ii) Inventive step-means it must represent a sufficient advance in relation to the state of the art before it was made to be considered worth patenting. (iii) industrial application an inventive step, and be capable of industrial application.

Can be patented

Generally a product or a process to be patentable, it must fulfils the following fundamental requirements-(i) the work must be novel. (ii) a patent cannot be granted for something previously unknown. (iii) the invention must be useful. Products patents and process patent make up the two major categories-(i) products include homogeneous substances-complex mixtures and various devices. (ii) Process includes preparative procedures-(i) methodologies and actual uses. The patenting of biotechnological invention[6-10] has been based on historical experience of patenting inventions by agricultural, fermentation, pharmaceutical and medical industries, i.e. Louis Pasture received a patent for a process for fermenting beer, and A. Chakrabarty also got a patent in 1980 for "a live" human made micro-organism. Common types of patent categories with e.g. from rDNA technology[11,12]-(A) Products patents-(i) substance-cloned genes, rProteins, monoclonal antibodies, plasmids, promoters, vectors, cloned DNA sequences and monovalent vaccines. (ii) composition of matter-multivalent vaccines, biofertilizers, bioinsecticides, pharmaceutical mixtures, micro-organisms and transgenic organism. (iii) devices-pulse field gel electrophoresis apparatus, DNA sequencing apparatus and microinjectable gene transfer machine. (B) Process patents-process of preparation-DNA isolation, synthesizing dcDNA, and vector insert construction, PCR applications, and purification of rProteins. Methods of working-Nucleic acid hybridization assays, diagnostic procedures, detection systems using PCR and mutant assays. (C) Use-applying biofertilizers and bioinsecticiders, fermentation of genetically modified organisms and nontherapeutical animal treatment systems.

Cannot be patented

There are things that can not be patented and usually excluded from the scope of patentability. For example the process of cloning human being or animal, things exist in nature (with few exception) can not be patented[12]. Inventions and discoveries that are not patentable include-(i) scientific theories, (ii) mathematical models and (iii) therapeutic treatment of human or animals. In addition a consistent principle of patent law is that patent cannot be granted for anything i.e. a "product of nature".

Indian patent law

The system of patents in India is governed by the patent act 1970, (was passed on 27 February 1970) which contains necessary provisions for protection of invention as well as prevention of abuse or misuse of patent rights. The principal objective of the Indian patent act-1970, is stated in section 83 of the said Act, namely that-(i) patent are granted to encourage and secure the invention. (ii) patent are not granted merely to enable patentee to enjoy a monopoly for the importation of patented article. Indian government always recognised the importance of patent system. This is obvious from that Indian patent system is 127 year old. The first provision in the nature of patent right in British India was enacted in 1856, but without the previous

sanction of the Queen of England. This act was therefore formally repeated in same in 1857, in 1859, another act free from defects of 1857, was passed in which monopolies were styled as "Exclusive privileges". The act of 1859 was further supplemented by the Patents and Design Protection Act of 1872 and 1883. Subsequently, all the three Acts of 1859, 1872, and 1883 were superseded by the Act V of 1888, which was further revised and replaced by the Indian Patent and Design Act 1911. This act was amended from time to time (in 1920, 1930, 1945 etc.). After independence in India a committee of enquiry was appointed to suggest the modifications and alterations needed for in the Indian Patent and Design Act 1911. Based on the final report (1951) of this committee a new patent bill-again based on the United Kingdom Patent Act 1949 was introduced in parliament in 1953. The bill could not be passed and justice N Raja Gopala Ayyangear was requested to advice the government regarding the provision of Indian patent law. Based on this report (1959) and the report of the joint committee of parliament the Indian patent act 1970 was passed on 27 February 1970[13].

Intellectual property and its protection

The constitution recognised new invention as the intellectual property, created and owned by the inventor[3] (Glick and Pasternak, 1994). Owner may use his property as he wishes and nobody else can lawfully use his property without his permission. The intellectual property is protected and governed by the appropriate national legislations. The national legislation specifically describes the inventions which are the subject matter of protection and those which are excluded from the protection. The different types of protection available in the IPR are as follows-patents, copyright, trademarks, designs, and know-how. Of these, patents are most important form of protection for research and development organisations.

General agreement on tariffs and trade

To promote and liberalised the international trade an organisation was formed in 1948 by the name of General Agreement on Tariffs and Trade (GATT). As a result of Uruguay Round the GATT was transformed into a World trade Organisation (WTO) with the effect from January 1995. The primary objective of GATT was to expend international trade by liberalising trade so as to bring about all-around economic prosperity. The preamble to the GATT mentioned the following as its important objectives-(i) raising standard of living. (ii) ensuring full employment and a large and steadily growing volume of real income and effective demand. (iii) developing full use of resources of the world and (iv) expansion of production and international trade. The eight rounds of the multilateral trade negotiations held under the auspicious of the GATT is known as Uruguay Round as it was launched in Punta del Este in Uruguray, a developing country, in September 1986. Because of the complexities of the issues involve and the conflicts of interests among the participating countries, the Uruguray round could not be concluded in December, 1990 as was originally scheduled. After modification final act was signed by ministers of 125 governments on 15th April 1994. The result of the Urugary Round was implemented within ten years since 1995. Different time period are given for effecting the different agreements. One of the major controversies regarding the Uruguray Round agreement under GATT about the trade related aspects of intellectual property rights (TRIPS). The TRIPs agreement of the Uruguray Round encompasses seven areas of intellectual property rights, namely, copyrights, trademarks, trade secrets, protection of undisclosed information, industrial design and traditional knowledge, geographical applications, integrated circuits and patents[14]. In these seven areas, it is only in the area of patents that India's policies, law and regulation are not in conformity with the TRIPs agreement. Under the Indian

Patent Act, 1970, for food, pharmaceuticals and agrochemicals there is only process patent, no product patent. This means that one can produce a product similar to the patented product through a different process or method than the patented one. This practise has been very prevalent in the Indian pharmaceutical industry this is the reason that in Indian pharmaceutical market the different brands of similar molecules are available from different manufacturers. Further, under the existing patent law in India, the duration of the patent protection for the above product was seven years and for the other product fourteen years. According to the TRIPs agreement of the Uruguary round, there shell be both process and product patents the period of the patent protection shell be 20 years. In India the process patent for the pharmaceuticals was adopted due to fear of monopolisation and resultant sharp increase in the price if the product patent was accepted seems to be exaggerated. Because in Indian contest the most of the research product or patented product have there therapeutic equivalent in the market means every molecule have there substitute. So the price war is always prevalent in the market which forces the competitive price policy by the different manufacturers. Patent, according to the Indian Patent act, 1970, could be obtained up to 31.12.1994 only for inventions of method or process of manufacturing in chemicals, pharmaceuticals and food with the issue of the Patent (amendment) ordinance 1994, promulgation of the new order accepting "Product" patent has been introduced with the effect from 01.01.1995 with the 20 years of life span of a patent. But finally it was adopted for the Pharmaceuticals in 01.01.2005 because, a transition period of the 10 years was provided to the India and other developing countries were provided under TRIPs agreement to amend their laws[13,15].

Patentable pharmaceuticals

The following types of inventions in pharmaceutical field may get patent-(i) new chemical entities. (ii) process for preparing new chemical entity. (iii) pharmaceutical intermediates. (iv) pharmaceutical compositions of new compounds. (v) new pharmaceutical compositions of old compounds. (vi) process for preparing new compositions. (vii) methods of treatments. (viii) first pharmaceutical use of a known compound, and (ix) second or new pharmaceutical use of a known compound.

Merits and demerits of patenting

Patients provide incentives to individuals by offering them recognition for their creativity and material rewards for their marketable inventions. The following are some of the benefits of patenting-(i) patenting permits discoveries to be disclosed adding to the scientific and technical knowledge. (ii) legal monopoly afforded by the patent. (iii) it constitutes incentives to new discoveries. (iv) patent ensures that the inventor company gets the benefit of its research. (v) society-at-large benefits wherever patented products useful to a number of people become available to public. (vi) society also benefits by learning about inventions through the publication process. Society benefits by obtaining something it lacked previously and which might never have been made available to the public except for publication of the patent. Demerits of patenting-(i) monopoly of patent holders. (ii) higher pricing. (iii) restricts competition. (iv) curtails new inventions. (v) these favour large corporations at the expense of the individual inventor or small companies, and (vi) with secrecy, time and effort wasted on repeated experiments[16,17].

Conclusion

All over the world the system of granting patents of new invention has been accepted to protect and encourage intellectual faculty of man. The progress and

prosperity of the nation depend on the level of scientific, industrial and technological development. A strong patent system helps in fast and better industrial, technological and economical development of the country. Because a strong Patent system provide a motivation to the innovator and industry both for the research and development with leads to new useful product in the market. The word wide growth of the pharmaceutical industry is dependent on the research and development process which is only feasible in strong patent system in the country. In lieu of above in India the patent may be granted as per Indian patent act, 1970 and patenting of pharmaceuticals was only effective from 01.01.2005 onwards to protects the rights of inventors engaged in the research and development of pharmaceuticals. This article may improve and update the knowledge of readers regarding the patenting of pharmaceuticals.

References

1. Saha R. Intellectual property rights (IPR), a bulletin from TIFAC, DST, New Delhi. 2002; 8(6): 1-16.
2. Saha R. Some questions and answers on patents copyrights, designs, trademarks, IL layout designs and geographical indications. TIFAC, DST, New Delhi. DOC: 2002; 023: 1-42.
3. Glick BR, Pasternak JJ. Molecular Biotechnology, Principles and applications of recombinant DNA, Ist eds., ASM Press, Washington, D.C. 1994.
4. Brunton LL, Lazo JS, Parker KL. (eds.): Goodman and Gilman's, The Pharmacological Basis of therapeutics, 11th eds.: McGraw-Hill, New York, 2006.
5. Coase RH. The problem of social cost. J. Law & Economics 1960; 3: 1-44.
6. Barton J. Patent scope in biotechnology. International review of industrial property and copyright law 1995; 26: 605-618.
7. Buccola ST and Xia Y. The rate of progress in agricultural biotechnology. Review of Agri. Economics 2004; 26(1): 3-18.
8. Heathcotte B, Robert JS. The strange case of the humanzee patent quest. Natl. Catholic Bioethics 2006; 6: 51-59.
9. Reichman JH, Dreyfuss RC. Harmonization without consensus: critical reflections on drafting a substantive patent law treaty. Duke Law J. 2007; 57(1): 110-111.
10. Malviya R, Bhardwaj V, Srivastava P, Bansal M, Sharma PK. Biotechnological innovations patents: a review. Intr. J. Pharmaceutical Sci. Rew. Res. 2010 3(2): 131-133.
11. Eisenberg RS. Genes, patents and product development. Science 1992; 257(5092): 903-908.
12. Hellar AM, Eisenberg SR. Can patents deter innovation, the anticommons in biomedical research? Science 1998; 280(5364): 698-701.
13. http://www.patentoffice.nic.in/ipr/patent/patents.htm
14. Ghai D. Patent protection and Indian pharmaceutical industry. Inter. J. Pharmaceutical Sci. Rew. Res. 2010; 3(2): 43-48.
15. Kaul A, Ahmed H. (). Prognosis on the new patents regime. ICFAI.
16. Boyd MR. The position of intellectual property rights in drug discovery and development from natural products. J. Ethnopharmacol. 1996; 51: 17-27.
17. Jain, N.K. (Eds.): Progress in controlled and novel drug delivery systems. (Ist eds.): Agarwal SP, Khanna R, Agarwal S, Karmarkar R. In: Patenting of novel drug delivery systems. CBS Publishers and Distributors. New Delhi. 2008; 21: 510-550.