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Patent in Medicines

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ABSTRACT: The Indian pharmaceutical industry is a promising industry focused on high technology that has seen steady growth over the past three decades. Several privately held Indian firms form the current industry players who have gained a large share of the domestic pharmaceutical market due to factors such as favorable government policies and limited overseas competition. However, as they continue to emerge from domestic markets and brace up for foreign competition, the liberalization of the Indian economy is revolutionizing Indian industries. A patent is a legal instrument that conveys to the patentee (the patent holder) the right to exclude others from making, using, selling, or offering to sell the subject matter of the patent “claims.” Medical patents, for purposes of the present article, will be defined broadly to include patents that relate to pharmaceuticals; methods of making and using them; medical treatment regimens; surgical procedures; medical devices; health care information technology for hospital and health care management systems. This paper discusses the same briefly.

KEYWORDS: Economy, Industrial Growth, Medicines, Pharmacy, Pharmaceutical Industry.

I. INTRODUCTION

As India opens its markets to foreign trading, the Indian pharmaceutical sector is a prime example of an industry which is being pressured to rethink its long-term policies and business models. Owing to the growing awareness of the need to ensure the security of important investments in research and development, considerations such as intellectual property protection are increasing in importance (R&D).

In India, attempts are being made to curb problems of poor enforceability of current laws on intellectual property, and the Indian government is working towards the development of a patent mechanism that is conducive to technical advances and complies with its global obligations. In 1856, for the first time in India, patent rights were introduced and the Act was signed, repealing all existing laws. India is also a signatory to the Convention of Paris on the Defense of Industrial Goods, 1883, and the Treaty of 1970 on Patent Cooperation.

The Patents Act specifies that the subject matter of a patent may be any invention that meets the conditions of creativity, non-obviousness and usefulness. Any of the non-patentable inventions under the Patents Act include agricultural or horticultural techniques, procedures for the care of human beings, animals or plants by medical, surgical, curative, prophylactic or other means, or substances obtained by a mere combination. This only results in the aggregation of the components' properties, etc.[1]

As far as pharmaceuticals are concerned, in the case of substances intended for use or capable of being used as foodstuffs, as medical products or as medicinal products or as substances created by chemical methods, patents shall be issued only for the production processes of those substances and not for the substances themselves. Thus, under Indian law, medicinal drugs are technically not given patent rights.[2]

II. DISCUSSION

India is also expected to conform with the minimum requirements laid down in the TRIPS Agreement with respect to inventions and patents. India's patent law must also provide requirements for the availability of patents for technologies

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for both pharmaceutical drugs and processes. Patents shall be issued to any creation of a medicinal substance or method that fulfills defined requirements for a minimum period of 20 years.

In a pharmaceutical corporation, a new medication is first created to be marketed for a disease disorder, first distributed as a brand name under which the medicine can be prescribed by physicians for consumer use. The medicine is protected by patent rights, ensuring that only the pharmaceutical firm owning the patent is able to produce, sell and potentially benefit from the drug. [3]

Under the Patents and Designs Act 1911, India had a commodity patent scheme for all inventions. The nation, however, enacted the new Patents Act in 1970, which disqualified pharmaceuticals and agrochemical products from patent eligibility. This exclusion was implemented to sever India's reliance on imports of bulk medicines and formulations and to encourage the growth of an indigenous pharmaceutical industry that is self-reliant.

Thus, in India, molecules that are products of chemical reactions are as such non-patentable under our current patent laws. This constraint, combined with the restriction on mere admixtures resulting in accumulation of properties in which no synergistic activity is displayed by the materials, significantly restricts the things that can be patented in India.

Health care Information Technology

Patents that focus on streamlining the flow of medical history information through electronic medical records, patient data picture archiving, health information exchange systems within or among hospital systems and/or physicians, web-based medical software applications, computerized physician order entry and digital imaging, are some examples of healthcare information technology related patents. This category of medical patents has been the fastest growing category of medical patents in recent years, and the number of medical patents in this area is expected to continue to grow.

The exponential growth of medical patents in this category stems partially out of a need to find new methods and systems designed to contain and manage medical costs more efficiently. 14 Medical patents in this category function to reduce the administrative costs of providing health care, while at the same time increasing the ease of access to medical services for greater numbers of patients.

As such, in India, "Actives" prepared by chemical synthesis are not patentable even though they possess functional properties. Similarly, in India, traditional drug formulations in which the components act as mere admixtures often do not apply for patents.

The lack of protection for product patents in pharmaceuticals and agrochemicals had a significant effect on the Indian pharmaceutical industry and contributed to the growth of significant reverse engineering skills in drugs that are patentable as products in the developed world but unprotected. As a result, the Indian pharmaceutical industry expanded quickly by producing cheaper versions of a range of domestic market-patented products and gradually shifted successfully to the multinational generic drug market after the expiry of international patents. Furthermore, a range of provisions are provided under the Patents Act to discourage misuse of patent rights and offer better access to medicines. [4]

The Government of India is working towards the development of a patent scheme that is conducive to technical innovations and complies with its global obligations. Patents shall be valid for a term of seven years from the date of filing or five years from the date of sealing of the patent, whichever is less, in the case of processes or methods of processing of a material intended to be used or capable of being used as a food or as a medicine or device [5], [6].

Patents relating to all such inventions shall, unless proven to be invalid, be issued for a term of 14 years from the date of filing of the patent. There are also clauses pertaining to compulsory licenses in the Patents Act [7].

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When three years have elapsed after the date of sealing of the patent, any person involved in working on a patented invention may apply for a compulsory license in respect of the invention. Only if the patent controller is convinced that the fair conditions of the public with regard to the patented invention have not been fulfilled or that the patented invention is not available to the public at a reasonable price, can the patent controller order the patent holder to issue such a license on such terms as may be considered fit[8].

III. CONCLUSION

"In addition to compulsory licensing, the Patents Act includes a provision for "licences of law" where, in certain cases, the central government may, after three years from the date of sealing of the patent, apply for an order that the word "licences of law" may be endorsed by the patent on the ground that the reasonable requirement is "licences of right Patents on those items which are not foodstuffs or drugs as such but which are capable of being used as foodstuffs or drugs shall be declared to have been endorsed automatically after three years from the date of sealing of the patent with the words "licence of right".

Medical patents and innovations in health care improve the quality and delivery of medical care and the quality of life for millions of people around the world, and especially in the United States. Challenges remain in finding the most effective manner for making these advances available to individuals in greatest need, primarily because of cost constraints. The United States system governing innovation and implementation of medical patents, in balance with commercial interests and safety/efficacy concerns, while time consuming and expensive, provides a measured framework within which societal health care benefit through products created through medical patents may be realized.

The result of endorsing a patent with the term 'licences of law' is that any person interested in operating a patented invention in India can apply for a license from the patentee. A license will be issued on terms mutually agreed upon, even though it is still the holder of a permit under the patent. In the event that the parties are not in a position to settle on the terms of the license, they can apply.

The creation of the World Trade Organisation (WTO) has contributed to a tremendous paradigm change in world trade. During the Uruguay Round of Trade Talks, the Deal on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was concluded under the General Agreement on Tariffs and Trade (GATT) and "one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry" 4 India signed the GATT on 15 April 1994, making it mandatory.

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