

An overview on the Management of Intellectual Property in Pharmaceutical Industries on Drug Patent Specification with the support of IPR -A Glimpse

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Abstract: Intellectual property (IP) is a term referring to a brand, invention, design or other kind of creation, which a person or business has legal rights over. Almost all businesses own some form of IP, which could be an asset. IP rights can be enforced by bringing actions to the civil courts or through criminal prosecution. India's IP laws set out procedures for both civil and criminal proceedings, as does the Competition Act. Criminal proceedings do not apply to patent and design infringements. . These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions. Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. This paper also deals with the history of IPR, objectives & types of IPRs. Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property.

Keywords: Drug, intellectual property, importance, patent, Patent Co-operation Treaty, pharmaceutical industry

INTRODUCTION

In wake of globalisation, it is utmost important to be ahead in innovations and creativeness to compete the stiff competitions in technology and trade. India is well recognised for its intellectual skills in the fields of software engineering, missile technology, Moon or Jupiter mission and other technological areas. However, India lags in generation of IPR assets in terms of registered patents, industrial design, trademarks, etc. In a recent report by the US Chamber of Commerce, India stood at 29 th position amongst 30 countries in IP index around the globe. It is very alarming condition for policy makers as well as for the nation as a whole. The development of any society directly depends on IPR and its policy

framework¹. Lack of IPR awareness resulted in the death of inventions, high risk of infringement, economic loss and decline of an intellectual era in the country. Thus, there is a dire need for dissemination of IPR information so as to boost indigenous inventions and developments in the field of research and technology.

Origin of IPR

The existence of IPRs is very old. The basic aim of conferring an IPR upon the person owning the same is to give a social recognition to its holder. This social recognition can further bring economic benefits to its holders. It is just and reasonable to award a person an IPR in the form of "limited monopolistic rights" for his/her labor and efforts². At the same time, exceptions in the form of various licenses are also made so that public interest cannot be compromised. The public interest and personal interests are thus reconciled in the form of limited period duration of these rights and their abuses can be tackled stringently, especially when public interest demands so³. Thus, the TRIPS Agreement was formulated to bring basic level harmonization in IPR laws all over the world. The provisions of the TRIPS Agreement are the most extensive and

1Jajpura L, Microfinance and Microentrepreneurship: A Paradigm Shift for Socital Development (Edited by Dr. Surender Mor, Vista International Publication House, Delhi), First Edition, 2015, 263-271.

2Sinha B, Joshi H & Ghosh P K, Challenges in creation and management of knowledge capital in technical educational institutions, Journal of Intellectual Property Rights, 14 (2009)340-345.

3 Melissa R , Something old, something new, something borrowed, something blue: A new tradition in non-traditional mark registrations, Cardozo Law Review, 27 (2005) 457.

rigorous in nature. They protect all forms of IPRs collectively. IPR is not a new concept. It is believed that IPR initially started in North Italy during the Renaissance era. In 1474, Venice issued a law regulating patents protection that granted an exclusive right for the owner. The copyright dates back to 1440 A.D. when Johannes Gutenberg invented the printing press with replaceable/moveable wooden or metal letters. Late in the 19th century, a number of countries felt the necessity of laying down laws regulating IPR⁴.

Importance of IPR

Intellectual property rights refer to ideas and innovations that are created by individuals. These are very important and have to be protected at all costs as without their protection, there would be no scope for further research and expense on development as people will start using other's ideas and kill the basic feeling or the first step of any basic product or service in the market, i.e., Innovation. These rights not only help individuals keep their intellectual property safe but also provide them with various ways in which they can use their intellectual property to expand their business without having to worry about the concept being copied or stolen. These rights also provide one with ways to start a chain of their business with having complete control and authority from a single place of their choice, thus leading to the best use of these intellectual property rights. The asset class of Intellectual Property generates revenue for business entities through licensing, franchising, sale of protected products or services⁵. In case of a merger or acquisition protected IP assets increase the value of business significantly. The importance of Intellectual Property is evident in export markets as well. Protected Intellectual Property assets can be exported abroad or franchising agreements can be sought with foreign companies. It is pivotal to note that the top organization in the world which have been ranked in billions namely, Apple, Microsoft, Blackberry have developed a powerful revenue stream because of their extensive IP assets.

4 Samaddar S G & Chaudhary B D, Practical insights into intellectual property strategy for technical institute, Journal of Intellectual Property Rights, 13 (2008) 590-600.

5 Michaels A. 2nd ed. London: Sweet and Maxwell; 1996. A practical guide to Trade Mark Law.

Maximum benefits can be reaped through a strong IP portfolio which can be used to increase revenue through licensing stream⁶.

Intellectual Properties and their Description

Originally, only patent, trademarks, and industrial designs were protected as 'Industrial Property', but now the term 'Intellectual Property' has a much wider meaning. A patent is awarded for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial or commercial application. Patents can be granted for products and processes. As per the Indian Patent Act 1970, the term of a patent was 14 years from the date of filing except for processes for preparing drugs and food items for which the term was 7 years from the date of the filing or 5 years from the date of the patent, whichever is earlier. No product patents were granted for drugs and food items⁷. A copyright generated in a member country of the Berne Convention is automatically protected in all the member countries, without any need for registration. India is a signatory to the Berne Convention and has a very good copyright legislation comparable to that of any country. However, the copyright will not be automatically available in countries that are not the members of the Berne Convention. Therefore, copyright may not be considered a territorial right in the strict sense. Like any other property IPR can be transferred, sold, or gifted⁸.

Patent Cooperation Treaty (PCT)

The patents are territorial rights; therefore applicant has to apply patent application to patent offices of different countries individually. This practice requires huge amount of investment, time and

6 Abbott F, Cottier T, Gurry F. London: Kluwer Law International; 1999. The international intellectual property system: Commentary and materials. Part I.

7 Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004. Law relating to intellectual property (A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case-Law and much more).

8 New Delhi: Commercial Law Publisher (India) Pvt. Ltd; 2005. Anonymous. The Copyright Act 1957 as amended up to 1999 along with Copyright Rules 1958 and International Copyright Order 1999.

energy. In the same concern Patent Cooperation Treaty (PCT) concluded in 1970 which provides a facility to file a single international patent application instead of filing several separate national or regional patent applications. Although granting of patent remains under the national or regional patent authorities of various PCT member nations but applicant get the priority date of first filing applicable in all member countries which is more than 145 in number with this single patent application⁹.

Basic of Pharmaceutical Industry

The race to unlock the secrets of human genome has produced an explosion of scientific knowledge and spurred the development of new technologies that are altering the economics of drug development. Biopharmaceuticals are likely to enjoy a special place and the ultimate goal will be to have personalized medicines, as everyone will have their own genome mapped and stored in a chip. Doctors will look at the information in the chip(s) and prescribe accordingly. The important IP issue associated would be the protection of such databases of personal information. Biotechnologically developed drugs will find more and more entry into the market. The protection procedure for such drug will be a little different from those conventional drugs, which are not biotechnologically developed¹⁰. While doing a novelty search, the databases of these depositories should also be consulted. Companies do not usually go for publishing their work, but it is good to make it a practice not to disclose the invention through publications or seminars until a patent application has been filed¹¹. Further, for inventions involving genes, gene expression, DNA, and RNA, the sequences also have to be described in the patent specification as has been seen in the past. The alliances could be for many different objectives such as for sharing R&D expertise and

9 Nair M D, TRIPS, WTO and IPR – World Patents, *Journal of Intellectual Property Rights*, 15 (2010) 151-53.

10 Mrudula BS, Durgadevi NK, Madhavi BR, Tejeswi B, Durga PV. Intellectual property rights pinpoint at IPR spotlights coveted R and D. *Drug Inv Today*. 2009;2:197–201.

11 Glasgow LJ. Stretching the limits of intellectual property rights: Has the pharmaceutical industry gone too far? *IDEA J Law Technol*. 2001;41:227–58.

facilities, utilizing marketing networks and sharing production facilities.

Drug Patent Specification

Writing patent specification is a highly professional skill, which is acquired over a period of time and needs a good combination of scientific, technological, and legal knowledge. Claims in any patent specification constitute the soul of the patent over which legal proprietary is sought. Discovery of a new property in a known material is not patentable. If one can put the property to a practical use one has made an invention which may be patentable. A discovery that a known substance is able to withstand mechanical shock would not be patentable but a railway sleeper made from the material could well be patented. A substance may not be new but has been found to have a new property. It may be possible to patent it in combination with some other known substances if in combination they exhibit some new result. The reason is that no one has earlier used that combination for producing an insecticide or fertilizer or drug. It is quite possible that an inventor has created a new molecule but its precise structure is not known. In such a case, description of the substance along with its properties and the method of producing the same will play an important role¹².

Management of Intellectual Property in Pharmaceutical Industries

More than any other technological area, drugs and pharmaceuticals match the description of globalization and need to have a strong IP system most closely. Knowing that the cost of introducing a new drug into the market may cost a company anywhere between \$ 300 million to \$1000 million along with all the associated risks at the developmental stage, no company will like to risk its IP becoming a public property without adequate returns. Creating, obtaining, protecting, and managing IP must become a corporate activity in the same manner as the raising of resources and funds. The knowledge revolution, which we are sure to witness, will demand a special pedestal for IP and

12 Subbaram NR. Hyderabad: Pharma Books Syndicate; 2003. What everyone should know about patents?

treatment in the overall decision-making process¹³. It is understood that the documents to be submitted to regulatory authorities have almost tripled in the last ten years. In addition, regulatory authorities now take much longer to approve a new drug. Many different strategies have been evolved during the last 10 to 15 years for cost containment and trade advantage. Some of these are out sourcing of R&D activity, forming R&D partnerships and establishing strategic alliances¹⁴.

CONCLUSION

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices. It is no longer driven purely by a national perspective. IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on. In other words, trade and commerce considerations are important in the management of IPR. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics. Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Pharmaceutical industry currently has an evolving IP strategy. Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry. Still many things remain to be resolved in this context. To conclude our discussions on IPRs, specifically patents, trademarks, copyrights, and trade secrets, we wish to emphasize that these IPRs are financial assets. Not merely registration, but meticulous protection of IPRs will lead to the indispensable road to economic growth.

¹³Angell M. The Pharmaceutical Industry. To Whom Is It Accountable? *N Engl J Med.* 2000;342:1902–4. doi: 10.1056/NEJM200006223422509.

¹⁴Mrudula BS, Durgadevi NK, Madhavi BR, Tejeswi B, Durga PV. Intellectual property rights pinpoint at IPR spotlights coveted R and D. *Drug Inv Today.* 2009;2:197–201.