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INTELLECTUAL PROPERTY RIGHTS: AN OVERVIEW AND IMPLICATIONS IN PHARMACEUTICAL INDUSTRY

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Abstract

Intellectual property rights (IPR) were defined as ideas, inventions, and creative expressions on the basis of which there is a willingness of the public to grant the property status. IPR grants certain exclusive rights to inventors or creators of that property, in order to enable them to take advantage of their creative efforts or reputation in commercial terms. There are many forms of protection of intellectual property such as patents, copyright, trademark, and so on. Patent is recognition for an invention that meets the global novelty, non-evidentness, and industrial application criteria. IPR is a requirement for enhancing the recognition, preparation, marketing, making, and thus defense of innovation or creativity. Every industry should develop its own IPR policies, style of management, techniques, and so on depending on its specialty field. Currently, the pharmaceutical industry has an evolving IPR strategy which requires a better focus and approach in the coming era.

Keywords: Drug, intellectual property, license, patent, pharmaceutical

INTRODUCTION

Intellectual property involves any original human intellect creation, such as artistic, literary, technological, or science creation. Intellectual property rights apply to the legal rights granted to the author or creator for a certain period of time to protect his invention or development. Such legal rights grant an exclusive right on the inventor/creator or on his assignor to make full use of his invention/creation for a given time span.[1] It is well known that IP has a crucial role to play in the global economy. It was also argued that due attention should be given to the intellectual labor associated with innovation so that the public good emanates from it.

[1] Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004.

Research and development (R&D) costs have undergone a quantum leap with an accompanying investment leap needed to put a new product on the market place. Technology developers' stakes have become very high, and thus the need to shield information from unauthorized use has become expedient, at least for a period of time, to ensure recovery of R&D and other associated costs and sufficient income for continuing R&D investment.

IPR is a powerful tool for protecting investments, time, money, effort invested by the inventor/creator of an IP, as it gives the inventor/creator an exclusive right to use his invention/creation for a period of time. Therefore IPR, by fostering healthy competition and supporting industrial production and economic growth, supports a country's economic development. The present review provides a brief overview of IPR, with a special focus on pharmaceutical products.

BRIEF HISTORY

IPR related laws and administrative procedures have their roots in Europe. In the fourteenth century, the process of patent granting began. Compared to other European countries, England was technologically advanced in some matters and was used on special terms to draw artisans from elsewhere. The first known copyrights showed up in Italy. Venice can be regarded as the cradle of the IP system since most legal thinking in this area has been done here; laws and systems have been made here in the world for the first time, and other countries have followed in due course.[2] In India, the patent act is over 150 years old. The inaugural one is the Act of 1856, which is based on the British patent system and has provided a 14-year patent term followed by numerous acts and amendments.

Role of Undisclosed Information in Intellectual Property

Security of confidential information is less understood and less spoken about by IPR participants, although it is probably the most critical form of defense for businesses, R&D institutions, and other IPR-related agencies. Unspecified information, commonly referred to as trade secret or confidential information, includes the formula, pattern, compilation, program, device, method, technique, or process. Protecting classified information or trade secrets is not really new to humanity; people have developed strategies at every point of evolution to keep sensitive

[2] Bainbridge DI. New York: Longman; 2002. Intellectual property.

information secret, usually by limiting access to family members. Laws pertaining to all forms of IPR are at different stages of implementation in India, however, there is no separate and exclusive law to protect secret or confidential information that is not disclosed / trade.[3]

During the 1950s to the 1980s, globalization or internationalization pressures were not intense, and many countries, including India, managed without a strong IPR system. Driven by the chemical, pharmaceutical, electronic and IT industries, globalization has resulted in significant investment in R&D. This method is characterized by rivals shortening the product cycle, the time, and the high risk of reverse engineering. Industries have come to realize that the trade secrets are not sufficient to guard a technology. It was difficult to reap the benefits of innovations unless there were uniform patent laws and rules, trademarks, copyrights, etc. And by this method, IPR became an important part of the World Trade Organization (WTO).[4]

Rationale of Patent

Patent is an acknowledgment of the innovation expressed in the form of an IP. Patents are granted for patentable inventions that satisfy the requirements of novelty and utility set out in the strict examination and opposition procedures laid down in the Indian Patents Act, 1970, but there is not even a *prima-facie* presumption as to the validity of the patent.

Most organizations have enacted national regimes within their jurisdiction to provide protection to the IPR. The immunity given to the inventor/creator in a country is limited to the territory where immunity is sought and is not applicable in other countries or territories, except in the case of copyrights. The underlying reason that an invention is patented is to make money by exclusivity, i.e. the inventor or his assignor will have a monopoly if,

(A)the inventor made an important invention in the light of the modifications made by the customer and

(B)if the patent officer has correctly identified and asserted the invention in the patent specification drawn up, the resulting patent will grant the patent proprietor an exclusive market.

[3]Michaels A. 2nd ed. London: Sweet and Maxwell; 1996. A practical guide to Trade Mark Law.
[4]Watal J. London: Kluwer Law International; 2001. Intellectual property rights in the WTO and developing countries.

The patent proprietor may exercise his exclusivity either by marketing himself the patented invention or by licensing it to a third party.

What would not count as patents should be:

I an idea that is false or says something that is evident or that is contrary to well known natural law. An invention whose primary or intended use would be contrary to law or morality, or harmful to public health

(ii) A research process, scientific theory or mathematical system

(iii) A simple discovery of any new property as well as a new use for a known substance or even the simple use of a known process, machine or apparatus, unless such known process results in a particular model or employs at least one new product is formed;

(iv) A substance produced by a pure admixture resulting only in the accumulation of the component properties of that substance or a method for the processing of that substance

(v) A simple arrangement or rearrangement or duplication of a known unit, each operating in its own way independently of each other

(vi) A method of farming or horticulture;

(vii) Any medical, surgical, curative, prophylactic, therapeutic or other treatment of human beings or any equivalent treatment of animals to make them disease-free or to improve their economic value or that of their products;

(viii) An atomic energy-related invention

(ix) Traditional knowledge, an invention in progress.

Rationale of License

A license is an agreement whereby the licensor authorizes the applicant to carry out such acts, which otherwise would have been illegal. The patentee (licensor) authorizes, for example, the licensee to exercise specified rights over the patent in a patent license. The purpose is to grant the

applicant the freedom to do what he/she would otherwise be prohibited to do, i.e. a license renders lawful what would otherwise be illegal.[5]

The licensor can also provide in a license agreement the license 'know-how' relating to the execution of the licensed patent right such as material, method, or system that occurs or is used in a business operation.Few know-how Examples are:

(i)technical information, such as formulas, methods and operating procedures;

(ii)commercial details such as customer lists and sales data, marketing, management, and professional procedures.

Indeed, any technical, commercial, commercial, or other information may be the subject of protection.

Licensor advantages:

(i) Opens new markets

(ii) Develop new revenue-generating areas

(iii) Helps to overcome the challenge of evolving technology in different markets, especially in foreign countries – lower cost and risk, and savings on distribution and marketing costs

Benefits to the licensee are:

(i) Elimination of risks associated with R&D and savings on R&D

(ii) Quick exploitation, before the market interest wanes, of market requirements

(iii) Products are the latest

The Role of Patent Cooperation Treaty

The Treaty on patent cooperation is a multilateral treaty that entered into force in 1978. Through PCT, an inventor of a member contracting state of PCT may at the same time obtain priority for his / her invention in all or any of the member countries without having to submit a separate

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

application in the countries of interest, by designating them in the PCT application. The world's intellectual property organization headquartered in Geneva oversees all activities related to PCT. [6]

To protect innovation in other countries, a separate patent application must be filed in each country of interest; in certain cases, in order to gain priority in those countries within a specified period. It will require a substantial investment in meeting expenses for filing fees, translation, attorney's fees, etc. within a short period. Therefore, it is believed that it might not be well established due to the limited time available for making the decision about whether to file a patent application in a country or not.[7]

On the other hand, inventors of PCT contracting states can simultaneously obtain priority for their inventions without having to apply separately in the countries of interest; thus saving initial investments towards filing fees, translation, etc. Additionally, the scheme offers a much longer time in the Member States for filing patent applications.

The time available for the obtaining of preference in other countries under the Paris Convention is 12 months from the date of initial filing. Under the PCT, the available time should be at least 20 months, and a maximum of 31 months. However, the search report prepared under the PCT method also helps an inventor to make sure that the claimed innovation is novel. The inventor could also opt for a preliminary examination to be doubly certain about the patentability of the invention before filing in other countries.[8]

Management of Intellectual Property in Pharmaceutical Industries

Drugs and pharmaceuticals fit the definition of globalization better than any other technical field, and need a strong IP framework most closely. Knowing that the cost of introducing a new drug into the market could cost a company anywhere between $300 million to $1000 million along with all the associated risks at the developmental stage, no company will want to risk its IP becoming a public property without adequate returns. The creation, acquisition, protection, and

[6] New York: WIPO Publication; 2001. Anonymous.WIPO intellectual property handbook.policy, law and use.
[7]Gutterman AS, Anderson BJ. London: Kluwer Law International; 1997. Intellectual property in global markets: A guide for foreign lawyers and managers.
[8]Bently L, Sherman B.,Oxford: Oxford University Press; 2001. Intellectual property law.

management of IP must become a corporate activity in the same way as the raising of resources and funds.[9]

Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and the success of a company will depend largely on its research and development efforts. Investments in R&D in the drug industry are therefore very high as a percentage of total sales; reports suggest that this could be as much as 15 percent of the sales. One of the key issues in this industry is innovative risk management while striving to gain a competitive advantage over rival organizations.The risk of failure in pharmaceutical R&D is associated with high costs with the production of new medicinal products that are unable to meet the strict safety requirements, being terminated, even after several years of investment. It takes about 8-10 years from the date when the compound was first synthesized for those medicines which do clear development hurdles. As brand patents emerge as the key tools for IP defense, drug companies may need to change their R&D focus from developing new methods for manufacturing existing drugs to creating a new drug molecule and a new chemical entity (NCE).During the 1980s the R&D focus shifted to long-term (chronic) diseases after a period of successful treatment of many short-term diseases. While searching for the global market, one has to make sure that different regulatory authorities have to meet the requirements.[10]

It is understood that, in the last ten years, the documents to be submitted to regulatory authorities have almost tripled. Additionally, regulatory authorities now take a great deal longer to approve a new drug. Subsequently, the patent protection period is the, resulting in the need to put extra efforts into making adequate profits.In the case of drugs produced through the biotechnology path, the situation may be more serious particularly those involving the use of genes. It is inevitable that the developed world will soon have to search for longer drug protection. It is also possible that many governments would be increasingly exercising price control in order to meet public objectives. It will, on the one hand, demonstrate the need for decreased drug growth, manufacturing, and marketing costs, and, on the other, entail preparing for lower profit margins in order to recover costs over a longer period of time. This is therefore clear that the drug industry has several competing conditions to wade through. During the last 10 to 15 years,

[9] Angell M.,The Pharmaceutical Industry.To Whom Is It Accountable? N Engl J Med. 2000;342:1902–4.
[10]Beier FK, Schricker G. Munich: Copyright and Competition Law; 1996.

several different approaches for cost control and trade advantage have developed. Some of these are R&D activity sourcing, R&D partnerships being developed and strategic alliances being created.[11]

Nature of Pharmaceutical Industry

The race to unlock the secrets of the human genome has produced an explosion of scientific knowledge and has spurred the development of new technologies that alter the drug development economies. Biopharmaceuticals are likely to enjoy a special place and the ultimate goal will be to have personalized medicines since everyone will have their own genome mapped and stored in a chip. Doctors will examine the chip's information, and prescribe accordingly.The significant IP problem associated with this will be the security of these personal information databases. Drugs which have been produced biotechnologically should find more and more market entry. The safety protocol for these drugs would be very different from those traditional drugs which are not developed biotechnologically. The patent application will describe the microbial strains that are used to produce a drug or vaccine. If the strain is already known and generally reviewed by scientists in the literature, then the situation is clear.Even so, several new strains are constantly discovered and produced and these are deposited under the Budapest Treaty with Foreign Depository Authorities. Even the records of these depositories should be checked when doing a novelty search. Companies usually do not go to publish their work but it is good to make it a practice not to disclose the invention through publications or seminars until a patent application is filed.[12]

Even when dealing with microbiological inventions, it is essential that the strain is deposited in one of the recognized depositories which would give the strain a registration number that should be quoted in the patent specification. This does away with the need to describe a form of life on paper. Depositing a strain often costs money, but that's not much if you don't deal with it, like cell lines for example. However, the sequences must also be defined in the patent specification for innovations involving genes, gene expression, DNA, and RNA, as has been seen in the past.

[11]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.

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

For several different reasons, the partnerships may be for sharing R&D knowledge and resources, using marketing networks, and sharing production facilities.

When entering into an R&D alliance, it is always advisable to establish a structured agreement covering issues such as ownership of IP in different countries, cost-sharing of acquiring and maintaining IP and revenue from it, methods of holding trade secrets, accounting for each company's IP before the alliance and IP generated during the project but not covered by the contract, dispute resolution.It should be remembered that if the IP portfolio is stronger than the partner concerned, an alliance would be favorable. This Agreement could have many other elements. Many drug companies will soon be using contract research services from academic institutions, private R&D agencies, under-government R&D institutions in India and abroad. All of the above-mentioned aspects will be very useful. Particular attention will need to be paid to maintaining research confidentiality.

The current state of the pharmaceutical companies indicates that IPR is being reinforced and misused unjustifiably at the expense of competition and consumer welfare.The drug industry 's lack of risk and creativity highlights the inequity that exists at the cost of the public good. It's an injustice that only institutional change can not remedy. Although Legislative attempts to close loopholes in current laws, along with new legislation to curb additionally unfavorable pharmaceutical industry market practices, may provide some relief, antitrust law must take appropriate steps.[13]Although antitrust laws have thoroughly scrutinized some business activities that the pharmaceutical industry uses, such as mergers and acquisitions and non-competitive deals, there are many other activities that need to be discussed. Patent granting on minor elements of an existing drug, reformulating old drugs to obtain new patents, and using ads and brand name creation to raise barriers for generic market entrants are all places where antitrust law can help maintain the balance between rewarding creativity and competitive protection.

In many developing countries and also in developed countries, traditional medicine dealing with natural botanical products is an important part of human health care which increases their commercial value. The global demand for these medicines has reached US$ 60 billion, with annual growth levels ranging from 5 % to 15%. Though purely traditional knowledge-based

[13]Gottlieb S. Drug firms use legal loopholes to safeguard brand names. BMJ. 2000;321:320.

medicines are not patent-friendly, people often claim that. Researchers or companies can also assert IPR over biological resources and/or conventional information after changing them slightly. The rapid increase of patent applications relating to herbal medicine clearly illustrates this phenomenon.Patent applications in the area of natural products, traditional herbal medicine, and natural herbal products are expected to deal with as food, pharmaceutical, and cosmetics purview of each country's own IPR policies, as appropriate. Medicinal plants and associated plant products are important targets for patent lawsuits, as they are of considerable interest to the globally integrated herbal and cosmetic industries.[14]

Some Special Aspects of Drug Patent Specification

Writing patent requirements is a highly specialized skill that is learned over time and involves a strong balance of science, technical, and legal knowledge. Claims in any patent specification form the essence of the patent in respect of which legitimate proprietary is sought.The Discovery of a new property is non-patentable in a known material. When one can bring the property to practical use one has made a patentable invention. A finding that a known substance can withstand mechanical shock would not be patentable but it may patent a railway sleeper made from the material.A material may not be new but a new business has been identified. This could be patentable in combination with any other recognized substances if they show any new outcome in combination. The explanation for this is that nobody used the mixture earlier to produce an insecticide or fertilizer or medication. An inventor may have produced a new molecule, but it is not known its precise structure. For such a case, the definition of the product may play an important role, along with its properties and the method of producing the same.[15]

Unless the substances have a working history when mixed, the combining of known substances into usable items may be a patent subject matter. No chemical reaction occurs in this case. It only confers a small degree of defense. Any use of single parts of the combination by others is beyond the scope of the patent. A patent on *aqua regia*, for example, won't stop others from combining the two acids in various amounts and having new patents. Treatment procedures for humans and animals in most countries are not patentable, with one exception being the USA, because they

[14]Kartal M. Intellectual property protection in the natural product drug discovery, traditional herbal medicine and herbal medicinal products. Phytother Res. 2007;21:113–9.
[15]SubbaramNR.,Hyderabad: Pharma Books Syndicate; 2003. What everyone should know about patents?.

are not deemed capable of industrial application.In respect of future medicinal use of a recognized drug, caution should be taken in writing claims because the argument does not offer an indication of a treatment process. Most applications concern drugs and pharmaceuticals including herbal medicines. There are limited applications related to engineering, electronics, and chemicals. Approximately 62 percent of applications include medications and pharmaceuticals.[16]

CONCLUSIONS

Managing IP and IPR is obviously a multidimensional task and calls for many different actions and strategies to be aligned with national laws and international treaties and practices. It is no longer solely motivated by a global viewpoint. IP and its related rights are strongly affected by consumer demands, customer reactions, costs associated with converting IP into commercial projects, and so on. In other words, considerations relating to trade and commerce are relevant in IPR management. Different types of IPR include specific care, management, preparation, and techniques and involvement of people with various domain expertise, such as technology, engineering, medicine, law, accounting, marketing, and economics. Depending on their area of specialization, each industry should develop its own IP policies, management style, strategies, etc .. Nowadays the pharmaceutical industry has an evolving IP strategy. Since there is an increased possibility that some IPR will be invalid, antitrust law must, therefore, intervene to ensure that invalid rights are not unlawfully asserted in order to establish and maintain illegitimate, albeit limited, monopolies in the pharmaceutical sector. However, many things are yet to be resolved in this context.

[16] Shukla S.,Patents: An Introduction. Indian Pharm. 2004;3:14–7.