Review Article

Intellectual property rights: An overview and implications in pharmaceutical industry

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Abstract

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. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is a recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

Key words: Drug, intellectual property, license, patent, pharmaceutical

INTRODUCTION

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.[1] These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period of time. It is very well settled that IP play a vital role in the modern economy. It has also been conclusively established that the intellectual labor associated with the innovation should be given due importance so that public good emanates from it. There has been a quantum jump in research and development (R&D) costs with an associated jump in investments required for putting a new technology in the market place.[2] The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from unlawful use has become expedient, at least for a period, that would ensure recovery of the R&D and other associated costs and adequate profits for continuous investments in R&D.[3] IPR is a strong tool, to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review furnishes a brief overview of IPR with special emphasis on pharmaceuticals.

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BRIEF HISTORY

The laws and administrative procedures relating to IPR have their roots in Europe. The trend of granting patents started in the fourteenth century. In comparison to other European countries, in some matters England was technologically advanced and used to attract artisans from elsewhere, on special terms. The first known copyrights appeared in Italy. Venice can be considered the cradle of IP system as most legal thinking in this area was done here; laws and systems were made here for the first time in the world, and

other countries followed in due course.[4] Patent act in India is more than 150 years old. The inaugural one is the 1856 Act, which is based on the British patent system and it has provided the patent term of 14 years followed by numerous acts and amendments.[1]

Types of 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. IPR enhances technology advancement in the following ways:[1-4]

(a) it provides a mechanism of handling infringement, piracy, and unauthorized use
(b) it provides a pool of information to the general public since all forms of IP are published except in case of trade secrets.

IP protection can be sought for a variety of intellectual efforts including

(i) Patents
(ii) Industrial designs relates to features of any shape, configuration, surface pattern, composition of lines and colors applied to an article whether 2-D, e.g., textile, or 3-D, e.g., toothbrush[5]
(iii) Trademarks relate to any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified. Trademarks can be bought, sold, and licensed. Trademark has no existence apart from the goodwill of the product or service it symbolizes[6]
(iv) Copyright relates to expression of ideas in material form and includes literary, musical, dramatic, artistic, cinematography work, audio tapes, and computer software[7]
(v) Geographical indications are indications, which identify as good as originating in the territory of a country or a region or locality in that territory where a given quality, reputation, or other characteristic of the goods is essentially attributable to its geographical origin[8]

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 items.[9] 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 gifted.[7]

Role of Undisclosed Information in Intellectual Property

Protection of undisclosed information is least known to players of IPR and also least talked about, although it is perhaps the most important form of protection for industries, R&D institutions and other agencies dealing with IPR. Undisclosed information, generally known as trade secret or confidential information, includes formula, pattern, compilation, programme, device, method, technique, or process. Protection of undisclosed information or trade secret is not really new to humanity; at every stage of development people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members. Laws relating to all forms of IPR are at different stages of implementation in India, but there is no separate and exclusive law for protecting undisclosed information/trade secret or confidential information.[10]

Pressures of globalisation or internationalisation were not intense during 1950s to 1980s, and many countries, including India, were able to manage without practising a strong system of IPR. Globalization driven by chemical, pharmaceutical, electronic, and IT industries has resulted into large investment in R&D. This process is characterized by shortening of product cycle, time and high risk of reverse engineering by competitors. Industries came to realize that trade secrets were not adequate to guard a technology. It was difficult to reap the benefits of innovations unless uniform laws and rules of patents, trademarks, copyright, etc. existed. That is how IPR became an important constituent of the World Trade Organization (WTO).[11]

Rationale of Patent

Patent is recognition to the form of IP manifested in invention. Patents are granted for patentable inventions, which satisfy the requirements of *novelty* and *utility* under the stringent examination and opposition procedures prescribed in the Indian Patents Act, 1970, but there is not even a *prima-facie* presumption as to the validity of the patent granted.[9]

Most countries have established national regimes to provide protection to the IPR within its jurisdiction. Except in the case of copyrights, the protection granted to the inventor/creator in a country (such as India) or a region (such as European Union) is restricted to that territory where protection is sought and is not valid in other countries or regions.[1] For example, a patent granted in India is valid only for India and not in the USA. The basic reason for patenting an invention is to make money through exclusivity, i.e., the inventor or his assignee would have a monopoly if,

(a) the inventor has made an important invention after taking

into account the modifications that the customer, and
(b) if the patent agent has described and claimed the invention correctly in the patent specification drafted, then the resultant patent would give the patent owner an exclusive market.

The patentee can exercise his exclusivity either by marketing the patented invention himself or by licensing it to a third party.

The following would not qualify as patents:
(i) An invention, which is frivolous or which claims anything obvious or contrary to the well established natural law. An invention, the primary or intended use of which would be contrary to law or morality or injurious to public health
(ii) A discovery, scientific theory, or mathematical method
(iii) A 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
(iv) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance
(v) A mere arrangement or re-arrangement or duplication of a known device each functioning independently of one another in its own way
(vi) A method of agriculture or horticulture
(vii) Any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products
(viii) An invention relating to atomic energy
(ix) An invention, which is in effect, is traditional knowledge

Rationale of License

A license is a contract by which the licensor authorizes the licensee to perform certain activities, which would otherwise have been unlawful. For example, in a patent license, the patentee (licensor) authorizes the licensee to exercise defined rights over the patent. The effect is to give to the licensee a right to do what he/she would otherwise be prohibited from doing, i.e., a license makes lawful what otherwise would be unlawful.[12]

The licensor may also license 'know-how' pertaining to the execution of the licensed patent right such as information, process, or device occurring or utilized in a business activity can also be included along with the patent right in a license agreement. Some examples of know-how are:
(i) technical information such as formulae, techniques, and operating procedures and
(ii) commercial information such as customer lists and sales data, marketing, professional and management procedures.

Indeed, any technical, trade, commercial, or other information, may be capable of being the subject of protection.[13]

Benefits to the licensor:
(i) Opens new markets
(ii) Creates new areas for revenue generation
(iii) Helps overcome the challenge of establishing the technology in different markets especially in foreign countries – lower costs and risk and savings on distribution and marketing expenses

Benefits to the licensee are:
(i) Savings on R&D and elimination of risks associated with R&D
(ii) Quick exploitation of market requirements before the market interest wanes
(iii) Ensures that products are the latest

The Role of Patent Cooperation Treaty

The patent cooperation treaty (PCT) is a multilateral treaty entered into force in 1978. Through PCT, an inventor of a member country contracting state of PCT can simultaneously obtain priority for his/her invention in all or any of the member countries, without having to file a separate application in the countries of interest, by designating them in the PCT application. All activities related to PCT are coordinated by the world intellectual property organization (WIPO) situated in Geneva.[14]

In order to protect invention in other countries, it is required to file an independent patent application in each country of interest; in some cases, within a stipulated time to obtain priority in these countries. This would entail a large investment, within a short time, to meet costs towards filing fees, translation, attorney charges, etc. In addition, it is assumed that due to the short time available for making the decision on whether to file a patent application in a country or not, may not be well founded.[15]

Inventors of contracting states of PCT on the other hand can simultaneously obtain priority for their inventions without having to file separate application in the countries of interest; thus, saving the initial investments towards filing fees, translation, etc. In addition, the system provides much longer time for filing patent application in the member countries.[15,16]

The time available under Paris convention for securing priority in other countries is 12 months from the date of initial filing. Under the PCT, the time available could be as

much as minimum 20 and maximum 31 months. Further, an inventor is also benefited by the search report prepared under the PCT system to be sure that the claimed invention is novel. The inventor could also opt for preliminary examination before filing in other countries to be doubly sure about the patentability of the invention.[16]

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 treatment in the overall decision-making process.[17]

Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very high as a percentage of total sales; reports suggest that it could be as much as 15% of the sale. One of the key issues in this industry is the management of innovative risks while one strives to gain a competitive advantage over rival organizations. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment. For those medicines that do clear development hurdles, it takes about 8-10 years from the date when the compound was first synthesized. As product patents emerge as the main tools for protecting IP, the drug companies will have to shift their focus of R&D from development of new processes for producing known drugs towards development of a new drug molecule and new chemical entity (NCE). During the 1980s, after a period of successfully treating many diseases of short-term duration, the R&D focus shifted to long duration (chronic) diseases. While looking for the global market, one has to ensure that requirements different regulatory authorities must be satisfied.[18]

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. Consequently, the period of patent protection is reduced, resulting in the need of putting in extra efforts to earn enough profits. The situation may be more severe in the case of drugs developed through the biotechnology route especially those involving utilization of genes. It is likely that the industrialized world would soon start canvassing for longer protection for drugs. It is also possible that many governments would exercise more and more price control to meet public goals. This would on one hand emphasize the need for reduced cost of drug development, production, and marketing, and on the other hand, necessitate planning for lower profit margins so as to recover costs over a longer period. It is thus obvious that the drug industry has to wade through many conflicting requirements. 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 alliances.[19]

Nature 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 developed. Microbial strains used for developing a drug or vaccine needs to be specified in the patent document. If the strain is already known and reported in the literature usually consulted by scientists, then the situation is simple. However, many new strains are discovered and developed continuously and these are deposited with International depository authorities under the Budapest Treaty. 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 filed.[20]

While dealing with microbiological inventions, it is essential to deposit the strain in one of the recognized depositories who would give a registration number to the strain which should be quoted in the patent specification. This obviates the need of describing a life form on paper. Depositing a strain also costs money, but this is not much if one is not dealing with, for example cell lines. 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 facilities, utilizing marketing networks

and sharing production facilities. While entering into an R&D alliance, it is always advisable to enter into a formal agreement covering issues like ownership of IP in different countries, sharing of costs of obtaining and maintaining IP and revenue accruing from it, methods of keeping trade secrets, accounting for IP of each company before the alliance and IP created during the project but not addressed in the plan, dispute settlements. It must be remembered that an alliance would be favorable if the IP portfolio is stronger than that of concerned partner. There could be many other elements of this agreement. Many drug companies will soon use the services of academic institutions, private R&D agencies, R&D institutions under government in India and abroad by way of contract research. All the above aspects mentioned above will be useful. Special attention will have to be paid towards maintaining confidentiality of research.[1-18]

The current state of the pharmaceutical industry indicates that IPR are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While congressional efforts to close loopholes in current statutes, along with new legislation to curtail additionally unfavorable business practices of the pharmaceutical industry, may provide some mitigation, antitrust law must appropriately step in.[21] While antitrust laws have appropriately scrutinized certain business practices employed by the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several other practices that need to be addressed. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition.[20]

Traditional medicine dealing with natural botanical products is an important part of human health care in many developing countries and also in developed countries, increasing their commercial value. The world market for such medicines has reached US $ 60 billion, with annual growth rates of between 5% and 15%. Although purely traditional knowledge based medicines do not qualify for patent, people often claim so. Researchers or companies may also claim IPR over biological resources and/or traditional knowledge, after slightly modifying them. The fast growth of patent applications related to herbal medicine shows this trend clearly. The patent applications in the field of natural products, traditional herbal medicine and herbal medicinal products are dealt with own IPR policies of each country as food, pharmaceutical and cosmetics purview, whichever appropriate. Medicinal plants and related plant products are important targets of patent claims since they have become of great interest to the global organized herbal drug and cosmetic industries.[22]

Some Special Aspects of 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 role.[23]

Combination of known substances into useful products may be a subject matter of a patent if the substances have some working relationship when combined together. In this case, no chemical reaction takes place. It confers only a limited protection. Any use by others of individual parts of the combination is beyond the scope of the patent. For example, a patent on *aqua regia* will not prohibit any one from mixing the two acids in different proportions and obtaining new patents. Methods of treatment for humans and animals are not patentable in most of the countries (one exception is USA) as they are not considered capable of industrial application. In case of new pharmaceutical use of a known substance, one should be careful in writing claims as the claim should not give an impression of a method of treatment. Most of the applications relate to drugs and pharmaceuticals including herbal drugs. A limited number of applications relate to engineering, electronics, and chemicals. About 62% of the applications are related to drugs and pharmaceuticals.[1-24]

CONCLUSIONS

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.

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