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Intellectual Property Rights And Their Impacts In The Pharmaceutical Industry

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Abstract

The pharmaceutical industry runs on innovation to expand in the market. The goal of any pharmaceutical is drug discovery and generating profits from such investments. The reward for success in innovation is generally high if it impacts multiple lives. Medications are developed by investing huge sums of money in the research and development of any drug. Any company that wants to achieve a good position in the market must constantly develop different strategies to gain a competitive advantage and protect its positions in the market. Intellectual property rights play a vital role.

Intellectual Property Rights help protect a company's invention. It helps to promote healthy competition in the market which proves to be beneficial for the country's economy. It is also an important tool to protect their invested time, money and effort, thereby promoting industrial development and economic growth.

There are several types of intellectual property protection, such as patent, copyright, trademark, etc. A patent is recognition of an invention that meets the criteria of global novelty, non-obviousness and industrial utility. Intellectual property rights are a prerequisite for better identification, planning, commercialization, rendering and thus protection of invention or creativity. Each industry should develop its own IPR policies, management style, strategies and so on depending on its area of specialization. The pharmaceutical industry currently has an evolving IPR strategy that requires better focus and approach in the coming era.

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

Introduction

Intellectual property (IP) refers to any original creation of the human intellect, such as an artistic, literary, technical or scientific creation. Intellectual property rights (IPRs) refer to the legal rights granted to an inventor or creator to protect his invention or creation for a

specified period of time.[1] These legal rights grant the inventor/creator or his assignee the exclusive right to fully exploit his invention/creation for a given period of time. It is well known that intellectual property plays a vital role in the modern economy. It has also been convincingly established that due importance should be given to the intellectual work associated with innovation so that the public good can result from it. There has been a quantum leap in research and development (R&D) spending and a corresponding leap in the investment required to bring new technology to market.[2] The stakes for technology developers have become very high, and therefore the need to protect knowledge from illegal use has become expedient, at least for a period that would ensure a return on R&D and other related costs and reasonable profits for continued investment in R&D.[3] Intellectual property rights are a powerful tool to protect the investment, time, money and effort made by the inventor/creator of intellectual property because they grant the inventor/creator the exclusive right to use their invention/creation for a certain period of time. Thus, in this way, IPR helps the economic development of the country by promoting healthy competition and promoting industrial development and economic growth. This review provides a brief overview of intellectual property rights with a particular focus on pharmaceuticals.

Types of mental properties and their description

Originally, only patents, trademarks and industrial designs were protected as "industrial property", but now the term "intellectual property" has a much broader meaning. IPR enhances technological progress in the following ways:[4]

- (a) provide a mechanism to deal with infringement, piracy and unauthorized use
- (b) provides a set of information to the general public as all forms of intellectual property are disclosed except in the case of trade secrets.

Intellectual property protection may be required for a variety of intellectual endeavors including

i. Patents
ii. Industrial designs refer to elements of any shape, configuration, surface pattern, composition of lines and colors applied to an object, whether 2-D, e.g. textile, or 3-D, e.g. toothbrush[5]
iii. Trademarks refers to any mark, name or logo under which any product or service is traded and by which the manufacturer or service provider is identified. Trademarks can be bought, sold and licensed. A trademark does not exist apart from the good name of the product or service it symbolizes[6]
iv. Copyright relates to the expression of ideas in tangible form and includes literary, musical, dramatic, artistic, cinematographic works, sound tapes and computer software[7].
v. Geographical indications are indications that identify goods as coming from the territory of a country or region or locality within that territory where the given quality, reputation or other characteristic of the good can be essentially attributed to its geographical origin[8]

A patent is granted for an invention that meets the criteria of global novelty, non-obviousness and industrial or commercial utility. Products and processes can be patented. Under the Indian Patents Act, 1970, the patent term was 14 years from the date of application except for processes for the preparation of drugs and food, for which the term was 7 years from the date of filing or 5 years from the date of filing. of the patent, whichever occurs first. No product patents have been granted for drugs and foods.[9] Copyrights created in a Berne Convention member country are automatically protected in all member countries without the need for registration. India is a signatory to the Berne Convention and has very good copyright legislation comparable to that of any country. However, copyright will not automatically be available in countries that are not members of the Berne Convention. Therefore, copyright cannot be considered a territorial right in the strict sense of the word. Like any other property, IPR can be transferred, sold or donated.

The role of undisclosed information in intellectual property

The protection of undisclosed information is the least known and least talked about by IPR players, although it is perhaps the most important form of protection for industry, research and development institutions and other IPR agencies. Undisclosed information, commonly known as a trade secret or confidential information, includes a formula, design, compilation, program, device, method, technique, or process. Protecting undisclosed information or trade secrets is not really new to mankind; at every stage of evolution, humans have developed methods to keep important information secret, usually by restricting knowledge to their family members. Laws relating to all forms of IPR are in various stages of implementation in India, but there is no separate and exclusive law to protect undisclosed information/trade secret or confidential information.[10]

The pressures of globalization or internationalization were not intense during the 1950s to 1980s, and many countries, including India, managed to get by without a strong system of intellectual property rights. Globalization driven by the chemical, pharmaceutical, electronics and IT industries has led to large investments in research and development. This process is characterized by shortening the product cycle, time and high risk of reverse engineering by competitors. Industries have realized that trade secrets are not enough to protect technology. It was difficult to reap the benefits of innovation unless there were uniform laws and rules for patents, trademarks, copyrights, etc. Thus, intellectual property rights became an important part of the World Trade Organization (WTO).[11]

The influence of the World Trade Organization on pharmaceutical companies on signatories

The impact of the World Trade Organization caused a paradigm shift in the world of business. The agreement on trade aspects of intellectual property rights was concluded in the Uruguay Round of the General Agreement on Tariffs and Trade for the basic reason of instilling intellectual property rights in the pharmaceutical industry, to protect the innovative sector and to help the economy of the countries strengthen.

India was a part of GATT in 1994 which made it mandatory for the country to comply with GATT requirements. India has to meet the minimum standards under the TRIPS agreement in relation to patents as well as patent laws in the pharmaceutical industry.
Indian patent laws should include provisions that include the availability of patents for both pharmaceutical products and process inventions. Patents should be granted for a minimum of 20 years for any pharmaceutical product or process invention that meets the specified criteria. Compulsory licensing provisions under Indian law will have to be limited and conditional on TRIPS compliance and the government will grant such licenses only on the merits of each case after allowing the patentee to be heard. Furthermore, in the case of process patents, there will be no discrimination between imported and domestic products and the burden of proof will be on the infringing party.

Patent justification

A patent is recognition of the form of intellectual property manifested in an invention. Patents are granted for patentable inventions that meet the requirements of novelty and utility under the rigorous examination and opposition procedures prescribed in the Indian Patents Act, 1970, but there is no prima facie presumption of validity of the patent granted.
Most countries have established national regimes to provide protection for intellectual property rights within their jurisdiction. Except in the case of copyright, the protection granted to an inventor/creator in a country (such as India) or region (such as the European Union) is limited to the territory where protection is sought and does not apply in other countries or regions. For example, a patent granted in India is valid only in India and not in the US. 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 which the customer,
b) if the patent attorney has correctly described and claimed the invention in the proposed patent specification, then the resulting patent will provide the patent owner with an exclusive market.

A patent owner can exercise its exclusivity either by marketing the patented invention itself or by licensing it to a third party.
The following cannot be considered patents:

i. An invention which is frivolous or which claims anything obvious or contrary to a well-established law of nature. An invention whose primary or intended use would be contrary to law or morality or harmful to public health
ii. A discovery, scientific theory or mathematical method
iii. The mere discovery of any new property or new use of a known substance or the mere use of a known process, machine or device, unless such known process leads to a new product or uses at least one new reactant.

iv. A substance obtained by mere admixture leading only to the aggregation of the properties of its constituents or the process of making such substance
v. A mere arrangement or rearrangement or duplication of a known device, each of which operates independently of the other in its own way
vi. Method of agriculture or horticulture
vii. Any procedure for the medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of humans or any procedure for the similar treatment of animals with the aim of ridding them of disease or increasing their economic value or the value of their products.
viii. Invention relating to atomic energy
ix. An invention that is in fact traditional knowledge

Reasoning for the license

A license is an agreement by which the licensor authorizes the licensee to perform certain activities that would otherwise be illegal. For example, in a patent license, the patentee (licensor) authorizes the licensee to exercise defined patent rights. The effect is to give the licensee the right to do what he would otherwise be prohibited from doing, i.e. the license makes legal what would otherwise be illegal.[12]

The licensor may also license "know-how" related to the exercise of the licensed patent right, such as information, process or equipment occurring or used in the business, may also be included together with the patent right in the license agreement. Some examples of know-how are:

i. technical information such as formulas, techniques and operating procedures and
ii. business information such as customer lists and sales data, marketing, professional and management practices.

Indeed, any technical, business, commercial or other information may be subject to protection.[13]

Benefits for licensors:

i. It opens up new markets
ii. It creates new areas for income generation
iii. Helps to overcome the challenge of establishing the technology in various markets, especially abroad – lower costs and risks and savings in distribution and marketing costs

Benefits for license holders are:

i. Savings on R&D and elimination of risks associated with R&D
ii. Rapid utilization of market requirements before market interest wanes
iii. Ensures that the products are latest

The role of the patent cooperation agreement

The Patent Cooperation Treaty (PCT) is a multilateral treaty that entered into force in 1978. Through the PCT, an inventor of a member state that is a party to the PCT can simultaneously obtain priority for his invention in all or any of the member countries without having to file a separate application in the countries of interest by indicating them in the PCT application. All PCT-related activities are coordinated by the Geneva-based World Intellectual Property Organization (WIPO).[14]

In order to protect an invention in other countries, it is necessary to file an independent patent application in each country of interest; in some cases within a specified period to obtain priority in these countries. This would mean a large investment in a short period of time to cover the costs of filing, translation, attorneys' fees, etc. Furthermore, it is assumed that due to the short time available to decide whether or not to file a patent application in a country, may not be well founded.[15]

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

The time available under the Paris Convention to secure priority in other countries is 12 months from the date of first filing. According to the PCT, the time available could be a minimum of 20 and a maximum of 31 months. In addition, the inventor also benefits from a search report prepared in the PCT system to ensure that the claimed invention is new. The inventor could also opt for preliminary research before filing the application in other countries to be doubly sure of the patentability of the invention.

Intellectual property management in the pharmaceutical industry

More than any other technology field, drugs and pharmaceuticals fit the description of globalization and need to have a strong IP system as closely as possible. Knowing that the cost of bringing a new drug to market can cost a company anywhere between $300 million to $1,000 million, along with all the associated risks in the development phase, no company is willing to risk its intellectual property becoming public property without commensurate returns. . The creation, acquisition, protection and management of intellectual property must become a business activity in the same way as the acquisition of resources and funds. The knowledge revolution we are sure to witness will require a special pedestal for intellectual property 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 largely depend on its research and development efforts. Investment in research and development in the pharmaceutical industry is therefore very high as a percentage of total sales; reports suggest it could be as much as 15% of sales. One of the key challenges in this industry is managing innovation risks while trying to gain a competitive advantage over competing organizations. High costs are

associated with the risk of pharmaceutical R&D failure, as development of potential drugs that are unable to meet stringent safety standards is terminated, sometimes after many years of investment. For those drugs that have clear development hurdles, it takes about 8-10 years from the date the compound was first synthesized. As product patents emerge as major tools for intellectual property protection, pharmaceutical companies will need to shift their R&D focus from developing new processes for making known drugs to developing new drug molecules and new chemical entities (NCEs). During the 1980s, after a period of successful treatment of many short-term diseases, the focus of research and development shifted to long-term (chronic) diseases. In seeking a global market, it is necessary to ensure that the requirements of various regulatory bodies are met.[18]

It is understood that documents to be submitted to regulators have almost tripled in the past ten years. In addition, regulatory authorities now take much longer to approve a new drug. As a result, the period of patent protection is shortened, resulting in the need to make extra efforts to obtain sufficient profits. A more serious situation can be in the case of drugs developed through biotechnology, especially those that involve the use of genes. It is likely that the industrialized world would soon start looking for longer drug protection. It is also possible that many governments will apply more and more price controls to meet public objectives. This would, on the one hand, emphasize the need to reduce the cost of drug development, production and marketing, and on the other, require planning for lower profit margins to cover costs over a longer period. So it is clear that the pharmaceutical industry has to navigate many conflicting demands. Over the past 10 to 15 years, many different strategies have been developed for cost containment and business advantage. Some of these are the provision of research and development activities, the creation of research and development partnerships and the establishment of strategic alliances.[19]

The nature of the pharmaceutical industry

The race to unlock the secrets of the human genome has sparked an explosion of scientific knowledge and spurred the development of new technologies that are changing the economics of drug development. Biopharmaceuticals will likely have a special place, and the ultimate goal will be personalized medicine, as everyone will have their own genome mapped and stored on a chip. Doctors look at the information in the chip(s) and prescribe accordingly. An important related intellectual property issue would be the protection of such databases of personal information. Biotechnologically developed drugs will find more and more entrances to the market. The protective procedure for such a drug will be a little different from those conventional drugs that are not biotechnologically developed. Microbial strains used for drug or vaccine development must be specified in the patent document. If the strain is already known and listed in the literature that scientists usually consult, then the situation is simple. However, many new strains are constantly being discovered and developed, which are deposited with international depository authorities under the Budapest Treaty. When looking for news, it is also necessary to consult the databases of these

depositories. Companies usually do not publish their work, but it is a good practice not to disclose an invention through publications or seminars until a patent application has been filed.[20]

When dealing with microbiological inventions, it is necessary to deposit the strain in one of the recognized depositories, which will assign the strain a registration number, which should be indicated in the patent specification. This eliminates the need to describe the form of life on paper. Storing a strain also costs money, but not much unless one deals with, for example, cell lines. Furthermore, for inventions involving genes, gene expression, DNA and RNA, the sequences must also be described in the patent specification, as seen in the past. An alliance could have many different objectives, such as sharing expertise and R&D facilities, leveraging marketing networks, and sharing manufacturing facilities. When entering into an R&D alliance, it is always advisable to enter into a formal agreement covering issues such as the ownership of intellectual property in different countries, the sharing of costs of acquiring and maintaining intellectual property and the revenues derived from it, methods of keeping trade secrets, accounting for each company's intellectual property before alliances and IP created during the project but not addressed in the plan, dispute resolution. It should be borne in mind that an alliance would be beneficial if the intellectual property portfolio is stronger than that of the partner concerned. This agreement may contain many other elements. Many pharmaceutical companies will soon use the services of academic institutions, private research and development agencies, government-run research and development institutions in India and abroad through contract research. All the above aspects will be helpful. Special attention will need to be paid to maintaining the confidentiality of the research·

The current state of the pharmaceutical industry suggests that intellectual property rights are being unduly strengthened and abused to the detriment of competition and consumer welfare. The lack of risk and innovation on the part of the pharmaceutical industry underscores the injustice that occurs at the expense of the public good. It is an injustice that cannot be cured by legislative reform alone. While efforts by Congress to close loopholes in current laws, along with new legislation to curb other adverse pharmaceutical industry business practices, may provide some relief, antitrust law must intervene accordingly.[21] While antitrust laws have properly scrutinized certain business practices used by the pharmaceutical industry, such as mergers and acquisitions and non-compete agreements, there are several other practices that need to be addressed. Patenting minor elements of an old drug, reformulating old drugs to secure new patents, and using advertising and brand development to raise barriers to entry in the generic market are all areas where antitrust law can help stabilize the balance. between rewarding innovation and maintaining competition.

Traditional medicine dealing with natural plant products is an important part of human health care in many developing and developed countries and increases their commercial value. The world market for such drugs has reached USD 60 billion with an annual growth

rate of between 5% and 15%. Although purely traditional knowledge-based medicines are not patent-eligible, people often claim that they are. Researchers or companies may also claim intellectual property rights to biological resources and/or traditional knowledge after slight modification. The rapid increase in patent applications related to herbal medicine clearly demonstrates this trend. Patent applications in the field of natural products, traditional herbal medicine and herbal medicinal products are handled by each country's own intellectual property rights policy, such as food, pharmaceutical and cosmetic fields, as appropriate. Medicinal plants and related plant products are an important target of patent claims as they have become the subject of great interest in the global organized herbal drug and cosmetic industry.[22]

Some special aspects of drug patent specification

Writing patent specifications is a highly professional skill that is acquired over time and requires a good combination of scientific, technological and legal knowledge. The claims in any patent specification form the soul of the patent for which legal ownership is claimed. The discovery of a new property in a known material is not patentable. If it is possible to make practical use of this feature, we have created an invention that can be patented. Finding that a known substance is able to withstand mechanical impact would not be patentable, but a railroad sleeper made of that material could be patented. The substance may not be new, but it has been found to have a new property. It may be possible to patent it in combination with some other known substances if they show some new result in combination. This is because no one has used this combination to make an insecticide, fertilizer or medicine before. It is quite possible that the inventor has created a new molecule, but its exact structure is unknown. In such a case, the description of the substance together with its properties and the method of its production will play an important role.[23]

The combination of known substances into useful products can be the subject of a patent if the substances have a certain working relationship when combined with each other. In this case, no chemical reaction occurs. It only provides limited protection. Any use of individual parts of the combination by others is beyond the scope of the patent. For example, a patent for aqua regia does not prohibit anyone from mixing two acids in different proportions and obtaining new patents. Treatment methods for humans and animals are not patentable in most countries (except the US) because they are not considered industrial. In the case of a new pharmaceutical use of a known substance, care should be taken when writing the claim, as the claim should not give the impression of a treatment method. Most of the applications are for drugs and medicines including herbal medicines. A limited number of applications are related to engineering, electronics and chemicals. About 62% of applications are for drugs and pharmaceuticals.[24]

Conclusions

It is clear that the management of intellectual property and intellectual property rights is a multidimensional task and requires many different actions and strategies that must be

consistent with national laws and international treaties and practices. It no longer follows a purely national perspective. Intellectual property and related rights are seriously affected by market needs, market response, costs associated with transferring intellectual property to a commercial enterprise, and so on. In other words, business and commercial considerations are important when managing intellectual property rights. Different forms of intellectual property rights require different treatment, handling, planning and strategies and the involvement of people with knowledge in different fields such as science, engineering, medicine, law, finance, marketing and economics. Each industry should develop its own IP policies, management style, strategies, etc. depending on its area of specialization. The pharmaceutical industry currently has an evolving IP strategy. Because there is an increased possibility that some intellectual property rights are invalid, antitrust law must intervene to ensure that invalid rights are not unlawfully invoked to create and maintain illegitimate, albeit limited, monopolies in the pharmaceutical industry. In this context, many things remain to be resolved.

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