International Journal of Leading Research Publication
IJLRP

© IJLRP | ISSN (O) - 2582-8010
May 2023 | Vol. 3 Issue. 9
www.ijlrp.com

INTELLECTUAL PROPERTY RIGHTS AND ITS ALLUSIONS IN PHARMA INDUSTRY

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ABSTRACT

Intellectual property rights have been characterised as those that apply to concepts, creations, and artistic works that have the support of a public consensus for granting them the status of property (IPR). IPR provide the property's authors or inventors specific exclusive rights so they may recoup their costs of creation or reputation. There are several ways to safeguard intellectual property, including patents, copyright, trademarks, and others. A patent is issued for an invention that satisfies the criteria of general novelty, non-obviousness, and industrial applicability. IPR is necessary for improved identification, planning, marketing, and rendering—and, as a result, for the protection of invention or creativity. Each industry should create its own IPR rules, management techniques, strategies, and other components according on its area of competence. A more targeted approach is required in light of the pharmaceutical industry's developing intellectual property rights strategy.

Keyword: *Drug, intellectual property, license, patent, pharmaceutical*

1. INTRODUCTION

Any original creation of human intelligence, including works of art, literature, science, and technology, is referred to as "intellectual property" (IP). Intellectual property rights are the legal privileges granted to an inventor or creator to safeguard their work for a defined period of time (IPR). These legal privileges provide the inventor, or his assignee, the only authority to make use of his invention or production for a predetermined period of time. It is commonly known that intellectual property is crucial to the functioning of the contemporary economy. Additionally, it has been unequivocally proven that the intellectual effort that went into the innovation must be given the proper weight in order for it to benefit the general welfare. The costs associated with "research and development" (R&D) as well as the capital necessary to introduce a new technology to the market have both risen. Because it gives the inventor or creator of an IP an exclusive right to use his or her invention or production for a specific length of time, IPR is a potent weapon for preserving investments in time, money, and effort. As a result, it is now imperative, at least temporarily, to safeguard information from unauthorised use in order to assure the recovery of R&D and other related expenditures as well as sufficient revenues for ongoing investments in R&D. Therefore, intellectual property rights (IPR) support a nation's economic development by fostering industry expansion and competitiveness.

2. HISTORICAL BACKGROUND

The IPR laws and administrative processes were developed in Europe. The practise of granting patents first emerged in the fourteenth century. England employed unique phrases to entice artists from other nations and was, in some respects, more technologically sophisticated than other European countries. The first copyrights known to exist were issued in Italy. The IP system may be viewed as having its roots in Venice, where the majority of legal analysis in this field was conducted. Here, the first laws and legal frameworks were created, and other countries quickly followed. Patent law in India has existed for more than 150 years. The first is the “1856 Act”, which established a 14-year patent term based on the British patent system and was subsequently followed by a number of legislation and modifications.”

2.1. TYPES OF IPR:

The phrase "Intellectual Property" now refers to a considerably wider range of things than "Industrial Property," which used to solely contain patents, trademarks, and industrial designs. Intellectual property laws facilitate technological advancement in the following ways:

(a) “It provides a method for dealing with infringement, piracy, and unauthorized use”;

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May 2023 | Vol. 3 Issue. 9
www.ijlrp.com

(b) "It provides a pool of information for the general public because all forms of intellectual property are published, with the exception of trade secrets".

For a variety of intellectual endeavors, IP protection can be sought, including

(i) "Patents"

(ii) "Industrial designs are features of any shape, configuration, surface pattern, line and color composition applied to a 2-D or 3-D object, such as a textile, for example Any mark, name, or logo that is used to trade in a product or service and identifies the manufacturer or service provider are considered trademarks".

(iii) "It is possible to acquire, sell, and license trademarks. Except for the goodwill associated with the product or service it represents, a trademark has no existence."

(iv) "Copyright covers literary, musical, dramatic, artistic, cinematographic, audio tape, and computer software as forms of material expression of ideas".

(v) "Geographical indications are indications that identify a product as having originated in the territory of a country, a region, or a locality within that territory, where a particular quality, reputation, or other characteristic of the product is primarily attributable to its geographical origin".

A patent is issued for an invention that satisfies the criteria of general novelty, non-obviousness, and industrial or commercial use. Patents may be issued for both processes and products. A patent is valid under the Indian Patent Act of 1970 for 14 years from the date of filing, with the exception of procedures for making pharmaceuticals and food, which have a period of 7 years following the date of filing or 5 years following the date of the patent, whichever comes first. Foods and medications were not eligible for product patents. In all other Berne Convention members, a copyright established in one of those members is immediately protected without the requirement for registration.

3. ROLE OF UNDISCLOSED INFORMATION IN IP

The protection of secret knowledge is one of the aspects of IPR that is mostly unknown and seldom discussed, despite the fact that it is possibly the most important kind of protection for corporations, research and development organisations, and other organisations that deal with IPR. Examples of concealed knowledge, sometimes known as trade secrets or confidential information, include formulas, patterns, compilations, programmes, devices, techniques, and processes. The protection of trade secrets and private information is a long-standing human tradition. People have created strategies to keep sensitive knowledge a secret at every stage of development, usually by limiting access to immediate relatives. The application of legislation covering all types of intellectual property rights in India is at various levels; However, there is no specific statute that only protects trade secrets or sensitive information."

"Few significant globalisation or internationalisation pressures existed between the 1950s and the 1980s, and several countries, like India, were able to endure without a strong framework of intellectual property rights. As a result of globalisation fostered by the chemical, pharmaceutical, electronic, and IT sectors, this process is distinguished by a shortening of the product cycle, a high risk of reverse engineering by rivals, and a significant investment in R&D. Industries understood that trade secrets weren't enough to safeguard a technology. It was difficult to capitalise on breakthroughs without consistent laws and rules governing copyright, trademarks, patents, and other sectors. In this way, IPR became an important part of the World Trade Organization (WTO).

4. RATIONALE OF PATENT

A patent is a declaration of the invention's intellectual property (IP). Under the severe examination and opposition processes specified in the Indian Patents Act of 1970, patents are awarded for inventions that are patentable and satisfy the standards of novelty and usefulness. The patent's validity is not, however, assumed in the first instance."

Most countries have national systems in place to safeguard intellectual property that falls within their purview. The protection granted to the inventor or creator in a nation (such as "India") or area (such as the "European Union"), with the exception of copyrights, only extends to the territory where the protection is requested. An Indian patent, for example, is only recognised in India and not in the United States. In order to profit from exclusivity, an invention must be patented. This indicates that the inventor or his assignee would hold a monopoly if, for example,

- "If the patent agent correctly described and claimed the invention in the drafted patent specification, the resulting patent would grant the patent owner an exclusive market, and";

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May 2023 | Vol. 3 Issue. 9
www.ijlrp.com

- "If the inventor has made an important invention after taking into account the customer's modifications".

To take advantage of his exclusivity, the patentee has the choice of selling the innovation directly to consumers or licencing it to a third party.

The following would not qualify as patents:

- "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"
- "A discovery, scientific theory, or mathematical method"
- "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"
- "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"
- "A mere arrangement or re-arrangement or duplication of a known device each functioning independently of one another in its own way"
- "A method of agriculture or horticulture"
- "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"
- "An invention relating to atomic energy"
- "An invention, which is in effect, is traditional knowledge"

5. MANAGEMENT OF IP IN PHARMACEUTICAL INDUSTRIES

More than any other technology area, the drug and pharmaceutical industries are directly related to globalisation and demand a strong IP system. Knowing that the price of bringing a new medication to market may vary anywhere from $300 million to $1,000 million, no corporation wants to take the chance that its intellectual property would end up as public property without receiving acceptable returns. It is a corporate activity to create, acquire, defend, and manage intellectual property, much as it is to raise resources and money. The knowledge revolution that we will definitely experience will call for a particular position for IP and its treatment in the decision-making process.

In the global pharmaceutical sector, where competitiveness is fueled by scientific understanding rather than manufacturing competence, a company's success will primarily depend on its R&D activities. As a result, the pharmaceutical sector spends a significant amount of money—up to 15% of revenues, according to reports—on research and development. One of the most urgent problems in this industry is the management of innovative risks in the quest to outperform competitors. It is expensive for pharmaceutical R&D to continue developing possible medications that can't adhere to the strict safety criteria, often after years of investment. It takes such medications between 8 and 10 years from the time the molecule was originally produced to go through development barriers. As product patents replace utility patents as the primary means of intellectual property protection, drug companies will need to reorient their research and development efforts away from creating new methods for manufacturing existing drugs and toward creating novel drug molecules and "New Chemical Entities (NCEs)". The emphasis of research and development turned to chronic (long-term) disorders in the 1980s after numerous short-term ailments were effectively treated. It's crucial to confirm that the standards of various regulatory agencies are satisfied while looking for a worldwide market.

"It is acknowledged that in the previous 10 years, the quantity of documents that must be delivered to regulatory bodies has practically quadrupled. Additionally, regulatory agencies are increasingly taking a lot longer to approve a new medicine. The outcome is a shorter patent protection term, demanding more work to make enough money. In the case of biotechnologically created pharmaceuticals, particularly those that employ genes, the situation may be substantially worse. The developed world is expected to start pushing for the expansion of medication safeguards as soon as possible. It is also feasible that many governments might tighten price regulation in order to achieve public goals. It is also feasible that many governments might tighten price regulation in order to achieve public goals. On the one hand, this would highlight the need for reduced costs associated with medication research, manufacture, and marketing, and on the other, it would call for budgeting

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May 2023 | Vol. 3 Issue. 9
www.ijlrp.com

for lower profit margins in order to spread out the associated expenditures over a longer period of time. It follows that the pharmaceutical sector must juggle a number of conflicting regulations. Numerous cost-containment and trade advantage tactics have surfaced during the last ten to fifteen years. Examples of this include outsourcing R&D work, creating R&D partnerships, and creating strategic alliances."

5.1 NATURE OF PHARMACEUTICAL INDUSTRIES:

The race to uncover the secrets of the human genome has resulted in an explosion of scientific knowledge and the creation of new technologies that are transforming the economics of drug development. "Biopharmaceuticals" are likely to hold a special place in the future due to the fact that each person's genome will be mapped and stored on a chip. Personalized medicines will be the ultimate goal. The data contained in the chips will serve as the basis for prescriptions. A major IP concern is the security of such databases containing personal information. There will be an increasing number of biotech-based drugs on the market. This drug's protection strategy will be slightly different from that of conventional drugs that were not developed using biotechnology. The microbial strains used to make a medicine or vaccine must be listed in the patent document. If the strain is already known and reported in the literature that scientists typically consult, the situation is straightforward.

Though countless new strains are consistently generated, identified, and deposited with international depository authorities in compliance with the Budapest Treaty. When doing a novelty search, the databases of these depositories should also be searched. Businesses generally do not share their work, even though it is a good idea to make it a rule not to reveal the innovation through publications or seminars until a patent application has been submitted.

""When dealing with microbial innovations, the strain needs to be deposited with one of the reputable depositories, where it will be given a registration number that needs to be stated in the patent specification. This eliminates the need for a written description of a life form. If one isn't dealing with things like cell lines, depositing a strain also costs money, although this isn't much. Additionally, as previously shown, the sequences for innovations involving genes, gene expression, DNA, and RNA must also be disclosed in the patent specification. The alliances could be established for a number of reasons, such as the use of marketing networks, the sharing of manufacturing facilities, and the pooling of R&D resources and knowledge. It is always a good idea to sign a formal agreement when forming an R&D alliance that specifies who owns IP in various countries, how to divide the costs of obtaining and maintaining IP and the revenue it generates, how to protect trade secrets, how to keep track of IP owned by each company prior to the alliance and IP created during the project but not specified in the plan, how to settle disputes, and other important details. Remember that an alliance would be beneficial if one party has a greater IP portfolio than the other partner. This Agreement may also contain various other elements."

Academic institutions, corporate R&D businesses, and public R&D institutes will soon employ contract research for several pharma companies in India and worldwide. The aforementioned elements will all be helpful. Special consideration will be needed to ensure the secrecy of the study.

According to the status of the pharmaceutical sector today, intellectual property rights are being unfairly bolstered and misused at the expense of competition and customer welfare. The absence of risk and innovation in the pharmaceutical sector is an example of the injustice that is occurring at the expense of the general welfare. Reforming the law cannot get rid of this injustice on its own. Even if congressional initiatives to address legal loopholes and new legislation to restrict the commercial practises of the pharmaceutical sector may offer some relief, antitrust law must nonetheless adequately interfere. While antitrust laws have rightly probed pharmaceutical sector business activities such mergers and acquisitions and agreements not to compete, there are a number of additional behaviours that require attention. In areas like the granting of patents on minor components of an old drug, the reformulation of old drugs to secure new patents, and the use of advertising and brand name development to increase barriers for generic market entrants, antitrust law can help stabilise the balance between rewarding innovation and maintaining competition.

Natural botanical items are more important to the pharmaceutical sector since they are employed in traditional medicine in many developing and industrialised nations. The market for these medications has grown annually by 5% to 15% and is now $60 billion. Many people claim that drugs that just use conventional knowledge are patentable. Researchers or enterprises may also claim intellectual property rights over traditional

© IJLRP | ISSN (O) - 2582-8010
May 2023 | Vol. 3 Issue. 9
www.ijlrp.com

knowledge and/or biological resources after a minor alteration. The sharp increase in patent requests for herbal medicine-related products shows this tendency. Each country's intellectual property rights laws, which fall into the categories of food, pharmaceuticals, or cosmetics, govern how patent applications for natural goods, traditional herbal remedies, and herbal medications are handled.

5.2 SIGNIFICANT ASPECTS OF DRUG PATENT SPECIFICATIONS:

To draft a specification is a highly specialised talent that may be acquired with practise and necessitates a solid foundation in law, technology, and science. The core of the innovation for which legal proprietary is sought is set out in the claims of the patent specification. Finding a novel property in a substance that was known before is not patentable. If one can use the property, they have made an innovation that could be patented. The discovery that a railway sleeper built of a well-known material can endure mechanical shock is not patentable. A novel property has been found in a material even if it may not be novel in itself. It could be conceivable to patent them in conjunction with other well-known compounds if they combine to create a unique effect. This is because no one has ever produced a medication, fertiliser, or pesticide with that combination previously. It is certainly feasible that a creator has created a unique molecule even while its exact structure is unknown. The description of the material, its characteristics, and the method of production will be crucial in this situation.

"A patent might cover the method of mixing the ingredients to create valuable goods if they interact in some way when combined. In this case, there is no chemical reaction. It simply offers a minimal level of safety. The use of individual elements of the combination by other parties is not covered by the patent. A patent on aqua regia, for instance, won't stop anyone from mixing the two acids in different quantities to get additional patents. Treatments for people and animals, with the exception of the United States, are generally often patentable since they are not considered to have practical industrial applications. Claims should be carefully crafted when a novel pharmacological application of a well-known drug is involved since they shouldn't indicate a course of therapy. Pharmaceuticals and medications, including herbal remedies, are involved in the majority of applications. Only a handful of the applications include those in engineering, electronics, and chemicals. Applications involving medications and drugs make about 62% of all submissions.

6. CONCLUSION

It should go without saying that "managing intellectual property and intellectual property rights (IPR) requires a variety of activities and tactics that must be in accordance with both domestic law and international treaties and norms. More than simply a national perspective is now a factor. IP and the associated rights are significantly impacted by the demands of the market, the market's reaction, the cost of turning IP into a business, and other variables. To put it another way, "trade and commerce are taken into consideration while administering intellectual property rights. Individuals with differing degrees of domain expertise in industries like health, law, and technology are required to participate in different types of intellectual property rights, IP policies, management methods, strategies, and other elements ought to develop uniquely for each sector. depending on its specialization. The IP strategy of the pharmaceutical sector is currently changing. Because there is a larger likelihood that certain IPR are unlawful, antitrust legislation must be used". Therefore, to establish and sustain illegitimate, if limited, monopolies within the pharmaceutical sector, it is important to avoid the illegal claim of invalid rights. There are still a lot of unanswered problems in this situation".

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May 2023 | Vol. 3 Issue. 9
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