Review Article

Indian Pharmaceutical Product Protection by Utilizing Intellectual Property Rights

Pasupuleti Dheeraj Krishna*, Deeksha Kethareshwara Sujatha, Balamuralidhara Veeranna

Department of Pharmaceutics, Regulatory Affairs Group, JSS College of Pharmacy, Mysuru, Karnataka, INDIA.

ABSTRACT

Background: Intellectual property rights (IPR) are described as concepts, creations, especially artistic endeavors around which the community is ready to confer the position of ownership. There are various sorts of intellectual property protection such as patents, copyright, trademarks, and so on. A patent is an acknowledgment of an innovation that meets the standards of worldwide uniqueness, non-obviousness, as well as commercial use. It is required for improved identifying, organizing, marketing, and rendering, and hence for the ownership of innovation or creation. Apart from copyright, which is worldwide in the meaning that it is instantly available in all Berne Convention members. It is crucial to note that, with the exception of copyright and trade secrets, all rights must be renewed on a regular basis in order to remain in effect. **Aim:** The goal of this work is to study the ways to protect pharmaceutical product by utilizing IPR. **Materials and Methods:** This study has been performed by gathering information from the official websites if IPR. **Results:** IPR, like every commodity, may be transferred, donated, sold, and licensed. An institution which is not independent may be unable to possess intellectual property. Improvements and modifications made to well-known items can be safeguarded. However, geographical indications might be used to safeguard particular agricultural as well as historical items. **Conclusion:** Apart from trademarks and geographical indications, that can have an indefinite life if reissued after a certain time period by submitting official fees, IPR have a fixed term.

Keywords: Drug protection, Intellectual property, License, Patent, Pharmaceutical protection, IPR.

INTRODUCTION

Intellectual property (IP) refers to every original work of a human mind, as in an aesthetic, creative, technological, or scientific production. IPR is the constitutional privilege given to the innovator or developer to safeguard the innovation or creativity for a set length of time. Such constitutional protections grant an innovator or its designee the only right to fully exploit his innovation and technology for a specified length of time. It is widely acknowledged that intellectual property (IP) plays a critical role in the modern economy. This has also been decisively proven intellectual effort connected with the invention must be given proper consideration for the community advantage to be derived from it.[1] There's been a significant increase in the expenses of research and development (R&D), as well as the capital necessary to bring a new product to market. The risks for innovators has grown quite large, and thus the necessity to safeguard information against illegal usage was becoming imperative, at least a minimum of time, to secure restitution of R&D as well as other related expenditures, as well as appropriate revenues enabling continuing development in R&D. IPR is a powerful weapon for protecting the innovator of an IP's resources, period, wealth, and effort because it offers the innovator an exclusive license for using his innovation and technology over a certain length of time.[2] In this approach, intellectual property rights contribute to the growth of the economy by enabling competitive

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Correspondence:
Mr. Pasupuleti Dheeraj Krishna
Research Student, Department of Pharmaceutics, Regulatory Affairs Group, JSS College of Pharmacy, Mysuru, Karnataka, INDIA.
E-mail: pdheerajkrishna25@gmail.com

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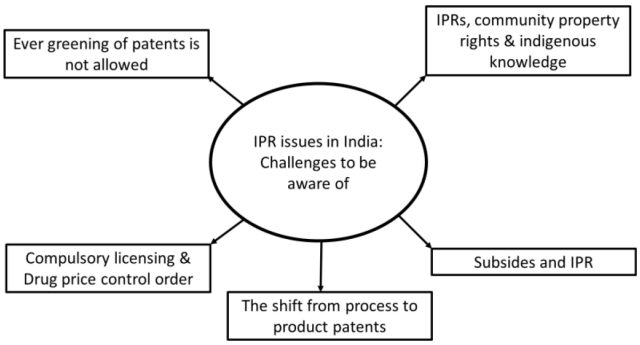

Figure 1: IPR Challenges in India.

spirit and supporting industrial progress and economic prosperity. The current study provides a quick summary of IPR with a focus on medicines.[3]

Figure 1 is about challenges that are facing in India while filling IR, Figure 2 gives information about the tyes of IPR.

Brief History

The rules, as well as management procedures governing intellectual property rights, have their origins in Europe. The practice of issuing patent protection began in the 14th century. In certain ways, England was technically sophisticated in compared to other European places, and it used to draw artisans from many other nations on favorable terms. The very first documented royalties were established in Italy. Venice can also be regarded as the birthplace of said intellectual property system since much intellectual thought inside this field was conducted there; rules and institutions were created together for the first time at the moment, as well as other nations responded in due order. The Indian Patent Act dates back more than 150 years. The first is the 1856 Law, which would be patterned upon that British patent system which provides a 14-year protection period, and it has been supported by several laws and modifications.[4]

Intellectual Property Types and Descriptions

Historically, mainly patents, trademarks, including industrial designs remained safeguarded under 'Industrial Property,' but the phrase 'Intellectual Property' today encompasses a considerably broader range of concepts. IPR contributes to technological progress in the accompanying directions[5]

a. t includes a method for dealing with plagiarism, counterfeiting, and unauthorized use.
b. It gives a wealth of ideas to a wider populace for, except proprietary information, every type of IPR is released.

IP clearance can be obtained for such a wide range of creative endeavors, namely

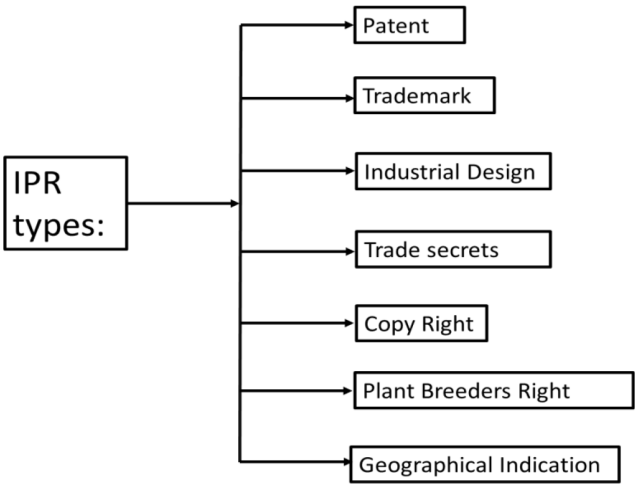

Figure 2: IPR types.

Figure 3 Indicates role of Intellectual property in industry.

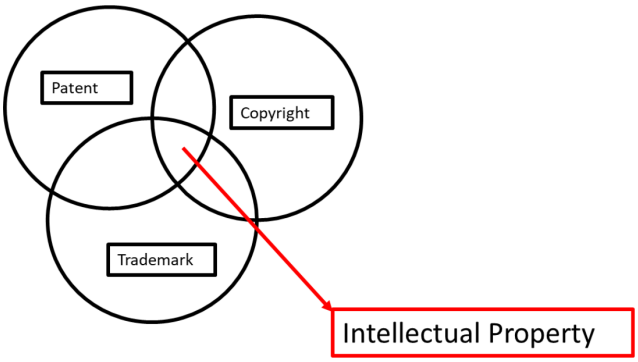

Figure 3: Intellectual property in Industry.

i. Patents
ii. Industrial designs are aspects of every geometry, arrangement, material design, line combination, including color concentration that is implemented to a product.
iii. Trademarks are some sign, title, otherwise symbol in which goods or services were traded as well as through which the maker or wireless carrier is recognized. Trademarks can indeed be purchased, sold, or rented. A trademark will have no validity separate from the reputation associated with a product as well as the services it represents.
iv. Copyright refers to the tangible manifestation of concepts and encompasses philosophical, orchestral, theatrical, aesthetic, cinematic output, audio cassettes, as well as software applications.
v. Geographical indications were indicators that designate any product with originated within limits of the country or an area or place within that area in which a specific grade, character, or even another

attribute of the item is primarily related to its geographical location.

A patent is granted for just an innovation that meets basic worldwide uniqueness, non-obviousness, as well as business or manufacturing applicability requirements. Patents may be issued for both items as well as methods. The duration of a patent under the Indian Patent Act dated 1970 is generally Fourteen years after the date of application, with exception of procedures for making pharmaceuticals and food products, which had a period of 7 years after the date of submission or 5 years after the date of the patent, whichever was sooner. There were almost no product patents awarded for pharmaceuticals or dietary goods. Copyright created in a Berne Agreement single nation is immediately secured in many other participating countries, registration not required. India is a cosigner towards the Berne Convention and also has copyright protection which is equivalent to almost any other country. Unfortunately, these copyrights will also not be immediately available in nations that are not Berne Agreement signatories. As an outcome, copyrights may not even be regarded as national property in the legal sense. IPR, as any type of property, can also be transmitted, leased, even donated.[5]

Undeclared Statement's Significance towards Intellectual Property

Safeguarding of secret information is indeed the least acknowledged most acknowledged the kind IPR protection, despite being the most crucial type of security for companies, R&D institutes, as well as other IPR-related organizations. Formulas, patterns, compilations, programmes, devices, methods, techniques, and processes are examples of undisclosed knowledge. Safeguarding of concealed material or trade secrets is also not a new concept to humans; at each and every evolutionary stage, humans have made strategies to keep valuable data private, most typically by confining awareness to families. Laws pertaining among all types of IPR are being implemented in India throughout various stages, although there is no unique and exclusive legislation safeguarding concealed knowledge/trade secrets or personal details. Global capitalism or internationalization process forces weren't really high from the 1950s to the 1980s, but many nations, like India, remained able to operate without the need for a robust IPR system. Globalization, fueled by the chemistry, pharmaceutical, electronics, and information technology sectors, has led to a significant R&D expenditure. Such procedure is distinguished by a reduction in product lifecycle duration as well as a serious potential of data manipulation by rivals. Companies recognized having proprietary information are insufficient to protect an innovation. That was impossible to fulfill the advantages of breakthroughs without unified rules and policies governing patents, trademarks, copyright, as well as other intellectual property rights. It is how intellectual property rights is now an essential component of such World Trade Organization.[6]

Rationale of Patent

A patent is acknowledgement of something like the field of intellectual property expressed in innovation. Patents are issued those marketable innovations that meet the standards of creativity and usefulness underneath the severe inspection and appeal process.[7]

Several governments have developed national systems to safeguard IPR under their authority. Apart from in the situation of copyrights, any protections offered to the innovator in such a nation (like as India) or area (like the European Union) is limited to a jurisdiction requested which is not applicable in those other regions and countries. Any license awarded in India, for particular, would be only legal within India but not in the United States. The primary motive for copyrighting an innovation should be to profit from restriction; that is, the innovator or his assignment will have a monopolies if,

a. The innovator who created any essential innovation while considering the alterations requested by the consumer, as well as
b. If somehow the legal agent accurately described but also asserted an innovation with in patent document, the resulting patent will grant the invention holder its exclusive market.

The patent holder might use their privilege by promoting the patented product directly or leasing this to a 3rd party. The preceding will not be considered as patents:

i. An innovation that is stupid or makes claims that are apparent or contradict well established laws of nature. An innovation whose main or proposed usage would indeed be illegal, immoral, or harmful to population health.
ii. A breakthrough, theory in science, or mathematical approach
iii. A simple identification of a novel usage with a recognized material, or else even simple application of the a identified technique, equipment, otherwise device, except those recognized procedure culminates in a new market or utilizes minimum 1 novel reactant.
iv. A material created using simple mixing that result merely in the accumulation of the qualities of its

constituents, or a procedure for making any such material

v. A simple configuration, s basically, or duplicate of an existing device, that each operates independently of the others in its entire manner.

vi. A farming or horticultural method

vii. Any method for such medical, therapeutic, rehabilitative, preventative analytical, rehabilitative, or even other therapy of humans, or indeed any process for such comparable suffering of living organisms, to make free from disease otherwise to raise economic worth or that of their goods.

viii. An atomic energy-related innovation.

ix. Innovation that is essence, conventional knowledge[7]

Justification about License

A license is an agreement under which the licensor permits the licensees to engage in acts that would otherwise have been illegal. In a patent license, for example, licensor grants the licensee special protections towards the property. The result is to provide the licensee the authority to do something that he or she would instead be barred from just doing, i.e., a licensee makes what otherwise would be illegal legal.[8]

The licensor may additionally license 'understand' relevant to the implementation of the licensed patent right, such like data, method, or device happening or employed in a commercial activity, which would be included in a commercial license alongside the patent right. Some examples of know-how are:

i. I technical data such as equations, methodologies, as well as operational processes as well as

ii. Financial records such like client lists as well as sales Figures, as well as advertising, administrative, and management practices.

Moreover, whatever technological, economic, financial, or even other knowledge could be entitled to protect.[8]

Licensor Benefits

1. Creates new markets.
2. Opens up additional avenues for revenue generating.
3. Assists in overcoming the barrier of developing the processes in different markets, particularly in foreign nations – lower costs and the risk, as well as discounts on distributing and advertising costs.[9]

   Benefits to the licensee are

   i. R&D cost savings and the removal of R&D hazards.

   ii. Quick exploitation of market requirements before the market interest wanes.

   iii. Guarantees that items are up to date.[9]

IPR Registration Process

1. Registering intellectual property rights in India.
2. Fill out the application form.
3. Preliminary analysis and examination.
4. Objections are communicated via a show-cause notice.
5. Publication in the IPR journal.
6. Opposition of registration.
7. IPR registration.

Duration of intellectual property rights

- The period of each patent will be Twenty years from the time of submission of the patent application, regardless of whether this is submitted with such a preliminary or definitive description. The day of patent seems to be the day upon which statement of claim is submitted.
- The period of each trademark registration is ten years from the date of filing, which is regarded to become the date of application.
- Copyright is typically valid for 60 years.
- Geographical Indication is typically valid for ten years.
- Chip Layout Design registration is valid for ten years from the date of submitting an application

Figure 4 Gives the registration process for getting IPR.

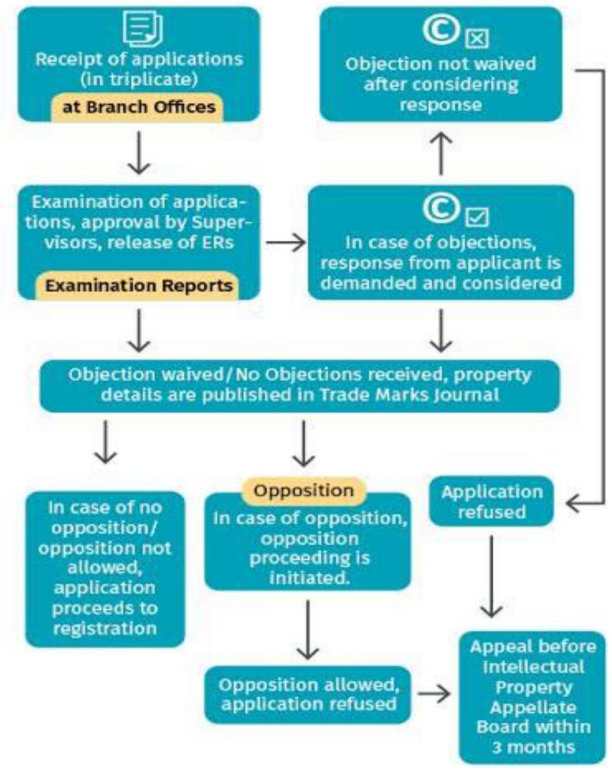

Figure 4: Registration process of IPR in India.

IPR	Target	Requirements for registration	How to obtain the protection
Patent	Product, method	New, differs fundamentally from the others and industrially applicable	Granted
Utility model	Product	New, differs clearly from the others and industrially applicable; but does not necessarily meet patent requirements	By registration
Registered design	Appearance of concrete object made industrially or by hand	Design differs essentially from others	By registration
Trademark	Symbol of product or service: character, work, number, pattern, signal, sound, etc.	Identifying, clearly distinctive, not contrary to good practice	By registration or establishing

Figure 5: Summary of Intellectual property rights.

Figure 5 About registration requirements for patent, design and trademark.

for registration or from the date of first commercialization wherever in India or in any convention nation or country identified by the Government of India, whichever one is sooner.

- Registered varieties have a variable term of protection for various crops, specifically 18 years on trees and vines and 15 years for other crops and existing kinds.

The Role of Patent Cooperation Treaty

The PCT is a multinational convention that was signed during 1978. An innovator of a member nation contracting party of CT can concurrently gain priority for innovation in all of participating countries. The World Intellectual Property Organization in Geneva coordinates all PCT related operations.

To protect an innovation in those other nations, it's indeed necessary to submit an individual statement of claim within every relevant area; in certain circumstances, within a certain time frame to get priority in such nations. This would need a significant expenditure in a short period of time to cover costs like as filing expenses, translations, legal fees, and so on. Furthermore, it is thought that owing to the little time available for deciding whether or not to submit a grant application in a nation, the choice may not have been properly justified.

Innovators from PCT participating nations, from the other hand, can get preference over their innovations without having to declare multiple applications with in nations of concern, conserving the original investment in submitting costs, translations, and so on. Furthermore, the arrangement gives member countries significantly more time to file patent applications.

The Paris treaty allows for a one-year opportunity as from moment of processes consist to get precedence in those other nations. The period allowed under the PCT might be as little as 20 months and as much as 31 months. Furthermore, an inventor benefits from the search report created under the PCT procedure in order to ensure that the patented invention is new. To be certain that the innovation is patentable; the innovator might request preliminary assessment prior submitting in those other countries.[10]

Intellectual Property Management within Pharma Industry

Drugs and medicines, more than any other technology field, closely meet the concept of globalization and require a robust IP framework. Knowing that the cost of launching a new medication onto the market may range from $300 million to $1 billion, not to mention the dangers connected with the development stage, no corporation wants to risk its intellectual property becoming public property without acceptable rewards. Producing, acquiring, preserving, and administering intellectual property (IP) has to become a business activity in the same way that generating supplies and finances. The impending technology explosion will necessitate a particular place for intellectual property and management in the entire judgment process.

Scientific information, rather than industrial know-how, drives competition in the global pharmaceutical sector, and a company's business is heavily reliant on its R&D activities. As a result, investments in R&D in the pharmaceutical business are highly high as a percentage of overall sales; studies claim that it might be as much as 15% of total sales. One of the most pressing concerns in this market is how to control inventive risks while attempting to acquire a commercial advantage over competing firms. The danger of failures in pharmaceutical Research and development comes at a significant cost, with both the production of prospective medications who are unable to fulfil demanding safety criteria getting abandoned, often after several years of investment. It takes around 8-10 years from the day the molecule was originally synthesized for medications to cross development barriers. As product patents become the primary weapon for safeguarding intellectual property, drug firms will need to change their R&D focus from developing new procedures for generating established medications to developing a new drug molecule and new chemical entity (NCE). After a time of effectively treating numerous short-term ailments, the R&D focus moved to long-term (chronic) diseases in the 1980s. When looking for a worldwide market, one must verify that the standards of various regulatory agencies are met.

It is believed that the number of papers need to be submitted to regulatory bodies has nearly quadrupled in the previous 10 years. Furthermore, regulatory agencies are increasingly taking significantly longer to approve a new medicine. As a result, the length of patent protection is limited, necessitating further work in order to make sufficient revenues. The issue may be worse in circumstance of medications generated by using biotechnology pathway, particularly those involving gene use. It is anticipated that the developed world will soon begin lobbying for increased medication protection. It is indeed feasible that so many administrations will use price controls to achieve public aims. This would underline the need for lower medication research, manufacturing, and marketing budgets, while also necessitating budgeting for lower profit margins in order to recoup expenses over a longer period of time. As a result, it is clear that the pharmaceutical business must navigate a maze of competing regulations. Many various tactics for cost conservation and trade advantages have developed over the last 10 to 15 years. Some of options include outsourcing R&D activities, forging R&D partnerships, and creating strong partnership.[11]

Pharma Industry Nature

The quest to discover the mysteries of the humanoid genome takes resulted in a detonation of technical information with the creation of new techniques which are changing fundamentals of medication creation. Biopharmaceuticals anticipated to have a specific position, with the eventual objective of having tailored treatments, as everyone's DNA will be charted then saved in a piece. Doctors will analyze the data contained within chip(s) and recommend suitably. The key IP concern related with such datasets of personally identifiable information will be the security of these kind of datasets. Biotechnologically created medications will continue to enter the market in greater numbers. The protection method for such a medicine will differ slightly from that of traditional pharmaceuticals that have not been biotechnologically produced. Microbial strains employed in the development of a medicine or vaccination must be described in the patent specification. If somehow the variant is already identified and documented in the research literature, the position is straightforward. Many novel strains are identified and cultivated on a regular basis, and they are lodged with transnational repository authority under the Budapest Agreement. When doing a uniqueness search, these depositories' databases should be reviewed as well. Companies don't normally share their work, but this is a good idea to avoid disclosing the innovation through journals or lectures unless a patent application has been submitted.

When working with microbiological innovations, it is critical to lodge the sample in one of the approved storage facilities, which will provide the strain a registration number that should be cited in the patent specification. This eliminates the need to write down a description of a biological form. Accumulating a strains certainly costs a lot of money, although not lot if one is not working with, say, cell lines. Furthermore, like in the past, for innovations containing genes, gene transcription, DNA, and RNA, the patterns must be specified in the patented invention. The partnerships might be formed for a variety of reasons, including the sharing of R&D skills and facilities, the use of marketing networks, and the sharing of manufacturing facilities. When attempting to enter into such an R&D partnership, it's often generally a good idea to gain entry into something like a legal contract cover aspects such as IP ownership in various countries, communicating of expenses of achieving and maintaining IP and income accumulating from this, methodologies of retaining trade secrets, financial reporting for IP for every company prior to the affiliation and IP generated even during task but again not discussed in the strategy, and conflict settlements. It should be noted how an agreement would've been advantageous if the IP collection is greater than those of the interested partnership. There might be several more components to this agreement. Many pharmaceutical corporations may soon contract research with university institutions, private R&D organizations, and government R&D institutes in India and overseas. All of the above-mentioned elements would be beneficial. Special care must be taken to ensure the secrecy of the study.

The current status of the pharma sector suggests that intellectual property rights are being unfairly reinforced and misused at the cost of market share and customer welfare. The pharma industry's lack of risk-taking and development highlights the inequality which is happening for expenditure of national. It is an inequity which cannot be remedied just via judicial change. Although legislative initiatives to eliminate gaps in present laws, as well as new legislation to curb other unfair commercial observes of the pharma sector, may give some relief, competition law must intervene effectively. Though monopolies have rightly analyzed some business methods used by the pharma sector, such as acquisitions and mergers through non-competition agreements, there are a number of additional behaviors that must be considered. The offer of patent applications on slight components of such an existing

drug, reformulations of existing drugs to premises infrastructure patents, including the use of marketing and brand title advancement to raise the obstacles for generic companies entering the market are now all areas where antitrust law can support stability among fulfilling revolution plus maintaining contestability.

Traditional medicine derived from natural plant metabolites is an essential aspect of human healthcare coverage throughout many industrialized and developing nations, boosting its commercial worth. The global marketplace for such drugs has approached sixty billion dollars, having yearly growing taxes ranging from five% to fifteen%. While simply conventional knowledge-based medications may not eligible for patent protection, individuals frequently argue that they do. Investigators or businesses can also assertion intellectual property rights on biological-resources and cultural traditions after minimally changing them. The rapid increase of patent applications linked to herbal remedies demonstrates this tendency clearly. Applications of patent in the realm of natural assets, historical herbal medicine, and herbal medical products are handled according to each country's own IPR rules,[12] as dietary, pharmaceuticals, and aesthetics purview, as applicable. Medicinal plants and associated natural sources were becoming key objects of patent claims as they have grown in popularity within the global established herbal medication and cosmetic industries.

Certain Particulars of Drug Patent Specification

Composing patent specifications is a truly skilled talent that must be honed across time but also requires a strong mixture of technical, industrial, plus regulatory understanding. Statements in a specifications of patent are heart of the subject across which legal ownership is desired. This is not possible to patent the newly discovered property in an existing substance. Whereas if property can sometimes be brought into actual application, that inventor has created an innovation that may be patented. Any research that a known materials can tolerate mechanical pressure will not be patented, but a railway sleeper composed of the material may be. A material may not be novel, yet it's been discovered to get a novel property. It may be feasible to patent it in conjunction with certain other existing chemicals if somehow the composition produces a novel outcome. The explanation for this is nobody has previously applied that composition to create a pesticides, fertilizers, or medicine. It is very feasible that a novel structure was produced by an innovator, but its specific structure is unknown. In such a circumstance, the characterization of the material, as well as its qualities and production method, will be critical.

Combining known compounds to create useful goods could be topic of the patent if an ingredients have some functioning connection when combined. There is no chemical change in this scenario. It merely provides modest safety. Further use of different pieces of the composition by anyone is prohibited under the patent. A patent on aqua region, for example, does not prevent someone from merging two acids in other quantities and gaining additional patents. Human and animal therapies are not patented across most nations (excluding the United States) since they're not future prospects of commercial use. In the event of a novel medicinal application of a recognized chemical, one should use caution when formulating claims, since the statement should not imply a technique of treatment. The majority of the requests are for medications and pharmaceuticals, include herbal medicines. A few applications[13] are related to engineering, electronics, but also chemistry. Approximately 62% of the submissions are for medications and pharmaceuticals.

Applications[14]

- Intellectual property rights apply to businesses such as industrial, medicinal, analytic, scientific, drug discovery, drug synthesizing, and production.
- Intellectual property rights are relevant in the fields of science, literature, and art.
- IPR is applicable of New Drug Application, Abbreviated New Drug Application and Investigational New Drug Application analysis of Pharmaceutical Formulations.
- IPR is exclusive right that is approved by government of India for safeguard of creation of inventor.
- It is related for novelty of work.
- It is an act that has certification as well as identity marks for individual products in a large market.
- It is related for determination of Indian Law system.
- It is chief for purpose of industrial designing and Layout.

CONCLUSION

The Indian Government provides the right to intellectual property as a government right. Intellectual property law is concerned with intellectual activity in the realms of industry, science, literature, and the arts. These rights protect artists and other producers of intellectual offerings by guaranteeing them time-limited power over their usage. The rights granted to individuals over the construction of their thoughts. They often grant the

inventor exclusive rights to utilize his or her creations for a set length of time. It is a government-granted exclusive right to protect the creativity and uniqueness of patent-oriented inventions.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

IPR: Intellectual Property Rights; **IP:** Intellectual property; **R&D:** Research and Development; **PCT:** Patent Cooperation Treaty; **WIPO:** World Intellectual Property Organization; **NCE:** New Chemical Entity.

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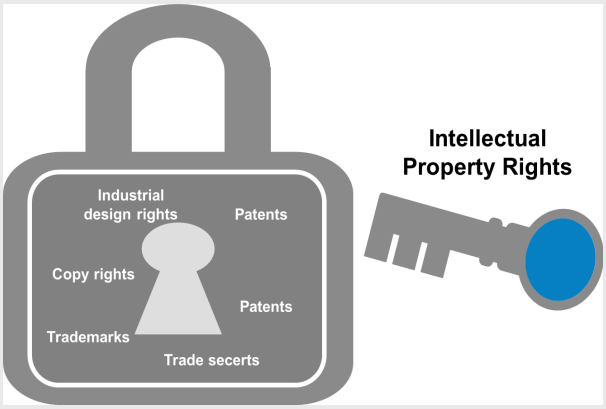
SUMMARY

It is evident that managing IP and IPR is a multifaceted process that necessitates a variety of activities and methods that must be consistent with national laws as well as international treaties and norms. It is no longer only motivated by national interests. Market demands, market reaction, the expense of turning IP into a commercial endeavor, and so on all have a significant impact on IP and its related rights. In other words, trade and commerce factors are critical in IPR management. Varied types of IPR need different treatment, handling, planning, and tactics, as well as the involvement of experts in subjects such as science, technology, medical, law, financing, advertising, and economics. Depending on its field of expertise, each sector should have its own IP rules, management style, strategies, and so on. The pharmaceutical sector is now developing an IP strategy. Given the greater likelihood that certain IPR are invalid, antitrust law must intervene to guarantee that invalid rights are not unlawfully asserted in order to build and perpetuate illegitimate, albeit limited, monopolies within the pharmaceutical business. Many issues remain unresolved in this setting.

PICTORIAL ABSTRACT



About Authors

Research Student, Department of Pharmaceutics, Regulatory Affairs Group, JSS College of Pharmacy, Mysuru, JSS Academy of Higher Education and Research, Mysuru-570015, Karnataka, India.

PhD- Research Scholar, Regulatory Affairs Group, Dept. of Pharmaceutics, JSS College of Pharmacy, Mysuru, JSS Academy of Higher Education and Research, Mysuru-570015, Karnataka, India.

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