

REVIEW ARTICLE

Intellectual property rights

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Healthcare is one industry where intellectual property (IP) is a valuable resource. The creation of medications to meet medical requirements and the discovery of new therapies necessitate the preservation of inventions. Protection of scientific and technological advancements inspires researchers and the business community to develop new and improved treatments and medications, extending and improving people's lives. Healthcare businesses may recoup their investments and continue to invest in fresh research because of IP protection. IP has raised the bar for medical and health research, and it will keep finding solutions to today's unmet demands. As it supports the financing scheme for R&D, IP is a crucial cornerstone of our healthcare system. This article discusses that in a variety of industries, including the healthcare industry, IP is a valuable asset. It is imperative to safeguard ideas and discoveries to find new cures and create drugs to meet medical needs. Protection of scientific and technological advancements motivates researchers and the business community to discover new and improved treatment options and medications, thereby enabling people to live longer and better lives (1).

Keywords: drugs, pharmaceuticals, healthcare system, patent and intellectual property rights

Introduction

Any original work of the human mind, including those in the arts, sciences, literature, technology, or other fields, is considered to be the subject of intellectual property (IP) (Figure 1). The term “intellectual property rights” (IPR) refers to the legal privileges granted to the inventor or creator to safeguard their work for a predetermined amount of time. These legal rights allow the inventor or creator, or his assignee, the sole right to fully exploit their idea or creativity for a specific amount of time. It is widely acknowledged that IP is essential to the modern economy. Moreover, it has been unequivocally proven that the intellectual labor connected to innovation deserves to be given the respect it deserves for it to serve the greater good. A change in drugs, pharmaceuticals, healthcare system, and IPR are some of the terms that are important.

In addition, it has been unequivocally proven that the intellectual labor connected to innovation deserves to be given the respect it deserves for it to serve the greater good. The price of research and development (R&D)

**FIGURE 1 |** Intellectual property.

has skyrocketed, and so have the investments needed to get a new technology to the market. As the stakes for technology developers have increased significantly, it is now imperative, at least temporarily, to safeguard information from unauthorized use in order to guarantee recovery of R&D and other related expenditures, as well as sufficient earnings for ongoing investments in R&D. IPR is a powerful weapon to safeguard the author's time, money, and effort put in developing an IP because it grants the creator

for a specified period, the inventor or his assignee may fully employ his invention or creativity (2). It is widely acknowledged that IP is essential to the modern economy. Additionally, it has been unequivocally proven that the intellectual labor connected to innovation deserves to be given the respect it deserves for it to serve the greater good. The price of R&D has skyrocketed, and so have the investments needed to get a new technology to the market. Since the stakes for technology creators have increased significantly, it is now imperative, at least temporarily, to safeguard knowledge from unauthorized use in order to guarantee reimbursement for R&D and other related costs as well as sufficient earnings for ongoing R&D expenditures. As it gives the inventor or creator of an IP an exclusive right to exploit his invention or product for a specific length of time, IPR is a powerful weapon for protecting investments in time, money, and effort. By enabling healthy competition, industrial progress, and economic expansion, IPR thereby contributes to the economic development of a nation. This review provides a succinct summary of IPR with a focus on medicines (3).

India will modify its position. They'll value innovation more, predicts Kierans. "If you look back through history, invention has been largely responsible for the major eras of wealth development rising tide raises all boats, as the proverb goes" (4).

Review of the literature

The general dispute about Indian pharmacies that has been mentioned is presumably complete from one source but varies by different. Besides creating its own pharmaceuticals, India has become a significant player in the global market for generic medications. It was claimed that anthrax scars required cheap cost brand medicine through the Independent nation while mentioning the United States. India combined as a possibility for the distribution of said generic acquired therapy among North Africans. The safeguarded pattern used by the nation creates identical one significant piece of generic medicine polygamy. In India, the year 1970 saw changes to the national standard. As of 30 months, Indian Pharma Company stated its objective for a ratio of USD 2.1 billion to USD 70 billion 1971 million earlier. A total of 465 large chemicals are currently used within the nation of India, where 24,000 industrial units are in charge. Additionally, 425 of these chemicals are created there. Indian industry entered the market as a result of the global trend toward the production of various bulk pharmaceuticals. Since unit leaders far specified enlargement with bulk drugs such as sulphamethoxazole and ethambutol, companies have emerged. For told lobe innovation, the country development link is exactly 50%. Different sectors, such as Ranbaxy, Dr. Reddy's, and Cipla, have played significant roles in recent years in becoming billion-dollar

businesses. Just 30% of the American population was protected, not correspondingly different manufacturing for the aforementioned global pharmaceutical corporation.

Later, it was claimed that a whole catalogue was available in local medicine and was listed in the following. In the advanced states with low produced countries, TRIP, mentioned IP component by informed Urge circle by recognized GAT Tray, had dropped prolong to a contentious topic (LDs). Chance interested in told increased globally focused huge damage through specific focus plus utilize by here new things in LCs. Another claim contends that because India is delaying the outside settlement and advancing technology alongside vast domestic literature and progress, public IPRs may benefit its citizens (R&D). On a certain layer, LDC governance was challenging in terms of knowing more costs like healthier IPR may entail along with instead of harming that their beginning will result in child-long technology. The developer believes that EMs will never become polycitizens of a foreign country by using that portal. The largest barrier to the EMR legislation's implementation, meanwhile, was the concern over a significant rise in drug prices and, hence, the additional fear that the Indian Medicine Company will lay off employees (5).

The importance of patent law in the pharmaceutical sector

The pharmaceutical sector is always a thriving and important sector for any nation, whether there is a recession or a boom. Every nation is always in need of medicines. IPRs come in a variety of forms and are widely used in the pharmaceutical sector. These include copyright, industrial designs, trade secrets, patents, and trademarks. However, when discussing the pharmaceutical business, the significance of patent law outweighs that of all other IPR types. The important points listed in the following will help to clarify the aforementioned truth.

- a. Protecting invention: When one develops a medication, it needs to be secured to prevent theft. As a result, the innovator has two possibilities. The first one should be protected under trade secrets, but this has the disadvantage that the other party could steal your drug engineering. Patent law offers substantially more protection for such drug inventions and their engineering than trade secrets do.
- b. Protection of the rights of customers and inventors: IPR's primary goal is to protect the interests of its customers, ensuring that public safety always comes first while extending patent protection to any invention or discovery of medications and medicines and providing customers with a range of products of guaranteed standard quality. IPR safeguards the interest and safety of its inventor besides

the interests and safety of the consumer. With the sole marketing rights to sell or license the patented creation of medications and treatments, patent law grants monopoly rights to the inventors and guarantees them huge earnings without any division.

- c. Creation of new medications to meet the demand on a global scale: As and when new diseases strike any country, there is a continuing need for innovation and the development of new drug formulations and treatments to meet the dynamic global demand for vaccines. In such circumstances, patent law serves its purpose by encouraging invention, safeguarding it against theft, and providing support to such innovators.
- d. Making an environment that is secure for inventors: In exchange for the acknowledgment of their effort and exclusive rights to sell or license their innovations, monopoly rights granted by patent law enable inventors to share their inventions with the public in a secure environment. Only when an inventor feels comfortable disclosing their innovations, the R&D industry of any nation will experience growth, leading to the introduction of novel medicine formulations. As a result, it is possible to argue that the function of patent laws in the development of the pharmaceutical business is quite symbolic (6).

Intellectual property rights in India are currently in a professional position

In the case of patents, TRIPS makes reference to the main provisions of the Paris Convention and demands that members abide by them (Figure 2). Currently, India has the lowest drug prices in the world, making them accessible to the general public. On average, medications made in India cost more than 100% less than comparable drugs made in the United States. By establishing a maximum sale price but still allowing some areas to make a sizable profit, the Indian government has fulfilled the constitutional mandate of social and economic balance. The improvement comes into clarity in 2003 as one makeable feature having a state for people who are not using medications on their own, for shipping made under mandate protection. Members of the TRIPS Agreement decided to permanently modify this choice in 2005. By introducing equivalent regulations for health, medications, chemicals, and compounds, the law also benefits procedure protection. It is asserted that specific involvement is a technique for doing through release falling in the categories indicated above and that the grant of patents is fixed by this procedure. Similar candidates could become the current focus for unit novel theory protection by changing a technique (7).

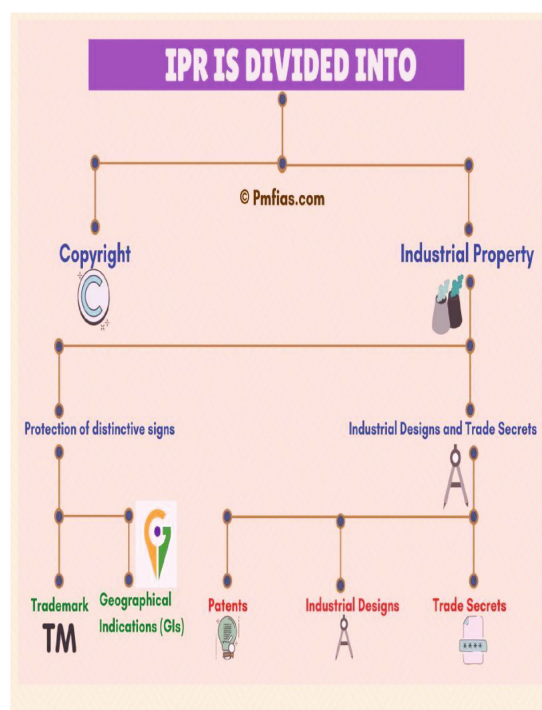


FIGURE 2 | Classification of intellectual property.

Referred to historical Indian IPR events

Half (50%) of the Indian public were living below the poverty line, which is why the margin of medicine is so difficult. As a result, habit expectancy is very low and the death rate from health problems is very high. The world government passed the Specified Medicine Act in 1940, which necessitated the issuance of drug licenses and led to the nationalization of hard narcotics in India. UN duty for preventing the mentioned cost of drugs, the local government has taken two specific steps to address the issue. First, the government established a plant to produce penicillin and other antibiotics by signing a contract with United Nations Children's Fund. As a result, Hindustan Antibiotic Limited was founded in 1957 to produce medications at a lower cost for the general populace. Later, a particular government joins the Rajagopala-Ayyangar Committee, a legal body, to introduce earlier patent laws by conforming to firm specifications. These assets are equally valuable to other complementing strategic assets of the company.

Patent system

The patent system promotes innovation by giving inventors a legal right and temporary control over their creations in exchange for full disclosure of their innovations (Figure 3).

Patents may cover any novel item or method that requires an inventive step, has the potential for industrial application,

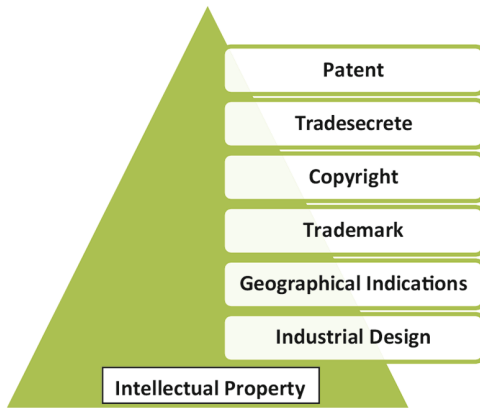


FIGURE 3 | Types of intellectual property.

and does not fall under any of the exceptions to patentability (Figure 4). Patents are territorial in nature and are only valid in the country where they are lodged. As novelty is a key factor in obtaining a patent, inventors must act quickly to submit patent applications, such as complete specifications or provisional applications, before the invention is employed commercially or disclosed to the public. In addition to the 20-year monopoly that is promised, there are many other reasons why property holders favor patent protection. Patents put the owner of the right in a position to, among other things, stop copying, pursue infringement claims, fight against them, collect licensing fees, improve their bargaining position, and increase the value of their company's assets.

- An invention is defined as a new product or procedure that completes the requirements of novelty and industrial application.
 - A patent is an exclusive right awarded for an invention. A patent gives the owner the authority to decide whether or how others may utilize an innovation.
1. Novelty: It should be novel (not previously published and not previously known by or in use by the Indian public).
 2. Non-obviousness: It must include an inventive step and be both technically advanced relative to prior knowledge and non-obvious to a person with the requisite technical expertise.
 3. Industrial use: It must be suitable for industrial use.
- “The Patent Act 1970,” which was updated in 2005 to comply with TRIPS, governs patents in India (Figure 5).

What is not patentable?

Agriculture or horticulture methods, traditional knowledge, computer programmes, inventions connected to atomic energy, plants and animals, and inventions that endanger public order, morality, or the health of people, plants, or animals are not patentable.

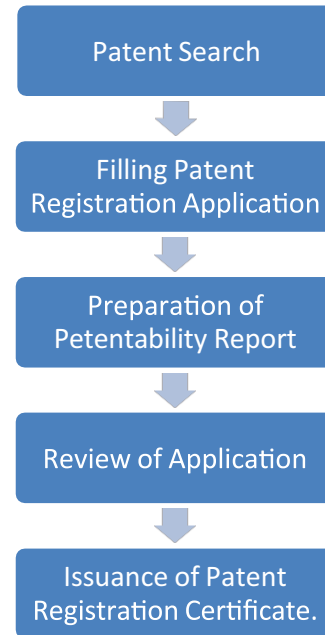


FIGURE 4 | Process of patent registration.



FIGURE 5 | Indian patent issuance standards.

- Simple scientific principle discovery 2020 Patent (Amendment) Rules
- The Patent (Amendment) Rules of 2020 have been updated and published by the national government.
- The disclosure statement that patentees and licensees must submit annually to the Patent Office has undergone changes as a result of the new regulations.
- The format includes revealing how much of the patented inventions have been used commercially or made available to the general public in the nation.
- The disclosure must be made in accordance with the Patent Rules of 2003 using the Form 27 format. This statutory requirement has been flagrantly ignored by the patentees, licensees, and Patent Office.
- The U.S. and MNCs have put a lot of pressure on other countries to eliminate this requirement.

2020 Patent (Amendment) Rules are under fire.

The effectiveness of India's compulsory licensing system, which depends on full disclosure of patent working information, may suffer as a result of the amendment's significant weakening of the disclosure information



FIGURE 6 | Copyright.

submission requirement. This, in turn, may make it more difficult for people to access important inventions, such as life-saving medicines.

In addition to the aforementioned reasons, Section 92 of the Act states that the Controller of Patents may grant compulsory licenses suo motu in response to a notification from the Central Government if there is a situation of imminent danger.

Copyrights

Copyrights are still another essential and significant type of IP (**Figure 6**), particularly in the pharmaceutical industry where it plays an important function. It is true in this era of immediately expanding intelligent networks.

Legislation merely safeguards ideas' representations, not their content. The core concepts and functions are not protected whether you build software source with the aid of copyright law; you may safeguard your expression while preventing significant copying.

Copyright protection is becoming more and more important in the healthcare industry, especially with regard to information.

For the healthcare sector, data are becoming more and more crucial. The sector is being overtaken by an "informatics" wave as companies employ technology for data sharing for better quality standards. Each year, enormous sums of money are invested in the use of commercial electronic databases, their development, segmentation, and dissemination.

These include compilations of medical treatment outcomes and efficacy studies, databases of chemical structures, gene sequence information for the scientific project, and progress and patient information. In general, it is protected by copyright laws as a collection that grants them some level of originality in the contents' choice, organization, or coordination.

Software has a growing impact on medical innovation as technology develops. Today, everything is controlled by software, from sophisticated analytical and diagnostic tools to surgical devices that combine cutting-edge hardware with next-generation analytics and controls. Therefore, it is crucial

that software used in the healthcare industry and other relevant industries is copyright protected.

The field of telemedicine, a relatively new branch of healthcare that is wholly dependent on technology, is another significant area where copyright protection is relevant. It enables the delivery of healthcare to patients in another geographic place via telecommunications and information technologies. Telematics makes it easier to access medical services and, when possible, lowers the cost of treatment. Copyright law may provide protection for software that permits to store as well as share patient and medical information.

Cover journals, medical literature, patient education pamphlets, websites and online sources, operational instructions, and other places may also be covered by copyright in the healthcare and medical fields.

1957's Copyright Act and 1991's Copyright Order

A recent 2012 amendment Six changes have been made since 1957: in 1983, 1984, 1992, 1994, 1999, and 2012.

Objective: To prevent the owner's work from being improperly used (Author).

The Copyright Act gives creators or owners of original works exclusive rights.

Duration: Copyright

Ideas on copyright symbols or (C)

The phrase "All rights reserved" should appear.

Exemptions from copyright include fair dealing for news reporting, criticism, review, and research, as well as use by libraries and archives for educational purposes and public administration.

Trademarks

Trademarks are crucial to the IP portfolio of a healthcare organization (**Figure 7**), just like they are for any product. Confusing sources for products and services, especially those in healthcare and related industries, frequently have very bad outcomes. Therefore, it is important to invest time and energy into developing different brands that will be able to distinguish the owners' services.

It is used for distinguishing phrases, designs, and other elements to set one proprietor's goods or services apart from those of another that is protected by trademark law.

It does not safeguard the actual commodities or concepts at issue. A trademark's distinctiveness is related to its "strength." The more protection a mark obtains in comparison to other marks, the more distinctive the mark (8).

A possibility of confusion regarding the area in question products is the basic test for trademark infringement.

A registered trademark's options are as follows:

- Judicial redress.
- Criminal court.
- Criminal penalties including incarceration and a fine.



FIGURE 7 | Trademark.

Administrative remedies

- Appellate Board for Intellectual Property passing off suit is a common remedy for an unregistered trademark.

What exactly does it consist of?

It consists of symbols such as words, monograms, labels, audiovisual signs, devices, designs, cartons, logos, colored marks, and 3-D signs.

Amendment: Service marks registered as TM, such as Airlines, may be owned by associations.

Marks of certification: Agmark and ISI

Designs

Any attributes that are required for a product, such as the unique qualities of the design, and that are used to piece in two or three-dimensional form and evaluated only sight, are included in the definition of design. The item needs to be brand-new, manufacturable, and marketable. Articles such as syringe and blister-like similar items that fulfill innovation in it are eligible for protection under designs in the healthcare industry.

In the event of an infringement, the registered owner of a design may launch a lawsuit against the offending party to stop the infringement from occurring and to seek compensation for damages. In the event of an infringement lawsuit, the court or other adjudicating authority would examine the articles from the perspective of the typical consumer and determine whether there is a clear likelihood that the two will lead to consumer misunderstanding.

Trade secrete

Trade secrets effectively have a longer lifespan than patents, which grant monopoly and proprietary rights for a short time before becoming public domain (Figure 8). There is no cost associated with applying for and maintaining patents when proprietary knowledge and data are kept as a trade secret.



FIGURE 8 | Trade secret.

Patient lists can also be protected as trade secrets as they consist of patient data that are not readily ascertainable to the outside world. This was affirmed in the decision *In re Phoenix Dental Systems, Inc. v. Phoenix Dental Systems*.

The key is to simply keep your confidential data a secret with only limited access to the same. Non-disclosure agreements and confidentiality provisions are important tactics in establishing trade secrets. There is no separate and exclusive law for protecting undisclosed secret or confidential information. As the biggest improvements in healthcare now rely on treatments such as combination therapies, and with the increasing use of data and software to improve existing technology, the healthcare sector needs to take appropriate steps by way of patent, copyright, designs, or trademark protection or by maintaining trade secrets, to protect its IP from misuse, authorized use wrong way copy and fine.

Healthcare rights

“The right to a standard of living adequate for his or her own health as well as the welfare of himself or of his or her family is to everyone, including clothing, housing, medical care, and necessary social services, as well as the right to security in the event of unemployment, illness, disability due to circumstances beyond his or her control.” As we can see, the State cannot ensure a person’s right to health in the same way that other rights, such as the right to freedom, may be applied. As a result, health is a result of other factors.

Therefore, a variety of factors, some of which are out of human control, function in concert to produce health. The mix of circumstances, such as food, medical support, hygiene, and so on, that contribute to the improvement of health, however, is what the State must guarantee. Access to medications, diagnostic tools for therapeutic purposes, and high-tech equipment for illness detection, treatment, and prevention all play crucial roles in ensuring human health within that set of conditions.

The System of Patents: It seems appropriate to quickly discuss IP in general before discussing the patent system. The phrase “intellectual property” is used to refer to the arbitrary rights that different legal systems assign to authors.

It assets with a creative genesis (9). These intangible assets might be either original works of literature and

art or distinguishing signs and inventions. Therefore, that property establishes the protection of ideas and designs in the industry, trade as well as the fields of art and technology. Legal literature has divided IP, the general word, into two subfields termed copyright and industrial property because there are disparities between the protection of literary and creative works on the one hand and distinguishing signs and inventions on the other. The purpose of copyright is to safeguard artistic and intellectual inventions, especially those that are esthetically beautiful. The crucial aspect of this area is that copyright protects the idea or the form which he does so and which is copyrighted. Contrarily, industrial property relates to items that can be utilized in industry and technology, including inventions in all of their forms, such as utility models and industrial designs, as well as commercial indications like trademarks and trade names. Industrial works are distinguished by their usefulness and serve a specific economic goal, in contrast to literary and artistic productions that foster an atmosphere of intellectual or esthetic satisfaction. Therefore, it is crucial to concentrate on patents as a way to safeguard inventions. One definition of an invention is a concept that aims to address a technical issue.

This explains the social function that has been given to inventions as development-promoting agents and crucial elements of any economic system. The titles bestowed by the State, which are known as patents, attest to the grant of the inventor's exclusive rights to use his creation. The compensation or incentive that the State gives the innovator for his contribution to the resolution of a technological or industrial challenge is the patent.

Make in India: The healthcare industry needs a robust IPR framework

Because of a shift in lifestyle and a strong demand for high quality healthcare, India's healthcare business is constantly growing, making it one of the country's economy's most promising sectors.

The emergence of novel business strategies, unexpected alliances, and quicker deliveries over the past two years have caused significant changes in the healthcare industry, necessitating active participation on the part of organisations in the growth, acceleration, and expansion of their innovation efforts. The pharmaceutical and healthcare sectors are currently battling for technological advances to create efficient vaccines and cures for diseases that are posing a threat to human life.

Protection of ideas and discoveries through IP: Researchers as well as businesses alike are encouraged to create new and improved treatment options because of the protection of scientific and technological inventions.

IPR has a significant effect on both the federal and state markets. Healthcare is one of the many sectors that depends on the efficient enforcement of its patents, trademarks, and copyrights. Consumers, on the other hand, profit from buying safe and approved products.

IPR promotes innovation and commercial concepts, aids in generating money from private investors, and offers protection for major discoveries around the world. Essential drug lists were created in the highly R&D-intensive pharmaceutical sector that is subject to patent protections. These medicines are crucial to saving or enhancing people's lives all throughout the world. The IPR aspires to develop and foster an environment where creativity pharmaceutical market in India has experienced upward growth. It has a global market cap of \$ 42 billion and is projected to grow between \$ 120 and \$ 130 billion by 2030. The production of high-quality medications at cheap cost, increased infrastructure, and investments in R&D and innovation have all contributed to the unmatched expansion of the Indian pharmacy business during the past 20 years. The industry has developed into a significant producer and exporter of pharmaceuticals and vaccines. These discoveries, which should fundamentally be protected by IPRs, have the potential to offer simple healthcare access through a variety of alliances and joint ventures (1).

The government's efforts to create a solid IPR framework have increased. The adoption of the National IPR Policy 2016 served as a catalyst for the country's oncoming IPR development (11). Through the establishment of an institutional system for implementation, monitoring, and review, the policy seeks to incorporate and adapt international best practices in India. With 256,000 industrial trademarks filed in 2021 alone, India has had a double growth in trademark registrations over the last 11 years.

Conclusion

It is imperative to safeguard ideas and discoveries to find new cures and create drugs to meet medical needs. Protection of scientific and technological advancements motivates researchers and the business community to discover new and improved treatment options and medications.

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