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Intellectual Property Rights and Indian Pharmaceutical Industry: An Overview

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ABSTRACT

There are several different kinds of intangible assets produced by human intellect that are referred to as intellectual property (IP). These intangible assets could include works of literature, inventions, or industrial designs, among other things. Once created, intellectual property may be protected by national laws. Under these laws, the owner of intellectual property gains a set of exclusive rights over his or her IP assets, known as Intellectual Property Rights (IPRs). Patents, trade secrets, industrial designs, trademarks, geographical indications, plant varieties, and copyrights are examples of common IPRs. These rights foster innovation by providing creators and inventors with recognition and financial benefits; conversely, a lack of understanding of intellectual property rights and its ineffective application may impede the country's advancements in technology, economics, and society. Therefore, it is imperative that IPR knowledge be disseminated and that it be implemented appropriately for every country. This article focuses on a number of intellectual property terminology, including copyright, patents, trademarks, industrial designs, and geographic indications. This review explores the intricate relationship between intellectual property rights (IPRs) and the Indian pharmaceutical industry, delving into its historical context, challenges, opportunities, and regulatory framework.

Keywords: *Intellectual Property Rights, patent, TRIPS, criteria of patentability, Indian pharmaceutical sector*

INTRODUCTION

Intellectual property (IP) refers to intangible property created by the human mind or intellect. The rights that result from the creation of intellectual property are known as intellectual property rights, or IPRs. The person who created these properties—the inventor, author, etc.—is granted these rights. Notably, even though intellectual property is intangible, only intellectual property rights can provide protection for its tangible material form [1]. Similar to physical property rights, intellectual property rights (IPR) are territorial rights that allow an owner to sell, purchase, or grant a license for their intellectual property (IP). However, in order to make use of IPR, one must register it with the appropriate legal body in a presentable or tangible format. Every kind of IPR grants the author or innovator exclusive rights to maintain and receive financial rewards, which encourages innovation and advances society [2].

IPRs are generally recognized to have two main effects on the pharmaceutical industry. First, there's the pricing and access issue, where the conversation centres on the connections

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between IPRs (especially patent rights), competitor exclusion, and the cost and accessibility of novel medications. The second concern is R&D incentives, or how IPRs help to incentivize the discovery, development, and commercialization of novel medications. It also involves how IPRs affect R&D spending and how it is distributed among diseases, nations, and organizations. These two problems are obviously closely related, and their interaction raises a number of extremely challenging policy and economic challenges [3].

The intersection of intellectual property rights (IPRs) and the pharmaceutical industry is a complex and crucial domain that significantly impacts innovation, access to medicines, and economic development [1]. This review aims to provide a detailed examination of the landscape of intellectual property rights within the context of the Indian pharmaceutical industry.

India has a rich history in pharmaceuticals, with a legacy of traditional medicine and a growing modern pharmaceutical sector. The introduction of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995 marked a significant shift in India's intellectual property regime, particularly in the pharmaceutical sector [4]. TRIPS compliance required India to revise its patent laws, leading to the introduction of product patents for pharmaceuticals in 2005 [5].

TYPES OF INTELLECTUAL PROPERTY RIGHTS

Patents

An invention that is novel, incorporates an inventive step, and has potential for industrial use is eligible for a patent, which is an exclusive right awarded by the state. It grants the patent holder the sole authority to forbid or restrict third parties from producing, utilising, offering for sale, importing, or selling a good or service derived from the invention without the owner's prior consent [6].

Patents are exclusively awarded for ideas that meet specific requirements referred to as the "criteria of patentability." A patent's limited term is 20 years, starting on the date the application was filed. As a territorial right, a patent can only be used in the nation in which it was granted. To get patent protection in different countries, a patent has to be applied in each of the countries. Patent Cooperation Treaty (PCT) provides a route to file an international patent application through which a patent can be filed in a large number of countries through a single patent application. However, after filing the PCT application, grant of patent remains under the discretion of the individual patent office only [1].

Any innovation that wants to be patentable must meet the following requirements:

- **Usefulness**: an invention must be employed for a practical purpose or have industrial applicability.
- **Novelty**: Before the date of patent filing, the invention must be a brand-new technological advancement that hasn't been previously published or made available in the nation's or any other country's prior art.
- **Non-obviousness:** An invention is not patentable if it can be performed by a person with ordinary skill. Thus, for an invention to be patentable, it must not be obvious [2].

Types of Pharmaceutical Patents in India

One of the "knowledge-driven" industries with the highest levels of competition is pharmaceuticals. The nature of pharmaceutical research is uncertain and extremely expensive. The research may yield a novel, creative, and practical procedure or product as its

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end result. It is crucial for pharmaceutical companies to get patent rights over their invented products or processes in order to safeguard their innovations from any unauthorised commercial use in this fiercely competitive sector.

1) **Drug compound patents**
   The chemical structure of a medicinal molecule is the basis for these patents' claims. Typically, these patent claims are referred to as Markush type claims. A claim that permits several "functionally equivalent" chemical entities in one or more drug compound parts is known as a Markush claim.

   The molecular structure of a new medicinal molecule used for parasite control, claimed in the Indian patent no. 202989.

2) **Formulation/ composition Patents**
   These patents claim a specific technology to prepare a formulation and/or quantity of its key ingredients. An Indian patent no. 203986, for instance, claimed the use of an ayurvedic anti-retroviral substance to treat acquired immunodeficiency syndrome.

3) **Synergistic combination Patents**
   When two or more medications interact in a way that amplifies or increases one or more of those drugs' effects, this is known as drug synergy. New synergistic medication combinations can be patented. For example, Indian Patent No. 206328 claimed a synergistic combination of salmeterol and roflumilast.

4) **Technology Patents**
   These patents are based on methods for resolving particular technological issues, such as taste masking, stabilisation, solubility enhancement, etc.

5) **Polymorph Patents**
   Variations in the crystal structure or physical form of a recognized substance are called polymorphs. In order to lower contaminants or improve the stability of the compounds, polymorphs are typically created.

   For instance, atorvastatin magnesium's crystalline form B4, as identified by an X-ray powder diffraction pattern, is claimed by Indian Patent No. 237261. Above 98% purity is demonstrated in said crystalline form.

6) **Biotechnology Patents**
   Patenting biotechnology has become a concern in the last two or three decades. Biotechnology is the application of organic modifications in animals, plants, microbes, and any biological material that can be assimilated by living matter. It covers any method that creates or modifies products using living things (or their parts) in order to enhance plants, animals, or microorganisms for particular applications. The unforeseen possibilities of biotechnology have been a factor in the challenges associated with patenting. For a long time, people have employed living things in baking and brewing. Through breeding, farmers have enhanced plant and animal variety. The topic of whether these traditional and modern biotechnological inventions should be patented is worth considering.

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Numerous medicinal, immunological, and diagnostic items are covered under biotechnology patents. An aqueous, human serum albumin-free Interferon solution, for instance, is claimed in Indian Patent No. 234072.It comprises interferon-alpha, a non-ionic detergent, a buffer to adjust the pH from 4.5 to 5.5, benzyl alcohol, and an isotonizing agent. Notably, following the establishment of the product patent regime in 2005, the Indian Patent Office awarded the first product patent, which is Indian Patent No. 234072. Switzerland's F. Hoffmann-La Roche Ltd. is the owner of the patent.

7) Process Patents

A process patent only covers a novel and creative method of producing a certain product; it does not claim the product itself. An example of a method to synthesize δ-lactone with formula 3,6dialkyl-5,6-dihydro-4-hydroxy-2h-pyran-2-one is claimed in Indian Patent No. 206678 [1].

INDIAN PATENT ACT

The patenting of living organisms and related technologies is prohibited by the Indian Patent Act of 1970. Furthermore, patents are not granted for biosubstances that are utilized in horticulture, agriculture, or the improvement or healing of human, animal, or plant life. The law of mortality and consideration for human health serve as the foundation for the Indian Patent Act for biological materials. In India, only process patents are accepted. In general, a "patent" refers to a formal statement that gives the sole authority to create, market, or profit from an inventive process, among other things. Patents on processes and products are outlined in technological patents. The Patent Act of 1970, amended in 1994, and the Design Act of 1911 govern intellectual property rights in India. IPR protection also includes the Trade and Merchandise Act of 1958 and the Copyright Act of 1957. The international treaties include the Berne Convention for the protection of literary and creative works and the WTO agreement on trade-related aspects of intellectual treaties. There's nothing like a 'World Patent' [7].

PATENT FILING PROCESS IN INDIA

Step 1: Filing a Patent or Priority Application

Chennai, Mumbai, New Delhi, and Kolkata (Head office) are the four locations of the patent offices. The applicant must submit a patent application in the proper format, including all necessary details about the invention, including a description, claims, abstract, and drawing. When a disclosed invention is still only conceptual in nature, the applicant may choose to file a provisional specification to establish priority of the invention. After that, the applicant has 12 months to file the entire specification in the format required.

Step 2: Publication of Application

Following an 18-month period, the patent application is published in the office journal. In addition, the applicant may submit a request for early publication by paying an extra price as specified.

Step 3: Opposition of Patent

Within three months of the patent publication, the pre-grant patent opposition, if any, may be submitted. If the applicant for a patent has submitted a request for patent examination, the controller of the patent office will consider this kind of opposition representation. Post-grant objections to patents are also covered.

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Step 4: Request for Examination
Within 48 months of filing a patent application and paying the required fees, the applicant must submit a second application for patent examination.

Step 5: Examination and Clarification of Raised Objections, if any
The patent examiner issues a First Examiner Report (FER) to the applicant after examining all aspects of patentability, including novelty, inventiveness, non-obviousness, and industrial application. In the event that the examination report contains objections, the applicant has a year to address them.

Step 6: Grant of Patent
Once the applicant overcomes the objections submitted throughout the examination procedure, the Controller grants the patent to the applicant. According to the Patent Amendment Act of 2002, in order to maintain the patent's validity, the applicant must periodically pay a renewal fee. The DIP&P website has all the information you need for Indian patents. Since 2007, it is also possible to file a patent. Once the rights are acquired, the owner can investigate their potential for industrial production or sell, distribute, or grant licences in accordance with his interests. The patent has a 20-year validity period. The invention becomes public knowledge after a patent expires, and anyone can utilize it [2].

COPYRIGHT

Creators of dramatic, musical, literary, and creative works as well as those who produce cinematographic films and sound recordings are granted the legal right to copyright. Copyright is a collection of rights that includes, among other things, the ability to reproduce, communicate with the public, adapt, and translate a work. Once registered, copyright is an equitable right that becomes a statutory one. As soon as a work is made or published, copyright is established. The artist's labour and skill in creating his work are protected by copyright. Works covered by copyright include computer programmes, literature, sound recordings, artworks, poems, and music. In India, copyright is governed under the Copyright Act, 1957. Copyright protection lasts for up to 60 years beyond the author's death [8].

1) **Trademark**

A trademark is a distinguishing mark that designates particular products or services as being created or offered by a particular individual or business. It could consist of a single word, several letters, or digits. They could be in the form of illustrations, symbols, three-dimensional indicators like the form and packaging of products, audio indicators like music or voice sounds, scents, or colours that are employed as differentiators. It protects the owner of the mark by granting them the exclusive right to use it to identify products or services, or to authorise others to use it in exchange for payment. Because the nature and quality of a product or service, as represented by its distinctive trademark, satisfy the needs of the consumer, it facilitates their identification and purchase. A trademark's registration serves as initial evidence of ownership, granting the owner statutory rights. The rights to a trademark may be retained forever. The first registration term is for ten years, after which it may be periodically renewed [9].

Trademark rights can be used to prevent others from using a confusingly similar mark, but they cannot stop others from producing or selling the same products or services under a plainly different mark. For instance, before making a decision in the pharmaceutical sector case, the court takes into account the buyer, the nature of the drug, and other

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factors. In the case of Win-Medicare Ltd v. DUA Pharmaceuticals Pvt Ltd, the plaintiff used Diclomol, whereas the defendant used Dicamol. The court determined that both products were comparable and took into account the fact that these medications are available without a prescription. Due to their similarity, these medications can be purchased over-the-counter by customers who lack literacy, which restricts the use of the trademark [5].

2) Industrial Designs

Industrial designs are creative activities that give rise to a product's formal or ornamental appearance, whereas design rights are unique or innovative creations that are granted to the owner of a legally registered design. Intellectual property includes industrial designs. Minimum criteria of protection for industrial designs have been established under the TRIPS Agreement. India, a developing nation, has already modified its national laws to include these minimum requirements. The promotion and protection of the design component of industrial production is the main goal of design law. It also aims to encourage innovations in the industrial sector. The New Designs Act, 2000, is India's current industrial design legislation, and it will serve its purpose well in light of rapid technological and international advances [9].

3) Geographical Indications

Geographical Indications (GIs) indicate the origin of a product. It is a means of identifying agricultural, natural, or manufactured goods that come from a specific territory, region, or locality. For manufactured goods, this means that one of the activities involved in the production, processing, or preparation of the goods occurs in this territory, region, or locality. The goods' given quality, reputation, or other characteristics are primarily attributable to their geographical origin. GI can be any term, geographical or figurative representation, or a combination of the two that conveys or suggests the geographical origin of the items to which it refers. GIs are designated as Intellectual Property because the name of a certain location, when combined with the name of the commodities, boosts their commercial value. Products covered by Geographical Indications include things like Basmati rice, Darjeeling tea, Nagpur oranges, Kanchipuram sarees, and so on. In India, GI protection is initially granted for ten years following the application's filing. Registration can be renewed every ten years for an infinite term by paying the prescribed amount [8].

4) Trade Secrets

A trade secret could be confidential commercial information that gives a company a competitive advantage. These are typically trade secrets and secrets related to manufacturing or industry. These consist of distribution and sales strategies, consumer profiles, advertising campaigns, supplier and customer databases, and production procedures. Unlike patents, trade secrets are protected without registration, safeguarded for a limitless period of time, but there must be a significant element of secrecy so that obtaining the information would be impossible unless using illicit means. Given the abundance of traditional knowledge in the country, protection under this will be critical for enjoying the advantages of such information. Trade secrets and traditional knowledge are also linked/associated with regional indicators [9]. A well-known instance of a trade secret is the Coca-Cola formula. The formula, also known by the code name "Merchandise 7X," is kept in an American bank vault and is only known to a select few individuals [8].

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Recent Modifications to India's Patent Laws for the Pharmaceutical Sector

The pharmaceutical sector in India has recently undergone revisions to its patent laws, which provide an opportunity to examine the effects of these institutional and regulatory changes on societal welfare and innovation in low-income markets. With its process-patent system in place, India's pharmaceutical sector expanded to become the fourth largest in the world between 1972 and 2004. Indian businesses were expanding into product R&D and becoming competitive on a worldwide scale in the generics and clinical testing markets [4].

The Role of Patent Cooperation Treaty

A global agreement known as the Patent Cooperation Treaty (PCT) came into effect in 1978. By indicating the countries of interest in the PCT application, an inventor of a member country contracting state of PCT can simultaneously get priority for his or her invention in all or any of the member countries, without having to file a separate application in each of those countries. The World Intellectual Property Organization (WIPO) in Geneva oversees all PCT-related operations [10].

PATENT INFRINGEMENT

The act of using a patented invention in violation of the law without the patent holder's consent is known as patent infringement. It happens when someone makes, uses, or sells an invention without the patent owner's consent, or, in the case of a licensed patent, in a manner that is not allowed under the license, infringing on the inventor's patent rights.

Types of Patent Infringement

a) Direct Infringement

It explicitly says that the third party willingly or intentionally stole the inventor's technology without his prior authorization.

It can involve the following: producing patented technology; utilizing patented technology; selling patented technology; importing patented technology; and passing off the patented.

b) Indirect Infringement

It refers to an unfair activity that fails to provide unambiguous evidence that the patent is purchased and sold in the market. It occurs, for example, when a device is claimed in a patent and a third party delivers a product that can only be legitimately utilized to manufacture the claimed device.

It can involve selling parts that can only be realistically utilized for a patented innovation; sell an invention with instructions on utilizing a specific method that infringes on a method patent. License an invention that is protected by another patent; sell material components that were specifically designed for use in a patented product and have no other commercial applications [9].

Controversial Patent Case Involving Traditional Knowledge and Genetic Resources

Turmeric

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Turmeric (*Curcuma longa*) is a ginger family plant that produces saffron-colored rhizomes that are used as a spice to flavour Indian cuisine. It also possesses qualities that make it an excellent ingredient in medications, cosmetics, and as a colouring agent. It has long been used to treat wounds and rashes.

In 1995, two Indian nationals at the University of Mississippi Medical Centre were issued US patent 5,401,504 for the "use of turmeric in wound healing." The Indian Council of Scientific and Industrial Research (CSIR) has asked the US Patent and Trademark Office (USPTO) to reexamine the patent. The CSIR demonstrated that turmeric had been used for thousands of years to treat wounds and rashes, thus its therapeutic use was not novel. Their claim was supported by documentary proof of traditional knowledge, such as an ancient Sanskrit manuscript and a 1953 paper published in the Journal of the Indian Medical Association. Despite protests from the patentees, the USPTO sustained the CSIR concerns and invalidated the patent.

Observations: The case involving turmeric was historic since it marked the first instance in which a patent derived from a developing nation's traditional knowledge was successfully contested. Based on calculations by the Indian government, the legal expenses incurred in this case came to around $10,000 US [11].

SIGNIFICANCE OF IPR IN PHARMACEUTICAL INDUSTRY

Invention Protection
You have composed or built a medication, and you must keep it secure or it will be stolen. Along these lines, the best way to secure it is to have it protected or to allow for competitive innovation. The problem with competitive invention is that the medication can be figured out, and so your creation can be stolen. Though a patent provides significantly more water tight assurance.

Economic Development and Intensity
Intellectual property rights are critical to an organization's financial prosperity. Granting the designer sole rights allows him to obtain rewards without division. The designers have exclusive showcasing rights to the item, which he can provide or enable. The organisation can win a lot and reinvest it. Investing in new work is critical for an organization's ability to remain on the bleeding edge.

Protects Customers and Families
The primary interest of IPR is public well-being. The security and well-being of the public are always prioritized. IPR assists the buyer in making the correct decision while selecting an item. IPR contributes to ensuring a standard and quality, allowing the customer to make an informed selection and feel secure.

Generate Answers for Worldwide Difficulties
While development is important, it needs to be subsidized in order to proceed. You can do it with the right support provided by IPR. New diseases are discovered daily, or the pathogen is improving its blockage, necessitating the development of new drugs and antibodies.

Encourage Development and Reward Business Visionaries

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Giving innovators the right kind of push is essential to keeping them motivated. Additionally, it is crucial that they are respected for the job they do. They get this support from IPR. By empowering a secured domain, it empowers an unrestricted flow of data. There will be a safe route for exchange if you are aware that it is okay to share your creation [12].

Impact of Trips Compliance

The transition to product patents had profound implications for the Indian pharmaceutical industry. Prior to TRIPS, India's patent law allowed for the patenting of processes rather than products, fostering a vibrant generics industry known for producing affordable versions of patented drugs. However, TRIPS compliance brought challenges such as increased competition, the need for research and development (R&D) investment, and heightened intellectual property enforcement [2].

Challenges and Opportunities

The Indian pharmaceutical industry faced various challenges post-TRIPS, including the need to adapt to new patent regulations, the threat of litigation from multinational pharmaceutical companies, and concerns over access to essential medicines. However, this period also presented opportunities for innovation, technology transfer, and global market expansion. Some Indian companies strategically leverage their expertise in reverse engineering and process innovation to develop their own patented drugs and expand into international markets [7].

Role of Intellectual Property Rights

Intellectual property rights play a dual role in the Indian pharmaceutical industry. On one hand, strong patent protection encourages innovation by providing incentives for R&D investment and rewards for inventors. On the other hand, overly restrictive patents can hinder competition, limit access to affordable medicines, and impede technological progress. Balancing these interests is crucial for fostering innovation while ensuring access to essential medicines for all segments of society [10].

Policy Initiatives and Regulatory Framework

The Indian government has implemented various policy initiatives to address the challenges posed by the TRIPS agreement and promote innovation in the pharmaceutical sector. These include the introduction of the Indian Patent Act of 1970, which included provisions for compulsory licensing and patent revocation to safeguard public health interests. Additionally, the government has established institutions such as the Department of Industrial Policy and Promotion (DIPP) and the Intellectual Property Office to oversee intellectual property matters and facilitate innovation [11].

CONCLUSION

It is obvious that managing IP and IPR is a multifaceted task that requires a variety of systems and actions that should be in accordance with both national laws and international agreements and customs. India now allows patents on a broad variety of pharmaceutical products with the establishment of the product patent regime. The researchers must thoroughly analyses the patentability requirements before submitting an application, and in this regard, consulting a patent specialist is highly recommended. Once obtained, patent rights can be assigned or licensed to other individuals or businesses. Patents are a useful instrument for technology transfer in organization’s like academic institutions and

universities that lack the capacity for manufacture or commercialization. These companies can make money by selling their patented goods or services to other parties, which allows them to recover the costs associated with developing such goods or services. Since it gives the creator/inventor an exclusive right to use his creation for a set amount of time, intellectual property rights (IPRs) are an effective tool for protecting the time, money, and effort that the creator/inventor has invested in creating an intellectual property. IPR thus supports a nation's economic development by fostering healthy competition, industrial progress, and economic prosperity.

The interface between intellectual property rights and the Indian pharmaceutical industry is dynamic and multifaceted, shaped by regulatory changes, global trends, and market dynamics. While challenges remain in ensuring access to affordable medicines and fostering innovation, India's pharmaceutical sector continues to evolve, driven by a combination of entrepreneurial spirit, technological advancement, and policy support. Moving forward, it is essential to strike a balance between intellectual property protection and public health interests to ensure the sustainable development of the pharmaceutical industry and equitable access to medicines for all.

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