

# IPR & PHARMACEUTICAL INDUSTRIES IN INDIAN MARKET – IN THE CONTEXT OF THE POST-COVID-19 SCENARIO

## Abstract

Intellectual property rights (IPR) play a vital role in the pharmaceutical industry by protecting the innovation and investment of pharmaceutical companies. This is especially important in the Indian market, which is one of the largest and most rapidly growing pharmaceutical markets in the world.

The COVID-19 pandemic has had a significant impact on the global pharmaceutical industry, and India has been no exception. The pandemic has highlighted the importance of IPR in supporting the development and production of new medicines and vaccines.

The post-COVID-19 scenario presents a number of opportunities and challenges for the Indian pharmaceutical industry. On the one hand, the pandemic has created a greater awareness of the importance of healthcare and pharmaceuticals. This is likely to lead to increased demand for pharmaceutical products in India in the coming years.

On the other hand, the pandemic has also exposed some of the vulnerabilities of the Indian pharmaceutical industry. For example, the industry is heavily dependent on imports of active pharmaceutical ingredients (APIs). This makes the industry vulnerable to supply chain disruptions.

The post-COVID-19 scenario also presents a number of challenges for IPR in the Indian pharmaceutical industry. One challenge is the balance between promoting innovation and ensuring access to affordable medicines. Another challenge is the enforcement of IPR in India.

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The Indian government has taken a number of steps to strengthen IPR protection in the country. For example, the government has amended the Patent Act to make it more compliant with international standards. The government has also established specialized courts to deal with IPR disputes.

However, there are still a number of challenges that need to be addressed in order to improve IPR protection in India. One challenge is the lack of awareness about IPR among the general public. Another challenge is the lack of resources for the enforcement of IPR. Despite the challenges, the post-COVID-19 scenario presents a number of opportunities for the Indian pharmaceutical industry. The industry is well-positioned to play a leading role in the global supply of pharmaceuticals. The Indian government is also supportive of the industry's growth.

The key to success for the Indian pharmaceutical industry in the post-COVID-19 scenario will be to strike a balance between promoting innovation and ensuring access to affordable medicines. The government and the industry need to work together to strengthen IPR protection in India and to create an environment that is conducive to innovation.

**Key Words:** Intellectual Property Rights, Pharmaceutical Industries, Post COVID – 19, Opportunities, Challenges, Innovation, Indian market

Intellectual property is a valuable asset. And anyone who owns such an asset is entitled to exercise its rights to the utmost extent possible. Intellectual property (IP) refers to the "ownership" of mental creations such as inventions, literary and artistic works, designs, symbols, and names and pictures used in business. The most well-known types of legal protection for this "property" include patents, utility models, copyright, trademarks, and industrial designs, among others. Because there are no mechanisms in place (such as the granting of exclusive licenses) to exclude nonpaying users (free-riders) of the innovation while providing full or limited access to those who pay for it, "innovation" is difficult to develop in the absence of any form of intellectual property protection. Intellectual property encompasses trademarks, copyright, patents, trade secrets, industrial designs, and other intangible assets that give financial support to their owners.

How an IP system is used will be determined by the creativity of the firms involved in invention-creation. Strong intellectual property rights are an essential component of thriving innovation ecosystems.

This article attempts to examine many issues of intellectual property rights (IPR) with a focus on the pharmaceutical industry in India.

Secondary sources were utilized as a source of information to make this article more acceptable.

The whole thing has been separated into four sections. Section I discusses the genesis, concept, definition, and relevance of intellectual property rights. Section II discusses the important Acts of India that safeguard intellectual property rights. Section III focuses on the status and value of intellectual property in the pharmaceutical industry in India, the role of intellectual property in the pharmaceutical industry in the Indian market during the post-covid-19 period, and Section IV concludes with a conclusion.

## Section I

**1. The IPR -Origin of the Concept:** Intellectual Property Rights (IPR) have its origins in ancient civilizations, which recognised various forms of protection for creative and inventive works. Although the framework of IPR emerged in the late Middle Ages and Renaissance period.

The Statute of Monopolies, 1624, adopted in London, plays an important role in highlighting the evolution of IPR. This law made a positive difference by allowing restricted monopolies exclusive rights to their technologies. Even though the statute prohibits most monopolies save for new innovations, the Patent System was born.

After being influenced by the English system, the US government legally enacted the first Patent Law in the second half of the 18th century. The US Government had granted the authority to promote the "Progress of Science and useful Arts" by granting authors and inventors exclusive rights to their respective writings and discoveries.

Over time, the concept of IPR evolved and expanded to include numerous forms like as trademarks, trade secrets, industrial designs, and so forth. These rights evolved over time and were redefined through national legislation, international treaties, agreements, norms, and regulations.

In terms of the global scenario, the World Intellectual Property Organisation (WIPO) was established in 1967 as a United Nations specialised body to promote and protect intellectual property worldwide. WIPO has played an important role in harmonising and facilitating international agreements and treaties related to intellectual property rights (IPR), such as the Paris Convention for the Protection of Industrial Property (1883), the Berne Convention for the Protection of Literary and Artistic Works (1886), and the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In today's world, intellectual property rights (IPR) have become the major foundation of global trade and innovation, with countries all over the world having their own legal frameworks to protect and enforce intellectual property rights. These policies strike a compromise between incentivizing innovation and creativity and maintaining equitable access and competition.

2. **IPR – The Concept:** The legal form of ownership provided to creative creations is referred to as intellectual property rights (IPR). The rights safeguard the use of such creations, grant the creators a limited monopoly, and compensate them for their intellectual efforts. Infringement is a term used to describe the violation of intellectual property rights (IPR). Infringement of intellectual property rights (IPR) is the act of utilising something for a purpose that its inventor or owner did not authorise. This includes counterfeiting, plagiarism, unlawful copying, and other infringements on creative works protected by intellectual property rights. Infringement of intellectual property rights can occur in any industry where innovation, creativity, and ingenuity are the primary sources of growth. In the digital world, there is an increasing problem of IPR infringement, and the internet has made it simpler for individuals to illegally access and utilise protected works without sufficient licence. The most popular types of IPR infringement are piracy and illicit downloading, with millions of unauthorised downloads and copies of copyrighted works made available on the internet with a single click.
3. **Definition of IPR:** Intellectual Property Rights (IPR) are the legal rights to an invention or discovery that are granted to an individual or group in the form of a monopoly for a set length of time. Copyright, patents, trademarks, geographical indications, performance rights, and industrial designs are all examples of intellectual property rights. These rights include tangible manifestations of creative endeavour such as innovations, inventions, and works of authorship.

These legal rights can be enforced by civil or administrative measures to protect the innovator's intellectual property ownership rights. IPRs are protected by both national and international legislation, which is intended to safeguard the rights of persons who use their creativity in their job.

Different authors have interpreted the term IPR as per their own observations and some of the important definitions are presented below:

According to the World Intellectual Property Organisation (WIPO), "intellectual property refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce."

William Fisher, Professor of Intellectual Property Law, Harvard Law School: "Intellectual property is a category of intangible rights protecting commercially valuable products of the human intellect. The four primary types of intellectual property are copyrights, patents, trademarks, and trade secrets."

The World Trade Organization (WTO): "Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time."

From the above discussions, it may be inferred that Intellectual Property Rights refer to the legal rights granted to creators and inventors over their intellectual creations, providing them with exclusive control and ownership to use and exploit their works for a specified period. These rights include patents, copyrights, trademarks, and trade secrets, and they aim to encourage innovation, creativity, and the advancement of society.

#### 4. **Significance of IPR:** IPR facilitates rather than hinders innovation.

The goal of establishing intellectual property rights is to ensure that individuals or organisations with creative, innovative, and artistic qualities are adequately compensated for their efforts and creativity. This permits them to profit financially from their efforts. IPR also makes it possible for the general public to obtain access to the works of authors, innovators, and designers in the form of products or services.

Intellectual property rights are meant to give the owner with specific economic benefits and to ensure that they are the only ones who may profit from the products of their ingenuity and work.

IPR increases market competitiveness, which has an impact on the profitability and sustainability of the firm. The impact of intellectual property rights on numerous aspects, which have both positive and bad effects on competitiveness, is explored below:

The positive effects of IPR are as follows:

- **Incentivizing Innovation:** IPR grants exclusive rights to the creators of new inventions, encouraging them to invest in research and development and as a result, it stimulates innovation and leads to the introduction of new products and technologies, which magnifies competition in the market.
- **Market Differentiation:** Intellectual property, such as trademarks and branding, allows businesses to differentiate their products or services from competitors and hence creating a competitive advantage, attract consumers, and increase market competition.
- **Encouraging Investment:** Strong IPR protection can provide a suitable environment for investment. Increased investment can lead to greater competition and the emergence of new market players.

The negative effects of IPR are as follows:

- **Monopolistic Behaviour:** When IPR grants exclusive rights to a particular business or individual, it leads to monopolistic behaviour. If a company possesses strong patents or copyrights, it may have a monopoly over a product or technology, limiting competition in the market and potentially reducing consumer choices.
- **Barriers to Entry:** Strict IPR enforcement may create barriers for new entrants. Startups and smaller business houses must struggle in order to compete with established brands that already hold strong intellectual property rights. This can hinder competition and limit the ability of new players to enter the market.
- **Higher Costs:** Licensing fees or royalties associated with the use of patented or copyrighted innovations can increase the cost of production for businesses. This can affect their profitability and sustainability.

## Section II

1. **Key Acts to Protect IPR in India:** Several acts give legal protection for innovative inventions, literary and creative works, brand names, and industrial designs, in that order. Over the years, India's IPR system has been significantly amended to conform with international standards such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The principal legislation that governs IPR in India is discussed below:

- **The Patents Act, 1970:** This Act covers patent granting and protection in India. It specifies the patentability standards, the patent registration process, and the rights and obligations of patent holders. The statute also includes measures for compulsory licensing and patent revocation under specific conditions.
- **The Trade Marks Act, 1999:** This Act governs trademark registration and protection in India. It describes the procedures for trademark registration, trademark owners' rights and remedies, and trademark infringement fines. The act also addresses collective and certifying marks.
- **The Copyright Act, 1957:** In India, this Act governs copyright protection. It outlines authors', creators', and copyright owners' rights and establishes means for copyright registration. The statute applies to different types of creative works, such as literary works, artistic works, musical works, films, and computer programmes. It also offers provisions for fair use and performer rights protection.
- **The Designs Act, 2000:** This Act covers industrial design protection in India. It allows for the registration and protection of innovative, original, and aesthetically pleasing designs. The legislation specifies the methods for registering designs, the rights of design owners, and the remedies available in the event of design infringement.

- **The Geographical Indications of Goods (Registration and Protection) Act, 1999:** This act provides for the registration and protection of Geographical Indications (GIs) in India. It aims to protect and promote the unique qualities, reputation, and origin of goods that are associated with a specific geographical location.
- **The Semiconductor Integrated Circuits Layout-Design Act, 2000:** This act governs the protection of layout designs of integrated circuits. It provides for the registration and protection of layout designs, the rights of layout design owners, and the remedies available in case of infringement.
- **The Plant Varieties Protection and Farmers' Rights Act, 2001:** This act provides for the protection of plant varieties and the rights of farmers in relation to plant genetic resources. It establishes a system for the registration and protection of plant varieties, while also recognizing the rights of farmers who have conserved, improved, and developed traditional varieties.

### Section III

#### 1. “Pharma Industry is the art of making billions from milligrams.” – Gerherd Kocher

Pharmaceutical Industries are like an evergreen industry in today’s competitive global scenario. What comes may, it is most likely impossible for this industry to reach the point of saturation. It does not matter whether the economy is in a stabilized situation or going through recession, the demand in this industry will never cease. Therefore, one can rightly say, the pharmaceutical industry is the principal source of medical innovation. Because Life is precious!

Bengal Chemicals & Pharmaceutical Works Ltd, our country's first pharmaceutical enterprise, was founded in 1901 in Kolkata, West Bengal by Acharya Prafulla Chandra Ray.

For a pharmaceutical company, Intellectual Property, significantly contributing to the company’s success, is indeed the most valuable resource. In today's competitive market, the pharmaceutical industry heavily relies on research and development (R&D) to create new drugs and treatments that can improve the quality of life for patients worldwide, which is why, stringent IP laws and systems help pharmaceutical companies to safeguard their investments in R&D, foster innovation, and incentivize the development of new breakthrough therapies.

This introduction aims to provide an overview of the critical relationship between IPR and the pharmaceutical industry, highlighting the importance of intellectual property protection in driving advancements in healthcare and addressing global health challenges. It is driven by constant innovation, research, and development (R&D) to discover and develop new drugs and therapies to combat various diseases and medical conditions.

Intellectual Property Rights (IPR) serve as a cornerstone of this industry, providing a legal framework that protects and incentivizes innovation by granting exclusive rights to the creators and inventors of new drugs and medical technologies.

IPR in the pharmaceutical industry encompasses various forms of intellectual property, including patents, trademarks, copyrights, and trade secrets.

Patents are particularly significant as they grant exclusive rights to the inventors to prevent others from making, using, or selling their inventions without permission. In the pharmaceutical context, patents typically protect novel and non-obvious drug compounds and formulations, manufacturing processes, and methods of treatment.

- 2. Management of IPR in the Pharmaceutical Industry:** Pharmaceuticals and medications fit with the present globalisation scenario and so necessitate a strong IP system. The costs of launching a new drug into the market are exorbitant, including the risks involved with the product's development stage. This is why no pharmaceutical business will perform a public service by putting its intellectual property in danger.

From the basic stage of creation to obtaining, protecting, and ultimately managing the IP of a company carefully, it has become more like a typical corporate task. The development of a product on a regular basis and evaluation of the knowledge, and frequent upgradation in the R&D demands a special platform for IP.

For competing in the global market, success stands with the scientific knowledge as compared to manufacturing know-how, and the master role is played with the investments in R&D.

- 3. Importance of IPR in the Pharmaceutical Industry:** The importance of intellectual property protection in the pharmaceutical industry cannot be overstated. The development of new drugs demands immense investment, time, and resources, often involving extensive clinical trials and regulatory approvals. Without robust IPR laws and systems, pharmaceutical companies would lack the necessary incentives to undertake such costly endeavours, risking a negative impact on the pace of innovation and the availability of life-saving medications.

- IPR rewards the innovators by providing them with a temporary monopoly over their inventions, generally for tenure of 20 years, enabling them to recoup their investments and generate profits. These profits, in turn, can be reinvested in further research and development, fostering a cycle of continuous innovation.
- The IPR protection helps create a level playing field for pharmaceutical companies. It ensures that innovators have a fair chance to commercialize their inventions before competitors can replicate or imitate them. This encourages healthy competition and prevents free-riding, allowing pharmaceutical companies to differentiate themselves through innovative products and therapies.



- IPR protection also plays a pivotal role in promoting access to medicines. While patents grant exclusivity to the inventors for a limited period, they also enable the dissemination of knowledge and information about the invention, once the patent protection expires. This paves the way for generic drug manufacturers to enter the market, offering more affordable alternatives to the original patented drugs.
- Balancing patent protection with mechanisms to facilitate access to medicines is a vital aspect of the pharmaceutical industry and global public health.

The relationship between IPR and the pharmaceutical industry is not free from controversy and challenges. The high costs of patented drugs, limited access to essential medications in developing countries, and concerns over the impact of strong patent protection on affordable healthcare are longstanding issues. Striking the right balance between promoting innovation and ensuring broad access to medicines still remains an ongoing global debate.

4. **Pharmaceutical Industry in the Indian Market:** The Indian Pharmacy market has accelerated at a very high pace and has shown eminent growth and development continuously for the past 50 years.

From the 5% contribution (as of 1969) in the global market, the industry has taken a robust shape and “Made in India” share has gone up to 80% as of 2020.

During this period, India established herself in the leading position in the global generic pharmaceutical arena and is termed as the “Pharmacy of the World”.

As per the reports of IBEF, exports of Indian pharma have reached US\$20.7b in FY 2020. The export valued US\$19.1b in 2019, marking the year-on-year growth as 8.4%. [<https://www.ibef.org/exports/pharmaceutical-exports-from-india>]

5. **COVID-19 Impact – Economic Shift & Evolving Healthcare:** India, with its strong vaccine manufacturing capability and capacity, has played a very crucial role in supplying the COVID-19 vaccines, globally. Few of the renowned international companies had collaborated with Indian Pharma companies to manufacture vaccines. The world’s biggest vaccine manufacturer, Serum Institute of India was offered to manufacture one billion doses of COVID-19 vaccine, which was developed by AstraZeneca and Oxford.

The COVID-19 pandemic has brought a steep focus on the need for healthcare reforms. It promotes all-around-the-world access to provide care units that are affordable for all backgrounds of human beings. This, as a result, helps in bridging the gap between different geographies, linking the socio-economic divisions.

COVID-19 has clearly underlined the importance of a strong healthcare structure. The absence of a good healthcare system can throw an entire nation’s socioeconomic condition at stake. India continues to fight COVID-19 and stabilize its economic growth trajectory, as it has shown a steep decline in its GDP graph. Hence, it is the right time for

the country to apply learning's from the challenges and best practices that emerged during the pandemic.

A few of the major challenges in attaining innovation, and R&D potential are discussed below:

- Requirement of innovative mindset and related skill augmentation.
- Complex regulatory approval process and Intellectual Property Regime (IPR)
- Financing restrictions and limited infrastructure
- Limited incentives from the government

In order to achieve victory in the post-pandemic world, the pharma industry needs to continue building on its strength and parallelly shall be making a giant leap towards innovation, investing in R&D.

## 6. Role of IPR in Pharmaceutical Industry in Indian Market during Post COVID-19 period

India is the largest source of generic pharmaceuticals. The pharmaceutical industry of the Indian market contributes:

- More than 50% of the world's demand for vaccinations.
- 40% of generic drugs and medicines in the US market.
- 1/4<sup>th</sup> of the overall pharmaceutical in the UK market.

The role of Intellectual Property Rights (IPR) in the pharmaceutical industry in the Indian market post Covid-19 is crucial and multifaceted. Following aspects may be considered to study the role played by IPR:

- **Encouraging Innovation:** IPR provides incentives for pharmaceutical companies to invest in research and development (R&D) and create new drugs, treatment methods, and medical devices. This helps in tackling the challenges posed by the pandemic and developing effective solutions.
- **Protection of Patents:** Patents grant pharmaceutical companies exclusive rights over their inventions for a limited period, allowing them to recover their R&D costs and gain a competitive advantage in the market. In the post Covid-19 scenario, IPR protection has become vital in ensuring that companies can continue investing in new drugs and treatments.
- **Access to Medicines:** Balancing IPR protection with the need for affordable access to medicines is especially important during a global health crisis. India has provisions for compulsory licensing, which allows the government to authorize third parties to produce generic versions of patented medicines during this situation of emergency and when they became unaffordable.

- **Collaborative Research and Technology Transfer:** IPR plays a role in facilitating collaborative research initiatives and technology transfers between pharmaceutical companies, academic institutions, and research organizations. In the post Covid-19 scenario, such collaborations can help expedite the development and production of vaccines, treatments, and other medical interventions.
- **Counterfeit and Substandard Medicines:** The pandemic has witnessed an increase in the production and distribution of counterfeit or substandard medicines, which pose significant health risks. Strengthening IPR enforcement, helped in combating these illegal activities and ensure the availability of genuine, safe, and effective medicines in the market.
- **Regulatory Considerations:** IPR also intersects with regulatory frameworks in the pharmaceutical industry. Post Covid-19, regulatory authorities tried their best to strike a balance between expedited approvals for essential medicines and the protection of IPR to promote innovation and quality.

Hence, it can be inferred that, IPR in the pharmaceutical industry in the Indian market post Covid-19 plays a critical role in incentivizing innovation, protecting patents, ensuring access to medicines, enabling collaborative research, combating counterfeit medicines, and aligning with regulatory considerations.

## Section IV

### I. CONCLUSION

It can be concluded that, IPR protection plays a critical role in driving innovation and progress in the pharmaceutical industry. It encourages R&D investments, rewards inventors, and fosters healthy competition. Striking the right balance between protecting intellectual property and ensuring access to affordable medicines is a complex and ongoing challenge.

It is a necessary endeavour to address global health needs and advance medical breakthroughs. It is done through mechanisms such as compulsory licensing and international agreements like the TRIPS Agreement. Such mechanisms allow countries to manufacture generic versions of patented drugs under certain conditions, ensuring access to affordable medicines for their populations. However, these measures are within the capability to spark legal battles between pharmaceutical companies and government authorities.

Patents grant exclusive rights to the inventor for a limited period, allowing them to have a monopoly over the drug. This incentivizes innovation and attracts investment, as companies are confident in their ability to protect their creations. While patents promote innovation, they also hinder access to affordable medicines, especially in developing countries where high drug prices can be life-threatening for many individuals. The issue of access to medicine raises ethical and moral questions, as the ability to afford or acquire life-saving drugs should not be determined solely by economic disparities.

Henceforth it can be stated that, IPR in the pharmaceutical industry is a complex issue with both benefits and challenges. It promotes innovation and investment in drug development but can also hinder access to affordable medicines.

With the continuous evolution of technology and scientific advancements, the IPR landscape in the pharmaceutical industry will continue to evolve, requiring ongoing discussions and reforms to ensure that innovation is encouraged while ensuring access to affordable and life-saving drugs for all. The global community must work together to find solutions that protect intellectual property rights and promote public health.

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