International Research Journal of Commerce and Law
Volume 14 Issue 04, April 2026 ISSN: 2349-705X Impact Factor: 8.893
Journal Homepage: http://ijmr.net.in, Email: irjmss@gmail.com
Double-Blind Peer Reviewed Refereed Open Access International Journal

PROTECTION OF PHARAMCEUTICAL INNOVATIONS THROUGH PATENT LAW IN INDIA

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DOI:ijmr.ijrcl.22980.33864

KEYWORDS

Indian Pharmaceutical Industry
Patents
Compulsory Licensing
Intellectual Property Rights
TRIPS Agreement
Generic Drug
Evergreening

ABSTRACT

One effective tool for stimulating innovation and investment within the pharmaceutical sector is through patents. In India, there have been significant developments in the patent regime, especially since the country adopted the obligations under the TRIPS agreement in 2005. After this development, the Indian pharmaceutical industry became a prominent player in the provision of low-cost medicines across the globe while concurrently operating under a stricter IP regime. This paper explores the evolution of patents within the Indian context and their impact on the growth of the pharmaceutical industry. The study further looks at how India strives to achieve a balance between pharmaceutical innovations and access to inexpensive drugs by the general population. Lastly, the paper evaluates some critical legal protections such as compulsory licensing and Section 3(d) of the Indian Patents Act.

INTRODUCTION

The international IP system is primarily regulated by the TRIPS Agreement under the World Trade Organization (WTO). It includes a number of types of intellectual property, such as patents, copyright, trademark, geographical indication, industrial design, layout-design of integrated circuits, and the protection of undisclosed information. In India, the protection of traditional knowledge has become another important area of concern within the framework of intellectual property protection. The TRIPS Agreement was adopted on 15 April 1994 under the Marrakesh Agreement Establishing the World Trade Organization. It determines the minimum standards of IP protection[1]. For instance, according to this agreement, inventions must be protected through

patents regardless of the field in which they were made; patents have to be granted in respect of any new inventions, provided they represent an advance in science and can be used industrially[2].

Patent refers to the exclusive right that the government provides to the inventor or true and first maker of an invention or process. This enables the patentee the right to manufacture, exploit, and distribute the invention for a certain period of time. Patent is considered a form of property right that is provided to an inventor through the patent agency, which enables the owner exclusive rights over the invention. Patents protect new inventions, technology, or processes which are novel, non-obvious, and useful. Patents are territorial in nature and typically provide protection for 20 years from the date of application.

During this time frame, the owner of the patent can prohibit any person or party from manufacturing, utilizing, selling, or importing the product without their consent. In some circumstances, where the product involves pharmaceuticals and plants, a supplementary form of patent protection known as the Supplementary Protection Certificate (SPC) may be considered, granting another five years of patent protection.

The historical background of Indian IPR

The history of patent protection in India goes back to the colonial period, when the first patent law was enacted during the nineteenth century[3]. These patent laws were mainly intended to protect the rights of foreign individuals or entities involved in inventing and doing business in India. During this era, the benefit of patents was mainly reaped by multinationals controlling the drug industry and selling drugs at inflated prices, making them less available to Indians. After India gained independence in 1947, the Indian government started reviewing their patent laws in an attempt to foster national industrial development[4].

Introduction of the Patents Act in 1970 was a major turning point in the field of intellectual property rights in India. The legislation introduced had been meant to encourage indigenous research and development and lessen the monopolistic powers of multi-national corporations in the Indian markets. Among the various laws that were incorporated into the Patent act included elimination of product patents in drugs and agrochemicals and permitting process patents instead[5]. Through this legislation, firms in India were allowed to obtain patents for processes involved in the manufacture of the drug and not for the product itself[6]. This led to the manufacture of medicine by Indian companies at significantly cheaper rates[7]. The patent law helped boost growth in India's pharmaceutical industry. This helped many Indian companies develop the requisite technology that would allow them to compete internationally. With the proliferation of generic medicines, healthcare became accessible to a vast number of people.

TRIPS Agreement and Patent Reforms

WTO membership in 1995 obliged India to abide by the terms of the TRIPS agreement, which provided minimum standards of protection for intellectual property, which included product patents for medicines8. In order to comply with its obligations, India revised the Patents Act of 1970 in 1999, 2002, and 20059.

However, the most critical development occurred in 2005 when India adopted product patents for pharmaceutical innovations, enabling firms to patent innovative medicines and prevent unauthorized production or distribution thereof.

In addition, some legal provisions were made in India in order to make sure that improved protection provided by the new law would not be detrimental to public health and accessibility to medicine[10].

Key Features of the Indian Pharmaceutical Patent System

Section 3(d) and the Prevention of Ever greening:

The Indian law contains the provision described in Section 3(d) of the Patents Act, 1970. The purpose of this provision is to avoid the process of "evergreening," when pharmaceutical companies attempt to prolong the period of protection by making minor changes to already existing medicines[11]. Under Section 3(d), a novel form of the known compound should have enhanced therapeutic efficacy in order to be patented[12].

The importance of Section 3(d) came into light through the Supreme Court of India ruling in the Novartis AG vs. Union of India case. In this particular instance, the Court declined to grant a patent on the drug known as Glivec due to the lack of a new effect in the treatment that the modified drug produced[13].

Compulsory Licensing

The compulsory license is an essential part of the patent system in India, as per the Patent Act of 1970. In such cases, the government can allow other firms to manufacture a patented drug without the consent of the patent owner in certain circumstances. This could be done if the drug was not available at a reasonable cost or if there was insufficient demand for the product, or even if the invention was not used enough within India[14].

One such case was the Bayer Corporation v. Natco Pharma, which resulted in the compulsory licensing for Natco Pharma to produce the generic form of the anticancer drug Nexavar that had been patented by Bayer. In this case, the licensing helped to significantly lower the price of the drug[15].

Growth of the Indian Pharmaceutical Industry

Expansion of Generic Drug Manufacturing

Indian pharma industry has grown considerably during the past decades and today India ranks among the top manufacturers of generic drugs globally. Indian companies have mastered the art of reverse engineering and production of large quantities of drugs that enables them to offer cheap drugs to other countries, especially developing nations[16].

India is renowned as the "pharmacy of the developing world" due to its contribution towards making cheap drugs available for global healthcare programs[17].

Export Growth and Global Presence

Indian pharmaceutical firms export their drugs to more than one hundred nations across the globe. This sector also holds significance in offering antiretroviral drugs required for the treatment of patients infected with HIV/AIDS[18].

Many Indian companies have also made their presence felt in countries like the US and Europe, which operate under heavy regulation, by seeking approval from regulatory agencies. The growth in drug exports has contributed to economic development in India and enhanced its standing in the international drug market[19].

Increasing Investment in Research and Development

In the recent past, there has been considerable growth in investment by Indian pharmaceutical manufacturers towards Research & Development activities. The trend indicates an increasing shift towards innovative and advanced pharmaceutical research, rather than the production of mostly generic drugs.

A number of companies have embarked upon research towards developing new drug formulations, biosimilar drugs, and advanced generics. The introduction of strong Intellectual Property Rights (IPR) provisions under the Patents Act, 1970, has spurred collaborations between Indian pharmaceutical manufacturers and global drug companies[20].

Challenges in the Indian Patent Regime

High Cost of Drug Development

The development of a new drug is both costly and time-consuming. It takes many years for a drug to come into the market after its initial discovery, and the costs incurred during this process amount to billions of dollars.

Due to these huge costs, patent protection is essential for pharmaceutical corporations in order to get exclusive rights to their inventions and to be able to recuperate the huge costs associated with R&D.

Rising Drug Prices

While patents foster innovation through giving exclusive rights to innovators, the same patents could lead to expensive medications since the inventor temporarily has monopoly powers over his or her invention. This issue becomes even more complicated when developing nations are concerned, as not everyone may be able to afford the expensive medicine.

Thus, keeping equilibrium between stimulating innovation and making medicines affordable remains an essential issue in patent policy

International Pressure and Trade Agreements

There is increased pressure on India from developed countries and international drug firms to enhance its IP laws even more. Some international trade agreements have patent laws that are stricter than those under the TRIPS Agreement[21]. The additional laws are referred to as "TRIPS-Plus" provisions and may prevent the use of public health policies such as compulsory licensing[22].

However, India must take into consideration these demands from the international community even as it protects its public health considerations and access to affordable medicines.

Future Prospects and Policy Suggestions

For the sustainable development of the pharmaceutical industry along with ensuring the safety of the people's health, the following policies may be considered:

First, the government needs to improve the effectiveness and efficiency of patent offices so that the patents can be reviewed in a much better manner.

Second, increased government funding for drug discovery and development can spur innovations in the local pharmaceutical sector. Funding, grants, and incentives can also promote collaboration between academic institutions and pharmaceutical firms.

Third, India must continue to take advantage of the flexibilities offered by the TRIPS Agreement, especially the provisions for compulsory licensing, when necessary.

Lastly, transparent policies that will improve price transparency in the pharmaceutical industry, as well as ensure healthy competition, may lead to more affordable medication without stifling innovation.

CONCLUSION

Patent protection is a significant contributor to the expansion of the pharmaceutical industry as it motivates innovations and encourages investment in research and development. The evolution of patent laws in India has been a crucial determinant of the development of the Indian pharmaceutical industry.

Under the Patent Act of 1970, the Indian pharmaceutical industry grew considerably because it facilitated process patents, which allowed Indian firms to produce cheap generic drugs. The introduction of product patents in India was a result of its obligation to implement the provisions of the TRIPS Agreement.

India continues to exercise several measures that safeguard public health despite introducing product patents. Such measures include Section 3(d), compulsory licensing, and opposition to patents. These provisions are intended to prevent the abuse of patent rights in the country.

In summary, India's patent regime is designed to promote innovation and public health interests.

References

1"TRIPS Agreement, Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994".
2"Law Relating to Intellectual Property Rights. LexisNexis Butterworths."
3 "History of Indian Patent System; http://www.patentoffice.nic.in/ipr/patent/history.htm"
4"S. K. Verma, 'Protection of Pharmaceutical Patents in India' (2010) *Journal of World Intellectual Property*.
5 " World Health Organization, *Public Health,* Innovation and Intellectual Property Rights Report (WHO 2006)".
6 " World Trade Organization, TRIPS Agreement and Public Health (WTO Publications 2001)".
7 " United Nations Development Programme, Guidelines for Pharmaceutical Patent Examination (UNDP 2007)."
8 "World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, 1995."
9 "Patents Act, 1970 and Patents (Amendment) Act, 2005, Government of India."
10 "Shamnad Basheer, "India's Tryst with TRIPS: The Patents (Amendment) Act, 2005," Indian Journal of Law and Technology."
11 " Government of India, *Patents Act, 1970*, Section 3(d)."
12 "World Health Organization, *Public Health, Innovation and Intellectual Property Rights Report*, 2006".
13 " Novartis AG v. Union of India, Supreme Court of India, (2013) 6 SCC 1".
14 "Patents Act, 1970, Sections 84–92 (Compulsory Licensing)."
15 "Bayer Corporation v. Natco Pharma Ltd., Order of the Controller of Patents, 2012."
16 "United Nations Conference on Trade and Development, The Indian Pharmaceutical Industry: Growth and Challenges."
17 "Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions, MSF Report."
18 "World Health Organization, Global HIV Treatment and Access to Medicines Report."
19"U.S. Food and Drug Administration, Generic Drug Approvals and Pharmaceutical Manufacturing in India."
20 "World Trade Organization, Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement."
21 "World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), 2001.
22 "Médecins Sans Frontières, TRIPS-Plus Provisions and Access to Medicines, Policy Report.