



e-ISSN: 2319-8753 | p-ISSN: 2347-6710

IJIRSET

International Journal of Innovative Research in
SCIENCE | ENGINEERING | TECHNOLOGY



INTERNATIONAL JOURNAL OF INNOVATIVE RESEARCH

IN SCIENCE | ENGINEERING | TECHNOLOGY

Volume 13, Issue 12, December 2024

ISSN INTERNATIONAL
STANDARD
SERIAL
NUMBER
INDIA

Impact Factor: 8.524

9940 572 462

6381 907 438

ijirset@gmail.com

www.ijirset.com

A Review Article on Patent Practice and Intellectual Property Right

K. Samuel Prasanna*, Dr.Y.Sarah Sujitha

Department of Pharmaceutics, Krishna Teja Pharmacy College, India

ABSTRACT: Since its establishment in 1856, the Indian patent system has experienced substantial change. In order to foster innovation and the general welfare, patent laws have been reformed by the Patent Act of 1970 and its follow-up revisions, such as its compliance with the TRIPS Agreement. This system, which first covers process patents before extending to product patents, particularly for pharmaceuticals, gives innovators exclusive rights for a predetermined amount of time. The evolution of the Indian pharmaceutical sector following the TRIPS agreement serves as an example of how to strike a compromise between the demands of public health and intellectual property rights. The historic Novartis case, in which patents for modest alterations without increased efficacy were rejected under Section 3(d) of the Patent Act, further demonstrated the value placed on accessibility over exclusivity. India's intellectual property system encourages innovation through strict patent laws while prioritizing affordability, especially in the pharmaceutical industry.

I. INTRODUCTION

In India, the first patent rights were established in 1856. The government gives the applicant an exclusive right to any invention for a set amount of time. The Patent Act, which was passed in 1970 and repealed previous laws, states that any invention that meets the requirements of novelty, non-obviousness, and utility may be the subject of a patent. The patent holder is granted exclusive rights for a duration of 14 years in accordance with the Act 1856. It falls within the category of intellectual or industrial property. It is impossible for a patent issued in one state to be enforced in another unless the innovation in question is also patented in that state. India has a system of product patents for all inventions. According to the 1911 Patent and Design Acts. In the pharmaceutical industry, patenting is a valuable legal privilege. Since India had signed the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), which covers the protection of intellectual property in related areas to a significant extent and is regarded as a comprehensive framework prescribing standards of intellectual property protection, patents for the pharmaceutical industry were only permitted to partially comply with India's obligations. In addition, the TRIPS agreement has a number of measures pertaining to all forms of intellectual property.



Fig.01: An example of Patent document

II. HISTORY OF INDIAN PATENT SYSTEM

Act VI of 1856 was the first piece of patent-related law in India. The aim of this legislation was to incentivize inventors to divulge their invention secrets and to promote the creation of novel and practical products by manufacturers. Statute IX of 1857 later annulled the statute because it had been passed without the sovereign's consent. Act XV of 1859 introduced the "exclusive privileges" in that year. Importers were not considered inventors under the act. While designs had been protected in the United Kingdom since 1842, the legislation of 1859 only offered protection for inventions. This gap was filled in 1872 with the passage of the "patterns and designs protection Act" (Act XII).

Any new and original pattern to any material or object of manufacture within the meaning of "new manufacture" was included in the statute that amended the 1859 statute. The Act XV of 1859 was further amended in 1883 by XVI to include a clause protecting the novelty of inventions that were disclosed in Indian exhibits prior to filing for protection. There was a six-month grace period for submitting these applications after the exhibition's opening date. New laws were adopted in 1888 with the intention of unifying and amending the laws pertaining to inventions and designs to be consistent with changes made to UK law act V of 1888 brought about changes to Indian law from UK legislation, among other things transfer of the Home Department's and the Secretary's administrative authority to the Government of India extending the Act's jurisdiction to courts outside than the Madras, Calcutta, and Bombay High Court reduction of the filing fee from Rs. 100 to Rs. 10 only Graduation of fee in accordance with the rising value that the invention gains as it is employed and becomes more widely recognized Enables anyone with a basic understanding of art or science to utilize the invention by providing comprehensive disclosure of the invention, including the optimal way to operate it in precise, succinct, and clear words.

III. BACKGROUND OF PATENTING IN PHARMACEUTICAL INDUSTRY

Before 2005, India had no laws pertaining to the patentability of medicinal items. Pharmaceutical product patents were permitted as long as India complied with its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). All signatory nations were obliged under the agreement to grant pharmaceutical patents, and for those that did not, the deadline for doing so was 2005.

When the TRIPS agreement was being formed, India's patent legislation provided provisions for process patents and had to grudgingly embrace the idea of product patents. Since the India Patents Act was passed in the 1970s, domestic businesses have been permitted to copy the medications that multinational corporations have copyrighted, which has caused the generic pharmaceutical industry to flourish. The public benefit was the goal of not adopting the product patent, however MNCs began to lose money and began to withdraw from India as a result. When private pharmaceutical companies began marketing generic medications, they began to worry about the safety of their medications. While the inventor firm was losing money, these private enterprises were making large profits with little investment. Since MNCs were no longer present in the market, India's generic pharmaceutical sector was founded and grew to become one of the world's most significant drug manufacturing sectors.

The Indian Journal of Integrated Law Research

Many additional steps had to be done when the Indian government chose to open the country to international investment in the 1990s in an effort to strengthen their economy. Participating in agreements, such as the TRIPS agreement, was one of such measures. They were required to accept product patents rather than process patents after joining the TRIPS agreement, in accordance with the global patenting trend.

Although India initially objected to this action, they were forced to follow through. To comply with the agreement, Section 3(d) of the Indian Patent Act was added, which caused a great deal of debate. It states that a patent will not be granted for the simple act of discovering a new form of a known substance that does not improve the substance's known efficacy, or for the simple act of discovering a new property or use for a known substance, or for the simple use of a known procedure.⁴ It attempted to avoid any possibility of a patent extension because even minor changes to the product would cause the value of patent protection to decline. Patent extension should only be allowed when there is a significant enhancement which can be demonstrated under this controversy related to section 3(d)'s constitutional validity, the decision given by the court in the case of Novartis AG vs. Union of India has proved to be an exemplary judgment. The facts of the case are such that Novartis applied for an Indian patent on the beta crystalline form of

imatinib mesylate. On which the Madras Patent Office rejected the patent application stating that imatinib mesylate was already known to the public and beta crystalline form was only one of the derivatives of imatinib mesylate.

Novartis then filed an appeal against the ruling at the Intellectual Property Appellate Board (IPAB). The IPAB changed the Patent Office's ruling by articulating several grounds of rejection, including the fact that the medication is not unique despite the necessity of novelty and nonobviousness in the beta crystalline form for patent issuance. It is merely an additional form of the material that is already there, slightly altered from the recognized compound.

Disappointed, Novartis filed a second case in the High Court of Madras, arguing that Section 3(d) of the Indian Patent Act, 1970 violates Article 14 of the Indian Constitution because the term "enhanced efficacy" used in the clause was not properly defined and violates the TRIPS Agreement. However, the High Court ruled that the clause under Section 3(d) was constitutional and that it complied with the TRIPS agreement. The Novartis case is significant because it shows that no one can deny the public access to life-saving medications because of their high cost and market exclusivity.

Due to favorable legislation and government policies, private pharmaceutical companies are flourishing in India and have nearly taken over the local pharmaceutical sector, according to the Supreme Court of India's 2013 opinion on the Novartis case. In India, there is also virtually little foreign rivalry.

IV. RULES AND REGULATIONS OF PATENT

The inventor, assignee, or legal representative of a deceased inventor or assignee may apply alone or in conjunction with another party. If the inventor requests it, he has the right to be named in the patent. As assignees, two or more corporations may submit a combined application.

Patent Registry

The Patent Office and its satellite offices will house the Register of Patents. After paying the required price, one can view or extract information from the Register of Patents. The complete information of a patent, including its number, the names and addresses of the patentees, notification of assignment, renewals, and specifics of the patent proprietorship, are contained in the Register of Patents.

RENEWAL FEE:

Annual renewal fees must be paid. The first renewal fee must be paid prior to the second anniversary of the patent and is due for the third year of the patent's life. Renewal costs may be accrued and paid either immediately after the patent is sealed or within three months of it being recordable in the Register of the Patents if the patent has not been issued within that time frame. The date of patent issuance is used to calculate the date of renewal fee payment. There is a six-month grace period with an extension cost. Unless the original patent is canceled and the patent of addition is transformed into an independent patent, renewal fees are not due on patents of addition; in that case, they are due for the balance of the period of the main patent. There are no renewal costs needed while a patent application is pending; those that are past due at that time must be paid upon sealing within three months of recordable in the Patent Register.

LICENSE:

For licenses and any other papers establishing an interest in a patent to be legitimate, applications must be submitted to the Controller on the designated form. Within six months of the document's date, a license must be recorded.

TIME FRAME:

If a provisional specification is filed with an application on January 1, 1989, and a complete specification is filed on January 1, 1990, the duration of the patent is calculated from January 1, 1990. A patent is valid for 14 years from the date of submitting the complete specification. However, the patent life for food, drug, and pesticide patents is either five years from the date of sealing or seven years from the date of complete specification, whichever comes first. Make an appeal. The High Court has the right of appeal. An appeal must be filed within three months of the Controller's ruling.

RULES For PATENT:

The Patents Act of 1970, Section 159, gives the Central Government the authority to establish regulations for the Act's implementation and management. As a result, on April 20, 1972, the Patents Rules, 1972 were announced and went into effect. These regulations were periodically revised until May 20, 2003, when the 1972 regulations were superseded by the new Patents Rules, 2003. Both the 2005 and 2006 Patents (Amendment) Rules made additional changes to these regulations. The final changes went into effect on May 5, 2006.

Details of fees and forms related to different kinds of actions needed under the Patents Act and its regulations are provided in the four Schedules to the Patents Rules

- Fees must be paid according to the First Schedule,
- while the Second Schedule lists the forms and their language that must be utilized whenever necessary in relation to different operations under the Patents Act.

The Fourth Schedule specifies costs to be granted in various actions before the Controller under the Act, whereas the Third Schedule specifies the form of the patent to be issued upon patent grant.

V. CLASSIFICATION OF PATENTS

A particular invention is protected by each of the three sorts of patents. However, a single innovation may be eligible for multiple patent types. Below is an explanation of these patents.

PATENT FOR UTILITIES:

This kind of patent covers manufacturers, equipment, new and practical processes, and material compositions. This kind of patent is applied for by almost everyone. Additionally, it can be utilized to acquire additional enhancements to utility patents that already exist.

PATENT FOR DESIGNS:

When a wholly unique, inventive, and elaborate design is applied to a product, these kinds of patents are granted. The patent holder prevents others from making, utilizing, or commercializing the design by obtaining this kind of patent. Only where the design is patented may one obtain this type of patent.

PLANT PATENT:

For up to 20 years following the date of patent filing, the patentee's use of this form of patent prevents anyone from producing, utilizing, or selling the plant.

PHARMACEUTICAL PATENT:

Patents pertaining mostly to pharmaceuticals are known as pharmaceutical patents. It includes cutting-edge preparations, active medications, and techniques. Drug accessibility is given a lot of weight since public health has always been the top priority for governments. This raises the price that society is ready to pay for a given drug. The Trade-Related Aspects of Intellectual Property Rights treaty, which stipulated a twenty-year blanket duration, has eliminated this issue. But this contract also included the idea of mandatory licensing, keeping in mind how important it is for pharmaceuticals to be accessible in developing countries. Therefore, modifying the patent's duration is exemplified by pharmaceutical patent protection.

TYPES PHARMACEUTICAL PATENT:

Pharmaceutical industries are the greatest industries. and are known for their expertise. The pharmaceutical patent gives the product's inventor patent rights, protecting their creation from unauthorized usage. Their products and processes are protected by many patents which are also approved in India. The patents in the pharmaceutical industry fall into the following areas.

DRUG COMPOUND PATENT:

The claims in the patent are commonly known as "Markush type" claims, because they specify a specific medicine based on its chemical form. Numerous "functionally equivalent chemical substances" are permissible in various components of a drug molecule, which prevents the drug from being produced and sold illegally via any other means.

FORMULATION PATENT:

A specific process of formulating the medication and its active ingredients is guaranteed by the patent. For instance, Indian Patent No. 203993 claimed a formulation of the pharmacological 3,7-diazabicyclo that was intended for quick release.

POLYMORPH PATENT:

This patent includes variations of the same medicine's structure that are usually made to prevent deterioration or make the drug more solid. This kind of polymorph is typically created to improve the compound's stability and reduce impurities.

PROCESS PATENT:

The product's manufacturing process and procedure are covered by the patent. For example, Indian Patent No. 223217 covers the production of 3-hydroxy 5B-H steroidal sapogenins. The specific technology techniques utilized to address technical problems like altering or taste masking are covered by the patent. Specific strategies are employed to reduce various faults; these patents are based on procedures that fall under this category. For example, Indian Patent No. 227933

BIOTECHNOLOGY PATENT:

Biotechnology patent covered a medicinal mixture that produced a distinctive flavor. It is a patent that covers a wide range of natural goods and guarantees that a live organism and its biological byproducts can produce a medicinal product. therapeutic, diagnostic, immunological, and a variety of Under this patent, such products are protected.

PATENT FOR SYNERGETIC COMBINATION:

If a drug interaction is compatible with another drug, drug synergy will ensue. Numerous novel medication synergistic combinations are covered by this patent. The Indian Patent No. 197822 example patented a synergistic antibacterial composition and a process for producing it.

VI. MANAGEMENT OF INTELLECTUAL PROPERTY

In the fiercely competitive global pharmaceutical sector, a robust intellectual property (IP) framework is essential to success. A new drug's introduction can cost anywhere from \$300 million to \$1000 million, therefore businesses need to make sure their intellectual property is well-managed and secured. A unique position for IP in the decision-making process will be required by the knowledge revolution. The pharmaceutical sector has significant R&D expenditures, which could account for 15% of total sales. Pharmaceutical R&D carries a significant risk of failure, with prospective medications being discontinued after years of investment. medication businesses need to change their attention from creating new procedures to creating novel medication compounds and chemical entities since product patents are now the primary means of safeguarding intellectual property. In order to achieve public objectives, the developed world is probably going to look for more price control and lengthier medication protection. Numerous tactics, like outsourcing research and development, forging R&D partnerships, and forming strategic alliances, have emerged to address these issues.

A FEW COMPONENTS FOR PHARAMCEUTICAL PATENT SPECIFICATION:

In the fiercely competitive global pharmaceutical sector, a robust intellectual property (IP) framework is essential to success. Companies must maintain their intellectual property to prevent it from being lost to the public, and the cost of launching a new drug can range from \$300 million to \$1000 million. The pharmaceutical sector has significant R&D expenditures, which could account for 15% of total sales. Pharmaceutical R&D carries a significant risk of failure, with prospective medications being discontinued after years of investment. medication businesses need to change their attention from creating new procedures to creating novel medication compounds and chemical entities since product patents are now the primary means of safeguarding intellectual property. Over the past ten years, the amount of paperwork that must be submitted to regulatory bodies has tripled and shorter patent protection terms have resulted from longer approval times for new medications. Governments may need to prepare for lower profit margins in order to recover costs over a longer period of time, as the industrialized world may soon want lengthier drug protection.

LIIMITATIONS FOR THE PATENTS:

An invention that is pointless, makes a claim that is clear, or goes against established natural law. An invention whose main or intended application would violate the law, morality, or public health A mathematical technique, scientific hypothesis, or discovery The identification of a new property or application for a known material, or the simple application of a known machine, device, or method, unless the known process results in a new reactant A material produced by a simple mixing that just causes the characteristics of its constituents to aggregate, or a method for creating such a material A simple configuration, reorganization, or replication of a well-known gadget that each operates independently in a unique manner A method of agriculture or horticulture Any procedure used to treat humans medically, surgically, curatively, prophylactically, diagnostically, therapeutically, or in any other way, or any procedure used to treat animals in a similar manner in order to cure them of sickness or to raise the value of their goods or themselves An innovation in the field of atomic energy Traditional wisdom is actually an invention.

There are two main ways that patent rights support the promotion of social welfare, innovation, and development (Peter S. Menell & Suzanne Scotchmer, 2007).The primary method is similar to the private incentive permitted for growth, thanks to the innovator's careful. component benefits from the recognition that the final outcome of the advancement process is the development of new knowledge. According to traditional arguments outlined by Arrow (Arrow 1962 Griliches according to Lichtenberg (1984) and Levin et al. (1987), knowledge also possesses common characteristics of "public goods"

VII. CONCLUSION

In conclusion, the evolution of patent laws in India has significantly shaped the country's pharmaceutical industry, promoting both innovation and the growth of generic drug manufacturing. Initially, India's patent laws favoured process patents over product patents, fostering the expansion of generic drug production while multinational corporations faced financial losses. However, with India's adherence to the TRIPS agreement, product patents became mandatory, marking a pivotal shift in its legal landscape. The case of Novartis AG vs. Union of India exemplified the balance between innovation protection and public interest, reinforcing the constitutional validity of Section 3(d) of the Indian Patent Act. This decision ensured that patent extensions would not be granted without substantial improvement to the efficacy of a known substance, preventing monopolization and ensuring access to affordable, life-saving medications. The legal framework, with its procedural and regulatory adjustments, has enabled India's pharmaceutical industry to thrive while aligning with global intellectual property standards. The Indian patent system continues to play a vital role in balancing innovation incentives with public health needs, ensuring a fair and sustainable environment for both domestic and international stakeholders.

additionally, the robust framework set by the Indian Patents Act and its amendments has established India as a global leader in generic drug production, while simultaneously encouraging innovation through stricter patent laws. The introduction of Section 3(d) has played a crucial role in preventing "evergreening," ensuring that patents are granted only for genuine advancements rather than minor modifications of existing drugs. This balance protects public health interests, especially in a country like India where affordable medication is critical. The evolution of the patent system demonstrates the country's ability to adapt to international standards, such as TRIPS, while safeguarding national priorities like access to essential medicines. India's pharmaceutical industry thus remains a pivotal sector in the global health landscape, showcasing the effectiveness of its legal measures in promoting both innovation and public welfare.

REFERENCES

1. Bishwanath P. Radhey S. v. H.M. Industries A.I.R. 1982 S.C. 1444, at Paragraph 17, 2010.
2. Kuchekar BS, Khadatare AM, Forensic Pharmacy, Ninth Edition, 2012; 16.8- 16.20.
3. Narayanan P., Intellectual property law by third edition, eastern law house, 2001; 11, 21.
4. Pope Alliance Corp. v. Spanish River Pulp & Paper Mills Ltd., A.I.R. 1929 P C.38, 2009.
5. Lakhapati Rai & Ors. v. Srikissen Dass & Ors. 1917.
6. Smith Kline Beecham Pic's (Paratoxetine Methanesulfonate) Paragraph 2, Patent 2006.
7. Sanjiv Agarwal, Fairfest Media Private Limited 22; (91) (22) 2009; 26372883/ 95.
8. Minnesota Mining & Manufacturing Co Rennicks Ltd, RPC 331, 1992; 3.79.
9. Subbaram NR, Handbook of Indian Patent Law and Practice, Second Edition, 2005; 46-48.

10. Yamamoto K, Okazaki, Ishikawa K, Control System for Automatic Transmission Decision of the Controller (1938) 2008; Re. Patent Application No. 23077.
11. Lallubhai Chakubhai v. Chimanlal Chunilal & Co. A.I.R. Bombay 99, 1937 Bombay LR 66 at 1936; 100, 101.
12. Chiron Corpn. Organon Teknika Ltd (No. 3) F.S.R. 202, 418, 437, 444, 447, 492 at 1994; 211-213.
13. Government of India, Ministry of Law, Justice and Company Affairs, The Gazette of India, PART II Section 1, Patents (Amendment) Act, 1999, dated 26th. March, 1999, w.e.f. 1 January 1995 Section 5 renamed as sub-section (1) 1999.
14. Government of India, Ministry of Law, Justice and Company Affairs, The Gazette of India, Sub-section (2) inserted by Patents (Amendment) Act, 1999, dated 26th. March, 1999, w.e.f. 1 January 1995.
15. Government of India, Ministry of Law, Justice and Company Affairs, The Gazette of India, PART II Section 1, Patents (Amendment) Act, 1999 (Omitted), March, 1999, w.e.f. Ist.. January, (1995). 1999; Sub-section (2).
16. Bagade OM. Pujari RR, Vanave MO, Shete AM, Kharat PP, Nemlekar NA. Evolving pace of patent in india and its corollary in past, present and future. Am J Adv Drug Deliv 2014;2:503-21.
17. Savale SK, Savale VK. Intellectual property rights (IPR), World J Pharm Pharm Sci 2016;5:2550-92.
18. Nandini V. Patents for pharmaceutical sector & people's right to access to health in India issues and challenges. Indian J Integrated Research In Law 2000;342:1902-4.
19. Janodia MD, Rao J, Pandey S, Sreedhar D. Ligade VS. Udupa N. Impact of patents on indian pharma industry's growth and competency a viewpoint of pharmaceutical companies in India. J Intellect Prop Rights 2009;14:432-6.
20. Heble NK, Gupta NV. Comparision of patenting system in India, US and European Countries. Int J Chem Tech Res 2017;10:975-86.
21. Abraham BP. Moitra SD. Innovation assessment through patent analysis. Technovation 21 2001;21:245-52
22. Tiwari R. Tiwari G. Rai AK, Srivastawa B. Management of intellectual property rights in India: an updated review, J Nat Sci Biol Med 2016;89:131-46.
23. Rao YS. Intellectual property rights in India: significance of patents. SCIRP 2014;4:121-34.
24. Chandran S, Roy A, Jain L. implication of new patent regimen on Indian pharmaceutical industry: challenges and opportunities. J Intellect Prop Rights 2005;10:269-80.
25. Dhanya A. The effect of trips on Indian pharmaceutical industry. Int J Innov Res Technol 2021;8:145-51.
26. WHO Technical Report Series, Annex 7, No. 961, 2011.
27. Guidance for Industry Q10 Pharmaceutical Quality System. U.S. Department of Health and Human Services Food and Drug Administration, ICH, April 2009.
28. Raw AS. QbD Scale-up Considerations Linking Exhibit Batches to Commercial Production. GPhA/FDA Quality by Design Workshop for ANDAs, FDA - CDER - Office of Generic Drugs, May 5, 2011.
29. Dave V, Pareek A, Yadav S, Sharma S, Paliwal S. Pharmaceutical industry and technology transfer agencies in India. The Pharma Review, jan-Feb, 2013, 116-112.
30. Dogra R, Garg R and Jatav P. Technology Transfer in Pharmaceutical Industry: Transfer of Process from Development to Commercialization. IJPSR, 4(5), 2013, 1692-1708.



INTERNATIONAL
STANDARD
SERIAL
NUMBER
INDIA



INTERNATIONAL JOURNAL OF INNOVATIVE RESEARCH

IN SCIENCE | ENGINEERING | TECHNOLOGY

 9940 572 462  6381 907 438  ijirset@gmail.com



www.ijirset.com

Scan to save the contact details