
THE ROLE OF PATENTS IN THE MEDICAL INDUSTRY: A CRITICAL LEGAL ANALYSIS

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ABSTRACT

The pharmaceutical industry is one of the most research-intensive industries, requiring substantial financial investment, technological development, clinical research and regulatory approval to develop new medicines and medical technologies. Patents give inventors exclusive rights to a drug for a certain period, which encourages innovation and lets pharmaceutical companies recoup their research and development expenses. However, pharmaceutical patents also raise issues of monopoly, affordability and access to life saving medicines particularly in developing countries. The paper analyses the role of patents in pharmaceutical industry with special focus on need of balance between innovation and public health interest in India¹. The paper also addresses the problem of evergreening, where pharmaceutical companies may seek to obtain further patent protection for modifications of existing medicines. The paper discusses some important judicial decisions like *Novartis AG v Union of India*, *Bayer Corporation v Natco Pharma Ltd* and *Roche Ltd v Cipla Ltd* which show the approach of Indian judiciary in matter of pharmaceutical patent protection and public health. It also cites mandated licensing as a way to address concerns over access and affordability. The paper concludes that a functional patent system should protect real pharmaceutical innovation but not at the cost of excessive monopolisation and should ensure the availability and affordability of vital medicines to the public.

¹ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

1. INTRODUCTION

The medical field is one of the most vibrant and research-intensive industries in the world. It is constantly evolving as new discoveries are made, new technologies developed and new ways of preventing, diagnosing and treating illness are found. But the road to market for a new drug or medical device is an expensive and lengthy one. Pharmaceutical and medical technology companies may spend billions of dollars and many years, or even decades, researching, conducting clinical trials and obtaining regulatory approval, before a product can be offered to patients. Patents are important in this context to protect the rights of innovators and to ensure that such huge investments are long term².

The healthcare sector is a leader in innovation; developments are ongoing and leading to better patient care, therapies, and diagnostics. Patents are critical to encourage innovation by safeguarding and encouraging the development of new technology, drugs, medical devices and procedures for health care. Patents are both a driver of innovation and a key factor in the complex ecosystem of modern health care. The medical sector faces a dual challenge of developing technology and ensuring fair access to life-saving therapies, with the legal framework of patent protection becoming a deciding factor. Pharmaceuticals, biotechnology, and medical devices are examples of high-cost, high-risk areas where patents encourage R & D. Patents are temporary monopoly rights granted to inventors. However, where exclusivity is necessary for business success, it often comes into conflict with public health needs, especially in low- and middle-income countries where access and affordability remain major concerns.

1.1 Objectives of the Study

The objective of this research is to critically examine the impact of patents on the encouragement of innovation and technological development within the medical industry. The study will also aim to analyse the relationship between patent protection and access to medicines, medical technologies and healthcare. It also aims to examine the barriers to granting and enforcing patents for pharmaceuticals and medical technologies particularly around affordability, competition and public health. The research also analyses the adequacy of the existing legislation to ensure the balance of the interests of patent holders and the general

² World Health Organization, World Intellectual Property Organization & World Trade Organization, Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade (2d ed. 2020).

interests of society.

1.2 Research Questions

1. How do patents promote innovation and development in the medical industry?
2. What is the relationship between patent protection and access to affordable medicines and health care?
3. What are the problems of legal and practical protection of patents in the medical sphere?

1.3 Hypothesis

The study hypothesizes that excessiveness or duration may obstruct competition and access to affordable health care. But patent protection is an important incentive for innovation and investment in the medical industry. Hence a balance between the intellectual property protection and the public health is needed.

1.4 Research Methodology

The study uses doctrinal and analytical research methodology. The research is mainly based on secondary sources, including statutory provisions, judicial decisions, international instruments, books, academic articles, research reports and relevant governmental and institutional publications. The study analyses the Indian patent law regime and relevant international standards such as TRIPS Agreement³. The collected materials are critically analysed with a view to identifying the existing legal challenges and to assess if the current framework strikes a proper balance between patent rights and public health considerations.

2. Meaning of Patent in Medical Industries:

A patent is a type of intellectual property right granted by the government generally. It gives the inventor the exclusive right to make, use, sell and distribute an invention for a limited period of time, usually 20 years from the date of filing⁴. A patent system aims to promote

³ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007).

⁴ Tanya Verma, *Patentability of Pharmaceutical Inventions Under Indian Law: Between Innovation Incentives and Access Imperatives*, 6 E-JAIRIPA 17 (2025).

innovation by providing an inventor with a temporary monopoly on their invention, and ultimately ensuring that the invention will enter the public domain when the patent expires. The medical industry is highly research-intensive, very expensive and directly affects people's lives through the availability of medicines, vaccines and healthcare technologies. Patents are thus critical to this sector.

The role of patents in pharmaceutical industries, The medical field is highly dependent on advanced technology, creativity and research. Discovering new medication or medical equipment is costly and time-consuming. It usually takes 10 to 15 years of research and more than \$1 billion in funding before a new treatment can hit the market. In this case, patents provide the basis for innovation.

3. Importance of Patents in Pharmaceutical Industries:

Advanced technology, creativity and research are very important for the medical sector. Finding a new medicine or medical device is time-consuming and expensive. The development and approval process for a new treatment can take 10 to 15 years and costs more than \$1 billion. In this situation patents are the basis of innovation. They give inventors exclusive rights for a specific period, generally 20 years, and stop unauthorised reproduction or sale of the idea⁵.

3.1 Promoting research and Innovation

Patents are important to promote innovation and research in the medical field . Years of hard work, scientific know-how and money go into developing a new drug or medical device. Research shows that it takes 10 to 15 years and more than \$1 to \$2 billion to develop a new drug and bring it to market. Patents reward innovators with a 20-year monopoly for their effort and financial investment. That's what makes exclusivity such a strong incentive . That's what makes companies invest in research and push medicine forward .

Examples: Cancer Medicines: Companies like and **Novartis** invested heavily in creating advanced cancer drugs like Glivec and Indian pharmaceutical companies like **Dr. Reddy's** and **Sun Pharma** invest in drug discovery because patents assure protection of their innovations⁶. These drugs became possible only because the patent system gave the companies security that

⁵ Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20 (2016).

⁶ Novartis AG v. Union of India & Others, (2013) 6 SCC 1 (Sup. Ct. India).

they could recover their investment through sales.

3.2 Protection of Intellectual Property (IP)

Patents are designed to protect original ideas and stop unauthorised copying. And that means that the inventor does not waste his time, his energy and his capital. Patents grant the original inventor the exclusive right to make, market, or license the product for 20 years. This encourages further research but also gives them financial reward and recognition.

Think back to the 2000s, when Cipla was making HIV medicines affordable by pricing them at less than \$1 a day. It also patented its formulas to protect them, to keep the medicines available for poor countries.

3.3 Boosting Economic Growth

Patents are a strong engine of economic growth through the conversion of innovative ideas into assets. If a company invents something new and patents it, then the company has the exclusive right to make and sell that product or use that process, and that is a very powerful competitive advantage. That will attract investors, encourage start-ups and allow businesses to expand to the global markets. India's IT and bio-technology sectors are patent intensive. Companies like Infosys and Wipro use patents in software and digital technologies to stay competitive at the international level. Biocon has patents in biotechnology for its insulin and cancer treatment technologies that have given the company a global reputation, and also create jobs and foreign investment⁷. In biotechnology, Biocon has patented its insulin and cancer treatment technologies, which not only give it global recognition but also create jobs and attract foreign investment.

3.4 Balancing public health and innovation

One of the key functions of patents in India is to strike a balance between public health and innovation. The Indian Patents Act, 1970, specifically Section 3(d) was brought in to see that patents are given only for real innovations having real therapeutic efficacy and not for minor modifications or 'evergreening' tactics to extend monopoly without real value. This would

⁷ Bao Q. Tran, Understanding the Economic Impact of Patents, Patent (undated), available at <https://patentpc.com/blog/understanding-the-economic-impact-of-patents>.

insulate patients against high prices but still reward real innovation⁸.

3.5 Facilitating Technology Transfer

Patents are a key enabler of technology transfer as they enable companies to legally transfer their technology through licensing or partnerships. It is a win-win situation. Inventors make royalties from their patented technologies. Other companies and countries have access to state-of-the-art knowledge and methods. Such partnerships speed up research, industrial development and availability of modern medical solutions.

Technology transfer was essential given the circumstances surrounding the COVID-19 pandemic. Indian pharmaceutical companies, such as Serum Institute of India (SII) and Dr. Reddy's Laboratories, entered into licensing agreements with global firms. These agreements, safeguarded by patents and licensing, helped India to become a global hub for affordable vaccine production and helped the world fight the pandemic.

4. Evergreening of Patents in Medical Industries:

Patents are important for stimulating inventions in the medical field. Through the provision of a monopoly for a limited period of time, patents offer the pharmaceuticals monopolists the capability to cover the cost of research and development and make a profit. But in practice, companies don't limit themselves to protecting true innovations. Instead, they attempt to expand their monopoly rights through a practice that is often referred to as "evergreening." Evergreening has been one of the most debated topics in the realm of patents pertaining to medicine, as its implications directly affect the range and cost of drugs, especially in developing countries (such as India). Evergreening is basically a practice by which pharma firms extend the life of a drug's patent, without actually enhancing its efficacy⁹.

The practice is widely derided because it helps to maintain artificially high drug prices. But for life-saving medicines — whether drugs against cancer, HIV/AIDS, or insulin — evergreening can be the difference between life and death for millions of patients¹⁰. By delaying generic competitors that may offer cheaper alternatives, evergreening simply allows pharma companies

⁸Sharmathi S, Balancing Intellectual Property Rights and Public Health: An Examination of Section 3(d) of the Indian Patents Act, 8 Indian J.L. & Legal Rsch. (2026).

⁹ Kashish Khurana, An Analysis Of Evergreening Of Patents, Intepat (Nov. 18, 2022), <https://www.intepat.com/blog/evergreening-of-patents>.

¹⁰ Patent Evergreening and Its Impact on Affordable Medicines in Developing Countries, IJFMR 1–2 (2026)

to maximise their profits to the detriment of public health. For those in developing nations where healthcare facilities are already poor and patients are not able to shell out money for costly drugs, the impact is worse.

Indian law has strongly suppressed this practice. This provision appears as a unique mechanism under the Patents Act, 1970 so as to enable the only true inventions to obtain the protection. Under this provision a new form of a known substance is not patentable unless it leads to a new and substantially improved efficacy effect. “In this context, 'efficacy' has been interpreted by Indian courts to be “therapeutic efficacy” and not "efficacy" simpliciter (i.e., merely 'improved efficacy' or superior properties, such as better flavor, appearance, or miscibility, stability or ease of storage of the product),” the decision read. This provision was inserted precisely to prevent big pharma companies from securing multiple patents on the same medicine to preclude generic versions.

Cases:

1. Novartis AG v. Union of India (2013)¹¹

Facts of the case:

Novartis, a Swiss multinational pharmaceutical company, developed Glivec, a life-saving anti-cancer drug used to treat Chronic Myeloid Leukemia (CML) and certain gastrointestinal tumors¹². Glivec itself has been highly effective evidenced by dramatic increases in survival clearly demonstrating that it prolongs the lives of patients with leukaemia. Novartis submitted a patent application in 1998 in India, for the beta crystalline form of imatinib mesylate (a modified version of the known compound imatinib). In 1998, India did not grant product patents for pharmaceutical products (under the Patents Act, 1970 India only provides process patents until the reforms in Patents with WTO-TRIPS obligations as of 2005).

After TRIPS, this patent application was subject to review. Many Indian generic manufacturers had entered the market (Natco, Ranbaxy, and Cipla) as well as patient groups for instance Cancer Patients Aid Association (CPAA) opposed the grant of patent. The basis of opposition is being used in that Novartis patent application was not based on a new invention but

¹¹ Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India)

¹² “Case Brief: Novartis v. Union of India,” The Legal Lock (date of publication if known, otherwise n.d.), <https://thelegallock.com/case-brief-novartis-v-union-of-india/> (last visited Aug. 29, 2025).

essentially a modified drug (imatinib mesylate) with only slight changes. Section 3(d) (amended in 2005) grants exclusion of patents on "mere discovery of new form of a known substance which does not result in enhanced efficacy". The whole purpose of this exclusion is to prevent evergreening of drugs which is when drug companies make minor changes to an old drug which allows the drug company to maintain monopoly rights even when there is no true innovation.

Judgement:

The Court determined that Novartis's beta crystalline form of Imatinib Mesylate was not an invention under Section 3(d). It did not exhibit enhanced therapeutic efficacy, which is essential for the patentability of modified drugs. The Court stated that "efficacy," in the field of medicine, is meant to include therapeutic efficacy (improvement in the curing or treatment of disease), and is not simply better physical properties (bioavailability, stability, and flow). Since Novartis could not demonstrate a better therapeutic effect, the application was unsuccessful. The Court also found Section 3(d) constitutional, valid, and compliant with TRIPS.

The Court pointed out that the law was needed to balance patent rights with the public health needs of patients suffering from diseases. By denying Novartis's patent, Indian generic manufacturers would be able to manufacture and sell inexpensive versions of Glivec. Price difference is Patented version of Glivec (Novartis): ₹1,20,000 per patient per month approximately, Generic version made in India: ₹8,000–₹10,000 per patient per month.

2. Bayer Corporation vs Natco Pharma Ltd. 2014¹³

Facts of the case:

Bayer Corporation, a German drug company, owned the patent for Sorafenib Tosylate (name brand: Nexavar), a life-saving medication used to treat kidney and liver cancers. Bayer marketed Nexavar in India for the outrageous price for ₹2.8 lakh per patient per month, which was not an option for the average Indian patient. It was estimated that only a few numbers of patients needing the drug were able to obtain it (about 2%). Bayer did not make the drug "reasonably affordable" in accordance with the patent requirements in India. The patented drug was not "reasonably worked in India," as Bayer imported drug in insufficient quantities instead

¹³ Bayer Corp. v. Union of India, 2014 SCC OnLine Bom 963 (India).

of producing Argent drug locally. Natco proposed to offer drug for ₹8,800 per patient per month (over 30 times cheaper) while agreeing to pay Bayer a 6% royalty on net sales.

Judgement:

Indian Patent Office in march 2012 granted Compulsory License to Natco Pharma. It found Bayer guilty of failing to satisfy the requirements of Section 84. Bayer challenged the decision before the Intellectual property Appellate Board¹⁴. IPAB Upheld the compulsory license in 2013, noting that Public Interest overrides excessive patent monopoly in matters of lifesaving drugs. Bayer further appealed, but the Bombay High Court dismissed Bayer's challenge and upheld the compulsory license order.

Bayer approached the Supreme Court in 2014 and the court refused to interfere and upheld the compulsory license, giving finality to Natco's right to manufacture the generic Version.

3. Roche Ltd vs Cipla Ltd¹⁵

Case Facts:

This dispute arose in the Delhi High Court regarding a Roche's drug 'Erlotinib' which is sold by Roche under the brand name TARCEVA. Roche and Cipla both use the compound Erlotinib Hydrochloride. In February 2007 Roche announced that it had received a patent on "Erlotinib" and began marketing the drug under the name TARCEVA. In January 2008, there were reports indicating Cipla's intention to launch a generic version of 'Erlotinib', prompting Roche to take legal action against Cipla for patent infringement. Roche claimed that it owned the patent, also known as 'Erlotinib Hydrochloride' and Cipla was infringing it. Roche lost the said suit as the court held that it would be detrimental to the public interest to stop Cipla's manufacturing and balance of convenience was in Cipla's favour.

On appeal, the Division Bench upheld the decision primarily on the ground of Roche's failure to make out a preliminary case of infringement. Roche's Special Leave Petition (SLP) against the verdict was also dismissed. The parties returned to the single judge for the initial relief trial. The judge made a judgement and Roche did not succeed sufficiently in proving that Cipla's

¹⁴ Case Analysis and Aftermath of Natco Pharma Ltd v. S. Bayer Corporation, Legal Service India, n.d., <https://www.legalserviceindia.com/legal/article-5286-case-analysis-and-aftermath-of-natco-pharma-ltd-v-s-bayer-corporation.html> (last visited Aug. 29, 2025).

¹⁵ F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2015 SCC OnLine Del 13619 (India).

manufacture of Erlocip infringed its patent IN774. The case was then placed before the Division Bench and the decision was in favour of Roche.

Judgement:

Ultimately, the two-judge panel ruled that there was no infringement because the patent at issue was for a combination of Polymorphs A and B, while the Tarceva drug contained only Polymorph B. It must be kept in mind that Roche had applied for a patent on Polymorph B but was rejected by the Indian Patent Office as it did not satisfy the criteria of Section 3(d) and the test of patentability. The court also considered the intention of the legislature in enacting Section 3(d) and the laws against evergreening and put the public good first. The court recognised that it was a life-saving drug and hence Cipla's drug was priced at one-third of Roche's drug.

Conclusion

Patents play a dual role in the medical industry, both as a motivation for innovation and a challenge to public health access. They encourage pharmaceutical companies to conduct expensive and time-consuming research and thus ensure progress in the area of medicine. But the problems arise when patents keep prices of medicines high and thus make them less available in countries like India where cost is a key factor. The problem of evergreening – patenting trivial modifications without any real innovation – further complicates the system. Indian patent law, especially Section 3(d) and landmark cases like *Novartis v. Union of India*, *Bayer v. Natco Pharma* and *Roche v. Cipla*, epitomizes India's middle path of rewarding genuine innovation while preventing monopolistic abuse. India provides access to life-saving medicines, through tools such as compulsory licensing. Thus, the patent system needs to strike a balance between innovators and society's interests, fostering medical progress without undermining the basic right to health. Now, we are always talking about patents on pharmaceuticals worldwide. It's pretty clear that no patent system is going to stay the same when public health needs keep evolving as they do. India's approach proves that robust protection of intellectual property and looking after the public interest are not mutually exclusive. Above all, patents must not violate the basic rights to health and dignity enshrined in constitutions.