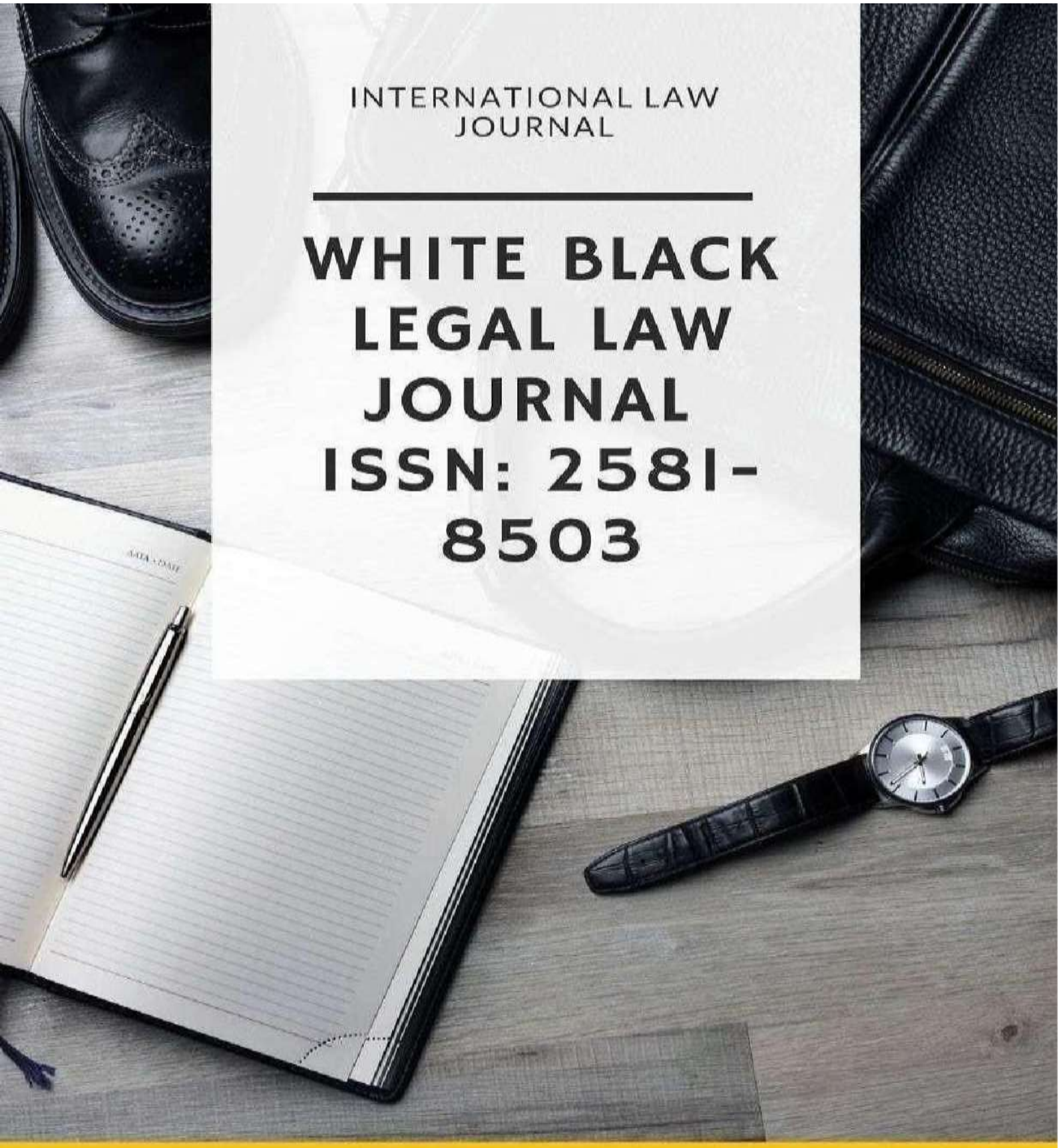

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INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES IN INDIA: A SOCIO-LEGAL ANALYSIS OF PATENT LAW

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Abstract

In the context of an increasingly stringent global intellectual property regime, the access to affordable medicines remains one of the most pressing public health challenges in India. Following the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) there was a significant shift in India's patent policy from a public health oriented framework from one that was more aligned with international intellectual property standards. This paper undertakes a socio-legal analysis of India's patent framework to examine the relationship between intellectual property rights and access to medicines.

The paper analyses the evolution of pharmaceutical patent protection in India, with specific emphasis on the Patents Amendment Act, 2005 and evaluates the key legal mechanisms that aim to safeguard public health interests. This paper is doctrinal and it explores the socio-economic impact on drug affordability, accessibility and healthcare. It highlights the disparities across class, gender and geography. It also examines the role of multinational pharmaceutical corporations and India's position as the "Pharmacy of the world".

Keywords: Intellectual Property Rights, Access to Affordable Medicines, Public Health Interests, Healthcare

Introduction

The relationship between intellectual property rights and access to medicines has become one of the most debated issues in modern legal and public health discussions. In countries like India that are still developing, a large portion of the population is dependent on affordable medicines, so the strengthening of pharmaceutical patent protection has direct impact on affordability and

accessibility of drugs[1]. Patent law aims to promote innovation through granting exclusive rights to inventors, public health policy places the importance on the need to ensure the availability of essential medicines to all sections of society. These objectives forms the foundation of this paper.

India's patent law has evolved a lot over time. Historically it was built in a way that it had prioritised had a public health oriented approach by recognising only process patents for pharmaceuticals[2]. The Patents Act, 1970 by recognizing only process patents for pharmaceutical substances as opposed to product patents the Act effectively prevented the creation of absolute market monopolies on essential medicines. This enabled the growth of a strong domestic industry and contributed to the availability of affordable medicines. Over the decades, India came to be recognised globally for its capacity to manufacture and export cost-effective pharmaceutical products. It cemented India's reputation as "Pharmacy of the World"[3]. With India's addition to the World Trade Organization and its commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), major amendments were made to the legal framework of patents. The Patents Amendment Act, 2005 marked a significant shift by introducing product patents for pharmaceuticals and making sure the domestic law was in line with the international intellectual property standards.

This paper adopts a socio-legal approach to examine the evolution of pharmaceutical patent protection in India and its relationship with access to medicines. It analyses the post-TRIPS legal framework and the mechanisms designed to safeguard public health interests, while also exploring the broader socio-economic dimensions of drug accessibility. The study intends to offer a thorough analysis of the current patent regime and its implications for drug availability by placing patent law within the context of India's healthcare actuality and its place in the global pharmaceutical landscape.

[1] Sahil Sajan Patade, *How Patenting Pharmaceutical and Medical Have an Impact on the Aspect of Accessibility, Affordability, and Availability in Relation With TRIPS*, 8 International Journal of Law Management & Humanities 843-850 (2025).
[2] The patents act § 5 (1970).
[3] *Why India is called the 'pharmacy of developing world'?*, Qualitroth Pharmaceuticals - (Aug. 7, 2023), https://qualitrothpharma.com/why-india-is-called-the-pharmacy-of-developing-world/.

Research methodology:

This paper is a uses a qualitative research method, so rather than focusing on numbers or surveys, it focuses on analysing the laws and judgments, written materials. The primary legal sources are Patent Act 1970 including 2005 amendments, the TRIPS agreement, and important cases like Novartis vs. Union of India and NACTO Pharmaceutical Ltd vs. Bayer Corporation. This paper also used secondary sources like research articles written by scholars and government reports like Pradhana Mantri Bhartiya Janaushadhi Pariyojana. This paper connects patent law with the right to health under Article 21 of the Indian Constitution and also includes how the patent rule impacts society based on gender, class and location.

Theoretical Framework of Patents:

According to the World Intellectual Property Organisation (WIPO), a patent could be described as a sole right bestowed upon an inventor for their invention. Patents have two-fold benefits, the inventors are given legal protection of their inventions while society is benefitted by having access to important practical information about these inventions[4].

Under Section 2(1)(j) of the Patents Act,1970 a creation could be classified as an "Invention" if it involves a new product or process with advancement in comparison to the already existing knowledge or if it could be used in any industry and reproduced with the same characteristics[5]. The rights conferred on the inventor involves the right to exploitation of the invention and the right to profit from it[6]. The TRIPS agreement grants the following rights to the patent owners; the subject matter could be a product or a process but a third party must acquire the consent before using the invention for commercial purposes. They also have the right to assign or transfer the patent as well end licensing agreements.[7]

Pharmaceutical Patents:

Pharmaceutical Patents primarily deals with the chemical compounds that are utilised to treat diseases, the procedure involved in creating these compounds as well as the process of

[4] *Patents*, https://www.wipo.int/en/web/patents.
[5] The patents act § 2(1)(j) (1970).
[6] *Benefits Of Patent Registration*, IPOI https://www.ipoi.gov.ie/en/types-of-ip/patents/understanding-patents/benefits-of-patent-registration/.
[7] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 28, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

transforming these compounds into medication.[8] After years of investment in drug development, clinical trials, and approvals, pharmaceutical patents assist drug discovery companies in generating a return on what they have invested. Pharmaceutical companies invest time and years of research into innovation to produce new medications that are safe and effective at treating illnesses.[9]

In India, the pharmaceutical patents are categorized by the subject matter which they protect. The product patents protect the actual chemical substance or drug while process patents protect the specific method used to manufacture a drug. The formulation and composition patents protect the dosage form and specific technology used to deliver the drug.[10]

Evolution of Pharmaceutical Patent Protection in India:

India's patent law came into effect in 1856. Despite the fact that the patent laws were amended throughout this time, they were still patenting pharmaceutical products. By the time India was declared Independent, the involvement of Indian firms was very minimal.[11]

Post Independence, the Government of India began drawing up a new legislation for patent protection. This led to the creation of The Patents Act, 1970. The act was the culmination of work over 20 years and it was a result of two committees; the Bakshi Tekchand Committee and Justice Rajagopal Ayyangar Committee. They prioritised the socioeconomic conditions of India, and the recommendations of the committees had noteworthy changes in patent law. Most of the changes were in respect food and drug patents as well as compulsory licensing. The 1970 Act had a significant impact on the growth of a lot of industries, which included the pharmaceutical industry.[12]

Pre-TRIPS regime and process patent system:

The Patents Act, 1970 originally allowed only process patents for drugs and pharmaceuticals,

[8] *Pharmaceutical Patent Definition | Legal Glossary | LexisNexis*, LexisNexis (Jan. 13, 2025), https://www.lexisnexis.co.uk/legal/glossary/pharmaceutical-patent.
[9] *A Quick Guide to Pharmaceutical Patents and Their Types*, PatSeer (July 25, 2023), https://patseer.com/a-quick-guide-to-pharmaceutical-patents-and-their-types/.
[10] Snigdha Joshi, *Guide to Pharmaceutical Patents and IP Rights*, (Mar. 27, 2025), https://www.pharmanow.live/knowledge-hub/research/pharmaceutical-patents-intellectual-property.
[11] Katherine Connor Linton & Nicholas Corrado, *A "Calibrated Approach": Pharmaceutical FDI and the Evolution of Indian Patent Law*, United States International Trade Commission (2007).
[12] Justice Madan B Lokur et al., *An International Guide to Patent Case Management for Judges*, WIPO https://www.wipo.int/patent-judicial-guide/en/full-guide/india/6.1.

it did not allow for products for medicines. This helped Indian companies legally manufacture generic versions of medicines. This resulted in affordable medicines and growth of Indian Pharma Industry. This system remained unchanged for about 24 years.[13]

1999 Amendment – Retrospective Application:

India joined the World Trade Organisation in 1995, this meant that it had to comply with TRIPS regulations. India was given a grace period for transition till 2005 to introduce pharmaceutical product patents and on 31st December 1994, India had issued an ordinance that made temporary changes to the act to begin the TRIPS compliance. This ordinance expired after 6 months. The government issued another ordinance in 1999, which was replaced by the Patents (Amendment) Act, 1999 which was applied retrospectively from 1st January 1995.

This amendment introduced two important concepts. TRIPS required India to accept applications from 1995 even if it wasn't accepting product patents yet so they devised a system in the act where companies could file applications for product patents in drugs, pharmaceuticals and agro-chemicals but these patents would not be looked at until after 31st December 2004.This was called the mail box system. The other concept was, if between the period of 1995-2000 a company had filed a patent in India, it got a patent in another WTO country as well as received marketing approval in India then it could get Exclusive Marketing Rights (EMR) for 5 years. This meant that they could exclusively sell that product in India temporarily. This was purely a transition setup before the full product patents were introduced.[14]

2002 Amendment – Strengthening The Patent Framework:

The Patents (Amendment) Act, 2002 extended the patent term to 20 years as per the TRIPS requirement. It also modified the definitions of terms like "invention", "inventive step" and so on. It strengthened the enforcement mechanisms and introduced new Patent Rules. The act focused on bringing Indian law closer to TRIPS standards but still product patents weren't granted to pharmaceuticals yet.[15]

2005 Amendment – Product Patents Introduced:

An ordinance came in 2004 which was then replaced by the Patents (Amendment) Act, 2005.

[13] *History of Indian Patent System*, Intellectual Property India, https://www.ipindia.gov.in/Patents/history_of_indian_patent_system (last visited Feb. 18, 2026).
[14] *Id.*
[15] *Id*

This was the most important amendment as it introduced product patents for pharmaceuticals. It ended the mailbox system, removed EMR and was completely in compliance with TRIPS. It inserted important safeguards like anti-evergreening and compulsory licensing refinements. This marked the complete transition from a proves patent regime to a product patent regime.[16]

The Indian patent framework's transition indicates a purposeful shift from a system that prioritized public health within the country to one that is focused on global trade compliance. The Patents Act of 1970 was initially intended to a socioeconomic tool that granted only process patents for pharmaceuticals and drugs, deliberately excluding product patents to prevent monopolies and guarantee the supply of reasonably priced medications. The government included necessary legal safeguards to protect public health even though the amendment brought India into compliance with international standards. It demonstrates the challenging tension between upholding international agreements and defending the fundamental right to health of the Indian people

Patent Law and Access to Medicine:

Patentability Criteria under The Patents Act, 1970:

Patentability is established under Sections 2, 3 and 4. An invention must fulfil three main criteria in order to be eligible for patent protection. These criteria includes novelty, inventive step and industrial applicability.[17]

The key definitions of novelty are found in Section 2(1)(j) and Section 2(1)(l), which define "Invention" and "New Invention," respectively. According to Section 2(1)(l), the invention had not been anticipated by publication in any document or used either domestically or internationally prior to the filing date. According to this "absolute novelty" criterion, the invention cannot be considered part of the "state of the art" or be in the public domain; in other words, it cannot have been known, used, or explained in a way that would allow someone with the necessary knowledge to implement the invention.

Unlike the "inventive step," which seeks creativity, novelty is a more demanding, actual comparison. The invention is "anticipated" and the patent is denied if even one prior publication or public use discloses each component of a claim. Pharmaceutical companies are prevented from re-patenting known substances or existing pharmaceuticals that have already been published in older scientific literature or traditional knowledge due to this legal obstacle

[16] *Id*

[17] *Patentability Criteria in India: Key Case Laws, Applications & More!*, https://thelegalschool.in/blog/patentability-criteria-in-india.

Section 2(1)(ja) serves as the "non-obviousness" gatekeeper of Indian patent law, a 20-year monopoly is only granted to genuine innovations rather than logical extensions of preexisting technology. An invention must demonstrate either technical advancement, such as a better solution to a technological problem, economic significance, such as a discernible drop in cost or improvement in efficiency, or both when compared to the prior art, which is all of the knowledge that existed before the patent filing.

The legal criterion for this is whether the innovation would be "non-obvious" to a Person Skilled in the Art (PSITA), which is a technician who lacks inventive faculty but has mediocre industry expertise. By requiring a creative "leap" rather than a simple step, this clause prevents pharmaceutical companies from "evergreening" patents with minor, reasonable adjustments, protecting the public's access to affordable generic medications.

An invention must possess industrial applicability for it to meet the requirements for patent protection. Under Section 2(1)(ac) of the Patents Act, 1970 it is stipulated that an invention must be “capable of being made or used in an industry”. This criteria ensures that a patent is not granted for purely theoretical ideas or abstract principles that have no functioning. This way patents are only granted for innovations that hold tangible and practical benefit.

In the context of pharmaceutical patents and access to medicines, this requirement puts a stop to patenting of “speculative” compounds, these compounds are the those where the therapeutic use or biological activity has not been proved yet. By making it mandatory that a drug or process demonstrate a real world application, the law makes sure that the 20 year monopoly is for an exchange for a functional contribution to the society instead of a way to block future research on a substance the patent applicant may not know how to use effectively.

Collectively, these statutory requirements ensure that the Indian Patent framework grants temporary monopolies in exchange for real technological progress that justifies the resulting impact on market competition and drug affordability.

Role of pharmaceutical patents in drug pricing:

The implementation of product patents in India after 2005 has created "legal monopolies" that have a direct impact on drug prices, drastically altering the pharmaceutical industry's economic environment. The existing system allows the patent holder to establish prices that cover research and development (R&D) expenses and effectively prevents generic competition by giving the innovating company exclusive rights for 20 years. With prices ranging from $800 million to $1 billion per molecule, innovator companies contend that high prices are a necessary

incentive for the "high-risk, high-investment" nature of drug discovery.[18] However, this pricing power frequently puts life-saving medications out of the reach of the typical Indian citizen. The price of the patented cancer medication Glivec was almost ten times higher than the previously available generic versions in the landmark Novartis v. Union of India case.[19] This shows how the lack of competition under a product patent regime can result in "monopoly markups" that elevate corporate earnings ahead of patient affordability. In India, the role of patents is a never-ending struggle between the constitutional duty under Article 21 to guarantee the right to health and life through accessible medicine and the statutory right to profit.

Section 3(d) of The Patents Act, 1970: Safeguard against Evergreening

The section states that a person can't get a patent just because they discovered a new form of a known substance unless that new form shows enhanced efficacy.[20] It prevents patents for new forms of known substances, new properties of known substances and new uses of known substances as well as known processes. It is designed to prevent "evergreening"

Evergreening is when pharmaceutical companies take an existing drug and make small modifications and then apply for a fresh patent to extend the monopoly for another 20 years. This delays generic competition and keeps drug prices high.[21]

A new form of known drug must show significant enhancement of known efficacy, not just better stability, flow properties, shelf life or solubility. It must improve therapeutic efficacy. This is interpreted as improved therapeutic effect in treating disease. The most important case interpreting Section 3(d) is Novartis AG v. Union of India[22] and in this case Novartis applied for a patent on a beta-crystalline form of Imatinib. They argued that it had better bioavailability, the Supreme court however held that improved bioavailability does not automatically improve therapeutic efficacy. The patent as a result was rejected.[23]

[18] Deloitte Ctr. for Health Sols., *Measuring the Return from Pharmaceutical Innovation 2024: Target Areas of Unmet Need*(2024)

[19] *Novartis AG v. Union of India*, (2013) 6 S.C.C. 1 (India).

[20] The patents act § 3 (1970).

[21] *Section 3(D) And the Novartis Case Unveiling The Power And Controversy In India's Patent Law*, Intellectual Property Rights Services Online (Dec. 1, 2025), https://iiprd.wordpress.com/2025/12/01/section-3d-and-the-novartis-case-unveiling-the-power-and-controversy-in-indias-patent-law/.

[22] *Novartis*, *supra* note 19.

[23]*Section 3(D)*, *supra* note 21

Compulsory Licensing as a Public Health Tool:

A compulsory licence is when the government allows someone else to use a patented invention without the permission of the patent holder. The "someone else" could manufacture the product, import it or the government itself may use it. The patent owner still gets paid royalties but they will lose exclusive control. Under international law, this flexibility exists in the TRIPS agreement. This means that patents give monopoly rights and compulsory licensing limits that monopoly in public interest situations. These flexibilities aren't new; they have existed in TRIPS since 1995.[24]

In pharmaceuticals, Compulsory licensing is mainly used when a life-saving drug is too expensive, the patent holder is not supplying enough quantity the drug is not manufactured locally or there is a public health emergency, it allows generic manufacturers to produce cheaper versions.[25]

India issued its first and only compulsory license in 2012. The drug was Nexavar and the patent holder was Bayer; the Indian generic company was Natco Pharma. The license can be granted under Section 84 of the Patents Act if the reasonable requirements of the public are not satisfied, the drug is not available at affordable price and the patent is not worked in India.[26]
In this case, Bayer was selling Nexavar at a very high price in comparison to Natco. Only a minimal number of patients could afford Bayer's version. Taking this into consideration the controller of Patents granted the compulsory license. [27]

Pharmaceuticals companies are of the opinion that patents incentivize R&D and weak enforcement discourages innovation. Public health advocates argue that monopolies create unaffordable drugs, life-saving medicines should not be luxury goods and TRIPS flexibilities are legal and necessary.

[24] *Compulsory licensing of pharmaceuticals and TRIPS*, World Trade Organisation https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[25] *Balancing public health and IP rights: compulsory licensing and evergreening practices*, International Bar Association https://www.ibanet.org/public-health-compulsory-licensing.
[26] The patents act § 84 (1970).
[27] Bayer Corporation v. Union of India, (Bombay High Ct. 2014).

Right to health vs patent monopoly:

Article 21 of the Indian Constitution concerns the right to life and personal liberty, and the Supreme Court has broadly interpreted the article to include the right to health, the right to medical treatment, and the right to affordable medicines[28]. If a person is denied proper medical treatment, then it violates Article 21. The Directive principle of state policy guides the government on what has to be done for people's welfare. Like Article 38 promotes the people's welfare, Article 39(e) protects the worker's health, Article 47 improves public health and nutrition, and Article 48A protects the environment.[29]

In the case of *Unnikrishnan v State of Andhra Pradesh*[30], the court held that it's the state's duty under Article 21 to provide health facilities, prevent harmful substances and help people who can't afford.

In India, according to patent act amended in 2005, it gives 20 years of monopoly for companies to new inventions. But, in India, according to section 3(d), stops the companies from patenting for small changes in old medicines until it gives a significant effectiveness.

In the case of *Novartis vs. the Union of India*, the Supreme Court ruled that a small modification cannot lead to the extension of a monopoly. So, the court refused to grant a patent for the modified version of the cancer drug Glivec. The extension of patents for minor modifications of medicines can make it more expensive for people to afford.

According to section 84 of the Patents Act, the government can permit another company to produce the patented, expensive medicines that are not available in sufficient quantity without the permission of the patent holder's company.

In the *Natco vs. Bayer case*, Natco was allowed to manufacture the bayer's version of the cancer drug nexavar a cheaper one. After this production, the price has reduced from about 2.8 lakhs to Rs. 8,800 per month, which is affordable for patients.

[28] **https://www.lawctopus.com/academike/article-21-of-the-constitution-of-india-right-to-life-and-personal-liberty/**
[29] **https://www.constitutionofindia.net/articles/article-47-duty-of-the-state-to-raise-the-level-of-nutrition-and-the-standard-of-living-and-to-improve-public-health/**
[30] Unni Krishnan, J.P. v. State of A.P., (1993) 1 S.C.C. 645 (India)

The court tries to balance the encouragement of innovation (so companies can come up with new inventions) and the right to health of the people.

In the *Roche vs. Natco*[31] case, the court examined both the public interest and the patients' rights.

Socio-Legal Impact of Pharmaceutical Patents in India:

Before 2005, India allowed only the process patents. Which made Indian companies make cheaper generic medicines. After 2005, India changed the patent law to comply with the World Trade Organisation. So, patents are given to the product also, and companies are getting stronger rights over the new medicines. Due to this change, many new medicines became expensive. Poor people couldn't able to afford treatment. Families have to spend a large part of their money on medicines, and many people go bankrupt due to medical expenses.

So, the government came up with a new scheme called Pradhan Mantri Bhartiya Janaushadhi Pariyojana (Jan Aushadhi Kendras)[32] to sell the generic medicines at 50%to 90% cheaper than the branded medicine.

By 2025:

- There will be more than 17000 Kendras operating.
- Uttar Pradesh has the highest number of operating stores, which is 3731 stores.

But there are some issues with:

- Sometimes, the medicines are out of stock.
- People think medicines are of low quality.
- Rural areas do not have enough stores.
- Uneven distribution across the states.

So, the scheme is helpful but not fully recovered.

India can use compulsory licensing, where the government allows other companies to make a patented drug during a public need at a lower price.

Because of expensive medicines, the public healthcare system is under pressure.

[31] F. Hoffmann-La Roche Ltd. v. Natco Pharma Ltd., (2007) 141 D.L.T. 182 (Del.) (India).
[32] **https://janaushadhistoree.in/**

- In some areas, over 50% of households spent on medicines only.
- Many people stop their treatment for chronic diseases like diabetes and hypertension.
- Government hospitals struggle to provide costly patented drugs.

The National Pharmaceutical Pricing Authority controls the prices of some essential medicines, but not all patented drugs are covered.

Even though the schemes are introduced, it does not reach everyone in India. People in rural area does not have better access to stores than urban areas. Uttar Pradesh has many stores, but when we look at the population size, the medicines have not reached the expected number, but in small regions like Andaman and Nicobar have better access. SO, the distribution is not equal.

Many women and poor communities suffer a lot because women usually earn less, have less mobility, and they financially depend on other, chronic disease are increasing among women and poor families, who can choose between food and medicines. Most rural women suffer a lot due to a medicine shortage, social bias towards the expensive branded drugs and limited health care access.

Role of Pharmaceutical Corporations and Industry Lobbying

Big pharmaceutical companies like Novartis try to make stronger patent laws in India. So, they can enjoy the patent rights for a longer time without any competition, with more profits. With this, one issue is evergreening; companies make a minor change to the existing medicines and try to get a new patent to enjoy the privileges of a monopoly, even if the medicine is not very effective.

India has strict patent rules that do not allow small modification for the existing patented medicines for new patenting. Because of complaints and pressure from American pharmaceutical companies, the United States trade representatives have placed India on their priority watch list. The U.S. believes that India doesn't have strong protection for pharmaceutical patents.

Section 3(d) stops the companies from applying for a patent for an already existing drug with

minor changes unless it gives a real improvement in therapeutic effect. This rule allows people to get medicines at a lower price. In *Novartis v. Union of India*, the Supreme Court of India rejected Novartis' application to patent the drug Glivec under section 3(d).

Some pharmaceutical organisations try to influence India's patent and drug policies according to their interest. The organisation of pharmaceutical producers of India mainly represents large multinational pharmaceutical companies, and the Indian Pharmaceutical Alliance represents major Indian generic drug manufacturers. The organisation of pharmaceutical producers asks for a longer patent period, a simple patent process, and strict measures against infringement.

India is known for its pharmacy in the Global South. 40% to 47% of generic medicines used in the U.S. were supplied by India. Around 40% of medicines imported in Africa were supplied by India. In the financial year 2024 to 2025, India exported medicines worth of$28,5 billon. Before 2005, India didn't allow product patents for medicines. So, Indian companies could legally follow the reverse engineering of drugs. This helped India to build a strong generic pharmaceutical industry. After 2005, India started following the global patent rules, which is TRIPS agreement. The legal tools are compulsory licensing and section 3(d). This helps India to produce affordable medicines for diseases like HIV, Tuberculosis and malaria[33].

India's Public Health Model: Successes and Challenges

India is known as the pharmacy of the world. $3o billion worth of medicines India exports. Nearly 20% supply of medicines were happened for by the world's generic medicines. The major markets include the US, UK and African countries. The growth rate is 9% annually, which is higher than the global average. India focuses on low-cost generic medicines. The Pradhan Mandri Bhartiya Janaushadhi Pariyojana provides affordable medicines. In 2014, only 80 stores had settled, but now over 14000 stores have been implemented. Due to the scheme, citizens saved around Rs. 30,000, medicines were available in 29 therapeutic categories, and the monthly sales reached Rs. 200 crores in 2014. During COVID – 19[34], India and South Africa proposed a TRIPS Waiver at the World Trade Organisation in 2020 to temporarily remove patent protection for producing the COVID-19 vaccines faster. So, this could help the developing countries to produce vaccines faster. India mostly depends on China for active

[33] **https://www.ipa-india.org/global-reach**
[34] https://www.thebureauinvestigates.com/stories/2025-04-16/indias-drugs-industry-global-medicine-market

pharmaceutical ingredients. During COVID – 19 the supply chain has been disrupted, risk increases due to geopolitical tensions and the concern has increased about the quality and production delay.

Even with the government schemes, the availability of medicines is not equal in every region. The medicines are available in states like Punjab and Tamil Nadu. But rural areas and underdeveloped area faces shortages. Private hospitals have better treatments, but with very high cost.

In 2012, Nacto Pharma got a compulsory license against Bayer's cancer drug Nexavar, which reduced the cost to around 2.8 lakhs per month to 8,800 per month, which is very low. But, in the *Lee Phara vs. AstraZeneca case*, the court rejected the application for compulsory licensing, which shows now court now protects the patent holder more.

Comparative Perspective: India and Other Jurisdictions

In countries like the US and the UK, they give strong protection for the patent to pharmaceutical companies to encourage innovation. The United States patent tenure is 20 years from the filing date. If the regulatory delay occurs, the companies will get an extra 5 years, and new chemical entities get an extra 5 years; rare disease drugs get 7 years exclusively. So, overall, companies enjoy 14 years of market after the approval. This goal rewards innovation and helps with the R and D cost. The United Kingdom patent term is for 20 years from the date of filing. Companies can apply for the supplementary protection certificate. This certificate can extend the protection up to 5 years, plus 6 months extra for pediatric use, and the UK system strongly encourages innovations and patent protection.

Under the World Trade Organisation, the countries follow an agreement known as TRIPS. After the Doha declaration2001 clarified that people are more important than patent protection. So, the countries can legally have the flexibility to make medicines affordable. The flexibility includes compulsory licensing, parallel imports and government use.

In India, compulsory licensing has used in a famous case, Natco Pharma vs. Bayer Corporation, and in Brazil, Brazil threatened to issue compulsory licenses for expensive medicines for HIV/AIDS. Brazil, instead of breaking the patent, warned the pharmaceutical company that it

could allow the local production to produce the medicines if they don't reduce the price; as a result, the drugs prise were reduced. In Thailand, the Thai government issued government use license for antiretroviral drugs. Which allowed the Thailand to produce or import the cheaper generic medicines from countries like India. This patent holds the paid royalties and the monopoly was controlled.

Conclusion

Since the 1970 Act to the TRIPS-compliant framework that was implemented after 2005, India's patent law has undergone a complex balancing act between supporting economic innovation and protecting the fundamental right to life. This analysis shows that India has effectively moved into a product patent system without completely giving up its position as the "Pharmacy of the World." This was accomplished by the use of Compulsory Licensing, as demonstrated in the Natco v. Bayer precedent.

This socio-legal environment is still difficult, nevertheless. Despite India's strong legal system, socioeconomic inequality still determines the practical availability and cost of life-saving medications. The Pradhan Mantri Bhartiya Janaushadhi Pariyojana and other programs demonstrate the state's acknowledgement of its obligation under Article 21, but the disparities in drug distribution by geography and gender show that a "one-size-fits-all" patent policy is not merely enough to guarantee universal health coverage.

Pressure from global pharmaceutical companies also highlight the continuous geopolitical conflict over intellectual property. India must continue to oppose the weakening of its patentability standards if it is to preserve its public health model. In conclusion, Indian patent law must continue to be deeply rooted in the socioeconomic realities of its people rather than only reflecting international commercial standards. The "Indian Model" demonstrates that intellectual property rights are a social compact rather than an absolute right. The survival of a patient must never be sacrificed for the protection of an inventor's profit in order for this contract to be enforceable.