VOLUME 5 | ISSUE 4

INTERNATIONAL JOURNAL OF ADVANCED LEGAL RESEARCH

BALANCING INNOVATION AND ACCESS: EVERGREENING, IPR, AND COMPETITION LAW IN THE INDIAN PHARMACEUTICAL INDUSTRY

- S. Chandana, Shalini Rajapur & Simran Subbaiah[1]

1. Abstract

This paper investigates India's balancing act of fostering pharmaceutical innovation while ensuring affordability for the public within its intellectual property and competition law structure. It outlines the history of patent law in India from the process - patent centric view of the Patents Act 1970 to the comprehensive changes made in compliance with the TRIPS Agreement. A key focus in this legal saga is Section 3(d) which aims to prevent "evergreening", a practice where non-therapeutic, trivial modifications are made to existing drugs to extend patent life and prolong market exclusivity. The paper discusses key judicial decisions such as Novartis AG v. Union of India, where India's policy of granting patents predominantly for significant therapeutic advances is reinforced. It analyses competition law and its role, especially through the actions of the Competition Commission of India, in mitigating the abuse of dominant position in relation to generic drug market access. They emphasize on the COVID-19 pandemic as a watershed in the conversation of intellectual rights and public health during a pandemic, looking at the vaccine race as a combination of competition and novel collaboration licensing as well as contentious development mechanism. Finally, the paper provides recommendations for strengthening standards for patent examination, clarifying the roles of regulatory authorities, increasing transparency, and improving the governance structure. Such measures are necessary to maintain a healthy legal environment that fosters innovation and offers adequate access to medicines.

Keywords: IPR, competition law, pharmaceutical industry, evergreening, COVID 19, patent law affordable medicine, innovation

[1] Student at St Joseph's College Of Law

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

https://www.ijalr.in/

2. Hypothesis:

India's enforcement of Section 3(d) of the Patents Act and proactive competition law enforcement successfully restrict evergreening in the pharmaceutical industry, favouring both legitimate innovation and low-cost access to medicines.

3. Research Questions:

i. Is Section 3(d) of the Indian Patents Act successful in curbing evergreening and promoting real pharmaceutical development?
ii. How does evergreening affect the Indian pharma industry?
iii. How has the COVID 19 pandemic exposed the symbiotic relationship vis-à-vis IPR and Competition law with regard to the pharma sector?

4. Scope of Research:

This study examines the domain of the IPR regime, competition law and public health in Indian pharmaceutical industry. It discusses the historic development of India's patent law, especially after the TRIPS amendments, the impact and success of Section 3(d) as a check against evergreening, the utility of the Competition Commission of India (CCI) in controlling anti-competitive practices centred around pharma. Landmark court rulings that balanced innovation and access. The impact of global developments (e.g., COVID-19) on India's IPRs and affordability of life saving drugs). The paper's focus is on India, but it touches several global frameworks and debates, particularly those concerning the access to life saving drugs in the developing world.

5. Research Methodology:

This paper makes use of doctrinal research methodology that was employed since according to the questions posed and when examining the legitimacy of statutory laws as well as their consequences of society it is necessary to refer to court cases, statutory laws, annotations, and other materials from the library. Since the subject of the research did not introduce the need for an inquiry based on empirical data in a great extent. We choose this method as the most appropriate method.

6. Introduction

Issues involving the inter relation between international trade law, the theory of IPRs, pharmaceutical innovation and public health concerns have come under legal and policy scrutiny lately, particularly in the developing world including India. With the dynamic growth of the pharmaceutical industry, its laws have to deal with new problems of affordability, accessibility, and competition for market share. One such problem is "evergreening," a practice whereby pharmaceutical companies extend patent protection for existing drugs by modifying them in trivial ways to block the entry of generic substitutes.

India's legal framework concerning this matter stands out due to the country's approach by balancing innovation and public welfare policy. India can be regarded as a case study for tackling the global intellectual property system challenges with built in protections for affordable healthcare. In this regard, this paper analyses innovations and access in India's pharmaceutical sector by investigating the impacts of patent, competition, and judicial activism focusing on evergreening practices on public health.

7. Patent Law Framework in India: An Overview

There have been important amendments to the patent law of India in response to achieving a balance between public health and protection of IPR. These transformations are particularly powerful in the pharmaceutical industry, which suffers from an enormous demand for access to low cost medicines.

7.1. Historical Context and the Patents Act, 1970

The backbone of the Indian patent system was the Patents Act of 1970 which aimed to stimulate local innovation while ensuring that vital medicines would remain economically available to the public at large. Interestingly, the Act only allowed pharmaceutical process patents, and thus permitted Indian businesses to produce substitute medications by changing the manufacturing method. This strategy sparked the expansion of India's generic pharmaceutical sector, positioning the nation as a major provider of economically accessible medications to underdeveloped countries.[2]

7.2. TRIPS Agreement and Subsequent Amendments

[2]WIPO, *Patent System of India,* World Intellectual Property Organization, https://www.wipo.int/patent-judicial-guide/en/full-guide/india (last visited May 10,2025).

i. India becoming a member of the WTO in 1995 mandated the Indian observance to the TRIPS Agreement. TRIPS mandated that member states protect patents for products in all technological sectors, including the pharmaceutical sector. In order to fulfil these obligations, India amended its patent laws.
ii. Patents (Amendment) Act 1999: Brought in the 'mailbox' system in India for filing product patent applications and introduced Exclusive Marketing Rights (EMR) on certain drugs.
iii. Amendments brought in Patents (Amendment) Act 2002 Provided new definition to important terms like "invention" and "inventive step". Secondly, it fixed the duration of a patent at 20 years to bring it in to line with TRIPS consistently.
iv. Patents (Amendment) Act 2005: Reinstated product patents in drugs, food, and pharmaceuticals, which was the last of the processes of complying with TRIPS by India.[3]

Together, these changes represent an emerging trend in the country towards more patent protection, with significant impacts for the pharmaceutical sector, for public health and for access to medicines.

7.3. Safeguards Against Evergreening:

A distinctive feature of Indian patent law is Section 3(d). This is to limit "evergreening' in which drug companies seek to maintain the monopoly provided by the patent by making minor alterations to the original drug (frequently with no clinically useful effect). According to Section 3(d), only mere discovery of a new form of a known substance will not be recognised as patentable unless it can demonstrate an improvement in the efficacy. This clause also safeguards that fake inventions do not see any patents, and cheap generic drugs remain accessible.

7.4. Provisions on Compulsory Licensing

Indian Patent Law also has provisions for both voluntary and compulsory licensing. These allow the government to authorize the manufacture of a patented medicine without permission from patent-holding drug-makers in certain limited circumstances.[4]

[3]Shambad Basheer, *Indian Patent Law: Working Within the TRIPS Agreement Flexibilities*, 3 Fla. St. U.L. Rev. 1(2006), https://ir.law.fsu.edu/cgi/viewcontent.cg? article=1294&context=jtip, (last visited May 10,2025).

8. India's Pharmaceutical Sector: A Contextual Overview

A Contextual Look at India's Pharmaceutical Sector Often called the "pharmacy of the world," India's pharmaceutical sector has unrivalled capacity to produce subsidised generic medications. The industry with its advanced manufacturing infrastructure and sufficient supply of qualified professionals also plays a significant role in the domestic as well as international healthcare supply chain. The paradox of encouraging new drug development while offering cheap access to necessary medicines is, however, inherent to pharmaceutical innovation driven by patents as the means of commercial protection.

Examining "patent law (as part of intellectual property rights)" in conjunction with "competition law" thus becomes crucial. Competition law attempts to restrict anti-competitive practices intended to parallel with the use of monopoly rights created by patent law. Patent law establishes the period of exclusivity given to pharmaceutical companies and the scope within which such exclusivity is exercised.

9.Understanding Evergreening in the Pharmaceutical Sector

In the context of the pharmaceutical industry, as discussed, “evergreening” pertains to the actions taken by patent owners to extend the commercial life of their patents beyond the stipulated 20 years. This is usually done through minor changes in formulation, dosages, or even delivery mechanisms of existing drugs and obtaining new patents for them. While these practices can be within the realm of legality, their associated issues tend to prevent access to affordable generic medicines in countries where public health concerns loom large.

To combat the issue of evergreening, India made certain amendments to its patent law. In particular, the 2005 amendment, introduces section 3(d) which looks to mitigate the problems of extending patent monopolies through trivial modifications that offer little therapeutic value.[5]

The ruling of the Supreme Court of India on Novartis AG v. Union of India (2013)[6]stands as a significant milestone in understanding the implementation of Section 3(d). Novartis applied

[4]Lei Liu, *Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patent Act, Harv.Int’l L.J,* *https:/journals.law.harvard.edu/ilj/wp- content/uploads/sites/84/561Liu.pdf* (last visited May 10,2025).
[5]Aditi Sharma, *Section 3(d) of Indian Patents Act 1970: Significance and Interpretation*, MONDAQ, https://www.mondaq.com/india/patent/295378/s ection-3d-of-indian-patents-act-1970- significance-and-interpretation (last visited May 10,2025).
[6]Novartis v. Union Of India (2013) 13 S.C.R 148

for a patent for the beta crystalline form of ImatinibMesylate (Glivec) alleging that its bioavailability was better than the recognized version. The Court, however, reasoned that enhanced bioavailability did not mean greater therapeutic efficacy. The Court stressed that for a new version of a known substance to be patentable under Section 3(d), it must show substantial therapeutic efficacy improvements, not mere enhancements in physical attributes like solubility or stability.

In *Bayer Corporation v. Union of India*[7], the case concerning Bayer's cancer medication, Nexavar also touched on the subject of evergreening. The Delhi High Court supported Natco Pharma's compulsory license allowing the company to manufacture a generic version of the medication. Given the high price of the patented medication and its limited accessibility and affordability, this was allowed, so highlighting the tension between patent protection and public health considerations.

Similarly, the Delhi High Court tracked Erlotinib, a lung cancer treatment, in F. Hoffmann-La Roche Ltd. v. Cipla Ltd. Denying Roche's request for an injunction against Cipla, the court emphasized the need of access to reasonably priced medications and examined the incremental innovation Roche sought to claim.

For the pharmaceutical sector in India, the implementation of Section 3(d) has major repercussions. It forces a move toward genuine invention that produces significant therapeutic changes rather than efforts for superficial changes to strengthen patent protection. This encourages even more the availability of affordable generic medications, which helps the public health strategy.

10. Interface Between IPR and Competition Law

The Relationship Between Competition Law and IPR Notwithstanding their differences, serve complementary functions in the economy. IPRs give creators exclusivity to promote innovation, but competition law makes sure that this is not done at the expense of market or competition. In the pharmaceutical industry, where innovation and accessibility must be carefully balanced, the interaction of these two legal disciplines is crucial.

The Patent Act of 1970 in India grants inventors' exclusive rights for a predetermined amount of time and permits the awarding and enforcement of patents. Conversely, the Competition

[7]Bayer Corporation v. Union of India (2014) 7 SCC 553.

Act of 2002 aims to eradicate practices that have a significant negative impact on market competition (AAEC). IPRs are given a limited exemption under Section 3(5) of the Competition Act, which argues that reasonable limitations to safeguard IPRs are not anti-competitive. Anticompetitive behaviour and actions deemed to be abuses of dominance are not covered by this exemption.

10.1. Compulsory Licensing and Access to Medicines

The government may authorize the production of patented medications without the patent owner's consent thanks to provisions for compulsory licensing included in India's patent law policies. Accessibility is the goal of this approach, particularly for medications that can save lives.[8]

Natco Pharma's application for compulsory licensing of Bayer's patented cancer medication, sorafenibtosylate, was accepted by the Indian Patent Office in 2012. The Patent Office's decision was based on the assumption that Natco's generic version would improve accessibility and the fact that two burdens were not met at the same time: Bayer's exorbitant pricing and restricted affordable access

10.2. Competition Law Interventions

Competition Commission of India (CCI) has been particularly harsh about the anti-competitive behaviour of the pharmaceutical industry. The CCI attempts to combat monopolistic practices which can lead to the restriction of access to drugs by looking at pricing strategies, inter market competition, and acquisitions.

Consider the CCI's probes into pharmaceutical companies accused of colluding to keep generics off the market. Such actions should be commended as they highlight the role of competition law in ensuring an equal and affordably accessible pharmaceutical market.

The jurisdictional division of the Competition Commission of India (CCI) and the Controller General of Patents has attracted legal attention. The Delhi High Court held in *Monsanto Holdings Pvt. Ltd. v. Competition Commission of India* that the CCI has jurisdiction over cases involving the detrimental effects of patent rights exercises that lead to anti-competitive practices like exorbitant pricing and/or license refusal.

[8]IIPRD, *Grant of Compulsory Licence in India: It's Provision and Need in Several Industries,* https://www.iprd.com/grant-of-compulsory- license-in-india-its-provisions-and-need-in- several-industries-in-india (last visited May 10,2025).

In the same spirit, the Delhi High Court recognized the Competition Commission of India's jurisdiction over claims of dominance abuse by a patent holder in *Telefonaktiebolaget LM Ericsson v. Competition Commission of India*[9], stating that the mere existence of patent rights does not negate the application of competition law.

10.3. Pharmaceutical Sector and Anti-Competitive Practices

The pharmaceutical sector is one of those sectors which have experienced abuses of patent rights in attempting to restrain wider competition through delaying the entry of generic medicines. In *Biocon Limited v. F. Hoffmann-La Roche AG*[10], the CCI investigated claims suggesting that Roche had attempted to inhibited competition by restraining biosimilar competitors from entering the Indian market for its cancer drug, Trastuzumab. Even though the CCI decision did not find any infringement of law, it highlighted the dangers posed by the use of patent rights to competition.

Another noteworthy matter involved the CCI and Madhya Pradesh Chemists and Druggists Association [11], where the CCI observed that the association's stipulation for No Objection Certificates (NOCs) from pharmaceutical companies prior to granting the stockist appointment was an anti-competitive practice, restricting new entry into the market.

The IPR and competition law relationship needs to strike a balance between the attendant rights of a patent holder and the potential negative impacts on the market to ensure fair competition. The Indian system, through courts and other regulatory bodies, tries to achieve this balance. India, by not allowing the abusive exercise of patent rights in competition law terms, seeks to ensure that innovation and consumer welfare coexist and flourish within the country.

11. COVID-19 and the IPR Debate: A Turning Point

The demands of the COVID-19 pandemic shone the spotlight on Intellectual Property Rights (IPRs) in global health. In October 2020, together, India and South Africa requested a temporary waiver of several provisions of the TRIPS Agreement, aiming to ensure an inclusive approach to medical products and negotiations at the WTO. this proposal was mediated to reduce the patent barriers of technologies related to COVID-19 so as to facilitate

[9]Telefonaktiebolaget LM Ericsson V.Competition Commission of India, (2014) 3Comp LJ 234 (Delhi).
[10]Biocon Ltd v. F. Hoffmann-La Roche AG, Case no. 53/2013.
[11]Madhya Pradesh Chemists & Druggist Association v. Competition Commission of India, Case no. 79/2013.

its manufacturing and distribution. Although the proposal was endorsed by a number of countries, it was outvoted by a high-income coalition, and then grudgingly endorsed a weaker agreement in June 2022 in relation to vaccine patents (with medical devices and technology issues were not covered).

Within India, the vaccination IPRs saw notable milestones. Covaxin — developed by the Indian company Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) — was the other vaccine used. There were, however, differences when Bharat Biotech applied for a patent on its own and did not recognise ICMR as a co-inventor. The company in subsequent admission stated that ICMR investment was valuable and therefore had been included as a co-owner of the patent.[12]

Another intriguing example is that of Emcure Pharmaceuticals and its subsidiary, Gennova Biopharmaceuticals. Gennova developed an mRNA-based vaccine against COVID-19 which was given emergency use authorisation in India. But HDT Bio, a United States firm, has accused Gennova of stealing its technology and patenting it in India without its consent. The disagreement was resolved by a settlement, allowing Emcure to license mRNA technology from HDT, and both parties agreeing to jointly develop future vaccines.

12. Post-Pandemic Implications for Patent Law and Public Health

The pandemic underlined the importance of balancing patent protections and public health interventions. India's experience demonstrated the importance of legal provisions to prevent evergreening. The landmark case *Novartis AG v. Union of India* profoundly shaped the landscape of patent law, underlining the principle that true innovations must be patentable, and that spurious, non-additive "innovations" shall not be entitled to such protections.

The pandemic also brought the use of voluntary licensing and its power to expand access to life-saving medicines to the fore. One such exception was production of Corbevax, a protein subunit COVID-19 vaccine, which included some patent-free technology transfer agreements that allowed scaling up production.

Now the time is ripe to strike the delicate balance between patent and competition law. Patent rights must then be surrendered in such a way that they do not dampen competition, for even this would stand in the way of innovation, affordability, and access to life-saving

[12]Chakravarthy, R., & Reddy, P. (2016), Evergreening of Patents: Legal Challenges and the Indian Response. Journal of Intellectual Property Rights, 21(4), 267-277.

drugs. India's approach acts as an example to follow in demonstrating how these issues can be balanced, showcasing that one can defend intellectual property rights without waging war on public health initiatives.[13]

13. Recommendation

In order to effectively deal with the issues posed by evergreening of patents while balancing intellectual property protections with healthy competition in the market, a detailed legal and policy recommendation is put forth:

i. Consistent Enforcement of Section 3(d):

Subsection 3(d) of the Indian Patents Act acts as a formidable barrier towards abuse of patent monopolies with evergreening through trivial changes. For this provision to be impactful, patent examiners must apply it with a clinical rigor, especially in reviewing patent applications on incremental pharmaceutical innovations. A more restricted, narrow, and therapeutic efficacy centered adjudicative framework should dominate the evaluation.

ii. Clarify Jurisdiction Between Regulatory Bodies:

The Patent Office and Competition Commission of India (CCI), are critical in avoiding overlap or a gap in regulation. A well-coordinated inter-agency protocol can ensure that patents are not abused beyond reason in a manner that throttles competition and/or access to vital medicines in a timely manner.

iii. Strengthen Transparency in Patent Disclosures:

Claimants must reveal any prior patents they have in addition to detailing the evolving steps of an invention as evidenced by documents and provide adequate evidence supporting their claims explaining how they distinguished themselves from prior art. Increased disclosure will allow generic manufacturers and civil society organizations more sophisticated means to identify and contest patent abuse and extensions.

iv. Encourage Stakeholder Engagement:

Broader stakeholder engagement such as public health professionals, non-profit organizations, academia, and even manufacturers of generic drugs during patent opposition

[13]Patel, S., & Mehta, A. (2015). India's Patent Lawand Public Health: The Role of Section 3(d), Asia Pacific Journal of Health Law, 16(1), 85-97.

processes and policy debates can ensure that the incentives provided for innovation do not block public access. Inclusion in decision making processes enables better outcomes and socially responsible results.

v. Build Institutional Capacity:

Training and development of employees in the Patent Office, CCI, and the judiciary is crucial and needs to be prioritized. Catering to their knowledge with regards to pharmaceutical sciences, patent law, and global standards will result in just and reasonable decisions in matters relating to patents and competition.

vi. Facilitate Data Sharing Between Institutions:

Effective and efficient coordination and enforcement of anti-competitive practices can be achieved with a good system of data sharing between regulatory bodies. Having access to patent information, market access rates, and pricing information saves time, speeding up enforcement procedures. This approach can prevent anti-competitive behaviour, enabling faster action.

vii. Promote Voluntary Licensing and Technology Transfer:

Promoting voluntary licensing and technology transfer for Public Health Organisations (PHO)s is essential for ensuring immediate access to necessary medicines. This encourages broad based production and provision of affordable drugs in a timely manner.

viii. Periodic Review of Patent Grants:

Establishing a system for incremental innovation patent's post-grant periodic review would guarantee the initial requirements for patentability are still subsisting. For example, if a patent is found later to not be a significant synergistic improvement, it can be reconsidered or invalidated.

With these provisions implemented, India can reinforce its position on a pharmaceutical ecosystem paradigm for promoting genuine innovation, moderating public health needs and competition within the market.

14. Conclusion

The pharmaceutical policy of India embodies a carefully crafted, adaptive strategy in encouraging medical innovation while ensuring the availability of essential medicines as a public good. Perhaps the most defining feature of this strategy has been the country's stance on patent evergreening practices that do not result in meaningful therapeutic improvements. By incorporating well-defined and strong criteria based on genuine innovation for the grant of a patent, India provides a balanced model to the public health and industry advocates.

Yet, the changing profile of pharmaceutical technologies, as well as the dynamic interaction of the intellectual property terrain and competition law, merits an attentive approach. Given the overlapping and sometimes conflicting legal and regulatory systems, policy articulation and institutional coordination are becoming more and more pressing. The lack of systems able to effectively respond to public health emergencies has been made painfully clear by the global health crisis brought on by the COVID-19 pandemic that has highlighted the importance of timely and equitable access to healthcare.

Proactively adopting sound legal systems and undertaking institutional reforms will be irrefutably critical in the context of India. Adopting a middle ground which both,